NHS National Services Scotland

Decontamination Facilities

Scottish Health Planning Note 13

part 1 - Central Decontamination Units (CDUs) in NHSScotland

SHPN 13

part 1

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Executive summary

This Scottish Health Planning Note (SHPN) provides guidance to help plan and design a new or an upgrade to a Central Decontamination Unit (CDU) in NHSScotland processing Reusable Medical Devices (RMDs) ready for next use on patients. The processing being done by CDU staff in a controlled manner as required by the quality management system (QMS) standard BS EN ISO 13485: 2021.

This SHPN is a full technical revision of the first version produced in 2011. It considers innovative technologies and current standards. It also takes account of lessons learned in CDU build projects, incidents, stakeholders' enquiries, sustainability matters, and the Post Occupancy Evaluation (POE).

Design principles and two new layouts of a CDU department are introduced, namely a single production and a dual production process facility. The individual rooms/ areas are specified by the 41 data sheets provided in Appendix A. The specifications cover requirements for design, finishes, mechanical and electrical, and equipment/ fixtures and fittings.

This guidance outlines the two interconnected workstreams that require to be resourced and controlled over the project of delivering a new/ upgraded CDU. The Validation Master Plan (VMP) identifies the activities in the validation workstream and the build workstream includes the business case stages, construction, procurement, and handover. The User Requirement Brief (URB), required at the start of the project, provides input to both workstreams, and is used to inform any bidders and the chosen principal contractor.

The Design Qualification (DQ) report for the facility and its site should be completed and approved by the Health board before commencement of the construction and procurement stages. Over the construction phase there should be verification activities including Installation Qualifications (IQ) and Operational Qualifications (OQ).

The Performance Qualification (PQ) of the facility is conducted after the handover from the principal contractor.

After start-up, routine production and maintenance of the facility and its service to Users is described in this guidance.

A substantial definitions section is included in this guidance.

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1. Scope and purpose

1.1. This Scottish Health Planning Note (SHPN) 13 Part 1 version 2 is the principal reference document that should be used for the purpose of planning a new build/ major refurbishment of a Central Decontamination Unit (CDU). As is standard with best practice guidance it is not intended to be applied retrospectively. SHPN 13 part 1 should be cited in each stage of any business case and used throughout the design/ construction/ start up and operation of a CDU. The SHPN is cited within GUID 5014 v3 the Compliance Requirements for CDUs published by Health Facilities Scotland (HFS) in 2024. Version 1 of SHPN 13 part 1 published by HFS in 2011 is superseded.

Legislation, policy, standards and guidance

Primary legislation

1.2. The Medicines and Medical Devices Act 2021 came into effect in 2021. This established a GB market as opposed to a UK market for medical devices.

Secondary legislation

1.3. The Medical Devices (Amendment) (Great Britain) Regulations Statutory Instrument (SI) 2023 no. 627 became effective in July 2023. This modified the 2002 medical device regulation SI 2002 no. 618.

Policy

1.4. The government letter Ross Scott 2007 on CDU accreditation established the requirement for CDUs to follow a quality management system (QMS) standard.

Standards

1.5. The standard BS EN ISO 13485: 2021 sets the requirements for a QMS as used in a CDU.

Guidance

1.6. The HFS compliance document GUID 5014 v3: 2024 sets the technical requirements for CDUs to follow.

1.7. The best practice engineering guidance Scottish Health Technical Memorandum (SHTM) 01-01: 2018 series covers decontamination in the CDU focussing on the decontamination equipment.

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CDU activities

1.8. A range of rooms may be considered in a CDU (see Table 1.1). 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 for example operating theatres and treatment rooms
- inspection, assembly, functionality testing and packaging of supplementary instruments, instrument trays and packs
- sterilization of supplementary instruments, instrument trays and packs
- product release for sterile products and disinfected devices where this is the required level of decontamination
- 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

1.9. Support activities could include:

- management of waste including recycling
- traffic management on site

List of rooms/ areas

Table 1.1 - Room or area number and associated description within the CDU

Room/ area number	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

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Room/ area number	Room/ area description
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 (DSR)
16	General Plant Room
17	CDU cleanroom
18	CDU cleanroom: Gowning Room
19	CDU cleanroom: DSR
20	CDU cleanroom Materials Transfer Room
21	Maintenance Manager's Office
22	Materials Store
23	Office
24	Processed Products Store
25	Quality Manager's Office
26	Wash Room: Gowning Room
27	Wash Room
28	Wash Room: DSR
29	Sterilizer Plant Room
30	Sterilizer Unload Area
31	Staff Changing Room(s)
32	Staff Room
33	Technicians Room
34	Test Equipment Room
35	Training Room
36	Vehicle Loading Bays (a to e)
37	Vehicle Wash Area
38	Wash Room Materials Transfer Room
39	WC
40	Sterilizer load area

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Room/ area number	Room/ area description
41	Chemical sterilizer room

1.10. The room/ area data sheets for each item in Table 1.1 is in Appendix A.

Service strategy considerations

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

1.12. 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

1.13. 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

1.14. 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

1.15. 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

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Service objectives

1.16. 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.

1.17. Key objectives which the QMS should define will include:

- identification of the decontamination level required for the intended use of the product
- how to provide decontaminated products to the required level
- 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 labelling and instructions for safe use
- ensure decontamination environment equipment, facilities and processes are validated
- hold appropriate documentation/ records to demonstrate compliance with required standards

1.18. The workload demand on a CDU will depend on the health board's sterile services policy. The health board should identify the units to be served, both in acute and non-acute settings and the sterile services policy should take these and foreseeable demands into account to determine the workload on the CDU. Future-proofing should be considered as part of this exercise. The policy therefore needs to be determined as early as possible, allowing for foreseeable future requirements to be identified.

1.19. It is important that the design rationale for the CDU should consider growth in capacity for example the need for additional washer disinfectors (WDs)/ sterilizers/ packing tables as well as plant such as boilers. The design rationale should also consider a growing workforce and ancillary space allowing adequate dirty/ clean separation.

New considerations in this first revision

1.20. New considerations since the previous version of this guidance are outlined below:

- use of the SHPN 13 part 1 version one guidance during new build projects (post project evaluation), enquiry questions on the guidance, CDU incidents and lessons learned have all provided some input to inform this revision. This included some things to consider and some things to avoid. Quality control of documentation is addressed in detail to aid design control throughout the project. A set of design principles are established. Some new definitions are introduced for clarity purposes

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- modern technologies for consideration have included low temperature sterilization for RMDs used in robotic surgery. A new room data sheet [Room 41] is introduced to describe a dedicated room with low temperature hydrogen peroxide sterilizers. A continuous monitoring system for the airborne particulate levels in the CDU cleanroom is introduced to bring improved assurance of control of its environment and potentially allow energy saving opportunities to be investigated in relation to its ventilation system
- a number of unplanned shutdowns of large scale CDUs (traditional builds of some 10 to 25 years old) have given rise to lessons learned reports and recommendations which are used to inform this latest guidance. This includes work required to demonstrate that a cleanroom facility is fit for purpose on start up after a prolonged shutdown
- national CDU cleanroom microbiological limits (Bio class 8) are established
- sustainability matters have become of major importance further to the announcement of the climate emergency. Sustainable design and construction guidance SHTN 02-01 is considered in this guidance. Movement away from the use of gas fired boilers for hot water and steam production to be replaced by electrical means is considered
- a better understanding of national fragility, associated with unplanned closures of large scale CDUs, leading to assessment of its presence/ absence in consideration of options appraisals at business case stages
- a new layout model, a dual production facility, is presented for the department to address some aspects of single points of failure with high impact as shown by unplanned shutdowns during incidents
- consideration of where contingency support for other boards is required is addressed in the User Requirement Brief (URB) and subsequent Design Qualification (DQ)
- a large range of standards have been revised/ released since 2011 and these are considered in this guidance as applicable
- inclusion of the requirement for Post Occupancy Evaluation (POE)

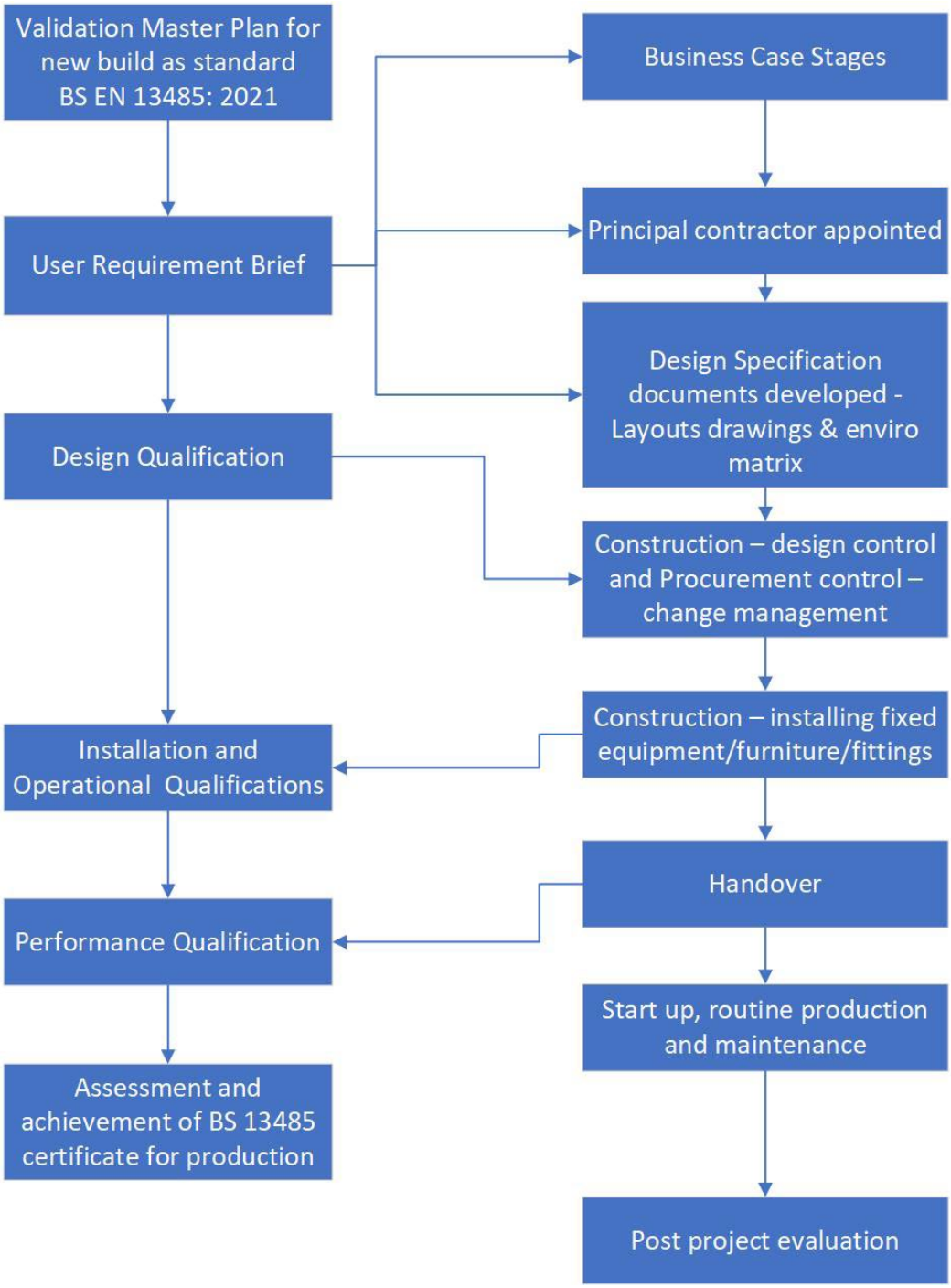
Awareness of the documentation workload and its resourcing

1.21. Figure 1.1 shows the multiple interconnected stages involved from initial conception to going live with a new build CDU. There are two principal workstreams that run in parallel. These are the validation workstream and the build workstream. The documentation workload in the validation workstream is enormous. All involved in the project require to acknowledge this and allocate sufficient resource. All new build and upgrading of CDUs should be validated in accordance with the requirements of the QMS standard BS EN ISO 13485: 2021. 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 (see figure 1.1). The DQ requires input by way of a clear URB that should be 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. It

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should be noted that this 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. 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.

Figure 1.1 - The interconnected validation workstream (left) and the build workstream (right) - the DQ to be completed before Construction commences



How long might it take to plan and build a CDU?

1.22. At the time of publication in 2024 there had been very few CDUs built in the previous ten years. Based on those that had been built in that timeframe indicated some four to five years are required from the development of Initial Assessment (IA) business case through to validating the performance of a new facility as satisfactory. There have been discussions about use of certain construction methods, such as modular construction, which may allow improvements in build timelines. At the time of publication of this guidance the evidence to support this is being considered. However new factors now require to be considered in planning. The damaging effects of Brexit on supply chains are clear. Excessively long lead times on components during the construction stage of build projects have resulted in design changes during construction with the resultant considerable additional workload/ costs of managing change control late on in a project. A government letter Department Letter (DL) (2024) 02 NHSScotland: Whole System Infrastructure Planning was released in February 2024. The letter introduced a new approach to strategic infrastructure planning and investment across NHSScotland. It requires each NHS Board to prepare and submit to government, a Programme Initial Agreement (PIA) which sets out a deliverable, whole-system service and infrastructure change plan for the next 20 to 30 years.

Background

1.23. In 2024 there were 15 CDUs in operation within NHSScotland, the majority of health boards having a single CDU. These facilities ranged from small scale facilities processing for one or two theatres up to large scale facilities processing for one hundred theatres. These facilities include:

- a CDU sited inside a hospital building alongside other departments
- a separate dedicated CDU built on hospital grounds
- a dedicated CDU built on industrial land away from the hospitals it serves
- a dedicated CDU built off site through refurbishment of a repurposed building

1.24. These facilities ranged from 3 years old to more than 30 years old.

1.25. In terms of output of RMDs, a survey indicated small scale units processed about 200,000 instruments per year, mid-range units abouts 1 to 4 million per year and large-scale units about 6 to 12 million. This can also be expressed in terms of the number of theatres supplied, small scale being less than 5 theatres, mid-scale around 20 theatres and large scale around 50 plus. Opening hours varied from 08:00 to 17:00 Monday to Friday to effectively 24 hours seven days a week for the four large scale units. Most facilities were over 25 years old with decontamination equipment such as washer-disinfectors (WDs) or sterilizers replaced several times within the facility lifetime. As of 2024 only two new CDUs had been designed and built since the SHPN 13 part 1 was first published in 2011.

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1.26. These facilities produce product for a range of specialities. It is predominately the large-scale facilities that process for most surgical specialities. These include:

- Cardiac
- Dental
- Ear, Nose and Throat (ENT)
- General
- Gynaecology
- Max/ Fac
- Neurosurgery
- Obstetrics
- Ophthalmic
- Orthopaedics
- Paediatric
- Plastics
- Podiatry
- Spinal
- Transplant
- Trauma
- Urology
- Vascular

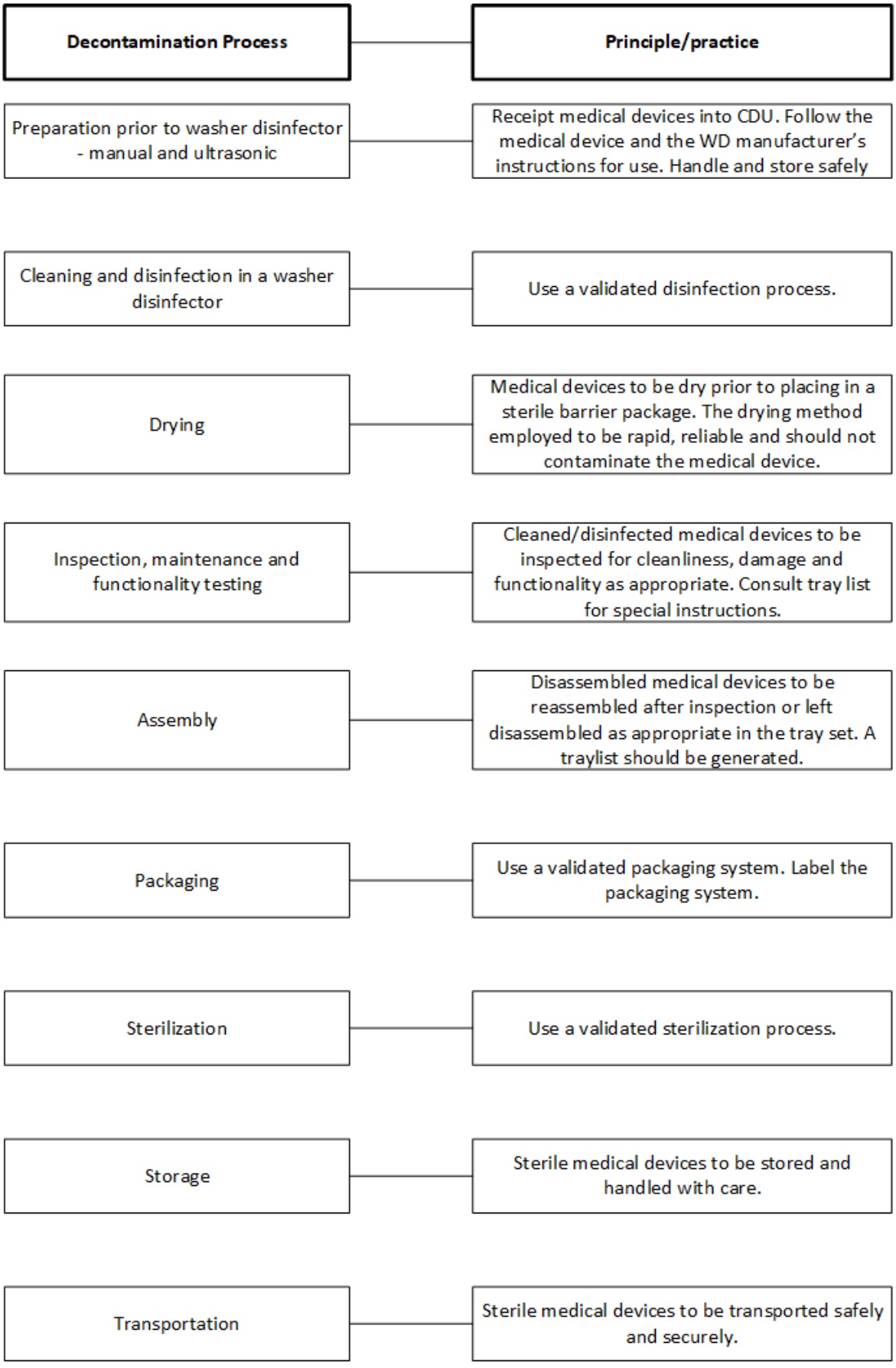
The decontamination process

1.27. The decontamination process is outlined in Scottish Health Technical Memorandum (SHTM) 01-01 part A: 2018. (set for revision in 2025)

1.28. The decontamination process stages with their associated principles are summarised in figure 1.2.

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Figure 1.2 - Principle/ practice to be followed at each stage over the decontamination process



2. Business case stages and the validation master plan

2.1. An important point to grasp is that the various stages within the business case development can take several years (possibly 3 years) to complete and be approved. Those involved in its development may not be around at later stages of the project such as during the construction stage.

2.2. Each of the business case stages can involve multiple meetings as well as workshops with associated preparation time for/ from each. Some of the project teams may be dedicated/ contractors but others will be operational mangers running an existing service while expected to contribute time to all these stages.

2.3. The Scottish Capital Investment Manual (SCIM) outlines a number of stages in business case progression. "…*processes and techniques to be applied in the development of all infrastructure and investment programmes and projects within NHSScotland*". The principles set out in SCIM are applicable to the development of all infrastructure and investment schemes regardless of their size or complexity and should be applied by all NHSScotland Bodies.

2.4. Scrutiny of the business case stages should be conducted by the NHSScotland Design Assessment Panel (NDAP) facilitated by Health Facilities Scotland (HFS) and its Principal Architects. The NDAP reviews are provided to the government.

NHSScotland Design Assessment Process

2.5. NDAP has been an integral part of the SCIM since the 1 July 2010.

2.6. NDAP support commences at the end of Initial Agreement (IA) and runs through-out Outline Business Case (OBC) and Final Business Case (FBC) stages. Board/ Client submit their Business case to Capital Investment Group (CIG) only following appropriate consideration of the formal NDAP responses. CIG approval is conditional on the level of support verified in the formal NDAP report sent at OBC or FBC submission. Feedback at Project Monitoring and Evaluation should ensure continuous improvement.

2.7. The purpose of the NDAP is to promote design quality and the service outcomes realised through this. It does this by mapping design standards to the key investment deliverables plus Scottish Government objectives and expectations for public investment, then demonstrating their delivery via self, and independent, assessments. NDAP supports continuous investment improvement, through sharing design standards and learning from comparable projects, thus building upon the best of what has gone on before.

Achieving excellence design evaluation toolkit

2.8. The Achieving Excellence Design Evaluation Toolkit (AEDET) evaluates a design by posing a series of clear, non-technical statements, based on three key criteria: Functionality, Build Quality and Impact. The use of a Design Quality Indicator Tool such as AEDET is a mandatory requirement of the NDAP under NHS Chief Executive Letter (CEL) 19 (2010) - A Policy on Design Quality for NHSScotland.

2.9. To satisfy SCIM, it is anticipated at least one AEDET workshop (depending on the scale and complexity of the project) should be held at the following key stages, and submitted via NDAP:

- use AEDET generic question set only
- IA - Target and Benchmark score(s)
- use combination of AEDET and project specific Design Statement (DS)
- OBC
- FBC, or Standard Business Case (SBC)
- Post Occupancy Evaluation (POE)

Key Stage Assurance Reviews (KSAR)

2.10. Government letter Department Letter (DL) (2023) 03 NHSScotland Assure: Key Stage Assurance Reviews (KSAR) - Commissioning and handover covers the commissioning, completion and handover part of the process and notifies that all building projects going through a KSAR, should not open to patients or the public until a 'supported status' is received from NHSScotland Assure. Project teams should liaise with their NHSScotland Assure KSAR team to ensure that their capital projects are completed satisfactorily to ensure that supported status is achieved. Any additional actions/ conditions included within the KSAR 'supported status' report for Commissioning and Handover must also be completed within agreed deadlines. Non-compliance with these requirements will deem the new facility as not appropriate for public/ patient occupation. When a supported status has been achieved, and the local NHS Board is content for the building to open, the Senior Responsible Officer should send a copy of the report to the Chair of the NHS CIG for information.

Strategic assessment

2.11. This should:

- describe the scope of the new proposal
- inform government of the project
- gain consensus and support from stakeholders

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- demonstrate priority over competing projects
- highlight service need and benefits

Programme initial agreement

2.12. In Feb 2024 via letter DL (2024) 02 NHSScotland: Whole System Infrastructure Planning replaced the requirement for IA to be submitted for individual capital investment projects. The new approach to strategic infrastructure planning and investment was via the Programme Initial Agreement (PIA).

2.13. Each NHS Board requires to prepare and submit to government, a PIA which sets out a deliverable, whole-system service and infrastructure change plan for the next 20 to 30 years. The PIA would also constitute the first step in the business case process, thus enabling individual capital investment projects to proceed straight to OBC stage, once agreed with government.

2.14. NHS Boards were required to submit their Do Minimum Business Continuity Option to government by 31 January 2025. The preferred way forward stage within the PIA specifies that decontamination needs to be embedded into whole-system plans for change, with a clear indication of its local, regional and national relevance.

Outline business case

2.15. The OBC requires several and different types of workshops to source information and make decisions on options.

2.16. The OBC should:

- confirm the status of the strategic case
- provide economic appraisal of alternative options for implementing the preferred strategic/ service solutions(s)
- identify a preferred and affordable option
- set out arrangements for delivering the preferred option and realising benefits
- confirm a readiness to proceed to procurement

2.17. 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

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2.18. The User Requirement Brief (URB) should have been developed at this stage.

Final business case

2.19. The FBC should:

- confirm that management, commercial, funding and financial arrangements are in place to deliver the project
- set out the contractual details of the project which the Board is being asked to sign-off
- identify and allocate resource for quality control checking of documentation both at design stage and construction stages where design changes may be required

2.20. The URB should have been agreed and signed off during/on completion of the FBC.

2.21. During the final business case development, there should be a procurement process to select the construction company for the build. This may involve looking over different designs presented as part of the bidding process. The selected bidder is commonly referred to as the Principal Supply Chain Partner (PSCP). At the start of the project the procurement activities focus on the building and later there will be procurement processes to follow for decontamination equipment such as the washer-disinfectors (WDs) and sterilizers.

2.22. NDAP support commences at the end of IA and runs through-out OBC and FBC stages. Board/ Client submit their Business case to CIG only following appropriate consideration of the formal NDAP responses. CIG approval is conditional on the level of support verified in the formal NDAP report sent at OBC or FBC submission.

Antifragility assessment

2.23. At the FBC stage an antifragility assessment (see Appendix C) should be carried out in relation to the service impact of an unplanned production shutdown of more than 3 days of the proposed Central Decontamination Unit (CDU) design. A principal determining factor in this assessment is the scale (planned production output) of the proposed CDU in relation to the output capability of the existing CDUs within the same region. When developing this guidance there were three regions to consider, these being the North, East and West.

2.24. At the time of writing this guidance the antifragility assessment was not part of the SCIM. The requirement for this assessment derived from lessons learned on a major CDU incident where fragility was identified as the principal cause of national disruption to sterile service provision and large-scale patient procedures being cancelled. A number of subsequent CDU incidents have verified the existence of fragility. As this was a new subject to stakeholders there was a clear need to define and explain associated terms. The developed and introduced antifragility assessment enables an examination of the national picture of sterile service provision.

2.25. The antifragility assessment should determine and classify the service property found into one of four as follows (see Table 2.1):

- **fragile sterile service** "*where the unplanned shutdown of one CDU in a region results in support being required from other CDUs across all regions, that is a single CDU causing nationwide disruption to the service and large scale patient procedure cancellations*"
- **resilient sterile service** "*where the unplanned shutdown of one CDU in a region is able to be supported by other CDUs within its region causing some local disruption with small scale patient procedure cancellations and the service level to Users is recovered reasonably quickly*"
- **robust sterile service** "*where the unplanned shutdown of one CDU in a region is able to be supported by other CDUs within its region causing some local minimal disruption but the service level to Users is maintained and there is no patient procedure cancellations*"
- **antifragile sterile service** "*where the unplanned shutdown of one CDU in a region is able to be supported by other CDUs within its region causing some local minimal disruption but the service level to Users is maintained and there are no patient procedure cancellations. This is the only one of the four properties which results in improvement of the service nationwide with respect to the impact of future unplanned shutdowns*"

2.26. Acceptance criteria - all categories other than "Fragile sterile service" are acceptable. Though it is desirable to design for a robust or antifragile property.

2.27. If the assessment does indicate the service property is "fragile sterile service" the business case options should be reconsidered with a view to providing a solution that is an acceptable category under the antifragility assessment.

Table 2.1 Antifragilty assessment - The four properties of sterile service provision with corresponding impacts with the unplanned CDU shutdown lasting 3 days of more

Property	Disruption to CDUs and Theatres	Patient procedures	Improvement post incident
Fragile	National	Large scale cancellations	No
Resilient	Local (confined to a region)	Small scale cancellations	No
Robust	Local	No cancellations	No
Antifragile	Local	No cancellations	Yes

2.28. This assessment is additional and separate to risk assessments required as part of SCIM. Risk being theoretical in nature, as it examines "likelihood", whereas the properties in the antifragility assessment are real in nature. Where an assessment determines a proposed solution as being "fragile sterile service" the solution should be changed such that the property changes to one of the acceptance categories. Mitigation measures found in risk management are not appropriate in dealing with a fragile property. A change of property is required as opposed to reduction measures.

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Validation Master Plan (VMP)

2.29. There should be a VMP for the project (see figure 1.1) which will define the qualification exercises required for the Design Qualification (DQ), Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ) of the facility. The DQ requires input by way of a clear URB 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.

The User Requirement Brief and version control

2.30. The URB, which is part of the Validation Masterplan process (see figure 1.1), should be prepared at an early stage in the business case stage (IA/ OBC). The URB should be agreed and signed off by relevant stakeholders at/ on completion of the OBC.

2.31. It is likely that several iterations of the URB will be produced as progression through the OBC to FBC occurs. It may be that discussions with preferred bidders at FBC may result in modifications to the Users requirements. The version of the URB that is signed off by the health board for the appointed principal contractor to consider should be the version that is checked against the design prepared by the principal contractor. This is done at the DQ stage. The URB will be informed by engagement from a range of stakeholders. This should include clinical input as service users defining their expectations, the decontamination management and their expectations, senior management expectations and the board's Authorising Engineer (Decontamination) (AE(D)).

2.32. The URB should state it is a controlled document and should be managed as such in line with the CDU's quality management system (QMS) standard BS EN ISO 13485: 2021. Change management should be included. The URB should state the requirement to follow the current version of guidance GUID 5014 (v3:2024) Requirements for compliant CDUs. This includes reference to the principal planning note Scottish Health Planning Note (SHPN) 13 part 1: version 2 - 2024. An outline of the commitment of the CDU service and the level of service given to service users should be outlined.

2.33. URB details, addressing capacity and capability, should include and define:

- service strategy and service objectives
- the specialities to be provided for and the range of packaging systems to be accommodated
- the daily throughput required and the annual throughput required
- the opening hours, expected number of shifts and number of staff
- whether or not there is a requirement to process thermolabile Reusable Medical Devices (RMDs)

- the range of decontamination equipment/ furniture required including the number of banks of manual wash sinks, ultrasonic cleaners (UCs), sorting tables, WDs, work stations and sterilizers
- the core production rooms and define the supporting rooms required
- those rooms/ areas of the 41 within the planning note that are not selected for use
- any room being specified for use that is not in the planning note
- approach to duplexing of utilities
- other required infrastructure on the site external to the building
- an outline of allowances to be made for future increase in demand from service users
- an outline of whether/ or not there is to be allowance for a defined level of support to other boards during a contingency event. Define the responsibilities for CDU manger and the level of contingency support should be specified in order that the architect can make allowance in sizing certain rooms, such as the Contaminated Returns Lobby Room 5, the Processed Goods Store Room 24 and Dispatch Room 9
- whether there is a preference to have the CDU core production and support areas all at ground level or leave for the bidders to interpret and provide design proposals
- flows for product - from receipt of soiled to dispatch of sterile product including storage requirements
- flow of received raw materials and distribution within the facility as the process requires including storage requirements
- flow of staff
- flow of waste

2.34. 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. If lifts are required to service, the CDU they should be dedicated.

2.35. 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. 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.

2.36. 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, Reverse Osmosis (RO) water, steam, clean steam, electricity, compressed air, heating, ventilation and air conditioning (HVAC), decontamination equipment and Information Technology (IT) systems.

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Note 1: Systems have been sold as ‘duplex’ but still share common elements, for example 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.

2.37. The areas to consider for use within the new CDU, along with a Site Data Sheet, are listed previously (see Table 1.1).

2.38. There may be circumstances where it is desirable to have the processing capabilities provided by a CDU and an Endoscope Decontamination Unit (EDU) within the same location in a hospital. For example, a limited staff resource where staff would be trained to work in both types of facilities and move between these as the workload demands.

Location of the CDU

2.39. 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 Appendix B 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 an 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 and 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 and technical support
- personnel issues, including proximity to local workforce
- security issues
- planning permission requirement
- customer base
- healthcare providers’ strategies

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- geographical and environmental constraints
- service and maintenance issues
- transport vehicle purchase and driver training

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3. Assessing bidders and appointment of the principal contractor

Assessing bidders

3.1. The various bidders should have reviewed the version controlled User Requirement Brief (URB) and produced their response to it. This may involve a number of passes and further requests for information to inform their return. Once finalised the returns from each bidder will be presented to the board for their consideration. The NHSScotland Design Assessment Panel (NDAP) should review the returns and comment. There may be workshops used in order to facilitate this process. The Central Decontamination Unit (CDU) manager and quality manager should be involved in this exercise, which may take several months. Therefore, at the outset, arrangements should be made to ensure this is possible, allowing for the fact that the CDU Manager may already be responsible for managing and operating an existing decontamination service. Decontamination technical advisors should also be involved in these assessments.

Appointment of the principal contractor

3.2. The board should notify the principal contractor once the Final Business Case (FBC) submission has been given Capital Investment Group (CIG) approval. Once the principal contractor is selected, work should begin on working up the more detailed documents required for the project. The documentation will likely require multiple iterations before arriving at an agreed package at this stage in the process. Again, this will be a time demanding exercise for the CDU manager and quality manager. The board's project management and the principal contractor should be made aware and acknowledge the validation requirements for the projects at the earliest opportunity. The board's designed person for validation of the project should have established contact at the start and maintain this throughout the project. All involved should be clear as to the handover process and the validation process (see figure 4.1). As some elements of the performance qualification (PQ) are carried out when the facility starts up, all involved should be clear that the handover of the facility to the board does not indicate that facility is satisfactory and fit for purpose. The PQ is the method employed to confirm the facility meets requirements and is satisfactory for use.

4. Design qualification of the CDU and its site

The project team

4.1. Some of those involved in the business case stages will remain and be part of the project team engaged in the detailed design. The project team may comprise of a Central Decontamination Unit (CDU) manager, a board project manager, construction company project manager, an architect, associated contractors Mechanical and Electrical, procurement staff, theatre manager, infection control, estates staff, technical advisors (decontamination) and Authorising Engineer (Decontamination) (AE(D)). The identified roles should be maintained throughout the project and where possible handovers when new staff are introduced to the team.

The project meetings

4.2. Over the duration of a project there may be a range of subgroups established to focus and progress on specific work items such as technical groups, delivery groups and commissioning groups. Regardless of the name of the group(s) there will likely be several hundred meetings for the CDU manager to attend. An awareness of how this can be managed at the same time as running an existing service should be discussed at the User Requirement Brief (URB) stage. Consider seeking assistance from other boards' CDU managers.

Sizing the department and its site

4.3. The size of a CDU and the site where it is located is based on the architect's interpretation of the requirements stated in the URB agreed before completion of the business case stages and addressing the eight design principles outlined in this guidance. Figure 4.1 shows a possible CDU layout (a single production process) following the design principles. Small scale CDUs supplying less than five theatres may not require a number of these support rooms (refer to design principle 2). For certain large scale model of production facilities, figure 4.2 presents a dual production process that provides the benefits of full duplexing. This allows maintenance activities and washer disinfectors (WDs) replacement to be carried out while retaining uninterrupted partial processing capability on site. Further still, if the facility is planned to provide contingency support to other CDUs, it would be possible to process the contingency work through a dedicated area and minimise disruption.

4.4. The URB should detail all the rooms required in the facility and also which rooms are not required. The architect should determine which of these rooms/ plant rooms are to be located at ground level, or at an upper level or whether some plant is located external to the CDU. The core production rooms should be located at ground level, with flexibility as to

where the support rooms are located, unless the URB specifically identifies where they should be located. The URB should identify any requirements for the CDU to provide contingency support to other CDUs. If so, an indication of the level of support should be specified in order that the architect can make allowance in sizing certain rooms, such as the contaminated return lobby Room 5, the processed goods store room 24 and Dispatch Room 9.

4.5. As each board's URB content will be different, it is clear that there will not be one size of CDU and its site to deliver a given output. A range of formats are possible and compliant with the design principles outlined in this guidance. There may also be restrictions to consider that will impact on the size of the facility. This can include the situation where a given area is provided and the CDU has to be located within this. Examples include locating the CDU inside an existing building or a new build where the CDU is part of a multifunctional healthcare facility.

4.6. The building design should be able to support the mechanical and electrical plant together with cable trays and trunking for cable support. If lifts are required to service the CDU, they should be dedicated.

4.7. It is essential to specify the department's required production throughput to aid assessment of 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

4.8. 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

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Considerations in selecting the location of the CDU

4.9. 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 Appendix B for an example of a site layout.

4.10. 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 an 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 and 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

The set of design principles

4.11. The design requirements should be informed by the User requirements, including operational policies for the new facility, duplexing considerations, contingency measures, sustainability and the requirements outlined in the room data sheets of this guidance. Design issues found during CDU incidents and construction projects over the last few years

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are addressed in the following principles. Those preparing the initial CDU design layout for consideration at this stage should follow these principles.

Principle one

4.12. There should be a core production set up within the CDU department comprising of the following rooms:

- contaminated returns lobby
- wash room (and its internal rooms)
- CDU cleanroom (and its internal rooms) - controlled environments pressure cascade
- sterilizer load area (including dedicated chemical sterilizer room if required)
- sterilizer unload area
- cooling area
- processed products store
- dispatch
- Quality Assurance (QA) office
- materials store

4.13. If there is to be contingency support provision in the new build the additional space required in each relevant room should be identified.

4.14. Figure 4.1 shows the expected room relationships for example the Wash Room (27) adjoins the CDU cleanroom (17) and the QA manager's office (25) adjoins both the Wash Room and the CDU cleanroom to enable viewing into both.

Note 2: The rooms are not scaled in figure 4.1.

Principle two

4.15. The support rooms required should be defined by the board in the URB. This includes a decision on the need for the use of a cart washer and its associated rooms. (A small scale CDU is likely to require significantly less support rooms than a large scale CDU).

Principle three

4.16. There should be separate and dedicated entrances (see figure 4.1) for the following:

- reception for staff/ visitors
- delivery of soiled Reusable Medical Devices (RMDs)
- removal of clinical/ general waste
- plant areas on the ground level
- delivery of raw materials
- dispatch of sterile RMDs

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Principle four

4.17. Corridors for movement of soiled RMDs and associated clinical waste should be dedicated and not cross over with (clean) circulation corridors used for movement of raw materials, sterile RMDs and staff not handling soiled RMDs/ clinical waste (see figure 4.1 General corridor 14).

Principle five

4.18. Staff making use of the staff changing rooms, staff rest room or training rooms accessed from General corridor 14 (see figure 4.1) should not cross paths with soiled RMDs/ clinical waste.

Principle six

4.19. The requirements [design, finishes, mechanical and electrical and equipment/ furniture/ fittings] specified in the room data sheets of this guidance should be complied with.

Principle seven

4.20. There should be no liquid carrying pipework above the CDU cleanroom ceiling. There should be protection measures to protect the CDU cleanroom ceiling from above. Plant and equipment above the ceiling should be minimal to reduce maintenance activity over the cleanroom ceiling. Other rooms within the production area should also be considered when taking measures to prevent ceiling damage from leaking pipework.

Principle eight

4.21. The board should be clear and document in the URB their approach to duplexing of critical services such electrical supply, water supply, ventilation and Information Technology (IT).

Lessons from incidents - building design

"New build/ refurbishment of cleanrooms - Design out the presence of liquids above the cleanroom ceiling. This includes drainpipes and wet fire systems. If not possible, protection measures from liquids for the cleanroom ceiling should be in place along with monitoring measures".

4.22. It should be noted that steam pipes, cold water or hot water pipework should not cross over the cleanroom ceiling. If a refurbishment is planned, a review of pipework above the cleanroom ceiling should be conducted. If any is found, look to remove in the first instance or provide protection and monitoring measures if the first choice is not feasible.

4.23. When considering the location (including an offsite build) for a new CDU consider risks from the surrounding environment that may adversely affect the building structure/ fabric.

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Workflow

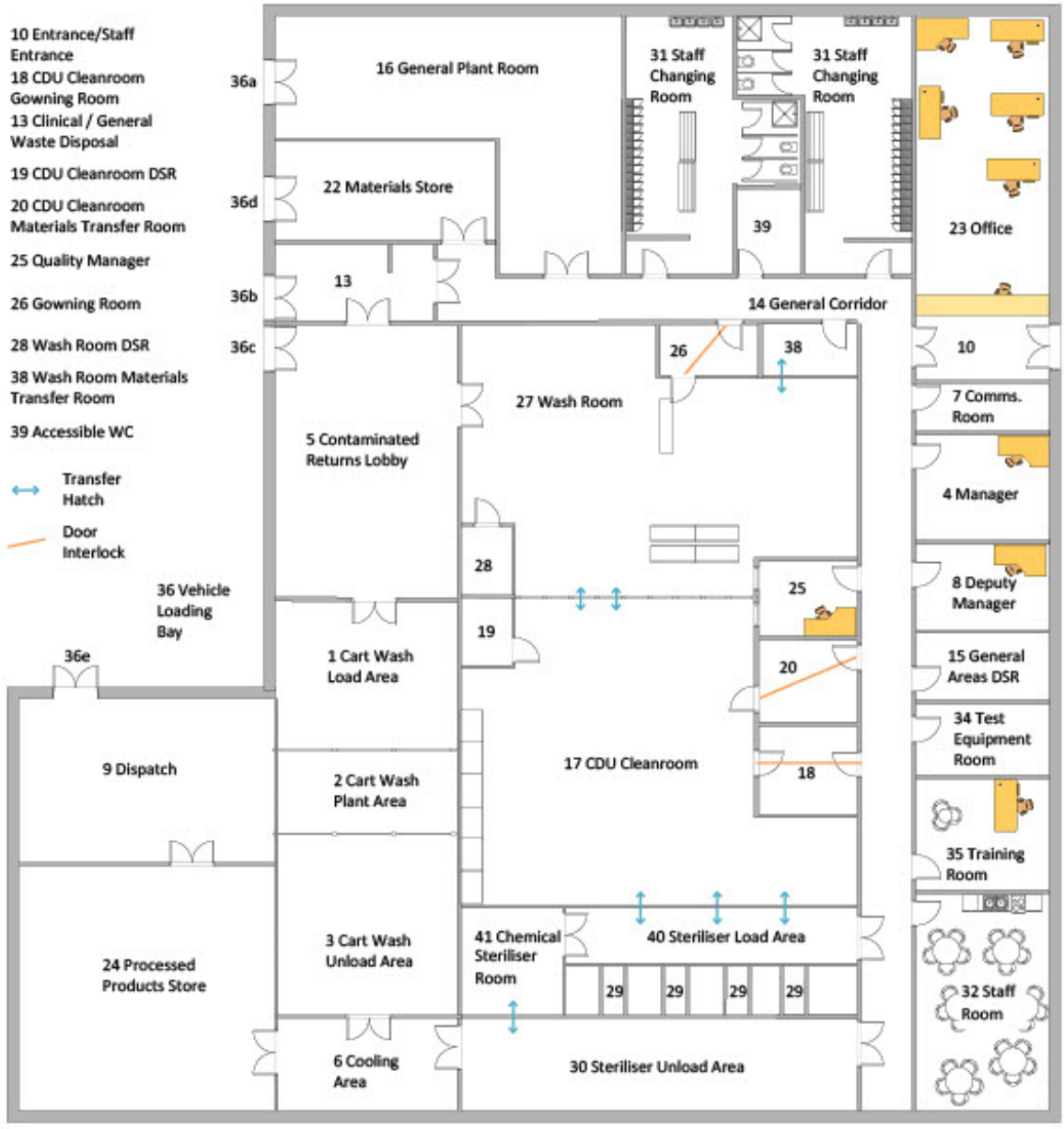
4.24. Two classifications of goods will be received at the CDU, namely contaminated items and raw materials. Design solutions should follow workflow principles, separating clean and dirty product, to avoid creating routes and cross-flows which could potentially recontaminate processed items, or adversely affect the microbiological status of raw materials. Figure 4.1 illustrates the layout of the single production process CDU model and figure 4.2 introduces a dual production process CDU. The General Corridor (14) shown in the layout is not exposed to trolleys containing used items. The activities within each room/ area are given in the Room Data Sheets (see Appendix A). Two model CDU layouts are identified for new builds to enable compliance with current technical requirements for decontamination. For certain upgrade projects these configurations may not be possible.

Single and dual production process CDU layouts

4.25. An example of a single production process layout is shown in figure 4.1. An example of a dual production process CDU layout is shown in figure 4.2.

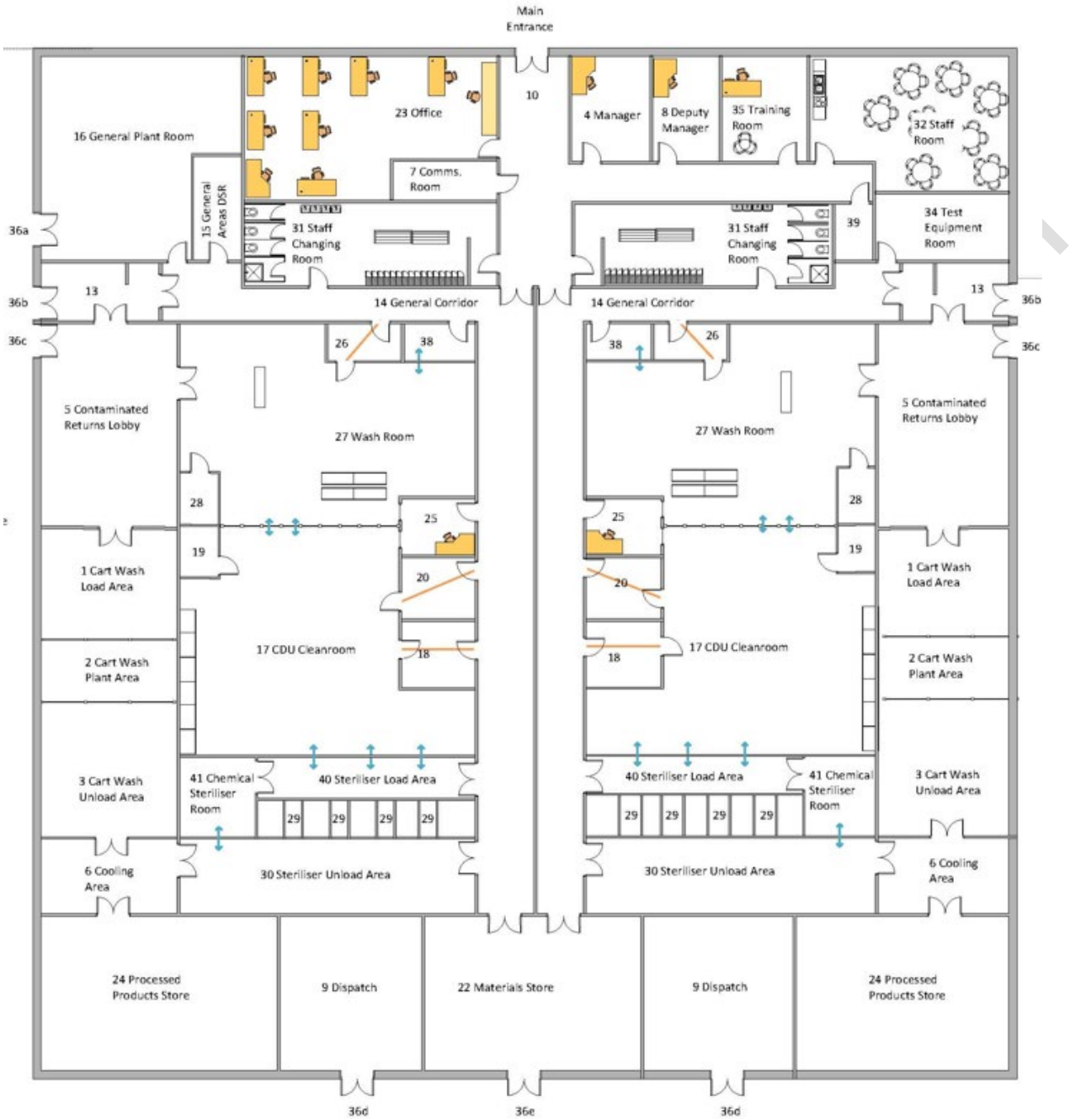
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Figure 4.1 - The single production process CDU - rooms are not scaled



Note 3: Each room within figure 4.1 has a reference number which corresponds to its Room Data Sheet. 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) and other plant areas may be required. These may be located on an upper floor. Fire exits are not shown in this figure.

Figure 4.2The dual production process CDU - dual production process side by side with some common support areas around the main entrance - rooms are not scaled



Definition of a ‘CDU cleanroom’

4.26. Two types of contamination should be controlled within the ‘CDU cleanroom’ under its operational occupancy state and these are:

- airborne particulates levels (to ISO class 8 in operational occupancy state as BS EN 14644-1: 2015)
- microbiological levels (introduced as Bio class 8 see Table 4.1)

4.27. These are the two principal parameters that require to be measured and be in control. The integrity of the ‘CDU cleanroom’ should also be maintained and satisfactory.

4.28. Other parameters should be measured and controlled, these include room air temperature and relative humidity, and pressure differentials. Other additional parameters should be measured at room commissioning and at revalidation activities. Refer to room 17 in Table A2.17. Control of the CDU cleanroom environment is one of the factors associated with the provision of reliable assurance that a processed product will be sterile and suitable for its intended use. The production activities in the CDU cleanroom consist of inspection, assembly and packing of RMDs and consumables within a variety of packaging systems ready for the next processing stage of sterilization.

Requirement for biocontamination control in CDU cleanroom

4.29. The first release of the planning note did state the need to control biocontamination in the cleanroom. However, to further strengthen the understanding of where this requirement comes from the requirements outlined in sterilization validation standards and also the principal quality management system (QMS) standard required to be followed in a CDU are discussed.

4.30. Sterilization validation standards (such as BS EN ISO 17665: 2024) indicate a sterile medical device is one that is free of viable microorganisms. Medical devices processed in the CDU in accordance with the requirements for QMS BS EN ISO 13485: 2021 may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such medical devices are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby change the non-sterile medical devices into sterile ones. The standards for QMS recognize that, for processing medical devices, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process monitored routinely and the equipment is maintained and calibrated.

4.31. However, as standard BS EN ISO 17665: 2024 indicates, exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use. This includes a number of considerations such as:

- the control of the environment in which the product is assembled and packaged
- the control of personnel and their hygiene

4.32. The standard BS EN ISO 13485:2016+A11:2021 ‘Medical devices - QMS - Requirements for regulatory purposes’ also sets a requirement to consider biocontamination control in the work environment.

4.33. In its section 6 Resource management - 6.1 Provision of resources it states “*The organization shall determine and provide the resources needed to: a) implement the quality management system and to maintain its effectiveness b) meet applicable regulatory and customer requirements*”.

4.34. Regarding 6.3 Infrastructure in its section 6.3 it states "*The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate*:

a) buildings, workspace and associated utilities

b) process equipment (both hardware and software)

c) supporting services (such as transport, communication, or information systems) The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained".

Establishing microbial limits for the CDU cleanroom

4.35. A lessons learned report recommended "*Consider the introduction of a national specification for microbial limits in the cleanroom to complement the existing non-viable contamination specification ISO class 8. Ensure there are separate limits for bacteria and fungi (yeasts/ moulds).*" As stated previously the Scottish Health Planning Note (SHPN) content applies to new builds/ major refurbishments and is not intended to be applied retrospectively. However, CDUs built before publication of this guidance should risk assess their existing in house biocontamination limits with respect to the national limits being introduced. The national microbial limits are outlined in Table 4.1. What follows is background information to aid understanding of the development of the national microbial limits given in Table 4.1.

Standards and biocontamination control in the CDU cleanroom

4.36. The QMS standard BS EN ISO 13485:2016+A11:2021 Medical devices, Quality management systems, Requirements for regulatory purposes states in its section 6.4.2 Contamination control "*As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes*."

Why is biocontamination standard BS EN 17141: 2020 applicable?

4.37. Standard BS EN ISO 13485:2016+A11:2021 does cite biocontamination control standard ISO 14698. However, this was superseded in Scotland by a new biocontamination control standard BS EN 17141:2020 Cleanrooms and associated controlled environments - Biocontamination control.

Note 4: BS EN 17141: 2020 is not an ISO standard.

4.38. The BS EN 17141:2020 foreword stated that it superseded BS EN ISO 14698 1:2003 and BS EN ISO 14698 2:2003, which were withdrawn. Scottish Health Technical Memorandum (SHTM) 03-01: 2022 also states the standard BS EN 17141:2020 should be followed in cleanrooms.

Requirements of standard BS EN 17141: 2020

4.39. The standard sets a range of requirements to consider including:

- establishment of microbiological environmental monitoring plan
- monitoring locations - The monitoring locations in the clean controlled environment and the associated number should be determined as part of the risk assessment and related to the degree of risk
- monitoring frequencies
- establishment of alert and action limits
- trend analysis
- culture media and incubation

4.40. In its Annex B it indicates, BS EN ISO 14971 dealing with medical device risk assessment and, BS EN ISO 13485 dealing with medical device quality management, are relevant documents to use as part of microbiological control.

4.41. Table B.1 of standard BS EN 17141: 2020 gives recommended limits for microbiological contamination monitoring for clean controlled environments during medical devices manufacture. The standard describes a Colony Forming Unit (CFU) as the formation of a single macroscopic colony after the introduction of one or more microorganisms to microbiological growth media. One colony forming unit is expressed as 1 CFU.

4.42. Figure 4.3 shows the limits for category 3 and 4 from the standard BS EN 17141: 2020. The limits are **average** values of all sample results and not for an individual sample site result.

Figure 4.3 - category limits given in BS EN 17141: 2020

Sampling method	Limit Category 3 (CFUs)	Limit Category 4 (CFUs)
Settle plate (90mm diameter) and four hour exposure	50	100
Contact plate (55mm diameter plate)	25	50

4.43. The standard indicated that appropriate alert and action levels should be set for microbiological monitoring based on a risk assessment and environmental monitoring

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results over time. If these levels are exceeded operating procedures should specify the corrective action required.

Note 5: These are average values of culturable viable microorganisms.

4.44. "Baseline microbiological contamination levels in the "At Rest" state and then "Operational state" should be established in order to set alert and action levels. The microbiological environmental monitoring plan should specify what objectionable species should be monitored and/ or the total CFU count as well as how the results should be evaluated, particularly adverse trends and corrective action required"

Rationale used in introduction of national biocontamination limits

4.45. Some points to note regarding limitations of the standard BS EN 17141: 2020 include:

- the standard does not specify the location of sample sites
- it does not specifically define the culture media
- the category limits are total count and do not distinguish between bacteria or fungal levels

Analysis

4.46. Active air sampling uses volumetric samplers with variable collection efficiencies between different models of samplers. The sampling volume can be standardised at 1000 litres but the format of culture media varies from strips to settle plates of variable diameter such as 90mm or 140 mm. Time to sample 1000 litres of air also varies across different samplers. The category 4 limit from the standard will be selected for bacterial levels, that is 200 CFU/ 1000 litres of air. The fungal limit will be set at 5 CFU/ 1000 litres of air.

4.47. Passive air sampling settle plate limits in the BS EN 17141: 2020 standard are based on a four hour exposure. This length of sample period is deemed impracticable in the CDU cleanroom due to the number of times that setting a work station may be performed in 4 hours and the potential for the plates to be disturbed. It is concluded setting a reduced exposure period of one hour would be practicable. Arbitrarily adjusting the standard's limits (dividing by four) would give amended category 3 limits (6/7 CFU) and category 4 (25 CFU). Again category 4 seems preferable (and cat 3 not achievable). This limit would be for the settle plate samples placed on the workstations with one hour exposure. A 2005 study of multiple CDUs for this type of settle plate monitoring showed average bacterial levels (4-16 CFU) and fungal levels (0-2 CFU), well within the limits proposed in Table 4.1. Samples placed in other areas such as the gowning room/ Domestic Services Rooms (DSR)/ material transfer hatch should be considered to have higher limits determined inhouse and are not established here.

4.48. The contact plate limit in the standard does not specify which surfaces should be sampled. Consider Category 3 limit for the workstation surface in the cleanroom as this is the surface where the RMDs are packed into their packaging system. A 2005 study of multiple CDUs

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for this type of contact plate monitoring showed average bacterial levels and fungal levels within the limits proposed in Table 4.1.

National biocontamination limits in the CDU cleanroom

4.49. The national biocontamination limits introduced in Table 4.1 relate to air and surface sampling in the CDU cleanroom. Air sampling should be performed by volumetric air samplers and settle plates. Surface sampling should be performed by contact plates. Dedicated separate sampling for bacteria and for fungi should be done using the specified selective media. Tryptic Soy Agar (TSA) culture media is selected for bacteria detection. Sabourand Dextrose Agar (SDA) culture media is selected for fungi detection. Two samples at each sample location are taken for fungal detection and incubated at different temperatures. Limits should be considered as the action levels. Boards should develop alert levels through trending their microbial monitoring exercise results. Routine sampling frequency should be monthly at start up then reduced to quarterly after three months.

Table 4.1 - Bio class 8 in the operational occupancy state of the CDU cleanroom

Bacteria limits - *culture media TSA (incubation minimum 3 days at 30-35°C). Limit is an average of all sample locations tested	Fungal limits - *culture media SDA (Two samples, one incubation 4 days at 20-25°C and other 4 days at 30-35°C). Limit is an average of all sample locations tested
Active air sampling. Sample 1000 litres of air at each sample location as Table 4.2 and sample at workstation height. Limit 200 CFU/ 1000 litres of air. [only bacterial counts recorded from these plates/ strips]	Active air sampling. Sample 1000 litres of air (twice) at each sample location as Table 4.2 and at workstation height. Limit 4 CFU/ 1000 litres of air. [only fungal counts recorded from these plates/ strips]
Passive air sampling. Settle plate limit of 25 CFU from one hour exposure on a 90mm diameter plate placed on each workstation identified in the sample plan. [only bacterial counts recorded from these plates]	Passive air sampling. Settle plate limit of 4 CFU from one hour exposure of two 90mm diameter plates placed on each workstation identified in the sample plan. [only fungal counts recorded from these plates
Surface sampling of workstation surface. Contact plate limit of 20 CFU/ 55mm diameter plate sampling the workstation surface. [only bacterial counts recorded from these plates]	Surface sampling of workstation surface. Contact plate limit of 4 CFU/ 55mm diameter plate sampling the workstation surface (twice). [only fungal counts recorded from these plates]

4.50. Where microbial limits are exceeded and investigation is required, the bacterial and/or fungal species of concern should be identified. There are seasonal variations in fungal levels in the outside environment, that is higher levels in summer, which should be considered in any risk assessment investigations.

4.51. The number of microbial sampling locations (three samples per location) for the active air sampling is given in Table 4.2 and is based on the CDU cleanroom floor area. This is based on the standard BS EN 17141: 2020. The number of workstations to be sampled (by settle plates and contact plates) should be based on a risk assessment and be identified on a sample plan. It should be a representative number and include workstations close to the gowning room door, the DSR door, any transfer hatch and any other area entrance/exit from the cleanroom. Boards should consider sampling other surfaces such as the floor and walls in the CDU cleanroom (17), its DSR (19) and gowning room (18). There are no national microbial limits set for these surfaces at this time. Boards should through trending their microbial monitoring data demonstrate that these surfaces are effectively cleaned and the microbial levels are in control.

Table 4.2 - The number of active air sample locations based on the CDU cleanroom floor area

CDU cleanroom area (m^2)	Minimum number of sample locations
Up to 52	3
53 to 68	4
69 to 104	5
105 to 148	6
149 to 232	7
233 to 436	8

Biocontamination limits in the at rest occupancy status in the CDU cleanroom

4.52. There are no proposed national limits for testing in the at-rest occupancy state. The expectation should be that the biocontamination levels would be within the limits proposed in Table 4.1. If the test results did not achieve this then further cleaning activities should be conducted prior to retesting in the at-rest occupancy state. Refer to the Operational Qualification (OQ) for the CDU cleanroom in section 6 of this guidance.

Continuous monitoring system for airborne particles in the CDU cleanroom

4.53. The fixed system is not used for classification purposes to verify the CDU cleanroom is compliant with ISO class 8 as is performed/ confirmed in a periodic exercise such as every 3 months. It should be used for monitoring purposes. PD ISO/ TR 14644-21:2023 Cleanrooms and associated controlled environments Part 21: Airborne particle sampling techniques distinguishes between classification and monitoring as applicable to the cleanroom.

4.54. Reasons for introduction of a fixed system to enable continuous monitoring of air particulate levels in the CDU cleanroom are as follows.

4.55. Lessons learned from recent major CDU incidents related to the CDU cleanroom.

4.56. Improved awareness of the room performance such as:

- the system may provide early alerts of problems that may be addressed asap and not develop into a bigger problem - such as shut down of production
- the fixed system will indicate recovery times for the cleanroom air particulate levels
- the fixed system will provide live data to indicate room performance when ramping up to full production that is when the maximum number of staff are working in the cleanroom

4.57. Sustainability considerations that now require to be considered that were not present when the SHPN 13 part 1 v1 was published in 2011. The energy management standard for cleanrooms BS EN 14644-16: 2022 includes examination of turn down of the air supply to the cleanroom. A fixed monitoring system enables this energy saving measure to be introduced and controlled.

4.58. The SHPN indicates there should be no ceiling hatches in the CDU cleanroom. If derogations are required concerning this, then suitable measures should be taken to address this.

4.59. A fast and reliable method is the use of a fixed system providing early warning of ceiling hatches not being closed properly or the seals being compromised. The greater the number of ceiling hatches the greater the need for live monitoring.

How to determine the number of sample locations required for the fixed system

4.60. The rationale is a risk assessment in providing coverage around workstations if possible with monitor boxes located on power pendants at a height that is not obtrusive to work station activities. If placing on walls locate away from air extracts or air pressure stabilisers or any obstruction and consider there may be an extract flow from the monitor boxes.

Note 6 - sampling probe may be positioned vertically.

4.61. Commissioning - once installed and operational, arrange a comparison with a portable particle counter and its results. The intention being to establish a correction factor into the monitoring system such that the fixed system is in line with the portable system. Again, to be clear, the fixed system does not provide full room coverage that is required and provided by a portable particle counter when conducting periodic testing. Note that cleaning activities with a vacuum cleaner will raise particle levels and be observed by the fixed system.

Project documents and quality control at design stage

4.62. The URB should have been produced as part of the final business case. Control of the resulting design that develops from the URB should be done through the Design Qualification (DQ) for the new CDU. This activity comprises of two parts, that being the method or protocol defining the qualification activities and the report defining the results/ conclusions of these activities.

The design qualification protocol

4.63. The DQ protocol should identify the project team individual(s) that are tasked with carrying out the necessary quality control checks of documentation over the project duration. This is a required element in the validation of the new CDU in line with compliance guidance GUID 5014 v3: 2024 and the QMS standard BS EN ISO 13485: 2021. The project documentation may comprise a range of formats of documents such as architectural drawings, Mechanical and Electrical drawings, and worksheets including an environmental matrix. The majority of this information requires to be checked across these different types of documents. This is to ensure that the information is in agreement and does not conflict between documents. For example, the information in the 1:200 scale layout CDU department drawing (see figure 4.4 for an example) and the 1:50 room layouts (see figure 4.5 for an example) should be agreement with the information contained in the environmental matrix. The quality control check should cite the revision of each document that was part of the review. There should be multiple quality control checks required over the duration of the project as the design developments and different revisions of the documentation are produced. All involved should be made aware of the scale of the exercise - a CDU may have 30 to 40 rooms each with multiple drawings covering layout, equipment schedule, finishes/ fixtures. Each of these may have multiple iterations before arriving at an agreed version.

4.64. The environmental matrix should be checked for agreement with the specifications given in the SHPN 13 part 1.

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Figure 4.4 - shows a 1:200 scale example layout drawing of a CDU (highlight blue)

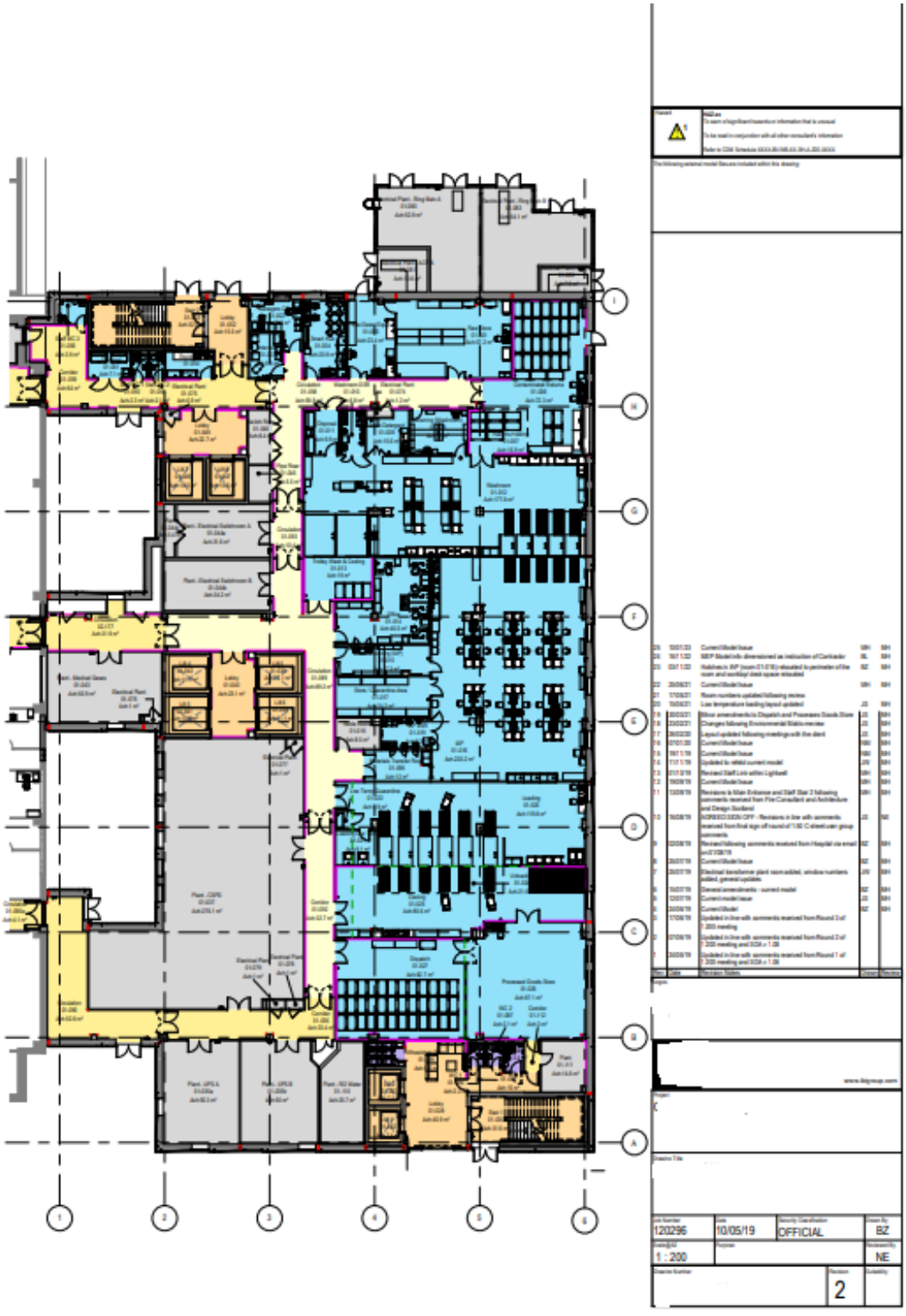
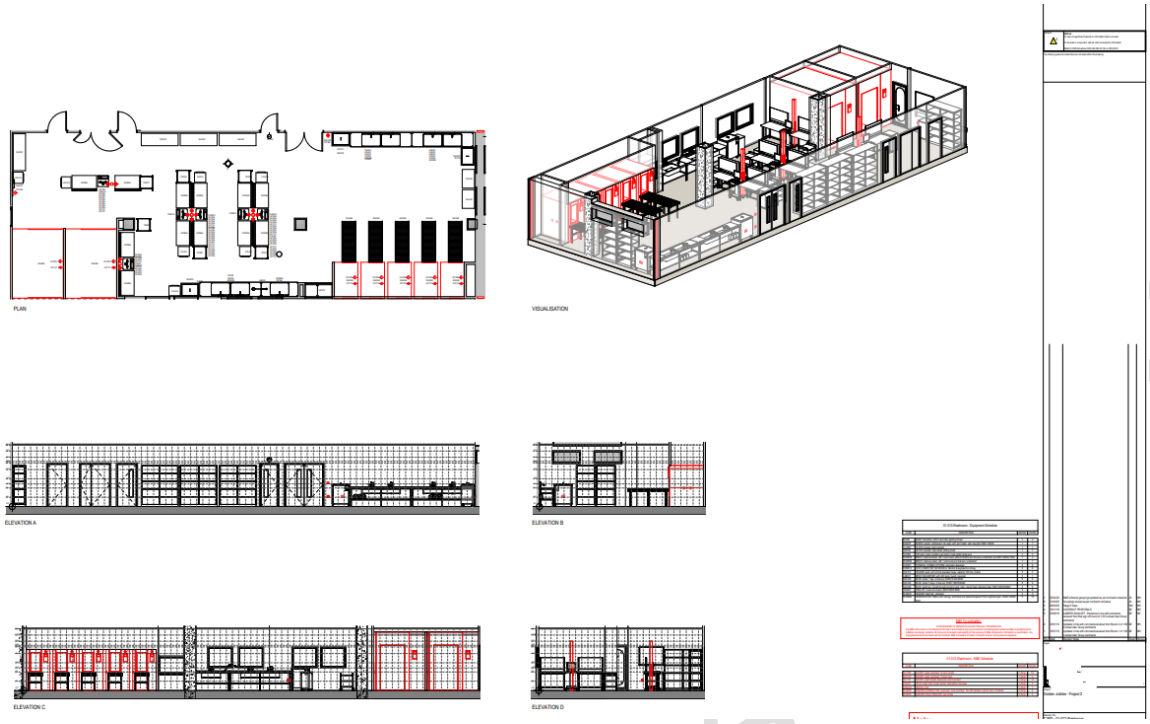


Figure 4.5 - 1:50 scale example layout drawing of a room



4.65. The verification exercise should confirm the department layout 1:200 meets the requirements stated in the approved URB. The qualification exercise should be independent of the architect that prepared the department layout drawing.

4.66. The verification exercise should confirm the environmental matrix meets the requirements stated in the approved URB. The environmental matrix should cite the current version of the 1:200 department layout drawing. These two items should be checked as a package. There should be clarity between board and the principal contractor architect on verification of group 2 items and challenges of group 3 items. The dimensions of fixed group 3 items should be specified on the 1:50 layout drawings.

4.67. The verification exercise should confirm that for every room in the CDU there is a corresponding 1:50 layout drawing (see figure 4.4 for an example) and their content meet the requirements stated in the approved URB.

4.68. The equipment/ fixtures schedule and other schedules (such as Mechanical and Electrical) on each 1:50 room layout should be checked to agree with the URB and the SHPN. The number of each item should be checked, the dimensions of each item should be stated. The description should be checked for accuracy, the group rating (1, 2 or 3) is correct and the count is correct and marries up with the room layout drawing.

4.69. Technical review that confirms the proposed design meets the requirements of this guidance namely SHPN 13 part 1 - non compliances should be identified, and an agreed documented record of the action taken.

4.70. The project team should sign off a design approval document which cites the revision number of each of the documents that comprise the design information. The agreed master

list of layout drawings and other information (such as the environmental matrix) should be produced prior to any construction activity.

4.71. The agreed master list of layout drawings and other information becomes the documents used in verifying the construction (that is at the operational qualification).

4.72. Who supplies, buys and installs equipment - explain categories 2,3,4 on 1:50 schedules 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

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

Approved and signed off master list of documentation

4.74. When planning a new build with an agreed URB - with the CDU model layout (see figure 4.1, figure 4.2 or other), the site layout (see figure B.1), the Site Data Sheet (see Table B.1) and the relevant 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 (see figure 4.1 or figure 4.2). The Room Data Sheets provide guidance on Design, Finishes, Mechanical and Electrical and Equipment/ Furniture/ Fittings. An example of a partially completed master list of layout drawings is shown in figure 4.6 and this requires signatures of approval by those specified in the DQ protocol.

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Figure 4.6 - Master list of layout drawings and environmental matrix

Layout scale	Area	Drawing title	Drawing reference number	Drawing version number	Date of version
*1:200 scale	Department				
1:50 scale	Contaminated Returns Lobby				
1:50 scale	Cooling Area				
1:50 scale	Communications Room				
--------	----------				
*Environmental	Matrix version	number	date	cites layout 1:200	
Master list approved by:_____			Date: ____		

4.75. For every room in the department 1:200 scale layout there should be an individual room layout drawing at 1:50 scale, this includes plant rooms.

4.76. Environmental matrix should be version controlled. The approved version should reference the approved version of the 1:200 layout drawing (see figure 4.6).

The design qualification report

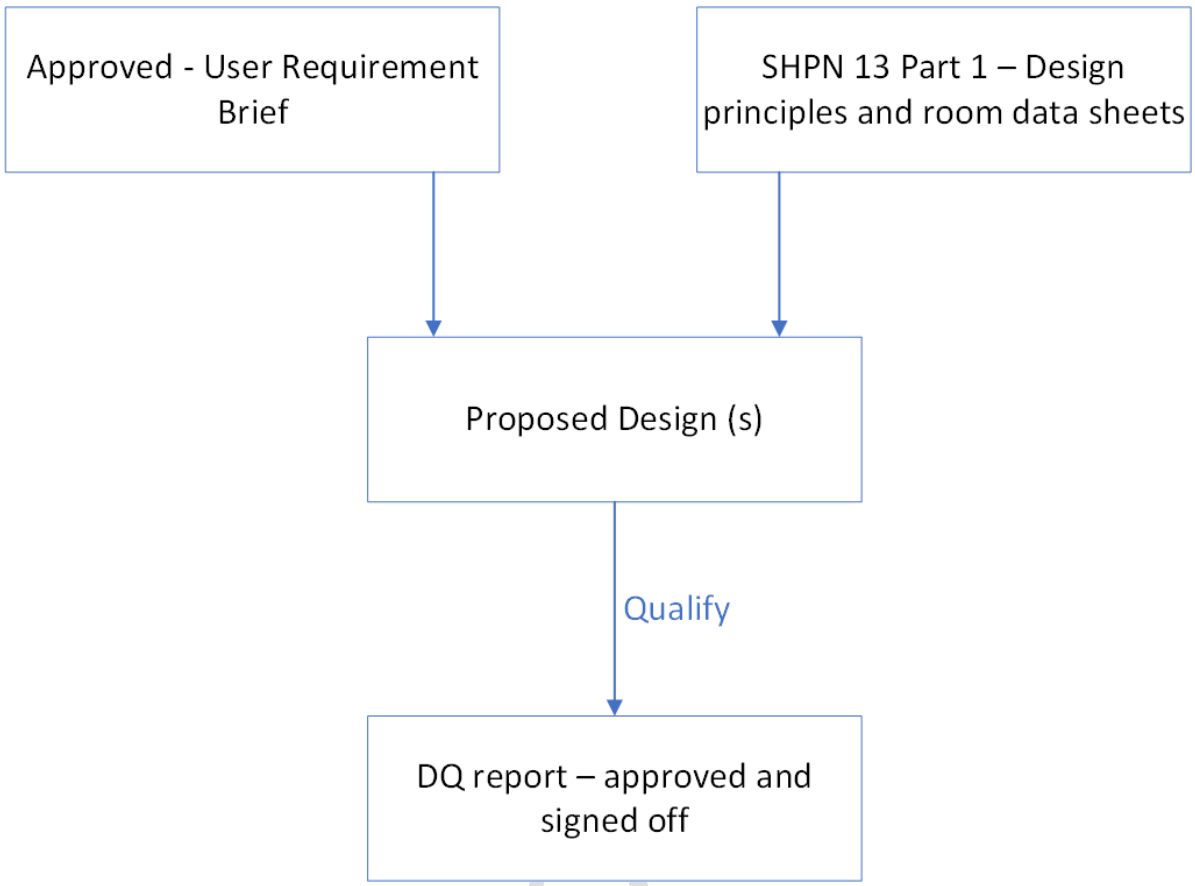
4.77. The DQ report should outline that the chosen design at this point in the project has:

- been assessed as per the DQ protocol
- considered the content of the approved version controlled URB
- met the design principles of this planning note
- defined and got agreement on any derogations
- the controlled master list of documentation included and signed off
- been confirmed as being satisfactory by all stakeholders
- been signed off prior to the commencement of construction of the new build

4.78. Figure 4.7 shows the information input needed or to be considered to set a proposed design that is then qualified as per the DQ protocol resulting in the DQ report.

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Figure 4.7 - Input required/ considered for proposed design then qualified as per the DQ protocol to produce the DQ report



Design change management

4.79. It is possible a design change is required after the project team has approved the design documentation. In this case standard change management practices should be followed. This should include an examination of the proposed change(s), options, any impacts and a sign-off by the project team prior to the implementation of any agreed changes.

4.80. When qualifying the design invalid reference guidance such as from Activity Data Bases (ADBs) and Health Building Note (HBN) 13 should not be used.

Sustainable design - SDaC

4.81. The Health Facilities Scotland (HFS) publication Scottish Health Technical Note (SHTN) 02-01: 2021 on Sustainable Design and Construction (SDaC) covers wellbeing, circularity and climate change. All elements outlined in the guidance should be considered. Some specific items are mentioned under staff wellbeing and climate change.

Staff wellbeing

4.82. The SDaC covers a range of items for consideration. Some specific items to consider for CDUs include:

- natural light as much as possible inside the department
- staff room facilities including space for recreation at breaks
- consideration of external space around facility for staff exercise at break times
- Greenspace considerations
- consideration of safety aspects given staff working night shifts
- good transport onto the site - and safe walking around the site
- choice of site location must consider staff safety walking to the site

Climate change

4.83. Climate change considerations include operational energy, emissions, embodied carbon, water consumption and waste. Look to identify the opportunities to remove/ reduce these factors. There should be an assessment of the decontamination equipment, the services (cold/ hot water, compressed air, air conditioning and consumables required to run the facility and operate the compliant decontamination process.

4.84. It is clear that CDUs have a high operational energy requirement given the decontamination equipment and associated services in use. WDs operating at 90°C, porous load sterilizers operating at 134°C and cart washers operating at 80°C are examples. Water treatment plant including Reverse Osmosis (RO) units can be hot systems. There can also be high chemical use and water consumption for WDs and cart washers. Waste water quantities may also be significant.

4.85. There has been a move away from gas boilers to produce steam in the CDU (Existing CDUs may still have gas boilers in use at the time of writing). Porous load sterilizers can now be purchased with electrically produced steam. WDs can be purchased with reduced water consumption requirements. Also there may be energy saving opportunities such heat recovery from WD waste water, and pre-heating water using heat pumps. These considerations should be addressed in the URB.

Circular design and construction

4.86. The SDaC states a circular design and construction approach should be adopted with the aim of keeping materials in use for longer. Commit to a circular procurement hierarchy approach, as defined by Zero Waste Scotland:

- prevention
- reduce
- reuse
- recycle
- recover

4.87. Design out waste and pollution from the start. Adopt responsible design, procurement and construction practices. Design to restore and regenerate natural systems. Design for

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assembly, disassembly and recoverability. Consider expected product lifespan for all building elements and 'durable' components, including management, maintenance and replacement. Consider opportunities for the use of reused, recycled and recyclable products.

Energy efficiency in the CDU cleanroom

4.88. At the heart of the decontamination unit is controlled environment, a cleanroom operating continuously with large quantities of highly conditioned air. The energy management standard for cleanrooms (BS EN 14644-16: 2019 Energy efficiency in cleanrooms and separative devices) addresses energy reduction potential. One of these is the turn down of the air supply to the cleanroom when production is not taking place. Within the standard there is in its Table B.1 an energy savings opportunity checklist which should be considered.

4.89. Also consider the need for duplexing in giving assurance of the maintenance of continuity of a sterile service provision and the sustainability impact of this.

Refurbishment - upgrading or adaptation of existing buildings/ services

4.90. Refurbishment activities should in the first instance look to comply with the design principles outlined in this guidance. It is recognised that this may present a significant challenge. Where that is the case a risk assessment should be carried out addressing each of the eight design principles.

4.91. 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 for example adjacencies. It is anticipated that the quality of finishes and mechanical and electrical 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 health boards. 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.

4.92. 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.

4.93. 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 including water mains, drains, emergency generators and boilers.

4.94. 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.

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

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

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

4.98. 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.

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4.99. 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.

4.100. 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 'Scottish Health Facilities Note (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 and turning may cause considerable disruption within a hospital site. Road/ footpath and surface water drainage may suffer damage as a result of construction related traffic.

Access and facilities for disabled people

4.101. 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'

4.102. Project teams are encouraged to refer to SHFN 14: 2000 'Disability access', which gives guidance and a set of ergonomic data sheets on access, space and equipment relating to disabled people in health buildings.

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

Building Environment

Natural lighting

4.104. 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.

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4.105. 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.

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

4.107. 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: part A 2014 Information for Design Teams, Construction Teams, Estates and Facilities and Infection Prevention and Control Teams.

Artificial lighting

4.108. 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 (Chartered Institute of Building Services Engineers (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.

4.109. 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 CDU cleanroom (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.

4.110. 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

4.111. 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 (also see the Engineering services section on ventilation).

4.112. Consideration of the ventilation requirements at the 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 WDs or sterilizers. Duplex air conditioning plant would be required to maintain the production environment while maintenance duties are performed on offline plant.

4.113. WDs and sterilizers emit considerable heat and humidity and 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 7: The Room Data Sheets specify where there should be no recirculation of extract air.

4.114. The CDU cleanroom Room (17) and its DSR (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: 2015. The CDU cleanroom Gowning Room (18) and the CDU cleanroom 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: 2015. The Room Data Sheets specify the required pressure differential cascade system in the CDU. Pressure differential indicators, visible from outside the CDU cleanroom 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 CDU cleanroom (17) should indicate this.

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

Noise

4.116. Careful consideration should be given to the choice of surface finishes (as specified in the Room Data Sheets) especially in the Wash Room (27), CDU cleanroom (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 08-01: 'Acoustics'). Equipment such as the Sterilizers may require to be sound-proofed. Noise Limits are specified in the Room Data Sheets in line with the Noise at Work Regulations 2005.

Maintenance

4.117. Building and engineering maintenance/ testing can compromise the integrity of the product or the production environment. Permit to work systems should be in place for facilities work as well as when working on decontamination equipment. Contractors whose work impacts on the CDU cleanroom should have suitable cleanroom training as part of the permit

system. A permit to work process is outlined in SHTM 01-01:2018 part A. Maintenance and testing which compromises the integrity of the CDU cleanroom (17) and/ or environment cannot be undertaken within the CDU cleanroom (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, for example ceiling hatches in the CDU cleanroom (17), the impact of downtime and recertification of the area prior to production start-up should be both understood and documented.

4.118. Test and maintenance equipment and tools brought into the CDU cleanroom 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 CDU cleanroom Room (17), a suitable dedicated storage location accessible only from the CDU cleanroom should be provided that is CDU cleanroom DSR (19).

4.119. 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.

4.120. Locating the plant areas of the CDU on an outside wall at ground-floor level as figure 4.1 will help maintenance staff to access these areas easily.

Cleaning

4.121. 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

4.122. 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 and sinks 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 CDU cleanroom (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.

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

4.124. 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 for example 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

4.125. 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

4.126. The floor finish should be hard-wearing, non-slip, easy to clean and, in the CDU cleanroom 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.

4.127. Doorways between adjoining rooms are points of stress in the floor finish and thus their design requires particular attention.

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

4.129. Structural expansion joints should be positioned with care to avoid heavily trafficked areas, particularly where trolleys turn corners. Construction and expansion joints in the floor structure of the CDU cleanroom (17) should be stable and sealed prior to application of the final floor finish.

Walls - see room data sheets for individual rooms

4.130. 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

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construction should eliminate these risks. Solid walls should be rendered to a finish as defined in the Room Data Sheets.

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

4.132. 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

4.133. 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 CDU cleanroom Room (17) or rooms directly connected to it.

4.134. Ceiling design solutions should not allow access to engineering services from the CDU cleanroom Room (17) or rooms accessible from within, unless unavoidable. The CDU cleanroom (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: 2022). Where access is from within the CDU cleanroom (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 CDU cleanroom (17) ceiling.

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

Door sets

4.136. 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 CDU cleanroom (17), its Gowning Room (18) and the CDU cleanroom 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.

4.137. All emergency exits should have a means (audible) of indicating they have been opened particularly in the CDU cleanroom (17) and preferably connected to a building management

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system (BMS) to record the event. Door seals should be checked regularly to avoid contamination ingress.

4.138. 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

4.139. Windows in the Wash room (27) and CDU cleanroom (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. Reflective glass where applicable should be considered to minimise passive heat gain.

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

Security

4.141. Consideration should be given to the provision of Closed circuit television (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

4.142. 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 and 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.

4.143. 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 and rinsing sinks (wash room 27 only)

4.144. 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.

Modular construction

4.145. The term modular construction is open to interpretation. And in this regard different suppliers of modular constructions may provide different products. This can range from supply of an “empty” module to a module that is fully fitted out with equipment, furnishings and fittings. That said, modular construction may provide a number of benefits when considered against a traditional build.

4.146. A module that is constructed offsite at a factory and has equipment/ furniture and fittings installed in the module before leaving the factory site should allow good quality control conditions under a factory’s QMS with temperature control and good lighting conditions. Contrast this with a busy construction site with multiple contractors competing for the same workspace sometimes at height and under limited light levels.

4.147. A module that is fitted out at the factory may allow customer visits at various stages to verify the construction is in line with the customer’s expectations. Certain amendments if required will be easily dealt with at the factory as opposed to modifications onsite to a CDU under construction.

4.148. Another significant difference to that of a traditional build is that the User Requirements specification for their CDU must be agreed and supplied at a significantly earlier stage in a project.

4.149. Sustainable design considerations may be better addressed by modular construction in terms of the end of life recovery of materials.

4.150. There are some unique challenges presented by modular construction. It is recognised that transporting modules from the factory site to the customer’s site will likely results in some cracking of the module. This should be discussed with the supplier and agree how this is to be addressed once the module arrives on site.

4.151. Experience indicates that storage of modules pending delivery or while stored in other locations can result in environment damage if insufficient protection is in place.

Engineering services

4.152. 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.

4.153. 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. There should be a 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: 2021 Medical devices - Quality management systems - Requirements for regulatory purposes. This VMP should include validation of engineering services.

4.154. 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

4.155. The DQ exercise as part of the VMP should consider all of the above matters.

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Technical specifications and manuals

4.156. 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 01-01: 2018. The Room Data Sheets within this planning note specify the required room conditions.

Economy and value management

4.157. 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

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

4.159. 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).

4.160. 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.

4.161. 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 BMS and metering arrangements should enable areas for performance improvement in the use of fossil fuels to be identified.

4.162. Energy management should be part of the site 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 08-05: 'Specialist services, Building management systems 2012'.

4.163. 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 WD discharge must be considered.

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Service requirements

4.164. 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 URB 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 DQ stage as required by the VMP.

4.165. The estimated maximum demand and storage requirement (where appropriate) for each engineering service (water, electrical, steam, gas) 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.

Space for plant and services

4.166. Enough space should be provided for the maximum required footprint for plant and services within the CDU. The amount of space (and dedicated rooms) 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, RO water generation, and water storage of defined capacity, for example 12 or 24 hours supply
- emergency backup 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
- solar panels and heat pumps
- air compressors
- emergency generators including fuel storage to allow a specified running time
- sprinkler systems
- control panels

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4.167. 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 CDU cleanroom 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

4.168. 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. 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).

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

4.170. 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 DQ. Emergency lighting, alarm sounders and illuminated exit signs at fire exit doors should be specified.

Access to control and isolation devices

4.171. Primary engineering distribution control and isolation devices should be:

- located in plant rather than working areas and not in the CDU cleanroom 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

4.172. The Health and Safety at Work Act 1974 (HSWA), and amendments by the Consumer Protection Act 1987, 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 (PUWER), impose statutory duties. Employers and designers require to minimise any risks arising from the use, cleaning or maintenance of engineering systems. One of the requirements of this legislation is to ensure, as far as is reasonably practicable, that design and construction is such that articles and equipment will

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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

4.173. It is essential that the design team familiarise themselves with the guidance contained in the Firecode suite of documents, which contains Scottish Government Health Department (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: 2023 should be used as a risk assessment tool to help formulate the fire action safety policy.

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

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

4.176. 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.

4.177. 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 CDU cleanroom (Room (17)) thereby impacting on production, while other systems for example 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' 2006
- SHTM 57: 'Internal glazing' 2006
- SHTM 58: 'Internal doorsets' 2006
- SHTM 59: 'Ironmongery' 2006
- SHTM 60: 'Ceilings' 2009
- 'Wayfinding' 2016

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

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

Noise and speech privacy

4.180. 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.

4.181. 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

4.182. There should be a VMP for the build project with qualification exercises for the design, installation, operation and performance of the facility. This will include the engineering services that should be validated in accordance with the methods identified in the current versions of the relevant SHTM. Flow measurement and proportional balancing of air and water systems require adequate test facilities to be incorporated at the design stage for example test points either side of filters for integrity testing. Guidance is also contained in commissioning codes A (1996) and W (1994) published by the CIBSE. Also, BS EN ISO 14644-3: 2019 will be applicable when testing high-efficiency particulate air (HEPA) filters.

Equipment validation

4.183. Decontamination equipment should be validated fully in accordance with the relevant protocol in SHTM 01-01: 2018 series, BS ISO 22441: 2021 for vH2O2 sterilizers and BS EN 15883-6: 2015 for WDs used to process transport carts.

Mechanical and electrical services

Heating

4.184. The production environment should be controlled by the mechanical ventilation system. That is there should be no radiators in the Wash Room (27), CDU cleanroom 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

4.185. 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. Facilities should be provided to override the control system on those occasions when the CDU needs to operate outside 'normal' working hours. 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. The choice of controls should take account of the extent to which they can be linked to, or provided by, a 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. Consideration should also be given to modulating the flow temperature to the heating appliances in accordance with the external ambient temperature.

Ventilation

4.186. The following factors determine the ventilation needs within the various spaces of a CDU (the ventilation needs are specified in the mechanical and electrical section of the Room Data Sheets):

- those associated with the functional requirements or process within the space, for example, minimization of contaminants within the CDU cleanroom
- 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
- maintenance of pressure differentials to provide controlled environmental requirements

4.187. 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. 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. Ventilation supply plant should include a pre-filter and a secondary filter (to BS EN ISO 16890-1: 2016) as defined in the Room Data Sheets such that the specified room conditions are achieved. It should be noted that BS EN ISO 16890-1:2019 established a new efficiency classification system of air filters for general ventilation based upon particulate matter (PM) when it superseded standard BS EN 779: 2012.

4.188. 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 CDU cleanroom Room (17) air supply, terminal HEPA filters should be considered. 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 CDU cleanroom (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.

4.189. A separate extract system will be required for sanitary facilities. A dual-motor fan unit with an automatic changeover facility should be provided. 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 (WDs) should be self-contained, dedicated to the equipment and be independent of the general department extract system. Reference should be made to SHTM 01-01:2018 ‘Washer-disinfectors.

4.190. The mechanical-ventilation system should be designed and constructed to ensure that, when the CDU cleanroom Room (17) and its DSR (18) is tested in accordance with BS EN ISO 14644-1: 2015 in the ‘operational’ occupancy state, that is during production the airborne particulate classification should be compliant with ISO class 8 (see Room Data Sheets 17 and 18). Consideration should also be given to heat gains from all sources, including process equipment and processed goods entering the CDU cleanroom Room (17) via the WDs. The Room Data Sheets specify the positive air pressure differential regime that must be maintained within the CDU cleanroom (17) and its adjoining areas. Room air temperature and relative humidity levels are also specified. To minimize outside air entering the CDU cleanroom Room (17), it will need to have non-openable windows and a sealed ceiling. Consequently, the spaces which communicate with the CDU cleanroom (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. Where small, open hatches are required to accommodate conveyor systems between the CDU cleanroom Room (17) and the Wash Room (27), for example, they should be validated to confirm they do not compromise the integrity of the CDU cleanroom Room (17).

4.191. 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 CDU cleanroom 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. 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. Air conditioning should be included where required to achieve the temperature and relative humidity limits specified for each room in the Room Data Sheets. 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 BMS serving the whole site. Indication and alarm of status of the ventilation system should be provided in the CDU cleanroom 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

4.192. Guidance on the design and installation of hot and cold water supply and distribution systems is contained in SHTM 04-01: Water safety for healthcare premises part A: Design, installation and testing: 2014. Requirements for the control of legionellae bacteria in hot and cold water systems are set out in the SHTM. 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 than 50°C. It should be boosted locally where necessary for WDs 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. RO water supply system(s) may be installed to ensure the quality of final rinse water to WDs meets the requirements of SHTM 01-01: 2018. These should be designed, installed, maintained and periodically tested according to the guidance in SHTM 01-01: 2018 and manufacturer's instructions.

Equipment

4.193. Energy-efficient equipment should be chosen where possible. Such equipment also reduces the load on ventilation systems. WDs, 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 WDs is contained in SHTM 01-01: 2018. Energy usage and water usage should be considered in the procurement stage.

Piped medical gases

4.194. 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 02-1 Medical gas pipeline systems. part A: Design, installation, validation and verification 2012.

Compressed air (industrial)

4.195. 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 SHTM 01-01: 2018.

Steam

4.196. Steam should be supplied in compliance with the requirements of SHTM 01-01: 2018 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 SHTM 01-01: 2018 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.

Fuel supply for back-up generator

4.197. Diesel fuel may still be required for a back-up generator (see Appendix B External Site Data Sheet).

Vacuum cleaning system

4.198. 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

4.199. Electrical installation should comply with BS 7671: 2018+A2: 2022 - 'Requirements for Electrical Installations'. The point of entry for the electrical supply will be a secure switchroom area (or switchrooms if duplexing) 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. The electrical installation in occupied areas should be concealed using thermoplastic-insulated cables and screwed steel conduit or trunking (in

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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. Also refer to SHTM 06-1: 2015 Electrical services supply and distribution part A: Design considerations.

Electrical interference

4.200. 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. Electrical products, systems and installations should not cause, or be unduly affected by, electromagnetic interference. Advice on the avoidance and abatement of electrical interference is contained in SHTM 06-01 part A 2015. Fluorescent luminaires should comply with BS EN IEC 55015:2019+A11:2020 Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment.

Lighting

4.201. Practical methods of lighting the various functional spaces are contained in the CIBSE Lighting Guide LG2, 'Hospitals and healthcare buildings'. Light levels and levels of protection (IP) of fittings/ enclosures are specified in the Room Data Sheets. Colour finishes and lighting throughout circulation areas should be coordinated to create a calm and welcoming atmosphere. The lighting solution should meet the Health and Safety (Display Screen Equipment) Regulations 1992. Further guidance is contained in the CIBSE Lighting Guide LG3. 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. 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. Energy-efficient luminaires should be used whenever possible. Intermittently and infrequently used luminaires may be fitted with compact source fluorescent or incandescent lamps. 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. 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. Safety lighting should be provided on primary escape routes in accordance with SHTM 06-01: 2015. Emergency lighting of control rooms should be arranged in accordance

with the requirements of users and the guidance in. The design team should ensure that emergency lighting and alternative equipment (torches) 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 CDU cleanroom 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 CDU cleanroom Room (17).

Socket-outlets and power connections

4.202. Consideration should be given to the provision of devices to protect the integrity of electronic data held within microprocessor-based equipment. 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 IP required of each socket. This covers protection regarding solids and liquids where applicable. 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. 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. 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 IP for electrical sockets in each area is specified in each Room Data Sheet. Heating appliances and automatic equipment should have indicator lights to show when they are energised. Indicators should be incorporated in the control panel of the apparatus, in the control switch, or in the socket-outlet from which the apparatus derives its supply. The electrical supply connections to electromedical equipment should comply with SHTM 06-01: 2015. 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. If appropriate socket-outlets should be

connected to essential circuits in accordance with the advice contained in SHTM 06-01: 2015. 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 to be maintained in the CDU area.

Emergency electrical supplies

4.203. Guidance on emergency electricity supplies is contained in SHTM 06-01: 2015 series 'Electrical services supply and distribution'. Requirements for connection of individual circuits and items of equipment to Uninterruptible Power Supply (UPS) and/ or standby generation systems should be discussed with users and with equipment suppliers. The 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. 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

4.204. 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). 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

4.205. 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

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4.206. The positioning of the various cable containment systems needs 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 and so on) are not damaged. Service ducts should be designed so that services can be easily accessed away from the CDU cleanroom Room (17). Reference should be made to SHTM 00: 2013 on 'Access and accommodation for engineering services'. Process verification data should be provided for WDs 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

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

4.208. Protection against lightning should be provided in accordance with SHTM 06-01: 2015 'Electrical services supply and distribution'.

Internal drainage

4.209. 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

4.210. The design of internal drainage should comply with the relevant Standards and Codes of Practice, including BS EN 12056-2: 2000, and the current building regulations. Recommendations for spatial and access requirements for public health engineering services are contained in SHTM 00: Best practice guidance for healthcare engineering Policies and principles 2013. The drains from steam sterilisers, WDs and cart washers should comply with local water regulations. (Further advice is provided in SHTM 01-01: 2018). 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. 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

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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 rainwater 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 CDU cleanroom Room (17). Reference should be made to SHTM 00: 2013 on access and accommodation for engineering services.

Other operational considerations

4.211. 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. 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 BMS) planned for the CDU.

Providing an Endoscope Decontamination Unit alongside a CDU

4.212. The URB may have identified the requirement for an Endoscope Decontamination Unit (EDU) to be provided alongside a CDU to enable the same staff and management to work across both facilities as workload demands. In this case the layout of the EDU should be compliant with SHPN 13 part 3: 2010.

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5. Construction and procurement

Control of design

5.1. Construction activities should not commence until a full set of documentation (see figure 4.6) has been prepared, agreed and signed off by the board. A master list should be controlled and available throughout the project. The board should have identified their responsible person for the master list including change management during construction. The full set of documentation includes: the Central Decontamination Unit (CDU) department layout drawing(s) at 1:200 scale accounting for all levels, a site drawing showing infrastructure, for every room in the department individual room layout drawings at 1:50 scale (there may be more than one for each room) and environmental matrix. The 1:50 individual room layouts should contain equipment schedules with equipment/ furniture and fittings specified. Other mechanical and electrical drawings will require to be approved and be part of the master list, for example ventilation layouts.

Working groups in operation during construction

5.2. There may be a range of working groups, some technical, some delivery in operation during construction. An awareness of the significant time commitment required should have been identified at the business case stages. CDU managers managing an existing facility while involved in the new build project will require substantial additional support to be able to actively participate in these working groups while still running a sterile service.

Control of procurement

5.3. Board procurement should procure as per the specification given in the equipment schedules of the individual rooms 1:50s layouts drawings as cited in the controlled master list. Items to be procured by others should be made clear in the equipment schedule. There are examples of where lack of scrutiny during procurement has led to project delays/ increased costs. These include:

- an equipment supplier providing a quotation which may include options that are in fact requirements
- services to equipment not being provided during the construction such as hot and cold water supply for Washer Disinfectors (WDs) and extract ventilation for WDs

5.4. At the early stage of design work, equipment may be identified for purchase but at the time of placing the order the equipment sought is not available or has a long lead time such as happened when BREXIT occurred. Design controls/ change management needs to be in place if alternative equipment/ components are required to be procured.

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Construction plan

5.5. General roles, responsibilities and activities should be described and assigned within the construction plan along with a schedule, a quality plan and a clean build protocol. All contractors' and sub-contractors' activities should be coordinated for the duration of the entire project. Responsibility for this coordination should be defined as a part of the construction plan.

5.6. Schedule construction activities should be coordinated using a schedule that documents timing, sequence and key milestones for the project. The plan should include the major items of decontamination equipment such as WD, sterilizers and cart washers. Each of these should detail the services required such as compressed air, cold water, hot water, extract ventilation and location of drains. The plan should detail when water pipework comes online. Temporary storage space should also be identified for delivery of the potentially significant volume of furniture/ fittings associated with the decontamination equipment. The concrete slab should not be poured until the location of the drains for all the decontamination equipment to be installed (or for future additional machines) has been specified on approved drawings on the master list.

5.7. Planning the go live of water systems should be clearly identified in the program. Achieving the satisfactory quality of water can take time and should be adequately allowed for in the program. For example, several disinfection exercises may be required over several weeks to arrive at acceptable microbiological levels in the water. Delays at this point may result in delays to contractors carrying out commissioning of decontamination equipment such as WDs and other equipment requiring a water supply(see Scottish Health Technical Memorandum (SHTM) 04-01 note variable dates of publications for different parts A to G).

Quality plan

5.8. A quality plan should be developed in consultation with relevant stakeholders and should consider procedures for:

- identifying changes that require an agreement
- identifying and documenting deviations
- assessing the impact of the consequences of these changes and deviations
- approval, by appropriate designated staff, of changes, deviations and corrective actions
- documenting the control of construction activities and information
- responsibility
- management of documentation

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Clean build protocol applicable to the CDU cleanroom

5.9. A clean build protocol should be considered for the construction project. Application across all construction and assembly related activities both on and off the construction site, should be considered. Examples of requirements for a clean build protocol include:

- the construction site should be protected from the external environment at the earliest practical opportunity
- areas should be provided for the set down of materials, including sufficient space for the inspection of incoming materials
- critical components, such as final filters, should be protected from contamination and impact until fixed in their final position
- materials that are delivered to site in a clean condition, such as cleanroom panels and heating, ventilation and air conditioning (HVAC) ducting, should be kept clean

5.10. Considerations should be given to include training and instruction for all personnel attending the construction site, including visitors. This should outline safe working procedures and assist in ensuring good workmanship, correct conduct on site and adherence to any clean build protocol implemented on site.

Construction verification during construction

5.11. A systematic set of verifications should be carried out throughout the construction to ensure that each part of the construction process is compliant with the agreed design documentation.

5.12. Some points to note during construction:

- cable trays should not be overloaded with cables and allow for spare capacity in place
- cable trays should be equipotential bonded
- cable ties should be metal and not plastic
- permanent quality labels should be in place for valves, cables, control panels and fixtures as safety isolators
- ceiling access hatches where allowed should be of suitable finish and clear access provided for the services being accessed, that is there should be no obstructions such as from cable trays, baskets or ladders

Modular build

5.13. A module that is constructed offsite at a factory and has equipment/ furniture and fittings installed in the module before leaving the factory site should allow good quality control conditions under a factory's quality management system (QMS) with temperature control and good lighting conditions.

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5.14. A module that is fitted out at the factory may allow customer visits at various stages to verify the construction is in line with the customer's expectations. Certain amendments if required may be more easily dealt with at the factory as opposed to modifications onsite to a CDU under construction.

5.15. There are some unique challenges presented by modular construction. It is recognised that transporting modules from the factory site to the customer's site will likely results in some cracking of the module(s). This should be discussed with the supplier and agree how this is to be addressed once the module(s) arrives on site.

5.16. Experience indicates that storage of modules pending delivery or while stored in other locations can result in environment damage if insufficient protection is in place.

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6. Verifying the construction, installation and operational qualifications

Decontamination equipment installation and operational qualification

6.1. The design information including the 1:50 relevant room layouts should have detailed the type and number of each type of decontamination equipment. The Installation Qualifications (IQ) and Operational Qualifications (OQ) of the decontamination equipment may be carried out prior to or at the same time of the IQ and OQ checks of the new decontamination facility. The equipment validation (IQ and OQ) stage is outlined in Health Facilities Scotland (HFS) publication Scottish Health Technical Memorandum (SHTM) 01-01 part A: 2018. These equipment qualifications are for fixed processing equipment such as washers disinfectors (WDs), sterilizers and cart washers. These qualifications should include the confirmation that the services (such as water, compressed air, extract ventilation, drains) provided to these machines are satisfactory. Further, the building fabric around these machines should be confirmed as finished to the required quality during the equipment installation. The subsequent construction verification exercise should include inspection of the building fabric finish quality around these machines.

Water quality confirmation impacting on the build program

6.2. The water supply used as that provided by Reverse Osmosis (RO) plant should be validated prior to connection of the feed water to decontamination equipment such as WDs. Confirmation of satisfactory microbiological water quality can take several weeks (or months if multiple disinfection exercises are required) and should be allowed for in the build program. Commissioning of certain decontamination equipment (such as WDs) cannot commence until the water supply quality is confirmed. This can have a knock-on effect impacting on for example commissioning of the Central Decontamination Unit (CDU) cleanroom.

Construction verification

6.3. A systematic set of verifications should be carried out at the end of the construction stage to ensure that it compliant with the agreed design documentation.

The facility installation qualification

6.4. Using the current approved master list of documentation (see figure 4.6) each room within the CDU should be visually inspected to confirm:

- it is compliant with the content of its 1:50 layout drawing

- the quality of the fabric finish is satisfactory

6.5. Items within the CDU site but external to the building should also be confirmed as being located as per the site data sheet.

6.6. Any variances found in the layout drawings should be logged and an action plan set to revise the drawings. Once revised and confirmed as satisfactory the master list of documentation should be updated (see figure 4.6).

6.7. Any issues found with the quality of the fabric finish should be addressed and an action plan set to achieve the required quality. Once completed the fabric finish should be confirmed in the facility Installation Qualification (IQ) report as being satisfactory.

The facility operational qualification

6.8. Using the current approved environmental matrix each room should be checked to confirm it meets the specification details in the matrix. It should be verified that there are as-built layout drawings at 1:50 scale for every room and for the department layout at 1:200 scale. Other as built drawings for the services should also be verified. Confirm that all necessary operating/ maintenance instructions have been received for any relevant facility fixtures/ fittings/ systems.

6.9. At the conclusion of the construction process a set of as-built drawings (if the IQ found discrepancies), operating instructions and construction verification results should be provided in a timely manner.

6.10. In order to prepare for start-up provision of the following information should be considered:

- checks and inspections to be completed prior to bringing the installation and systems into operation
- procedures to start, stop and restart the installation under normal and failure mode situations
- acceptable ranges of the performance parameters
- off peak and turn-down procedure
- procedures to follow when alert or action limits being reached
- information on how to operate airlocks, pass-through hatches, and other areas where special ventilation schemes are used
- calibration, operation, and maintenance information for on the monitoring system
- procedure for verification and testing after maintenance activities

6.11. Visual verification of the quality/ integrity of finish of fabric is required. A snagging process should identify any areas requiring attention.

6.12. Clean down of the facility is arranged and documented by the principal contractor.

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6.13. Initial testing of air handling system to determine impact of turn-down on pressure differential cascade (these findings will inform the testing under Performance Qualification (PQ) conditions).

Handover - what it is and is not

6.14. The handover of the facility should be defined and agreed between the principal contractor and the board and documented. During the design qualification (DQ) it should be clear what equipment is to be installed by the principal contractor and the equipment to be installed by board assigned contractor's such as suppliers of WDs. As the quality of room fabric finish can impact room performance it should be clear which parties are responsible for ensuring the required quality is delivered.

6.15. Handover by the principal contractor to the board at the end of the construction and prior to the facility PQ is not acceptance by board that the facility is fit for purpose (and satisfactory). Acceptable results reported at the PQ of facility conducted/ arranged by the board provide evidence of a satisfactory build. The principal contractor should have been made aware of this at the start of the project to avoid disputes at the end of the project. Contractors that install decontamination equipment such as WD are not under principal contractor control. It should be clear who is responsible for ensuring the cleanroom integrity post installation of WDs.

CDU Cleanroom OQ: Functional verification - room at-rest occupancy status

6.16. Upon completion of the setting to work phase a set of functional tests should be executed to confirm satisfactory technical function of the CDU cleanroom. BS EN ISO 14644-3: 2019 provides guidance on sequencing and testing as well as reference test methods and test instrument specifications. The following tests are required out as part of functional verification:

- door interlock function and timing
- supply air volume flow rate/ airflow at each high-efficiency particulate air (HEPA) filter
- air-handling systems pressure drops
- room pressure differentials
- in situ HEPA filter leak test
- containment leak test
- temperature and humidity test
- noise and light levels
- failure modes tests (fan interlocks, stand-by systems)
- energy consumption and efficiency evaluation - operational and turn-down (see BS ISO 14644-16: 2019)
- air cleanliness classification by particle concentration (see BS ISO 14644-1: 2015)
- air and surface microbial cleanliness (see BS EN 17141: 2020)

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7. Verifying performance on start-up, the performance qualification

The performance qualification protocol

7.1. The Performance Qualification (PQ) protocol agreed by the Central Decontamination Units (CDU's) quality management team should identify that the following records/ documents are available:

- installation qualification (IQ) data and reports signed as approved
- operational qualification (OQ) data and reports signed as approved
- PQ data

Performance verification

Decontamination equipment

7.2. The PQs of the decontamination equipment should be compliant with requirements in the Scottish Health Technical Memorandum (SHTM) 01-01: 2018 series. Any item of decontamination equipment not in the scope of the SHTM should be validated to the latest relevant standard.

Facility - CDU cleanroom

7.3. Upon completion of setting to work and functional verification phases, a set of performance tests should be executed to confirm satisfactory performance of the installation in maintaining required cleanliness classes and levels. The following CDU cleanroom tests are required as part of performance verification:

- air cleanliness classification by particle concentration (see BS EN ISO 14644-1: 2015)
- airborne particle recovery time in non- Unidirectional Airflow (UDAF) systems (see BS EN ISO 14644-3: 2019)
- airflow visualization (see BS EN ISO 14644-3: 2019)
- air and surface microbial cleanliness (see BS EN 17141: 2020)
- air temperature/ relativity humidity controlled within in this planning note limits
- pressure differentials controlled within limits specified in this Scottish Health Planning Note (SHPN)

7.4. After satisfactory OQ and any subsequent cleandown activity, verification tests should be of sufficient duration to demonstrate consistent performance of the CDU cleanroom. Real production or simulated production may be used provided it is a true reflection of testing under the operational occupancy status for the CDU cleanroom. For example, the air

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temperature/ relative humidity and the pressure differentials should be demonstrated over three working days (that is in the operational occupancy state) to be within limits. Then the airborne particulate levels should be tested over three days (in the operational occupancy state) and verified as being within limits. The number of sample locations should be in line with BS EN ISO 14644-1: 2015 Table A.1. The sample locations should be shown on a sample plan identifying the locations within the CDU cleanroom (17). The microbial monitoring should be carried out over three separate days (in the operational occupancy state) and be within limits given in this guidance (see table 4.1).

7.5. Correlation of the fixed monitoring system for airborne particulates within the CDU cleanroom with the results from the portable air particle counter should be undertaken and documented.

The performance qualification report

7.6. The PQ report should confirm the following:

- the Design Qualification (DQ) report of the facility was completed, satisfactory and signed as approved by the board
- the installation and operational qualifications reports of the facility were completed, satisfactory and signed as approved by the board
- the PQ requirements detailed in the protocol for equipment and the facility were completed and were satisfactory, reported in the PQ report and confirmed by the CDU's quality management team
- any change management activities throughout the project should be listed and the final list agreed as satisfactory
- if there any outstanding actions a corrective action plan should be included in the report

Warranties

7.7. These should only become active after a satisfactory PQ report is published.

Training

7.8. Management should ensure that the personnel operating and maintaining the installation are competent for their assigned duties and have received appropriate training for the specific installation in preparation for handover. Training should include relevant practices for cleanroom operation, energy management and maintenance. The responsibility for providing training should be defined. Training should be carried out as specified and documented.

Maintenance instructions

7.9. Maintenance activities and their frequency should be defined and implemented as per the manufacturer's instructions. Impact on the installation and processes should be considered

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when planning and executing all maintenance activities. A record of any maintenance carried out upon the installation during start-up should be maintained. A record of all training given should be maintained. Training content, identification of personnel providing and receiving the training and training date and duration should form part of the record.

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8. Routine production and maintenance

8.1. It has been government policy since 2007 [Ross Scott 2007 letter on Central Decontamination Units (CDU) accreditation] that CDUs are accredited to a Quality Management System (QMS). The current applicable QMS standard BS EN ISO 13485: 2016+A11:2021 sets requirements for the decontamination process and the work environment. The QMS standard is also cited in Health Facilities Scotland (HFS) compliance publication GUID 5014 NHSScotland Requirements for compliant CDUs version 3: 2024.

Quality management system standard

8.2. Section 5 of the QMS standard states under Management Responsibility that "*Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness*". Section 8.5.3 on Preventive action states "*The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems*."

8.3. In the QMS standard Section 6 Resource management, 6.1 Provision of resources states "*The organization shall determine and provide the resources needed to: a) implement the quality management system and to maintain its effectiveness b) meet applicable regulatory and customer requirements*".

8.4. In the QMS standard Section 6.3 Infrastructure it states "*The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities b) process equipment (both hardware and software) c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained*".

8.5. In the QMS standard Section 6.4 Work environment and contamination control, 6.4.1 Work environment it states "*The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment. The organization shall: a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or*

work environment could affect medical device safety or performance b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person. NOTE Further information can be found in ISO 14644 and ISO 14698."

8.6. In the QMS standard Section 6.4.2 Contamination control it states "*As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes*."

Quality manual

8.7. The CDU quality manual should consider all the elements outlined in the QMS standard. This will include a quality policy, procedures, work instructions and records. Operational policies are included in this guidance and follow.

Operational policies

Used instrument/ equipment - contaminated returns

8.8. 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

8.9. All reusable medical devices (RMDs) returned to the department should be treated as contaminated and be subjected to standard precautions. In addition, those devices contacting high Creutzfeldt Jakob Disease (CJD) transmission risk tissues require additional consideration and management as Scottish Health Technical Memorandum (SHTM) 01-01: 2018 and GUID 5019: 2022. These devices should be quarantined at point of use and not returned to the CDU.

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

8.11. It is recommended that cleaning, disinfection and drying processes are automated, and should in all cases be controlled and validated as required by the QMS BS EN ISO 13485: 2021.

8.12. All items should be cleaned and thermally disinfected in a validated washer-disinfector (WD) conforming to SHTM 01-01:2018 and the relevant standard BS EN ISO 15883 Part 1: 2014 and Part 2: 2009. In some cases, the device manufacturer may recommend manual cleaning and mechanical drying and compliant facilities/ equipment for this will be required.

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8.13. Enough WDs should be installed to maintain production. Servicing and maintenance should be planned around, and not be disruptive to, production. It is important to locate WDs 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.

8.14. Consideration should be given to the advantages of having WDs with interchangeable load handling equipment. WDs should be of a pass-through design.

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

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

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

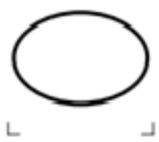
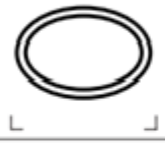
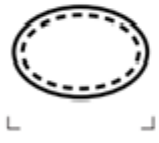
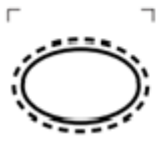
8.18. A dedicated domestic services room (DSR), the Wash Room: DSR (28) needs to have direct access from the Wash Room.

Inspection, assembly and packing

8.19. The CDU cleanroom Room (17) should receive goods from the Wash Room (27) and materials from the CDU cleanroom Materials Transfer Room (20). These should be inspected and assembled onto trays and into procedure packs with appropriate labelling (see new symbol in figure 8.1) in preparation for sterilization. Adventitious contamination should be minimised by all practicable means. The CDU cleanroom 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.

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Figure 8.1 - Labelling symbols as standard BS EN 15223-1: 2021 used to describe packing systems

5.2.11 	Single *sterile* barrier system	Indicates a single *sterile* barrier system		NOTE 1 A solid line identifies a *sterile* barrier system.
5.2.12 	Double *sterile* barrier system	Indicates two *sterile* barrier systems		NOTE 1 A double solid line indicates a double *sterile* barrier system.
5.2.13 	Single *sterile* barrier system with protective packaging inside	Indicates a single *sterile* barrier system with protective packaging inside		NOTE 1 The protective packaging located inside the *sterile* barrier system is designed to prevent damage to the contents or to help with aseptic presentation. It does not provide a microbial barrier to maintain sterility.
5.2.14 	Single *sterile* barrier system with protective packaging outside	Indicates a single *sterile* barrier system with protective packaging outside		NOTE 1 The protective packaging located outside the *sterile* barrier system is designed to prevent damage to the *sterile* barrier system and the contents. The protection can be against physical hazards, particulate contamination or other environmental hazards, but it does not include a microbial barrier.

8.20. A room directly connected to the CDU cleanroom, namely the CDU cleanroom 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 CDU cleanroom.

8.21. A dedicated DSR, namely the CDU cleanroom DSR (19) should be an ISO Class 8 cleanroom in the 'operational' occupancy state. This room shall have direct access only from the CDU cleanroom Room (17). A Standard Operating Procedure (SOP) should be in place for cleaning of the CDU cleanroom. This includes noting the impact of room cleaning on the fixed airborne particle monitoring system.

8.22. Controlled entry and exit of personnel and materials via separate dedicated air locks/ transfer hatches should be incorporated to maintain the integrity of the CDU cleanroom Room (17). Staff shall not be able to leave or enter the CDU cleanroom Room other than via the CDU cleanroom 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 should enter the CDU cleanroom Room (17) via the CDU cleanroom Materials Transfer Room (20). Trolleys should not pass into or out of the CDU cleanroom Room (17) unless the procedure has been validated to ensure acceptable levels of contamination are not exceeded.

8.23. All wet processes including hand-washing should take place outwith the CDU cleanroom 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

8.24. Most items processed in the CDU cleanroom 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.

8.25. The choice, purchase, installation, operation, testing and maintenance of porous-load steam sterilizers should conform to the requirements given in SHTM 01-01: 2018. Chemical based sterilizers for processing thermolabile medical devices should follow requirements in SHTM 01-01: 2018.

8.26. 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.

8.27. It is important to locate sterilizers as per the DQ 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 WDs) together with drainage connection ports should be provided as part of the initial installation work for the new CDU.

8.28. 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.

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

Staff changing

8.30. Staff should 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).

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

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

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

8.34. 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 and Welfare) Regulations 1992, relating to the number of staff working at any one time.

Education and training

8.35. 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

8.36. 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). The layout model shows a comms room 7 within the department. Consideration of single points of failure and possible location of the IT servers at other locations.

Staff rest

8.37. A Staff Room (32) should be provided, 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

8.38. High standards of cleanliness are essential in all areas of the CDU and this environmental cleaning has a critical role in maintaining the CDU in a fit state for use. In some areas such as the CDU cleanroom the cleaning is required to primarily protect the product quality and in other areas such as the Wash Room staff safety is the principal reason. A minimum of three different types of DSR, serving different purposes, should be provided each with dedicated cleaning equipment. The DSRs being a Wash Room DSR (28), a CDU cleanroom DSR (19) and the General Areas DSR (15). The room data sheet for each DSR defines 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. The cleaning equipment held within the CDU cleanroom DSR (19) should be of the required standard for cleanroom use. This should include equipment such as cleanroom vacuum cleaners and floor scrubbing equipment.

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8.39. Buckets or containers with wringers that are compatible with the cleanroom operation are required for wet or damp cleaning operations. The buckets or containers should be constructed of plastic or stainless steel (not galvanized). The wringer system used in mopping should be compatible with the style and material of the mop head. Standard commercial floor scrubbers or buffers should never be used within the CDU cleanroom, as the process would contaminate the environment. Machines designed for scrubbing cleanroom floors should be used where necessary. These machines have special shrouds and built-in high-efficiency particulate air (HEPA) or Ultra Low Particulate Air (ULPA) filtered vacuum cleaners to control contamination redistribution. They also have HEPA or ULPA filtered exhaust casings for the motor chambers. Careful evaluation for cleanroom and flooring compatibility should precede the use of such equipment. Waxes and other non-permanent sealers flake off and cause contamination with traffic and therefore any equipment used to apply or buff such finishes should not be used. Brooms, brushes, or similar tools should not be used in the CDU cleanroom, as they will cause gross particle generation. The bristles themselves are very large fibres that are also a contaminant.

8.40. Cleaning equipment should be cleaned as per the manufacturer's instructions.

8.41. The effectiveness of the environmental cleaning in the CDU cleanroom is determined by physical measurement of the air particulates in the air and microbial levels in the air and on specified surfaces.

Waste management

8.42. 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 that is within the General/ Clinical Waste Disposal Area (13). Management of waste materials recycling should also be carried out.

Storage

8.43. 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.

8.44. Sufficient stock levels of raw materials are important for a CDU to operate smoothly. Adequate storage space should be considered and specified in the design. This should also consider space requirements for pallet and forklift truck movement.

8.45. 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, that is the Materials Store (22)
- a store for process chemicals (this could be in the General Plant Room 16)
- a processed products area, that is the Processed Products Store (24)
- documentation storage could be in multiple rooms. Rationale as regards archiving records should 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.

8.46. 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 is required so that cleaning equipment used can be segregated to the specific areas of use that is required in the Wash Room Materials Transfer Room (38) and the CDU cleanroom Materials Transfer Room (20).

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

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

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

8.50. 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 the external site data sheet in Appendix B.

Trolleys and internal transportation

8.51. 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

8.52. 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.

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

8.54. 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.

8.55. 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 for example theatre areas.

8.56. Where battery-powered vehicles or floor trolleys are used, 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. (see 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. (see the external site data sheet in Appendix B).

Offsite transportation

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

Maintenance

8.58. There should be a maintenance procedure(s) that document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements should apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance should be maintained.

8.59. Critical maintenance in the cleanroom - maintenance and testing of decontamination equipment and building fabric needs to be allowed to take place and not put off due to production pressure. Support should be given from senior management at the health board to allow essential maintenance. There should be adequate provision of estates staff to enable this maintenance to be completed in a timely manner. There should also be a procedure to describe what to do in the event of unplanned maintenance work arising from example water passing through the ceiling or the floor being flooded. There should be a national programme of major maintenance and equipment replacement.

8.60. If maintenance activities are undertaken while production is live there should be clear evidence that the cleanroom continues to meet its required performance over this period.

8.61. Lessons learned - impact on reducing incubation time of micro plates CDU incident recommendations. A survey of the plantroom is conducted to identify all pipework (carrying liquids) that cross over the cleanroom ceiling. The survey should include consideration of the possibility of installing a form of liquid catchment to protect the ceiling and moisture sensors connected to the Building Management System (BMS) to give early warning of a problem. The survey results to be added to a maintenance procedure.

8.62. A maintenance procedure is introduced that includes regular visual inspections for leaks in the plant room above/ around the cleanroom ceiling. The procedure to include training of all staff/ contractors working above the cleanroom and being clear on the precautions to take given the significant negative impact on production and delivery of sterile product if the ceiling is damaged. A permit to work system should be in place for such work.

8.63. Review inhouse quality system procedures to ensure the circumstances are clear when microbiological sampling of the cleanroom is required such as when the cleanroom fabric is damaged/compromised exposing the cleanroom to uncontrolled air.

8.64. Measures to be taken in the event of a production shut down include:

- Immediately notify HFS and Health Protection Scotland (HPS) and senior management and the comms officer
- within the site recovery plan have a detailed start-up/ recommissioning plan for the cleanroom in the event of a significant shutdown period. This would define those responsible for approving the start-up of production
- implement the tracking system agreed between user and providers of a contingency service
- a communications plan should be in place for CDU staff, theatre staff, government and press
- clear guidance on staffing should be employed ensuring staff representative involvement
- follow procedure with regard to extra instrumentation and dealing with missing or damaged instruments
- follow procedure on transport and storage as relevant to the situation

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Start-up procedure following CDU cleanroom shutdown

8.65. First confirm the repair is satisfactory. If the repair included the building fabric, then the quality of finish is part of the confirmation requirement that the CDU cleanroom integrity is satisfactory. Then a cleandown should be carried out followed by a settling period prior to any testing of the cleanroom environment.

8.66. With respect to the CDU cleanroom, a range of tests are required to be carried out and confirmed as giving satisfactory results. These may comprise of testing in the 'at-rest' occupancy state followed by testing in the 'operational' occupancy state.

8.67. Testing should confirm satisfactory airborne particulate levels that is ISO class 8 conditions for considered particle sizes 0.5 and 5 micron tested in the 'operational' occupancy state as BS EN ISO 14644-1: 2015.

8.68. Testing should confirm satisfactory biocontamination levels in the air and surfaces as outlined in Table 4.1, that is Bio class 8 for the CDU cleanroom.

8.69. Other parameters such as the room air temperature/ relative humidity and the pressure differential cascade levels should be confirmed as being within specification.

8.70. The agreed responsible person should confirm all test records are complete and the results are satisfactory. The confirmation for start-up should be recorded and communicated to relevant stakeholders.

Why sterilization is not the only factor associated with the provision of reliable assurance that the product is sterile and suitable for its intended use

8.71. A sterile medical device is one that is free of viable microorganisms. Medical devices produced under standard manufacturing conditions in accordance with the requirements for QMS may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such medical devices are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices into sterile ones. The standards for QMS recognize that, for certain processes used in reprocessing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process monitored routinely, and the equipment is maintained and calibrated.

8.72. However, *exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use*. Attention is therefore given to a number of considerations including:

- the microbiological status of incoming raw materials and/ or components
- the validation and routine control of any cleaning and disinfection procedures used on the product

- the control of the environment in which the product is reprocessed, assembled and packaged
- the control of equipment and processes
- the control of personnel and their hygiene
- the manner and materials in which the product is packaged
- the conditions under which product is stored. [source BS EN ISO 17665: 2024]

Contingency support/ contingency requirement

8.73. A number of unplanned shutdowns of CDUs have occurred over the last few years. Focusing on the large scale (output) CDUs, shows closure periods have varied from 6 days to 26 days.

8.74. In these events, support was sought and provided from multiple (four to five) health boards' CDUs and also the private sector. Despite this level of support, in some cases multiple patient procedures were cancelled.

8.75. A fast response time in providing processing support is critical if patient cancellations are to be avoided. Ability to operate major trauma units may also be impacted if there is no assurance of supply of sterile product. Response times for contingency support of more than 24 hours are likely to have these negative outcomes if buffer stocks of medical devices are inadequate. Holidays and weekend closures of support CDUs may contribute to negative outcomes. Very low stock levels of instruments for certain specialities may also contribute to negative outcomes.

Lessons from contingency events

8.76. Instrument stocks, running lean on certain specialities such as Vascular sets, can mean that on day 2 of an incident, patient treatments are affected. This may include impact on operation of major trauma units.

8.77. It is clear that fast action is required, after the request for help is sounded, if patient cancellations are to be avoided. Current infrastructure from health boards and available private sector assistance requires to address this, particularly when it is large scale CDUs requiring contingency support.

8.78. Clinical specialities that require to be available immediately should be reviewed with regard to stock levels. Past experience includes - Orthopaedic, General, Urology, Vascular, Neurology, Ophthalmic and max fax. Insufficient stocks of these specialities may result in patient procedures being cancelled or a lack of assurance of instruments to supply major trauma units.

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9. Post occupancy evaluation

9.1. The project plan for the build should identify that a post project evaluation will be conducted and completed in a timely fashion. The project plan should identify the individual(s) who will carry out this work and where the evaluation is to be communicated.

9.2. The Post Occupancy Evaluation (POE) is described in the Scottish capital investment manual Project Monitoring and Service Benefits Evaluation 2017. The evaluation has a project monitoring stage and a service benefits stage (see figure 9.1).

Figure 9.1 - Assessing project monitoring stages and service benefits evaluation

What will be assessed:	When it will be carried out		How it will be done (approach)
	Milestone Date	Report submission	
Project Monitoring stage:			
Project Costs			
Project Programme			
Project Scope Changes			
Health & Safety Performance			
Design & Technical Aspects			
Risk Management Issues			
Service Benefits Evaluation stage:			
Expected benefits			
Stakeholder expectations			
Impact of service change			
Service activity & performance			

9.3. The Project Scope Changes element under the project monitoring stage in figure 9.1 should have been summarised in the Change management activities reported in the performance

qualification (PQ) report (see section 7). The design and technical aspects should also have been confirmed as satisfactory in the approved and board signed PQ report.

9.4. The stakeholder expectations should have been clear in the User Requirement Brief (URB) at the start of the project and this would also be referred to in the PQ report.

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Appendix A Room data sheets

Room 1 - Cart wash load area

Table A.1 - Room 1 (Cart wash load area) - Design requirements

Subject	Room 1 design requirements
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	Direct access to Contaminated Returns Lobby (5). Direct access to the Cart Wash Plant Area (2).

Table A.2 - Room 1 (Cart wash load area) - Finishes

Subject	Room 1 finishes
Wall finish	Surface Finish (Scottish Health Technical Memorandum (SHTM) 56: 2006): Performance category 2. Recommended finish elastomeric vinyl compound or epoxy coating.

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Subject	Room 1 finishes
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 2. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	SHTM 58: 2006 compliant.
Windows type	(SHTM 55: 2006: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	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: 2006) should be considered, such as 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.

Table A.3 - Room 1 (Cart wash load area) - Mechanical and electrical

Subject	Room one mechanical and electrical
Air temperature	Winter and Summer 16 to 19 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	Minimum 10 (with no recirculation into the room supply).
Relative pressure	Same pressure as the Contaminated Returns Lobby (5).
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.

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Subject	Room one mechanical and electrical
Air notes	Filter standard EN ISO 16890-1: 2016.
Lighting level	300 (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01 series 2015.
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 08-01: 2015.
Hot surface temperature degrees Celsius	43
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Warning note that water in cart washer is hot (potentially 80^0C during the cycle).
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	The selection, type and placement of smoke detection systems must also take account of false alarms due to humidity spikes.

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Room 1 - equipment/ fixtures and fittings

A.1 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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 Index of protection (IP) 54 rated
- socket outlet switched 13 Amp single, ac, wall mounted and IP 54 rated

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Room 2 - Cart wash plant area

Table A.4 - Room 2 (Cart wash plant area) - design requirements

Subject	Room 2 design requirements
Function	This is a controlled area used to support the cart washer allowing maintenance and test activities.
Occupancy	Specify the maximum number of personnel working in this area.
Activities	Periodic Testing of cart washer and 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	It should contain the cart washer and associated plant. Direct access from the Cart Wash Load Area (1) only.

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Table A.5 - Room 2 (Cart wash plant area) - Finishes

Subject	Room 2 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish stainless steel panels.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category not defined. There may be no ceiling in this plant space.
Door sets	SHTM 58: 2006 compliant.
Windows type	Not applicable.
Internal glazing	Not applicable.
Ceiling hatches	If required to be in line with ceiling finish.
Finish notes	Heavy Duty protection (SHTM 69: 2006) should be considered. Stainless steel panels may be an option.

Table A.6 - Room 2 (Cart wash plant area) - Mechanical and electrical

Subject	Room 2 mechanical and electrical
Air temperature	Winter and Summer <30 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure	Negative with respect to other areas.
Final filtration	Not specified.

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Subject	Room 2 mechanical and electrical
Air relative humidity	Not specified.
Air notes	Air specification is not applicable if the plant area has no ceiling.
Lighting level	300 lux at bench height.
Colour rendering	No
Standby lighting grade	B
Lighting notes	Design as SHTM 06-01: 2015 - consider wall lighting if no ceiling is in place.
Noise-privacy factor	<70
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43
Hot water temperature degrees Celsius	Cycle dependent.
Safety notes	None
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	The selection, type and placement of smoke detection systems must also take account of false alarms due to humidity spikes.

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Room 2 - equipment/ fixtures and fittings

A.2 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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. Ensure location of drains is identified before pouring the concrete slab
- 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
- fire alarm
- smoke detector
- fire extinguishers
- workbench

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Room 3 - Cart wash unload area

Table A.7 - Room 3 (Cart wash unload area) - Design requirements

Subject	Room 3 design requirements
Function	This is an area used to unload clean disinfected containers/ trolleys from the cart washer and store until required.
Occupancy	Specify the maximum number of personnel 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	Direct access to Steriliser Unload Area (30). The Cart Wash Unload Area is connected to the cart washer. This area has secure and controlled access from the Sterilizer Unload Area (30).

Table A.8 - Room three (Cart wash unload area) - Finishes

Subject	Room 3 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish stainless steel panels.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category not defined. There may be no ceiling in this plant space.
Door sets	SHTM 58: 2006 compliant.

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Subject	Room 3 finishes
Windows type	Not applicable
Internal glazing	Not applicable
Ceiling hatches	If required to be in line with ceiling finish.
Finish notes	Heavy Duty protection (SHTM 69: 2006) should be considered. Stainless steel panels may be an option.

Table A.9 - Room 3 (Cart wash unload area) - Mechanical and electrical

Subject	Room 3 mechanical and electrical
Air temperature	Winter and Summer 16 to 19 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure	Same pressure as the Sterilizer Unload Area (30).
Final filtration	ISO ePM2.5, 80%
Air relative humidity	Not specified.
Air notes	Filter standard EN ISO 16890-1: 2016.
Lighting level	300 lux at bench height.
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	70
Mechanical services- NR noise level	40

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Subject	Room 3 mechanical and electrical
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 08-01: 2015.
Hot surface temperature degrees Celsius	43
Hot water temperature degrees Celsius	Cycle dependent.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 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.

Room 3 - equipment/ fixtures and fittings

A.3 Select from the list of items and include the number of each and dimensions of each as applicable:

- fire alarm
- smoke detector
- fire extinguishers
- workbench

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Room 4 - CDU manager's office

Table A.10 - Room 4 (Central Decontamination Unit (CDU) Manager's office) - Design requirements

Subject	Room 4 design requirements
Function	This is an area used to provide an appropriate environment to undertake managerial duties.
Occupancy	Specify the maximum number of personnel in this room, such as 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 (BMS). 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	Direct access to the General Corridor (14). Close to the Office (23).

Table A.11 - Room 4 (CDU Manager's office) - Finishes

Subject	Room 4 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommend acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	SHTM 58: 2006 compliant.

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Subject	Room 4 finishes
Windows type	(SHTM 55: 2006) Not essential. Consult CDU manager for privacy requirements.
Internal glazing	(SHTM 57: 2006) Not essential. Consult CDU manager for privacy requirements.
Ceiling hatches	If required to be in line with ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall.

Table A.12 - Room 4 (CDU Manager's office) - Mechanical and electrical

Subject	Room 4 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure	Same as the General Corridor (14).
Final filtration	ISO ePM2.5, 80%
Air relative humidity	Not specified.
Air notes	Filter standard EN ISO 16890-1: 2016.
Lighting level	300 lux bench height.
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	80 normal speech inaudible.
Mechanical services- NR noise level	30

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Subject	Room 4 mechanical and electrical
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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector

Room 4 - equipment/ fixtures and fittings

A.4 Select from the list of items and include the number of each and dimensions of each as applicable:

- fire alarm
- smoke detector
- fire extinguishers
- clock battery operated and wall mounted
- security alarm with push button and wall mounted
- coat hooks with shelving
- table
- desk

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- chairs
- filing cabinet
- computer and printer
- telephone
- wall mounted marker board
- computer(s) for floor management system and or BMS
- 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

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Room 5 - Contaminated returns lobby

Table A.13 - Room 5 (Contaminated returns lobby) - Design requirement

Subject	Room 5 design requirements
Function	This is an area for receiving contaminated return containers/ trolleys.
Occupancy	Specify the maximum number of staff working in this area.
Activities	1. Receiving and holding soiled returns. 2. Wash Room staff collect goods. 3. Scanning equipment trolleys. 4. Scanning trays. 5. 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 (WDs) 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	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).

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Table A.13 - Room 5 (Contaminated returns lobby) - Finishes

Subject	Room 5 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 2. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 2. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	SHTM 58: 2006 compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	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: 2006) should be considered such as 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.

Table A.13 - Room 5 (Contaminated returns lobby) - Mechanical and electrical

Subject	Room 5 mechanical and electrical
Air temperature	Winter and Summer 16 to 19 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	Minimum 10 (with no recirculation into the room supply).

Subject	Room 5 mechanical and electrical
Relative pressure	Negative pressure with respect to the Wash Room (27).
Final filtration	ISO ePM2.5, 80%
Air relative humidity	Not specified.
Air notes	Filter standard EN ISO 16890-1: 2016.
Lighting level	300 lux bench height.
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	70
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

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Room 5 - Equipment/ fixtures and fittings

A.5 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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 SHTM 64: 2009. Waste-flush, grated, metal, 32mm, no plug as SHTM 64: 2009
- 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

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Room 6 - Cooling area

Table A.13 - Room 6 (Cooling area) - Design requirements

Subject	Room 6 design requirements
Function	This is an area used for cooling of instrument trays, packs and supplementary items following sterilization.
Occupancy	Specify the maximum number of staff working in this 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	Direct access to the Sterilizer Unload Area (30). Direct access to the General Corridor (14), Processed Products Store (24) and Dispatch (9).

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Table A.14 - Room six (Cooling area) - Finishes

Subject	Room 6 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	SHTM 58: 2006 compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	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: 2006) should be considered such as 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.

Table A.14 - Room six (Cooling area) - Mechanical and electrical

Subject	Room 6 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.

Subject	Room 6 mechanical and electrical
Relative pressure	Negative pressure with respect to Sterilizer Unload Area (30).
Final filtration	ISO ePM2.5, 80%
Air relative humidity	30 to 60%RH.
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 ISO 16890-1: 2016.
Lighting level	300 lux at bench height.
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	70
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).

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Subject	Room 6 mechanical and electrical
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.

Room 6 - Equipment/ fixtures and fittings

A.6 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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

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- 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

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Room 7 - Communications room

Table A.15 - Room 7 (Communications room) - Design requirements

Subject	Room 7 design requirements
Function	This is a controlled area(s) used to site the various IT servers required to support the quality management system (QMS). It may also contain the telephone switchgear. There may be more than one Communications Room required to avoid single points of failure. This may involve locating the room(s) outwith the department.
Occupancy	Specify the maximum number of staff working in this area.
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 Uninterruptible Power Supply (UPS) back up. Node cabinets may be required in more than one location to provide data security and back up that is 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	Each Communications Room should be connected to the General Corridor (14).

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Table A.16 - Room 7 (Communications room) – Finishes

Subject	Room 7 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish mineral fibre tiles, factory finished with acrylic paint.
Door sets	(SHTM 58: 2006) Compliant, no vision panel in door for security purposes.
Windows type	(SHTM 55: 2006) Not essential.
Internal glazing	Not applicable.
Ceiling hatches	If required to be in line with ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall.

Table A.17 - Room seven (Communications room) - Mechanical and electrical

Subject	Room 7 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to meet minimum fresh air requirements for IT staff.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure	Same as the General Corridor (14).
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	30 to 60%RH.

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Subject	Room 7 mechanical and electrical
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux bench height.
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	70 audible but not intrusive.
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

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Room 7 - Equipment/ fixtures and fittings

A.7 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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

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Room 8 - Deputy CDU manager's office

Table A.18 - Room 8 (Deputy CDU Manager's office) - Design requirements

Subject	Room 8 design requirements
Function	This is an area used to provide an appropriate environment to undertake managerial duties of the deputy CDU Manager.
Occupancy	Specify the maximum number of personnel in this room such as 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 BMS. 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	Direct access to the General Corridor (14).

Table A.19 - Room 8 (Deputy CDU Manager's office) - Finishes

Subject	Room 8 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.

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Subject	Room 8 finishes
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	If required, to be in line with ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall.

Table A.20 - Room 8 (Deputy CDU Manager's office) - Mechanical and electrical

Subject	Room 8 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure	Same as the General Corridor (14).
Final filtration	ISO ePM2.5, 80%
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	80 (normal speech inaudible).
Mechanical services- NR noise level	30

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Subject	Room 8 mechanical and electrical
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	SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke Detector.

Room 8 - equipment/ fixtures and fittings

A.8 Select from the list of items and include the number of each and dimensions of each as applicable:

- fire alarm
- smoke detector
- fire extinguishers
- clock battery operated and wall mounted
- security alarm with push button and wall mounted
- coat hook
- shelving
- table

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- desk
- chairs
- filing cabinet
- computer
- telephone
- wall mounted marker board
- computer for floor management system and or BMS
- 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

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Room 9 - Dispatch

Table A.21 - Room 9 (Dispatch) - Design requirements

Subject	Room 9 design requirements
Function	This is an area used for assembling batches of processed products for distribution.
Occupancy	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 and 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 and rodents 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	Direct access to the Processed Products Store (24). Direct access to the Vehicle Loading Bay (36e).

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Table A.22 - Room nine (Dispatch) - Finishes

Subject	Room 9 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant. Suitable door protection required.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	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: 2006) should be considered such as 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.

Table A.22 - Room 9 (Dispatch) - Mechanical and electrical

Subject	Room 9 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.

Subject	Room 9 mechanical and electrical
Relative pressure	Negative pressure with respect to the Processed Products Store (24).
Final filtration	ISO ePM2.5, 80% .
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	70 (audible but not intrusive).
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke Detector.

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Room 9 - equipment/ fixtures and fittings

A.9 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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 and 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

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Room 10 - Entrance for staff and visitors

Table A.23 - Room 10 (Entrance for staff and visitors) - Design requirements

Subject	Room 10 design requirements
Function	To provide controlled secure access for staff and visitors. May provide a waiting area for a defined number of visitors.
Occupancy	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 Closed circuit television (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. Entrance should be ramp-approached.
Adjacencies	Connects to General Corridor (14). Adjacent to Office (23). Close to Managers' offices (4, 8 and 25).

Table A.24 - Room 10 (Entrance for staff and visitors) - Finishes

Subject	Room 10 finishes
Wall finish	Surface Finish (SHTM 56: 2006): performance category 5. Recommended finish acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): performance category 4. Recommended finish mineral fibre tiles.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Not applicable.

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Subject	Room 10 finishes
Wall hatch	Sliding, glazed, secure and lockable.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.

Table A.25 - Room 10 (Entrance for staff and visitors) - Mechanical and electrical

Subject	Room 10 mechanical and electrical
Air temperature	Winter and Summer 16 to 24 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure	Same as the corridor.
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015. 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- NR noise level	Not specified.
Intrusive noise (NR) noise level	Not specified.

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Subject	Room 10 mechanical and electrical
Acceptable sound level	As specified in the Control of Noise at Work Regulations 2005.
Speech privacy	No
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke Detector.

Room 10 - equipment/ fixtures and fittings

A.10 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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

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- chair, stacking, polypropylene, with seat and 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

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Room 11 - Estate manager's office

Table A.26 - Room 11 (Estate Manager's office) - Design requirements

Subject	Room 11 design requirements
Function	This is an area used to provide an appropriate environment to undertake management of the Estate.
Occupancy	Specify the maximum number of personnel in this room such as 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 BMS. 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.

Table A.27 - Room 11 (Estate Manager's office) - Finishes

Subject	Room 11 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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.

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Subject	Room 11 finishes
Ceiling finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	If required, to be in line with ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall.

Table A.28 - Room 11 (Estate Manager's office) – Mechanical and electrical

Subject	Room 11 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	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	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A

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Subject	Room 11 mechanical and electrical
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	80 (normal speech inaudible).
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke Detector.

Room 11 - equipment/ fixtures and fittings

A.11 Select from the list of items and include the number of each and dimensions of each as applicable:

- fire alarm
- smoke detector
- fire extinguishers
- clock battery operated and wall mounted
- security alarm with push button and wall mounted

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- coat hooks
- shelving
- table
- desk
- chairs
- filing cabinet
- computer
- telephone
- wall mounted marker board
- computer for floor management system and or BMS
- 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

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Room 12 - First aid room

Table A.29 - Room 12 (First aid room) - Design requirements

Subject	Room 12 design requirements
Function	This is an area used to provide a dedicated private area for First Aid.
Occupancy	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.

Table A.30 - Room 12 (First aid room) - Finishes

Subject	Room 12 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish mineral fibre tiles.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	Not applicable.
Internal glazing	Not applicable.
Ceiling hatches	If required, to be in line with ceiling finish.

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Subject	Room 12 finishes
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall.

Table A.31 - Room 12 (First aid room) - Mechanical and electrical

Subject	Room 12 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	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	ISO ePM2.5, 80%.
Air relative humidity	< 70%RH.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	80 (normal speech inaudible).
Mechanical services- NR noise level	30
Intrusive noise (NR) noise level	35
Acceptable sound level	As specified in the Control of Noise at Work Regulations 2005.

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Subject	Room 12 mechanical and electrical
Speech privacy	Yes
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke Detector.

Room 12 - equipment/ fixtures and fittings

A.12 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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: 2009
- IPS panel
- hands free waste bin

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- 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

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Room 13 - General/ clinical waste disposal area

Table A.32 - Room 13 (General/ clinical waste disposal area) - Design requirements

Subject	Room 13 design requirements
Function	This is an area for storing clinical and general waste awaiting collection.
Occupancy	Specify the maximum number of staff working in this area.
Activities	Receiving and 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. Design should take into account the flammability of stored materials and consider the fire protection guidance in SHTM 81. 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 B.1). 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).

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Subject	Room 13 design requirements
Adjacencies	Direct access (interlocked) to Clinical/ General Waste exit (36b). Direct access (interlocked) to General Corridor (14). Direct access (interlocked) to Contaminated Returns Lobby (5).

Table A.33 - Room 13 (General/ clinical waste disposal area) - Finishes

Subject	Room 13 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 3. Recommended finish acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 5. Recommended finish mineral fibre tiles.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	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: 2006) should be considered such as 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.

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Table A.34 - Room 13 (General/ clinical waste disposal area) - Mechanical and electrical

Subject	Room 13 mechanical and electrical
Air temperature	Winter and Summer 16 to 19 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	Minimum 10 (with no recirculation into the room supply).
Relative pressure	Negative pressure with respect to adjoining areas.
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	70
Mechanical services - 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.

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Subject	Room 13 mechanical and electrical
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke Detector.

Room 13 - equipment/ fixtures and fittings

A.13 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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 SMTM 64
- wash hand basin as SHTM 64: 2009
- 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

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Room 14 - General corridor

Table A.35 - Room 14 (General corridor) - Design requirements

Subject	Room 14 design requirements
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 should not enter this corridor).
Occupancy	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, for example 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	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 and 25), WC (39), Training Room (35), Staff Room (32), General Areas Domestic Services Rooms (DSR) (15), Wash Room Material Transfer Room (38), Materials Store (22), CDU cleanroom Materials Transfer Room (20), Wash Room Gowning Room (26), CDU cleanroom Gowning Room (18), Cooling Area (6) and First Aid Room (12).

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Table A.36 - Room 14 (General corridor) - Finishes

Subject	Room 14 finishes
Wall finish	Surface Finish (SHTM 56: 2006): 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: 2006.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): performance category 4. Recommended finish mineral fibre tiles, factory finished with acrylic paint.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	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: 2006) should be considered such as mid height crash rail, durable materials on lower part of walls and splayed skirting. Corner protection should also be considered.

Table A.37 - Room 14 (General corridor) - Mechanical and electrical

Subject	Room 14 mechanical and electrical
Air temperature	Winter and Summer 16 to 24 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	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.

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Subject	Room 14 mechanical and electrical
Final filtration	ISO ePM2.5, 80%
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	200 lux (at floor level).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01.
Noise-privacy factor	Not applicable.
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke Detector.

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Room 14 - equipment/ fixtures and fittings

A.14 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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

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Room 15 - General areas domestic services room

Table A.38 - Room 15 (General areas domestic services room) - Design requirements

Subject	Room 15 design requirements
Function	This is a controlled area used for storing dedicated 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	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. Refer to the national cleaning services specification 2024.
Adjacencies	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.

Table A.39 - Room 15 (General areas domestic services room) - Finishes

Subject	Room 15 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish mineral fibre tiles, factory finished with acrylic paint.

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Subject	Room 15 finishes
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential.
Internal glazing	Not applicable.
Ceiling hatches	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: 2006) should be considered such as mid height crash rail, durable materials on lower part of walls, splayed skirting and protective corners.

Table A.40 - Room 15 (General areas domestic services room) - Mechanical and electrical

Subject	Room 15 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure	Same as the General Corridor (14).
Final filtration	Not specified.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (at bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.

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Subject	Room 15 mechanical and electrical
Noise-privacy factor	70
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke Detector.

Room 15 - equipment/ fixtures and fittings

A.15 Select from the list of items and include the number of each and dimensions of each as applicable:

- dedicated cleaning equipment
- scrubbing/ polishing machine
- dry suction machine
- warning cone
- cleaner's trolley 3 bucket system and floor mop
- fire alarm

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- smoke detector
- fire extinguishers
- low level bucket sink
- wash hand basin - vitreous china or stainless steel, no tap holes, no overflow and concealed pipe work as SHTM 64: 2009. 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

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Room 16 - General plant room

Table A.41 - Room 16 (General plant room) - Design requirements

Subject	Room 16 design requirements
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	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 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 (for example 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 for example 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, for example 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

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Subject	Room 16 design requirements
	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, for example 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 B.1). 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. 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 WDs, sterilizers, pumps, auto control components for air handling plant, water filtration plant and Reverse Osmosis (RO) plant. 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.
Adjacencies	Direct secure access to outside of building (36a). Direct access to General Corridor (14) or other if plant room on upper level.

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Table A.42 - Room 16 (General plant room) - Finishes

Subject	Room 16 finishes
Wall finish	Surface Finish (SHTM 56: 2006): performance category 5: Recommended finish sealed block work. Exposed steelwork to be painted.
Floor finish	Surface Finish (SHTM 61: 2009): 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 on the first floor to accommodate ventilation plant/ ducting may be galvanised steel open mesh grid.
Ceiling finish	Surface Finish (SHTM 60: 2006): self-finish roof cladding.
Door sets	(SHTM 58: 2006) Compliant. Full width kick panels.
Windows type	(SHTM 55: 2006) Not essential.
Internal glazing	(SHTM 57: 2006) Not applicable.
Ceiling hatches	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: 2006) 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.

Table A.43 - Room 16 (General plant room) - Mechanical and electrical

Subject	Room 16 mechanical and electrical
Air temperature	Winter and Summer <30 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.

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Subject	Room 16 mechanical and electrical
Relative pressure	Negative with respect to adjoining areas.
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux at floor.
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	<70
Mechanical services- 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	none
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke Detector. Located to avoid false alarms from humidity spikes.

Draft for consultation

Room 16 - equipment/ fixtures and fittings

A.16 Select from the list of items and include the number of each and dimensions of each as applicable:

- water treatment plant, Reverse Osmosis (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) and 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 and distribution board-sealed secure watertight with fixed signage conforming to the Institute of Electrical and Electronics Engineers (IEEE) regulations
- air compressors
- phone
- fire alarm
- smoke detector
- fire extinguishers
- clock battery operated and wall mounted
- security alarm with push button and wall mounted

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- 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

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Room 17 - CDU cleanroom

Table A.44 - Room 17 (CDU cleanroom) - Design requirements

Subject	Room 17 design requirements
Function	The CDU cleanroom (17) provides a suitable controlled environment for the receipt, inspection, testing, assembly, packing and labelling of cleaned and disinfected reusable medical devices (RMDs).
Occupancy	Specify the maximum number of persons to be permitted in the CDU cleanroom 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 for example 100% polyester cleanroom gowns, mobcaps and dedicated cleanroom footwear.
Activities	These may include: Receiving clean, dry, disinfected devices from the Wash Room (27) via WDs or clean dry manually cleaned devices via a transfer hatch or drying cabinet connecting the two rooms. Receiving packing materials from the CDU cleanroom 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 CDU cleanroom 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.
Design notes	The CDU cleanroom (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 cleanroom 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: 2015. The contamination, affecting product quality, to be controlled includes both viable and non-viable types. Microbial limits based on BS EN 17141: 2020 for air and surfaces are established (see Table 4.1) and should be met in the operational

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Subject	Room 17 design requirements
	occupancy state. Non-unidirectional airflow provides control of the environment through dilution of any airborne contamination by the introduction of clean supply air into the CDU cleanroom. The clean supply air mixes with contaminated room air and the mixed air is removed continuously. The clean air is supplied at a specific temperature and humidity to control thermal environmental conditions and comfort of occupants also by mixing. The number, location and type of supply air diffuser and distribution are critical in achieving the required CDU cleanroom performance. Similarly, the number and location of positions (return air or exhaust) where air exits the CDU cleanroom is also an important design consideration. Supply air diffusers protect any terminally mounted filters from damage during general operations and cleaning. 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 WD 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. “New build/ refurbishment of cleanrooms - Design out the presence of liquids above the cleanroom ceiling. This includes drain pipes and wet fire systems. If not possible, protection measures from liquids for the cleanroom ceiling should be in place along with monitoring measures”. [source: Cowlairs 2018 CDU incident report - recommendation 5.8]. It should be noted that steam pipes, cold water or hot water pipework should not cross over the cleanroom ceiling. If a refurbishment is planned, a review of pipework above the cleanroom ceiling should be conducted. If any is found, look to remove in the first instance or provide protection and monitoring measures if the first choice is not feasible. No liquid carrying pipework should be installed over the ceiling.

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Subject	Room 17 design requirements
	The CDU cleanroom (17) design should consider the impact of noise generated from mechanical services. WDs and Sterilizers connected to the CDU cleanroom may generate significant noise during operation. If the original design plans for future installation of equipment such as pass-through WDs 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 CDU cleanroom 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 CDU cleanroom. Loading systems/trolleys for WDs 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. 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 for example VESDA that can be maintained externally to the cleanroom environment would be preferable providing the room integrity, that is the room airborne particle classification and pressure differential regime is not adversely affected. 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	Adjacent to the Sterilizer unload Area (30) via pass through sterilizers. Adjacent to the Wash Room (27) connected via pass through WDs and transfer hatch. May also connect to the Wash Room (27) via an interlocked heated drying cabinet. Direct access to the CDU cleanroom DSR (19). Direct access to the CDU cleanroom Materials Transfer Room (20). Direct access to CDU cleanroom Gowning Room (18).

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Table A.45 - Room 17 (CDU cleanroom) - Finishes

Subject	Room 17 finishes
Wall finish	Surface Finish SHTM 56: 2006: performance category 3. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface finish (SHTM 60: 2006): performance category 1.
Door sets	(SHTM 58: 2006) Compliant. The interlocked door from the CDU cleanroom Room (17) into its gowning room (18) should have a flush fitting smooth vision panel.
Windows type	(SHTM 55: 2006) Desirable. If provided - clear, solar control, without opening, airtight.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	No access hatches in the cleanroom ceiling.
Pass thru hatch	Built-in, pass through, sliding interlocking doors. Flush to the wall in the cleanroom.
Finish notes	There should be no exposed wooden finishes in the CDU cleanroom. 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. Air pressure stabilisers to be flush with wall on cleanroom side. 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. Construction and expansion joints in the floor structure of the CDU cleanroom (17) should be stable and sealed prior to application of the final floor finish. 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 WDs or sterilizers. The “cut outs” and “in fill panels” around equipment

Subject	Room 17 finishes
	such as pass through - WDs 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 for example the fire exit signage. The emergency exit door seals must be appropriate for the cleanroom environment.

Table A.46 - Room 17 (CDU cleanroom) - Mechanical and electrical

Subject	Room 17 mechanical and electrical
Air temperature	Winter and Summer 16-21 degrees Celsius during production.
Supply air changes per hour	That required to deliver the specified room conditions for 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 air changes per hour	That required to deliver the specified room conditions. Low level extract grills to be used.
Relative pressure – Pascals (Pa)	CDU cleanroom (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). (minimum of +15) • +15 wrt the Sterilizer Load Area (40) and also to the Chemical Sterilizer Room (41)

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Subject	Room 17 mechanical and electrical
	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 filter ISO ePM10, 60% and secondary fine filter grade ISO ePM1, 85% as filter standard BS EN ISO 16890-1: 2016 and terminal high-efficiency particulate air (HEPA) filters (grade H13 as BS EN 1822-1: 2019).
Air relative humidity	40-70 % RH during production.
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: 2015. 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.
Lighting level	500 lux at each workstation surface during production. 300 lux at floor level.
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015. Dust Tight Light Fittings/ enclosures protected against splashing water - IP 64 rated.
Noise-privacy factor	<70
Mechanical services- NR noise level	40
Intrusive noise (NR) noise level	Not specified.

Subject	Room 17 mechanical and electrical
Acceptable sound level	As specified in the Control of Noise at Work Regulations 2005.
Speech privacy	No
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 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.

Room 17 - equipment/ fixtures and fittings

A.17 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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)

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- 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 CDU cleanroom it must be via a HEPA filter (grade H13 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 CDU cleanroom environment
- fire extinguishers
- socket outlet switched 13 amp double, ac, wall or ceiling mounted and IP 64 rated

fixtures should be flush will the cleanroom wall and not protrude into the cleanroom as these provide a surface for contamination build-up. Examples include air pressure stabilisers and pass through hatches.

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Room 18 - CDU cleanroom gowning room

Table A.47 - Room 18 (CDU cleanroom gowning room) - Design requirements

Subject	Room 18 design requirements
Function	To provide controlled entry and exit of personnel in line with good cleanroom discipline thereby minimizing the introduction of contamination into the CDU cleanroom (17). Provide staff/ supervised visitors with a facility for changing into and out of cleanroom overgarments, dedicated footwear and carry out hand hygiene.
Occupancy	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 CDU cleanroom (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 CDU cleanroom (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 and both types of footwear such as CDU cleanroom footwear and general footwear. Hanging partially used cleanroom overgarments during staff breaks. Disposing of used cleanroom overgarments into appropriate bins.
Design notes	The CDU Cleanroom Gowning Room (18) acts as an airlock between the CDU cleanroom (17) and the General Corridor (14). The CDU Cleanroom 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: 2015. Contamination to be controlled in this room includes both viable and non-viable types. Pressure differential monitoring between this room and the CDU cleanroom (17) and the General Corridor (14) is 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 CDU cleanroom Gowning Room (18). To facilitate change between the dirty side (corridor side of the gowning room) and the clean side (CDU cleanroom 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

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Subject	Room 18 design requirements
	of the CDU cleanroom (17) is one of a number of measures intended to minimize the introduction of contamination into the cleanroom. 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. There should be adequate wall space on each side of the step-over 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. 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 CDU cleanroom (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.
Adjacencies	Direct access (interlocked) to the CDU cleanroom (17). Direct access (interlocked) to General Corridor (14).

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Table A.48 - Room 18 (CDU cleanroom gowning room) - Finishes

Subject	Room 18 finishes
Wall finish	Surface Finish (SHTM 56: 2006): performance category 3: Recommended finish elastomeric vinyl compound or epoxy coating/ acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): performance category 3 Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant. Both interlocked doors should have vision panels which are flush fitting and smooth.
Windows type	(SHTM 55: 2006) Not essential. If provided - clear, without opening, airtight.
Internal glazing	(SHTM 57: 2006) Not applicable.
Ceiling hatches	None
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.

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Table A.49 - Room 18 (CDU cleanroom gowning room) - Mechanical and electrical

Subject	Room 18 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius during production.
Supply air changes per hour	That required to deliver the specified room conditions of airborne particle classification (at occupancy status “Operational”), temperature, relative humidity and pressure differential.
Extract air changes per hour	That required to deliver the specified room conditions. Low level extract grills to be used.
Relative pressure, Pascals (Pa)	-10Pa with respect to the CDU cleanroom (17). +15Pa with respect to the General Corridor (14).
Final filtration	Primary filter grade ISO ePM10, 60% and secondary filter grade ISO ePM1, 85% as filter standard BS EN ISO 16890-1: 2016.
Air 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: 2015.
Lighting level	300 lux at floor.
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	<70
Mechanical services- 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.

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Subject	Room 18 mechanical and electrical
Speech privacy	No
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 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.

Room 18 - equipment/ fixtures and fittings

A.18 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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 and traps for the waste pipes should be accessible from outside of the gowning room and 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

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- 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 CDU cleanroom 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)

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Room 19 - CDU cleanroom DSR

Table A.50 - Room 19 (CDU cleanroom DSR) - Design requirements

Subject	Room 19 design requirements
Function	This is a controlled area used for storing approved dedicated equipment and supplies used for cleaning the CDU cleanroom (17), the clean side of the step-over bench in the CDU cleanroom Gowning Room (18) and the clean side of the barrier in the CDU cleanroom Materials Transfer Room (20).
Occupancy	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 CDU cleanroom DSR (19) connects directly only to the CDU cleanroom (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: 2015. It should have minimal impact with respect to the controlled environment of the CDU cleanroom 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	Direct access from the CDU cleanroom (17) only.

Table A.51 - Room 19 (CDU cleanroom DSR) - Finishes

Subject	Room 19 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 3. Recommended finish acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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.

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Subject	Room 19 finishes
Ceiling finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish imperforate smooth metal tray with sound-attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Not applicable.
Ceiling hatches	None
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.

Table A.52 - Room 19 (CDU cleanroom DSR) - Mechanical and electrical

Subject	Room 19 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius during production.
Supply air changes per hour	That required to deliver the specified room conditions of airborne particle classification (at occupancy status "Operational"), temperature, relative humidity and pressure differential.

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Subject	Room 19 mechanical and electrical
Extract air changes per hour	That required to deliver the specified room conditions. Low level extract grills to be used.
Relative pressure, Pascals (Pa)	Negative with respect to CDU cleanroom (17).
Final filtration	Primary filter grade ISO ePM10, 60% and secondary filter grade ISO ePM1, 85% as filter standard BS EN ISO 16890-1: 2016. Terminal HEPA filters to be grade H13 as BS EN 1822-1: 2019.
Air 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: 2015. 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 level	300 lux at bench height.
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015. Dust Tight Light Fittings/enclosures protected against splashing water - IP64.
Noise-privacy factor	Not specified.
Mechanical services- 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 08-01: 2015.

Subject	Room 19 mechanical and electrical
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 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.

Room 19 - equipment/ fixtures and fittings

A.19 All equipment/ furniture/ fittings in this room should be of cleanroom quality. There should be no exposed wooden surfaces in this room. Select from the list of items and include the number of each and dimensions of each as applicable:

- dedicated cleanroom cleaning equipment
- scrubbing/ polishing machine
- dry suction machine
- warning cone
- cleaner's trolley 3 bucket system and floor mop
- fire alarm and 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: 2009. 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

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- 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

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Room 20 - CDU cleanroom materials transfer room

Table A.53 - Room 20 (CDU cleanroom materials transfer room) - Design requirements

Subject	Room 20 design requirements
Function	This room is used to control the movement of materials into (and out) of the CDU cleanroom (17). This room provides an air lock between the CDU cleanroom and the General Corridor (14) in order that the level of contamination introduced and generated within the CDU cleanroom is minimized.
Occupancy	Specify the maximum number of staff working in this room.
Activities	Transfer of raw materials from the Material Store (22) to the CDU cleanroom (17). Inspecting incoming goods. Remove waste from the CDU cleanroom (17). Short term storage.
Design notes	State the space requirements needed for transfer of materials to meet the maximum specified production throughput. The CDU cleanroom Materials Transfer Room provides an airlock between the CDU cleanroom (17) and the General Corridor (14). The CDU cleanroom 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: 2015. A transfer barrier divides the room. This barrier will prevent the movement of personnel through this room into the CDU cleanroom. Pressure gauge recording pressure differential with respect to the CDU cleanroom (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 CDU cleanroom Materials Transfer Room (20) and the CDU cleanroom (17). Entrance doors must accommodate bulk handling activities if required.
Adjacencies	The room adjoins the CDU cleanroom (17). The room adjoins the General Corridor (14).

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Table A.54 - Room 20 (CDU cleanroom materials transfer room) - Finishes

Subject	Room 20 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 3. Recommended finish acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Transfer 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 CDU cleanroom 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.

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Table A.55 - Room 20 (CDU cleanroom materials transfer room) - Mechanical and electrical

Subject	Room 20 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius during production.
Supply air changes per hour	That required to deliver the specified room conditions of airborne particle classification (at occupancy status 'Operational'), temperature, relative humidity and pressure differential.
Extract air changes per hour	That required to deliver the specified room conditions. Low level extract grills to be used.
Relative pressure, Pascals (Pa)	+15Pa with respect to General Corridor (14). -10 Pa with respect to CDU cleanroom (17).
Final filtration	Primary filter grade ISO ePM10, 60% and secondary filter grade ISO ePM1, 85% as filter standard BS EN ISO 16890-1: 2016.
Air relative humidity	30 to 60%RH.
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: 2015.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	<70
Mechanical services- 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.

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Subject	Room 20 mechanical and electrical
Speech privacy	No
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	Not applicable.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 20 - equipment/ fixtures and fittings

A.20 Select from the list of items and include the number of each and dimensions of each as applicable:

- computer
- data scanner
- fire alarm
- clock battery operated and wall mounted
- fire extinguishers
- intercom wall mounted
- transfer barrier
- waste container on corridor side of barrier
- storage racking metal
- telephone

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- 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

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Room 21 - Maintenance manager's office

Table A.56 - Room 21 (Maintenance manager's office) - Design requirements

Subject	Room 21 design requirements
Function	This is an area used to provide an appropriate environment to undertake management of the facility maintenance.
Occupancy	Specify the maximum number of personnel in this room such as 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.

Table A.57 - Room 21 (Maintenance manager's office) - Finishes

Subject	Room 21 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.

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Subject	Room 21 finishes
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Not essential. If provided should be clear.
Ceiling hatches	If required, to be in line with the ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.

Table A.58 - Room 21 (Maintenance manager's office) - Mechanical and electrical

Subject	Room 21 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure, Pascals (Pa)	Same as the corridor.
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.

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Subject	Room 21 mechanical and electrical
Noise-privacy factor	80 (normal speech inaudible).
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	none
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 21 - equipment/ fixtures and fittings

A.21 Select from the list of items and include the number of each and dimensions of each as applicable:

- fire alarm
- fire extinguishers
- clock battery operated and wall mounted
- security alarm with push button and wall mounted
- coat hooks
- shelving

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- table
- desk
- chairs
- filing cabinet
- computer
- telephone
- wall mounted marker board
- computer for floor management system and or BMS
- 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

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Room 22 - Materials store

Table A.59 - Room 22 (Materials store) - Design requirements

Subject	Room 22 design requirements
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	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. Instrument marking activities.
Design notes	Specify the space required to accommodate the storage of instruments and materials sufficient to meet the maximum specified production throughput. A dedicated area may be beneficial for storage of instruments and associated activities such as instrument marking/ etching. 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 B.1). Forklift 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

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Subject	Room 22 design requirements
	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. Entrance doors must accommodate bulk handling activities if required.
Adjacencies	Direct access to the General Corridor (14). Direct secure access to Vehicle Loading Bay (36d).

Table A.60 - Room 22 (Materials store) - Finishes

Subject	Room 22 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Not essential. If provided should be clear.
Ceiling hatches	If required, to be in line with the ceiling finish.
Finish notes	Heavy Duty protection (SHTM 69: 2006) should be considered such as 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.

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Table A.61 - Room 22 (Materials store) - Mechanical and electrical

Subject	Room 22 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure, Pascals (Pa)	Same pressure as General Corridor (14) and positive pressure with respect to outside environment.
Final filtration	ISO ePM2.5, 80%
Air relative humidity	Not specified [check if any materials required to be stored under controlled humidity conditions - if so then an appropriate range must be set for control].
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	70 audible but not intrusive.
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.

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Subject	Room 22 mechanical and electrical
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 22 - equipment/ fixtures and fittings

A.22 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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

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panel. wall mounted dispenser, with non-refillable hand wash solution. wall mounted, easily cleanable dispenser for single use paper towels

- waste container
- workbench
- equipment for marking/ etching instruments
- admin desk and filing cabinet
- flammables storage cabinet
- Personal Protective Equipment (PPE) storage example hard hats and 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

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Room 23 - Office

Table A.62 - Room 23 (Office) - Design requirements

Subject	Room 23 design requirements
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	Specify the maximum number of staff working in the office.
Activities	Controlling visitor access internally and at site entrance gate (see Figure B.1) if applicable. Administrative work. Financial management. Supporting the QMS - 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	Adjacent to the Entrance Staff/ Visitors (10). Direct access to the General Corridor (14).

Table A.63 - Room 23 (Office) - Finishes

Subject	Room 23 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Reception point could consist of horizontal sliding glass with locking device.

Subject	Room 23 finishes
Internal glazing	(SHTM 57: 2006) Clear.
Ceiling hatches	If required, to be in line with the ceiling finish.
Finish notes	Consideration of protection (SHTM 69: 2006) of the walls may be required dependent on the activities planned for the room.

Table A.64 - Room 23 (Office) - Mechanical and electrical

Subject	Room 23 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure, Pascals (Pa)	Same pressure as General Corridor (14).
Final filtration	ISO ePM2.5, 80%
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	75 (normal speech audible but not intelligible).
Mechanical services- NR noise level	35
Intrusive noise (NR) noise level	40

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Subject	Room 23 mechanical and electrical
Acceptable sound level	As specified in the Control of Noise at Work Regulations 2005.
Speech privacy	Yes
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	none
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 23 - equipment/ fixtures and fittings

A.23 Select from the list of items and include the number of each and dimensions of each as applicable:

- fire alarm
- fire extinguishers
- clock battery operated and wall mounted
- security alarm with push button and wall mounted
- coat hooks
- shelving
- table
- desk
- chairs

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- filing cabinet
- photocopier
- computer
- telephone
- CCTV and remote socket double outlet computer data
- wall mounted marker board
- 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 control of site entrance gates

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Room 24 - Processed products store

Table A.65 - Room 24 (Processed products store) - Design requirements

Subject	Room 24 design requirements
Function	This is an area used for storage of processed products released for distribution.
Occupancy	Specify the maximum number of staff working in the area.
Activities	Receiving processed goods from Cooling Area (6). Placing trays/packs into transport carts/ containers. Short term storage of sterile trays and 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	Direct access to the Cooling Area (6). Direct access to Dispatch (9). Direct access to the Sterilizer Unload Area (30).

Table A.66 - Room 24 (Processed products store) - Finishes

Subject	Room 24 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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.

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Subject	Room 24 finishes
Ceiling finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	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: 2006) should be considered such as 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.

Table A.67 - Room 24 (Processed products store) - Mechanical and electrical

Subject	Room 24 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure, Pascals (Pa)	Positive pressure with respect to Dispatch (9).
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	30-70 %RH.
Air notes	Filter standard BS EN ISO 16890-1: 2016.

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Subject	Room 24 mechanical and electrical
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	Not specified.
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	none
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 24 - equipment/ fixtures and fittings

A.24 Select from the list of items and include the number of each and dimensions of each as applicable:

- transport carts
- transport containers

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- 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. [may be high density storage system]
- 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

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Room 25 - Quality manager's office

Table A.68 - Room 25 (Quality manager's office) - Design requirements

Subject	Room 25 design requirements
Function	This is an area used to provide an appropriate environment to undertake management of the quality system.
Occupancy	Specify the maximum number of personnel in this room such as the Quality Manager and the maximum number of persons during a meeting.
Activities	Managing the QMS in compliance with BS EN ISO 13485: 2021. 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 CDU cleanroom (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	Direct access to the General Corridor (14). Located adjacent and with viewing windows to both the Wash Room (27) and the CDU cleanroom (17).

Table A.69 - Room 25 (Quality manager's office) - Finishes

Subject	Room 25 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Essential to view into the Wash Room (27) and the CDU cleanroom (17).

Subject	Room 25 finishes
Internal glazing	(SHTM 57: 2006) Clear.
Ceiling hatches	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: 2006) should be considered such as mid height buffer rail and/ or durable finish on middle or lower part of the wall.

Table A.70 - Room 25 (Quality manager's office) - Mechanical and electrical

Subject	Room 25 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure, Pascals (Pa)	Same as the general corridor.
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	80 (normal speech inaudible).
Mechanical services- NR noise level	35

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Subject	Room 25 mechanical and electrical
Intrusive noise (NR) noise level	30
Acceptable sound level	As specified in the Control of Noise at Work Regulations 2005.
Speech privacy	Yes
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	none
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 25 - equipment/ fixtures and fittings

A.25 Select from the list of items and include the number of each and dimensions of each as applicable:

- fire alarm
- fire extinguishers
- clock battery operated and wall mounted
- security alarm with push button and wall mounted
- coat hooks
- shelving
- table
- desk

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- chair
- filing cabinet
- computer
- telephone
- wall mounted marker board
- computer for floor management system and or BMS
- 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

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Room 26 - Wash room gowning room

Table A.71 - Room 26 (Wash room gowning room) - Design requirements

Subject	Room 26 design requirements
Function	To provide controlled entry and exit of personnel. Provide staff with a facility for changing into and out of PPE required for Wash Room activities and hand hygiene.
Occupancy	State the maximum number of staff the room can accommodate.
Activities	Hand hygiene. Changing into/out of PPE. Using transfer bench to change into dedicated Wash Room footwear. Holding PPE and 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. 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.
Adjacencies	Direct access to Wash Room (27). Direct access to the General Corridor (14).

Table A.72 - Room 26 (Wash room gowning room) - Finishes

Subject	Room 26 finishes
Wall finish	Surface Finish (SHTM 56: 2006): performance category 5: Recommended finish elastomeric vinyl compound or epoxy coating/ acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): performance category 3 Recommended finish imperforate smooth metal tray with sound attenuating insert.

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Subject	Room 26 finishes
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided - clear, without opening, airtight.
Internal glazing	(SHTM 57: 2006) Not applicable.
Ceiling hatches	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: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.

Table A.73 - Room 26 (Wash room gowning room) - Mechanical and electrical

Subject	Room 26 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure, Pascals (Pa)	Not positive with respect to adjoining areas.
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.

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Subject	Room 26 mechanical and electrical
Noise-privacy factor	Not specified
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 26 - equipment/ fixtures and fittings

A.26 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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 SHTM 64: 2009. waste- flush, grated, metal and no plug. tap-single horizontal spout, wall mounted, with proximity sensor and concealed mixer controls

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- 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)

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Room 27 - Wash room

Table A.74 - Room 27 (Wash room) - Design requirements

Subject	Room 27 design requirements
Function	This is a controlled area used in the disassembly and preparation of RMDs and associated equipment before cleaning, disinfecting and drying.
Occupancy	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 WDs and other cleaning equipment such as ultrasonic cleaners. Segregation and streaming/ batching of high Creutzfeldt Jakob Disease (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 CDU cleanroom (17). Receiving empty WD baskets from the CDU cleanroom (17). Receiving unsatisfactorily processed medical devices back from the CDU cleanroom (17) via the transfer hatch. Tracking of medical devices through the room.
Design notes	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. For example, different lengths of manual wash sinks may be required. Also ensure all the services required for equipment are defined, for example hot and cold water supply for WD, extract ventilation for WD, electrical supply. If the original design plans for future installation of equipment such as pass-through WDs then consideration should be given to suitable wall configuration for example 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

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Subject	Room 27 design requirements
	to the installation site. Pressure gauge recording pressure differential with respect to the General Corridor (14) and to the CDU cleanroom (17) required.
Adjacencies	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 CDU cleanroom (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.

Table A.75 - Room 27 (Wash room) - Finishes

Subject	Room 27 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 2. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 2. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	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: 2006) should be considered such as 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

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Subject	Room 27 finishes
	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 WDs. The 'cut outs' and 'in fill panels' around equipment such as WDs 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.

Table A.76 - Room 27 (Wash room) - Mechanical and electrical

Subject	Room 27 mechanical and electrical
Air temperature	Winter and Summer 16 to 19 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	Minimum 10 (with no recirculation into the room supply).
Relative pressure, Pascals (Pa)	-5Pa wrt General Corridor (14), not positive with respect to surrounding areas. -30Pa wrt the CDU cleanroom (17). Note the minimum to be -15Pa with respect to CDU cleanroom (17).
Final filtration	ISO ePM1, 85%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	Consider the potential effects of glare from the stainless steel workstations.
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015. Lighting enclosures IP 54 rated.
Noise-privacy factor	Not specified.

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Subject	Room 27 mechanical and electrical
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 27 - equipment/ fixtures and fittings

A.27 Select from the list of items and include the number of each and dimensions of each as applicable:

- thermal washer-disinfectors (WDs) for surgical instruments compliant with SHTM 01-01:2018
- consider waste water heat recovery systems
- container/ trolley WDs
- accessories and associated equipment and fittings for WDs [water services hot/ cold, compressed air, extract ventilation, electrical supply]
- fire alarm
- smoke detector

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- 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 01-1: 2018
- accessories and associated equipment for ultrasonic cleaners/ irrigators
- accessories and associated cleaning equipment for specialised medical devices, for example phaco and dental handpieces
- double stainless steel sink(s) for manual cleaning - one wash sink and one rinse sink (fitted with automated dosing systems)
- 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
- materials transfer facility - detergents and raw materials 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 and drench shower (if required after COSHH assessment)
- eye-wash station with mirror wall mounted
- computer
- data scanner
- stainless steel workbench for admin purposes

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- 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

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Room 28 - Wash room DSR

Table A.77 - Room 28 (Wash room DSR) - Design requirements

Subject	Room 28 design requirements
Function	This is a controlled area used for storing dedicated 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	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 for example scrubbing machine and dry suction machine. Define the number, type and room location of each item of equipment/ furniture/ fittings as selected from the room data sheet. Also refer to the national cleaning services specification 2024.
Adjacencies	Direct access from the Wash Room (27) only.

Table A.78 - Room 28 (Wash room DSR) - Finishes

Subject	Room 28 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish tiles factory finished with acrylic paint.
Door sets	(SHTM 58: 2006) Compliant.

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Subject	Room 28 finishes
Windows type	(SHTM 55: 2006) Not essential.
Internal glazing	(SHTM 57: 2006) Not essential.
Ceiling hatches	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: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall with splayed skirting and protective corners.

Table A.79 - Room 28 (Wash room DSR) - Mechanical and electrical

Subject	Room 28 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits and pressure differential level.
Relative pressure	Same as the Wash Room (27).
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	None.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015. Lighting enclosures IP54 rated.
Noise-privacy factor	Not specified.

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Subject	Room 28 mechanical and electrical
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 28 - equipment/ fixtures and fittings

A.28 Select from the list of items and include the number of each and dimensions of each as applicable:

- dedicated cleaning equipment
- scrubbing/ polishing machine
- dry suction machine
- warning cone
- cleaner's trolley 3 bucket system and floor mop
- fire alarm
- smoke detector

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- 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: 2009. 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

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Room 29 - Sterilizer plant room

Table A.80 - Room 29 (Sterilizer plant room) - Design requirements

Subject	Room 29 design requirements
Function	Accommodating (porous load) sterilizers and associated plant (which may include equipment for clean steam generation).
Occupancy	State the maximum number of staff the room/ area 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. 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/ area connects with room 30 and room 40. 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.
Adjacencies	It should be adjacent to the Sterilizer Unload Area (30) and Sterilizer Load area (40).

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Table A.81 - Room 29 (Sterilizer plant room) - Finishes

Subject	Room 29 finishes
Wall finish	Surface Finish (SHTM 56: 2006): performance category 5: Recommended finish elastomeric vinyl compound or epoxy coating/ acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): performance category 2. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential.
Internal glazing	(SHTM 57: 2006) Not applicable.
Ceiling hatches	If required to be in line with ceiling finish.
Finish notes	Heavy Duty protection (SHTM 69: 2006) should be considered, that is mid height crash rail, durable materials on lower part of walls and splayed skirting.

Table A.82 - Room 29 (Sterilizer plant room) - Mechanical and electrical

Subject	Room 29 mechanical and electrical
Air temperature	Winter and Summer < 30 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits and pressure differential level.
Relative pressure, Pascals (Pa)	Negative to room 30 and room 40.

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Subject	Room 29 mechanical and electrical
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	None.
Lighting level	300 lux (floor height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015. Lighting enclosures IP 56 rated.
Noise-privacy factor	Not specified.
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

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Room 29 - equipment/ fixtures and fittings

A.29 Select from the list of items and include the number of each and dimensions of each as applicable:

- sterilizer porous load, 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

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Room 30 - Sterilizer unload area

Table A.83 - Room 30 (Sterilizer unload area) - Design requirements

Subject	Room 30 design requirements
Function	Accommodating porous load sterilizers and associated plant (which may include equipment for clean steam generation).
Occupancy	State the maximum number of staff the room can accommodate.
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 and so on) 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.
Adjacencies	Direct access to the Cooling Area (6) and the General Corridor (14).

Table A.84 - Room 30 (Sterilizer unload area) - Finishes

Subject	Room 30 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor finish	Surface Finish (SHTM 61: 2009): 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.

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Subject	Room 30 finishes
Ceiling finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant SHTM 55: 2006) Not essential. If provided should be clear.
Windows type	(SHTM 55: 2006) Not essential.
Internal glazing	(SHTM 57: 2006) Not applicable.
Ceiling hatches	If required to be in line with ceiling finish.
Finish notes	Heavy Duty protection (SHTM 69: 2006) should be considered such as 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.

Table A.85 - Room 30 (Sterilizer unload area) - Mechanical and electrical

Subject	Room 30 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature & RH limits.
Extract air changes per hour	That required to deliver the specified room temperature limits and pressure differential level.
Relative pressure, Pascals (Pa)	Positive pressure with respect to Sterilizer Plantroom (29). Positive pressure with respect to the General Corridor (14).
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified
Air notes	Filter standard BS EN ISO 16890-1: 2016.

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Subject	Room 30 mechanical and electrical
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015. Lighting enclosures IP 54 rated.
Noise-privacy factor	Not specified.
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 30 - equipment/ fixtures and fittings

A.30 Select from the list of items and include the number of each and dimensions of each as applicable:

- sterilizer unloading trolleys
- transport carts

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- 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

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Room 31 - Staff changing rooms

Table A.86 - Room 31 (Staff changing rooms) - Design requirements

Subject	Room 31 design requirements
Function	This is an area used to provide an appropriate environment for changing clothing and security for personal valuables.
Occupancy	Specify the maximum number of personnel (production and 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 and cold water required and drainage.
Adjacencies	Direct access to the General Corridor (14). Easy access from the Entrance Staff/ Visitors (10) and to the production areas.

Table A.87 - Room 31 (Staff changing rooms) - Finishes

Subject	Room 31 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish mineral fibre tiles.
Door sets	(SHTM 58: 2006) Compliant. Door kickplates recommended.
Windows type	(SHTM 55: 2006) Not essential.
Internal glazing	(SHTM 57: 2006) not applicable.

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Subject	Room 31 finishes
Ceiling hatches	If required in line with ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.

Table A.88 - Room 31 (Staff changing rooms) - Mechanical and electrical

Subject	Room 31 mechanical and electrical
Air temperature	Winter and Summer 19 to 23 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure, Pascals (Pa)	Same as the corridor.
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Lighting enclosures IP 54 rated. Design as SHTM 06-01: 2015.
Noise-privacy factor	80 (normal speech inaudible).
Mechanical services- NR noise level	30
Intrusive noise (NR) noise level	35
Acceptable sound level	As specified in the Control of Noise at Work Regulations 2005.

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Subject	Room 31 mechanical and electrical
Speech privacy	Yes
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 31 - equipment/ fixtures and fittings

A.31 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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

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- 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 SHTM 64: 2009. 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

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Room 32 - Staff room

Table A.89 - Room 32 (Staff room) - Design requirements

Subject	Room 32 design requirements
Function	This is an area used to provide an appropriate environment for staff rest including preparation and consumption of food.
Occupancy	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. 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 and 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	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).

Table A.90 - Room 32 (Staff room) - Finishes

Subject	Room 32 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish mineral fibre tiles.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential.
Internal glazing	(SHTM 57: 2006) not applicable.

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Subject	Room 32 finishes
Ceiling hatches	If required, to be in line with the ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and/ or durable finish on middle or lower part of the wall and protective corners.

Table A.91 - Room 32 (Staff room) - Mechanical and electrical

Subject	Room 32 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure, Pascals (Pa)	Same as the corridor.
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	75 (audible but not intelligible).
Mechanical services- NR noise level	35
Intrusive noise (NR) noise level	45
Acceptable sound level	As specified in the Control of Noise at Work Regulations 2005.

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Subject	Room 32 mechanical and electrical
Speech privacy	No
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 32 - equipment/ fixtures and fittings

A.32 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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

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- 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 SHTM 64: 2009. 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

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Room 33 - Technicians room

Table A.92 - Room 33 (Technicians room) - Design requirements

Subject	Room 33 design requirements
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	Specify the maximum number of personnel working in this room.
Activities	Repair of equipment for example 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, for example 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 and relative humidity levels specified. Hot and 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, BMSs, 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.

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Table A.93 - Room 33 (Technicians room) - Finishes

Subject	Room 33 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish mineral fibre tiles, factory finished with acrylic paint.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 57: 2006) not applicable.
Internal glazing	Not applicable.
Ceiling hatches	If required, to be in line with the ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and/ or durable finish on middle or lower part of the wall and protective corners.

Table A.94 - Room 33 (Technicians room) - Mechanical and electrical

Subject	Room 33 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature & RH limits.
Extract air changes per hour	That required to deliver the specified room temperature & RH limits.
Relative pressure	Same as the corridor.
Final filtration	ISO ePM2.5, 80%.

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Subject	Room 33 mechanical and electrical
Air relative humidity	30 to 70 %RH.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	B
Lighting notes	Design as SHTM 06-01: 2015. Lighting enclosure IP 52 rated.
Noise-privacy factor	70 audible but not intrusive.
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

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Room 33 - equipment/ fixtures and fittings

A.33 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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 SHTM 64: 2009. 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

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Room 34 - Test equipment room

Table A.95 - Room 34 (Test equipment room) - Design requirements

Subject	Room 34 design requirements
Function	This is a secure area used to provide an appropriate environment to support the testing of the CDU's decontamination equipment.
Occupancy	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 and relative humidity levels specified. This is a requirement for storage of electronic test and calibration equipment. Hot and 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	Direct access from the General Corridor (14).

Table A.96 - Room 34 (Test equipment room) - Finishes

Subject	Room 34 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish mineral fibre tiles, factory finished with acrylic paint.
Door sets	(SHTM 58: 2006) Compliant.

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Subject	Room 34 finishes
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) not applicable.
Ceiling hatches	If required, to be in line with the ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and/ or durable finish on middle or lower part of the wall.

Table A.97 - Room 34 (Test equipment room) - Mechanical and electrical

Subject	Room 34 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature & RH limits.
Extract air changes per hour	That required to deliver the specified room temperature & RH limits.
Relative pressure, Pascals (Pa)	Same as the corridor.
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	30 to 70 %RH.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	B
Lighting notes	Design as SHTM 06-01: 2015. Lighting enclosure IP 52 rated.
Noise-privacy factor	70 audible but not intrusive.
Mechanical services- NR noise level	40

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Subject	Room 34 mechanical and electrical
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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 34 - equipment/ fixtures and fittings

A.34 Select from the list of items and include the number of each and dimensions of each as applicable:

- computer
- table
- phone
- worktop
- secure storage cupboard for equipment
- secure storage cupboard for documentation
- fire alarm
- smoke detector

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- 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: 2009
- 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

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Room 35 - Training room

Table A.98 - Room 35 (Training room) - Design requirements

Subject	Room 35 design requirements
Function	This is an area used to provide an appropriate environment for staff training.
Occupancy	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 WDs.
Adjacencies	Direct access to the General Corridor (14). Easy access from the Entrance Staff/ Visitors (10) and to the production areas.

Table A.99 - Room 35 (Training room) - Finishes

Subject	Room 35 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic paint. (see design notes)
Floor finish	Surface Finish (SHTM 61: 2009): 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.

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Subject	Room 35 finishes
Ceiling finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish mineral fibre tiles.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) not applicable.
Ceiling hatches	If required, to be in line with the ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as 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.

Table A.100 - Room 35 (Training room) - Mechanical and electrical

Subject	Room 35 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature & RH limits.
Extract air changes per hour	That required to deliver the specified room temperature & RH limits.
Relative pressure, Pascals (Pa)	Same as the corridor.
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Less than 70%RH.
Air notes	Not applicable.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	B

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Subject	Room 35 mechanical and electrical
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	80 (normal speech inaudible).
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 35 - equipment/ fixtures and fittings

A.35 Select from the list of items and include the number of each and dimensions of each as applicable:

- fire alarm
- smoke detector
- fire extinguishers
- clock battery operated and wall mounted
- security alarm with push button and wall mounted

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- tables and chairs
- computer and 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

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Area 36 - Vehicle loading bays

Table A.101 - Area 36 (Vehicle loading bays) - Design requirements

Subject	Area 36 design requirements
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	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	Controlled access is required to each area to ensure product and staff safety. 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 for example a 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

Subject	Area 36 design requirements
	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? • 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. 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	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)

for Consultation

Table A.102 - Area 36 (Vehicle loading days) - Finishes

Subject	Area 36 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic Surface Finish (SHTM 56): Smooth finished brick, block, plastered cement render with spray or brush resin or acrylic paint. Wall protection is essential. (see design notes)
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Need to determine if the loading bay is covered.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.
Internal glazing	(SHTM 57: 2006) Not applicable.
Ceiling hatches	Not applicable.
Finish notes	Heavy Duty protection (SHTM 69: 2006) is essential such as 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 forklifts or pallet trolleys are in use.

Table A.103 - Area 36 (Vehicle loading days) - Mechanical and electrical

Subject	Area 36 mechanical and electrical
Air temperature	Not applicable.
Supply air changes per hour	Not applicable.
Extract air changes per hour	Not applicable.
Relative pressure	Not applicable.
Final filtration	Not applicable.

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Subject	Area 36 mechanical and electrical
Air relative humidity	Not applicable.
Air notes	Not applicable.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	B
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	Not applicable.
Mechanical services- NR noise level	Not applicable.
Intrusive noise (NR) noise level	Not applicable.
Acceptable sound level	As specified in the Control of Noise at Work Regulations 2005.
Speech privacy	Not applicable.
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	Not applicable.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

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Area 36 - equipment/ fixtures and fittings

A.36 Select from the list of items and include the number of each and dimensions of each as applicable:

- doorbell
- external lighting (high wattage with proximity sensor)
- CCTV and 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

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Area 37 - Vehicle wash area

Table A.104 - Area 37 (Vehicle wash area) - Design requirements

Subject	Area 37 design requirements
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	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. The electrical switch supply should be isolated from within the main building when not in use. Define the size of vehicle to be accommodated for example a Luton van with tailgate 6.7m (L) x 2.5m (W) x 3.3m (H).
Adjacencies	On site external to the CDU building.

Table A.105 - Area 37 (Vehicle wash area) - Finishes

Subject	Area 37 finishes
Wall finish	Not applicable.
Floor finish	Concrete base.
Ceiling finish	Not applicable.
Door sets	Not applicable.
Windows type	Not applicable.
Internal glazing	Not applicable.

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Subject	Area 37 finishes
Ceiling hatches	Not applicable.
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.

Table A.106 - Area (Vehicle wash area) - Mechanical and electrical

Subject	Area 37 mechanical and electrical
Air temperature	Not applicable.
Supply air changes per hour	Not applicable.
Extract air changes per hour	Not applicable.
Relative pressure	Not applicable.
Final filtration	Not applicable.
Air relative humidity	Not applicable.
Air notes	Not applicable.
Lighting level	Flood lighting if cleaning/ waste management required at night.
Colour rendering	No
Standby lighting grade	B
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	Not applicable.
Mechanical services- NR noise level	Not applicable.
Intrusive noise (NR) noise level	Not applicable.
Acceptable sound level	As specified in the Control of Noise at Work Regulations 2005.

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Subject	Area 37 mechanical and electrical
Speech privacy	No
Noise notes	Not applicable.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector

Area 37 - equipment/ fixtures and fittings

A.37 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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

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Room 38 - Wash room materials transfer room

Table A.107 - Room 38 (Wash room materials transfer room) - Design requirements

Subject	Room 38 design requirements
Function	This room is used to control the movement of materials into (and out) of the Wash Room (27).
Occupancy	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 airlock 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. Entrance doors must accommodate bulk handling activities if required.
Adjacencies	The room adjoins the Wash Room (27). The room adjoins the General Corridor (14).

Table A.108 - Room 38 (Wash room materials transfer room) - Finishes

Subject	Room 38 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 3. Recommended finish acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	(SHTM 55: 2006) Not essential. If provided should be clear.

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Subject	Room 38 finishes
Internal glazing	(SHTM 57: 2006) Clear, (for observation from adjacent work areas).
Ceiling hatches	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: 2006) should be considered such as mid height buffer rail and/ or durable finish on middle or lower part of the wall and protective corners.

Table A.109 - Room 38 (Wash room materials transfer room) - Mechanical and electrical

Subject	Room 38 mechanical and electrical
Air temperature	16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits.
Relative pressure	+ve with respect to the Wash Room (27).
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	Not specified.
Mechanical services- NR noise level	Not specified.

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Subject	Room 38 mechanical and electrical
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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 38 - equipment/ fixtures and fittings

A.38 Select from the list of items and include the number of each and dimensions of each as applicable:

- computer
- data scanner
- fire alarm
- smoke detector
- fire extinguishers
- hands free Intercom wall mounted
- general waste bin
- security alarm with push button and wall mounted

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- 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

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Room 39 - WC

Table A.110 - Room 39 (WC) - Design requirements

Subject	Room 39 design requirements
Function	This is an area used to provide toilets facilities for visitors.
Occupancy	Single person.
Activities	Use of WC. Hand hygiene.
Design notes	Ensure there is wheelchair access. Hold and 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	Direct access to the General Corridor (14). Controlled access from the Entrance Staff/ Visitors (10).

Table A.111 - Room 39 (WC) - Finishes

Subject	Room 39 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 6. Recommended acrylic paint.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 6. Recommended finish mineral fibre tiles.
Door sets	(SHTM 58: 2006) Compliant.
Windows type	None.
Internal glazing	None.

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Subject	Room 39 finishes
Ceiling hatches	If required, to be in line with the ceiling finish.
Finish notes	Medium Duty protection (SHTM 69: 2006) should be considered such as mid height buffer rail and /or durable finish on middle or lower part of the wall and protective corners.

Table A.112 - Room 39 (WC) - Mechanical and electrical

Subject	Room 39 mechanical and electrical
Air temperature	19 to 23 degrees Celsius.
Supply air changes per hour	That required to meet the building regulations.
Extract air changes per hour	10
Relative pressure	-ve with respect to the General Corridor (14).
Final filtration	That required to meet the building regulations.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	That required to meet the building regulations.
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015.
Noise-privacy factor	80 (normal speech inaudible).
Mechanical services- NR noise level	30
Intrusive noise (NR) noise level	35
Acceptable sound level	As specified in the Control of Noise at Work Regulations 2005.

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Subject	Room 39 mechanical and electrical
Speech privacy	Yes
Noise notes	Design as SHTM 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	41 maximum.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

Room 39 - equipment/ fixtures and fittings

A.39 Select from the list of items and include the number of each and dimensions of each as applicable:

- 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 SHTM 64: 2009
- 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

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Room 40 - Sterilizer load area

Table A.113 - 40 (Sterilizer load area) - Design requirements

Subject	Room 40 design requirements
Function	Accommodating sterilizers and associated plant (which may include equipment for clean steam generation).
Occupancy	State the maximum number of staff the room can accommodate.
Activities	Loading of the porous load sterilizers. Validation/ routine testing and maintenance of sterilizers.
Design notes	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. Specify an area for quarantine of product that has failed a cycle and is unloaded back into the room. A storage facility for PPE is required (heat resistant gloves and so on) 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 CDU cleanroom (17). Controlled access is required to this area.
Adjacencies	It should be adjacent to the CDU cleanroom (17) and the chemical sterilizer area (41). Direct access from the General Corridor (14) and to the chemical sterilizer room (41).

Table A.114 - Room 40 (Sterilizer load area) - Finishes

Subject	Room 40 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.

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Subject	Room 40 finishes
Door sets	(SHTM 58: 2006) Compliant SHTM 55: 2006) Not essential. If provided should be clear.
Windows type	(SHTM 55: 2006) Not essential.
Internal glazing	(SHTM 57: 2006) Not applicable.
Ceiling hatches	If required to be in line with ceiling finish.
Finish notes	Heavy Duty protection (SHTM 69: 2006) should be considered such as 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.

Table A.115 - Room 40 (Sterilizer load area) - Mechanical and electrical

Subject	Room 40 mechanical and electrical
Air temperature	Winter and Summer 16 to 21 degrees Celsius.
Supply air changes per hour	That required to deliver the specified room temperature limits.
Extract air changes per hour	That required to deliver the specified room temperature limits and pressure differential level.
Relative pressure	Positive pressure with respect to the General Corridor (14) and Sterilizer Plantroom (29). -15Pa with respect to the CDU cleanroom (17). +5Pa with respect to the chemical sterilizer room (41).
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).

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Subject	Room 40 mechanical and electrical
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015. Lighting enclosures IP 54 rated.
Noise-privacy factor	Not specified.
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).
Fire detection	Smoke detector.

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Room 40 - equipment/ fixtures and fittings

A.40 Select from the list of items and include the number of each and dimensions of each as applicable:

- sterilizer loading trolleys
- 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

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Room 41 - Chemical sterilizer room

Table A.116 - Room 41 (Chemical sterilizer room) - Design requirements

Subject	Room 41 design requirements
Function	Accommodating single ended low temperature sterilizers and storage of chemically sterilizer product under quarantine pending satisfactory biological indicator results as part of the product release criteria.
Occupancy	State the maximum number of staff the room can accommodate.
Activities	Loading and unloading the low temperature chemical sterilizer. Recovery of the biological indicators and placing in the incubator. Noting of the biological indicator results. Validation/ routine testing and maintenance of sterilizers.
Design notes	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. Specify an area for quarantine of product that has failed a cycle and is unloaded back into the room. A storage facility for PPE is required and a spill kit appropriate to the chemical sterilant being used. 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 the Sterilizer Load Room (40). Controlled access is required to this area. Double ended low temperature sterilizers may be available. If considered the unloading door would be flush to the wall in Room 30. Other areas for storage of quarantined product pending biological indicator results would require to be identified as well as an area of incubating the biological indicators.
Adjacencies	It should be adjacent to the Sterilizer Load Room (40) and the Sterilizer Unload Room (30). Direct access only from the Sterilizer Load Room (40).

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Table A.117 - Room 41 (Chemical sterilizer room) - Finishes

Subject	Room 41 finishes
Wall finish	Surface Finish (SHTM 56: 2006): Performance category 5. Recommended finish elastomeric vinyl compound or epoxy coating.
Floor finish	Surface Finish (SHTM 61: 2009): 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 finish	Surface Finish (SHTM 60: 2006): Performance category 3. Recommended finish imperforate smooth metal tray with sound attenuating insert.
Door sets	(SHTM 58: 2006) Compliant SHTM 55: 2006) Not essential. If provided should be clear.
Windows type	(SHTM 55: 2006) Not essential.
Internal glazing	(SHTM 57: 2006) Not applicable.
Ceiling hatches	If required to be in line with ceiling finish.
Finish notes	Heavy Duty protection (SHTM 69: 2006) should be considered such as 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.

Table A.118 - Room 41 (Chemical sterilizer room) - Mechanical and electrical

Subject	Room 41 mechanical and electrical
Air temperature	16 to 21 degrees Celsius.
Supply air changes per hour	Nominal 9. That required to deliver the specified room temperature limits.
Extract air changes per hour	Minimum of 10. That required to deliver the specified room temperature limits and pressure differential level.

Subject	Room 41 mechanical and electrical
Relative pressure, Pascal (Pa)	Between -5 to -10 Pa pressure with respect to the Sterilizer Load Room (40). -5Pa with respect to the Sterilizer Unload Room (30). -15Pa with respect to the CDU cleanroom (17).
Final filtration	ISO ePM2.5, 80%.
Air relative humidity	Not specified.
Air notes	Filter standard BS EN ISO 16890-1: 2016.
Lighting level	300 lux (bench height).
Colour rendering	No
Standby lighting grade	A
Lighting notes	Design as SHTM 06-01: 2015. Lighting enclosures IP 54 rated.
Noise-privacy factor	Not specified.
Mechanical services- 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 08-01: 2015.
Hot surface temperature degrees Celsius	43 maximum.
Hot water temperature degrees Celsius	Not applicable.
Safety notes	None.
Fire enclosure	Fire risk assessment in line with SHTM 86: 2023 including review of fire-resisting construction (integrity and insulation).

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Subject	Room 41 mechanical and electrical
Fire detection	Smoke detector.

Room 41 - equipment/ fixtures and fittings

A.41 Select from the list of items and include the number of each and dimensions of each as applicable:

- low temperature chemical sterilizer
- pass thru hatch
- storage of biological indicators
- incubator for biological indicators
- storage rack for processed product under quarantine
- sterilizer loading trolleys
- 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
- PPE storage and spill kit
- socket double outlet computer data
- socket outlet telephone, wall mounted

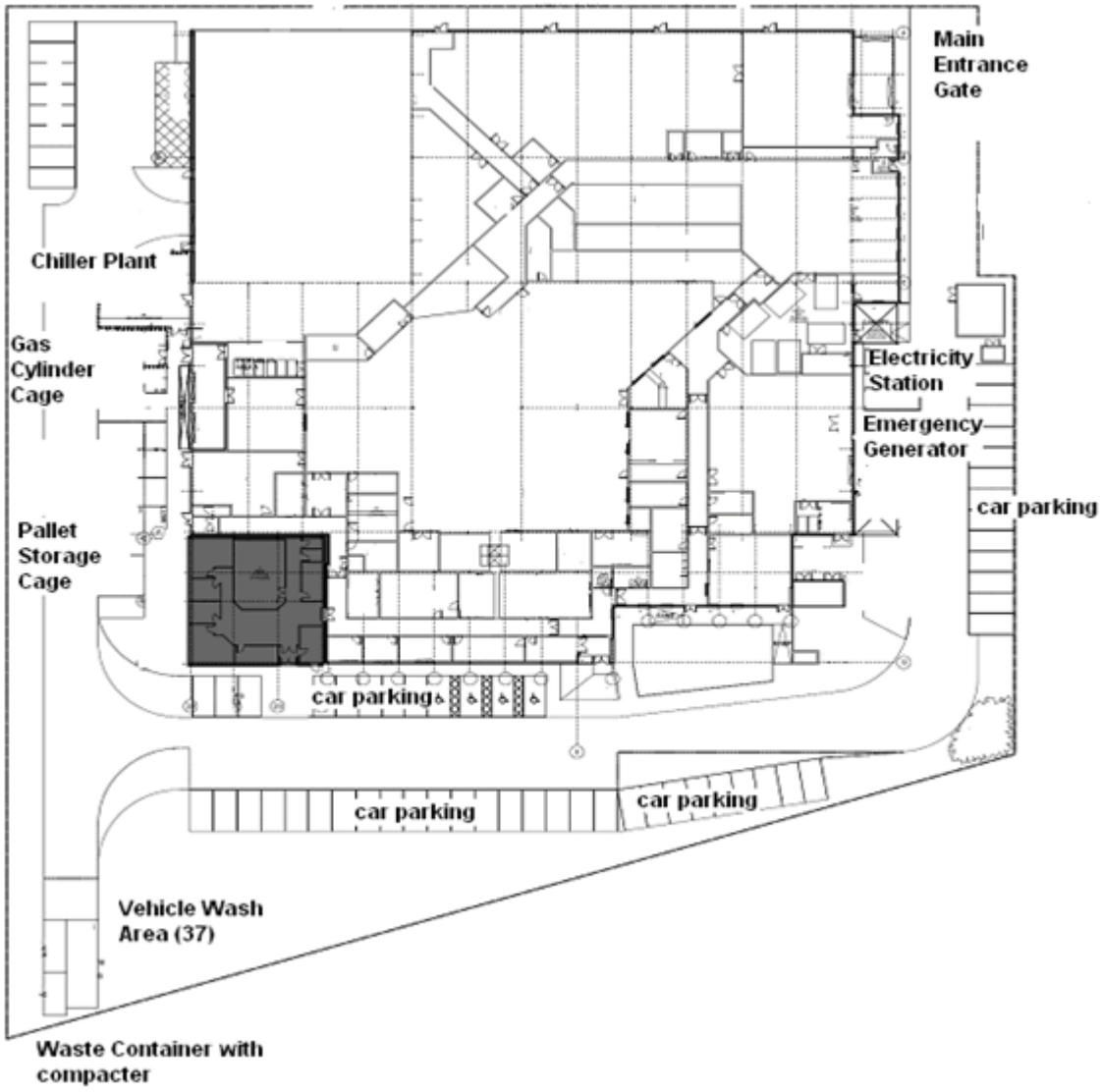
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- socket outlet intercom, wall mounted
- socket outlet switched 13 Amp double, ac, wall mounted and IP 55 rated. Socket outlet switched 13 Amp single, ac, wall mounted and IP 55 rated

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Appendix B Site layout

Figure B.1 - Site layout



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Table B.1 – Site design requirements

Subject	Site design requirements
Function	The enclosed area around the Central Decontamination Unit (CDU) building is used to support the CDU's activities.
Occupancy	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 and waste container lorries.
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 4.1 (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 for example 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. Electric charging points to be considered. 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 B.1). These may include items such as chiller plant and emergency generator. Enclosed spaces may also be required for diesel storage tanks for emergency generator, electricity station, waste storage areas (domestic, clinical and recycled cardboard/ plastics), 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 B.1 for the site layout drawing. Cowlairs recommendation 5.9 - When considering the location (including an offsite build) for a new CDU consider risks from the surrounding environment that may adversely affect the building structure/ fabric. Sustainable design and construction (SDaC) guidance Scottish Health Technical Memorandum (SHTN) 02-01: 2021 should be followed. Heat pumps and solar panels should be considered. Staff wellbeing should be a primary focus. Refer to the design section 4.

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Appendix C Antifragility assessment

C.1 These examples are for demonstration purposes only and no other interpretation should be applied to the imaginary data in these tables. The assessment is with respect to the impact of unplanned shutdown of Central Decontamination Units (CDUs) and contingency support provided by other CDUs.

First scenario - national impact - demonstration of fragile sterile service

Table C.1 - Antifragility assessment of a CDU in each of the regions (as data).

Region X CDU ref/ number of theatres supplied	Region Y CDU ref/ number of theatres supplied	Region Z CDU ref/ number of theatres supplied
CDU one - 48 (large scale CDU)	CDU one - 62 (large scale CDU)	CDU one - 100 (large scale CDU)
CDU two - 35	CDU two - 6	CDU two - 25
CDU three - 22	Not applicable	CDU three - 24
CDU four - 3	Not applicable	CDU four - 18
CDU five - 2	Not applicable	CDU five - 20
CDU six - 2	Not applicable	CDU six - 11
Total 113 theatres in region X	Total 68 theatres in region Y	Total 209 theatres in region Z

C.2 CDU one (a large scale CDU) in region Z clearly cannot be supported from with its region as the other five CDUs in its region cannot cope with the workload of an additional 100 theatres at no notice as occurs at unplanned shutdowns. The workload has to be spread across all regions X, Y and Z. Therefore, this event has national impact. The corresponding antifragility assessment would therefore be “fragile sterile service”.

C.3 Looking at Table C.1 it is clear that in region Y if CDU one (a large scale CDU) has an unplanned shutdown, then CDU two in region Y cannot cope with the additional workload of 62 theatres. The workload has to be spread across all regions X, Y and Z. Therefore, this event has national impact. The corresponding antifragility assessment would therefore be “fragile sterile service”.

C.4 Looking at Table C.1 if CDU one (a large scale CDU) in region X has an unplanned shutdown the picture looks less clear at first glance. However, to maintain service levels a

fast response is required at times when large scale CDUs have unplanned shutdowns and require contingency support. In this case the additional workload of 35 theatres cannot be supported in a timely manner from within the other five CDUs in region X. Consequently, the workload has to be spread across all regions X, Y and Z. Therefore, this event has national impact. The corresponding antifragility assessment would therefore be "fragile sterile service".

C.5 In each of these three cases it is readily seen that the CDU referenced due to the scale of its activity (number of theatres) relative to the others in its region would overwhelm these other CDUs in its region if contingency support was required. Thus, support is required from across all regions that is national support and national impact.

Second scenario - local impact - full support provided from within the region

Table C.2 - Antifragility assessment of a CDU in region A (as data)

Region A CDU ref/ number of theatres supplied
CDU one – 48 (large scale CDU)
CDU two - 48
CDU three - 40
CDU four - 3
CDU five - 2
CDU six - 2
Total 113 theatres in region X

C.6 CDU one (a large scale CDU) in region A can be supported from other CDUs in its region as CDU two and CDU three are of comparable scale. Therefore, this event is able to be contained within its region and is considered to be local impact. The corresponding antifragility assessment would therefore be that it is not a "fragile sterile service". Assigning the property to the other three classes of a resilient/ robust/ antifragile sterile service requires more work.

Appendix D CDU incident lessons

D.1 Lessons learned and recommendations reported on Central Decontamination Unit (CDU) Incident with steps to improve performance. The prevention measures are highlighted here.

Prevention measures

D.2 Notified body audit non conformities recommendations include:

- assurance should be given to the government that the service takes immediate corrective actions to deal with the non-conformities raised and highlight risks for potential future non conformities
- minimise the number of notified body non-conformities raised through the increase of internal audit or peer review audits
- feedback from audit activities non conformities should be included on Boards' clinical governance. The actions dealing with non conformities should be timely, monitored and reported to senior management as a part of escalation process
- audit non conformities should be shared with other Boards through the agenda for the National expert steering group Reusable Medical Devices-Decontamination Operational Group (RMD-DOG), the Quality Group and other stakeholders

D.3 Notice of suspension of production quality certification recommendation:

- a system with clear lines of communication (including backup contacts) is established to ensure that where a notified body recommends the suspension of a CDU's production quality certificate, the following organization are contacted prior to a decision by the notified body to suspend the certificate: Health Facilities Scotland (HFS) - who will liaise with Medicines and Healthcare products Regulatory Agency (MHRA).

D.4 Building design recommendations include:

- new build/ refurbishment of cleanrooms - Design out the presence of liquids above the cleanroom ceiling. This includes drain pipes and wet fire systems. If not possible, protection measures from liquids for the cleanroom ceiling should be in place along with monitoring measures
- when considering the location (including an offsite build) for a new CDU consider risks from the surrounding environment that may adversely affect the building structure/ fabric

D.5 Maintenance recommendations include:

- critical maintenance in the cleanroom - Maintenance and testing of decontamination equipment and building fabric needs to be allowed to take place and not put off due to production pressure. Support should be given from senior management at the health board to allow essential maintenance. There should be adequate provision of estates staff to enable this maintenance to be completed in a timely manner. There should also be a procedure to describe what to do in the event of unplanned maintenance work arising from example water passing through the ceiling or the floor being flooded. There should be a national programme of major maintenance and equipment replacement

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- if maintenance activities are undertaken while production is live there should be clear evidence that the cleanroom continues to meet its required performance over this period

D.6 Cleanroom microbial limits recommendation:

- consider the introduction of a national specification for microbial limits in the cleanroom to complement the existing non-viable contamination specification ISO class 8. Ensure there are separate limits for bacteria and fungi (yeasts/ moulds)

D.7 Training recommendations:

- review the cleanroom training of all staff interacting with the cleanroom including those involved in investigations including Infection Control Doctors, Microbiologists (Decontamination) and Estates staff
- regular refresher training on staff dealing with auditors should be in place
- establish training in the use of SHPN 13 part 1 for Boards developing outline business cases and as a commissioning tool for Users
- there should be provision of Quality Management System (QMS) training particularly for the manager, quality manager and supervisors
- cleanroom expertise comprising of microbiology/ engineering and controlled environments required and employed in internal audits

D.8 Contingency and Capacity recommendations:

- a sufficiently sized workforce should be developed to aid contingency provision
- robust business continuity and national contingency plans, that have been tested, should be developed
- existing contingency plans should be reviewed with respect to this report
- arrangements should be made to enable staff to be familiar with the equipment, facility of other CDUs providing contingency
- a review of CDU capacity should be undertaken with a view to increasing capacity
- where the board requiring contingency has supplied staff to work at the contingency site, the supervisors' authority must be clear for all concerned at the contingency provider site
- an electronic tracking system which is compatible across all NHSScotland boards should be in place

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Abbreviations

AE(D): Authorising Engineer (Decontamination)

AEDET: Achieving Excellence Design Evaluation Toolkit

:

BMS: Building Management System

BS: British Standards

BSI: British Standards Institution

CCTV: Closed Circuit Television

CDM: Construction (Design and Management)

CDU: Central Decontamination Unit

CEL: Chief Executive Letter

CFU Colony Forming Unit

CHP: Combined Heat and Power Systems

CIBSE: Chartered Institute of Building Services Engineers

CIG: Capital Investment Group

CJD: Creutzfeldt Jakob Disease

DL: Department Letter

DQ: Design Qualification

DS: Design Statement

DSR: Domestic Service Room [3 different types within a CDU]

EDU: Endoscope Decontamination Unit

EN: European Standard

ENT: Ear, Nose and Throat

EU: European Union

FBC: Final Business Case

:

HDL: Health Department Letter

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HEPA: High-Efficiency Particulate Air

HFS: Health Facilities Scotland

HPS: Health Protection Scotland

HSWA: Health and Safety at Work Act

HVAC: Heating, Ventilation and Air Conditioning

IA Initial Agreement

IEEE: Institute of Electrical and Electronics Engineers

IFU Instructions for Use

IP: Index of Protection

IPS: Infection Prevention Society

IQ: Installation Qualification

ISO: International Organization for Standardization

IT: Information Technology

KSAR: Key Stage Assurance Review

LEV: Local Exhaust Ventilation

MHRA: Medicines & Healthcare products Regulatory Agency

NDAP: National Design Assessment Panel

NES: NHS Education for Scotland

non-UDAF: Non Unidirectional Airflow

NR: Noise Rating

OBC: Outline Business Case

OEL: Occupational Exposure Limit

OQ: Operational Qualification

PIA: Programme Initial Agreement

PM: Particulate Matter

POE: Post Occupancy Evaluation

PPE: Personal Protective Equipment

PQ: Performance Qualification

PSCP: Principal Supply Chain Partner

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PUWER: Provision and Use of Work Equipment Regulations

QA: Quality Assurance

QMS: Quality Management System

RMD: Reusable Medical Device

RMD-DOG: Reusable Medical Device-Decontamination Operational Group

RO: Reverse Osmosis

SBC: Standard Business Case

SCIM: Scottish Capital Investment Manual

SDA: Sabourand Dextrose Agar

SDaC: Sustainable Design and Construction

SEPA: Scottish Environment Protection Agency

SGHD: Scottish Government Health Department

SHFN: Scottish Health Facilities Note

SHPN: NHSScotland Health Planning Note

SHTM: Scottish Health Technical Memorandum

SHTN: Scottish Health Technical Note

SI: Statutory Instrument

SOP: Standard Operating Procedure

TRV: Thermostatic Radiator Valves

TSA: Tryptic Soya Agar

UC: Ultrasonic Cleaners

UDAF: Unidirectional Airflow

ULPA: Ultra Low Particulate Air

UPS: Uninterruptible Power Supply

URB: User Requirement Brief

vCJD: variant Creutzfeldt Jakob Disease

VMP: Validation Master Plan

WD: Washer Disinfector

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Glossary

Absolute pressure - pressure for which the zero value is associated with absolute vacuum. [*SOURCE: EN ISO 11139: 2018 section 3 definitions]*

Accessory for a medical device - means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/ their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/ their intended purpose(s). [SOURCE: Regulations (EU) 2017/745 article 2 - (2)]

Active ingredient - chemical or biological component that is included in the formulation of a health care product to achieve the intended purpose. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

Adaptive control - capability of the system to modify its own operation parameters automatically to achieve the best possible performances in various modes operations year-around. [*SOURCE: BS EN ISO 14644-16: 2019 section 3 definitions*]

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

Aeration - part of the sterilization cycle during which the sterilizing agent and/ or its reaction products desorb from the health care produce until predetermined levels are reached. {SOURCE: EN ISO 11139: 2018 section 3 definitions}

Air change rate - rate of air exchange expressed as number of air changes per unit of time and calculated by dividing the volume of air delivered in the unit of time by the volume of the cleanroom. [*SOURCE: BS EN ISO 14644-16:2019*]

Air detector - device designed to detect the presence of non-condensable gases in the chamber or in a stream of steam and condensate. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Antifragility - property of a system that improves when exposed to shock or stressors

Aseptic presentation - transfer of the sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Automatic controller - device that directs the equipment sequentially through required stages of the cycle in response to programmed cycle parameters. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

A_0 - measure of microbiological lethality delivered by a moist heat disinfection process expressed in terms of the equivalent time in seconds at 80 °C with reference to a microorganism with a z value of 10 K. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

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Bioburden - population of viable microorganisms on or in a product and/ or sterile barrier system. [*SOURCE: EN ISO 11737-1: 2018 section 3 definitions*]

Biological indicator - test system containing viable microorganisms providing a defined resistance to a specified sterilization process. [*SOURCE: EN ISO 11138-1: 2017 section 3 definitions*]

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 (QMS) BS EN 13485 and the Medical Device Regulations. It has dedicated management and operational staff. The unit can supply third party legal entities.

CDU cleanroom - a controlled production environment where inspection, assembly and packing of reusable medical devices (RMDs) takes place. The environmental controls include:

- airborne particulates levels (ISO class 8 specification)
- microbiological levels (introduced as Bio class 8 specification in this guidance)
- maintenance of the room integrity
- room air temperature and relative humidity within limits
- pressure differentials with limits

Clean - visually free of soil and below specified levels of analytes. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Cleaning - removal of contaminants to the extent necessary for further processing or for intended use. Note: Cleaning consists of the removal, usually with detergent and water, of adherent soil (for example blood, protein substances and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated process that prepares the items for safe handling and/ or further processing. [*SOURCE: EN ISO 17664: 2017 section 3 definitions*]

Cleaning agent - physical or chemical entity, or combination of entities, having activity to render an item clean. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Chemical indicator non-biological indicator - test system that reveals change in one or more pre-defined process variables based on a chemical or physical change resulting from exposure to a process [*SOURCE: EN ISO 17665: 2006 section 3 definitions*]

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Conditioning - treatment of product prior to the exposure phase to attain a specified temperature, relative humidity, or other process variable throughout the load. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Cycle complete - message from the automatic controller that the operating cycle has ended successfully. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

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

Decontamination - refer to definitions for “processing” and “reprocessing”.

Diffuser - device placed on inlet air supply terminal to improve distribution of incoming air with room air Note 1 to entry: A mesh grille or a perforated screen is not considered to be a diffuser. [*SOURCE: BS EN ISO 14644-16 section 3 definitions*]

Disinfection - process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose. [*SOURCE: EN ISO 17664: 2017 section 3 definitions*]

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

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 (QMS) BS EN 13485. They have the responsibility for approving the Validation Master Plan (VMP) for delivery of the CDU.

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 for example control panels or storage tanks.

Endotoxin - lipopolysaccharide component of the cell wall of Gram-negative bacteria that is heat stable and elicits a variety of inflammatory responses in animals and humans. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

EO-cartridge - hermetically sealed container that holds a predetermined weight of ethylene oxide (EO) for single use. Note 1 to entry: The EO-cartridge is designed to be used in low volume chambers and/or to be activated while in the flexible sterilization bag, releasing EO. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

F_0 value - measure of microbiological lethality delivered by a moist heat sterilization process expressed in terms of the equivalent time, in minutes, at a temperature of 121.1 °C with reference to microorganisms with a z value of 10 K. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

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Flexible sterilization bag - <EO-sterilization> container constructed from a malleable membrane that acts as the sterilization chamber.

Note 9 to the above entry: the material from which the flexible sterilization bag is manufactured can be either permeable or impermeable to EO gas. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Gas concentration - weight of a specific gas in a given volume. Note 1 to entry: Concentration can be expressed as mg/l or g/m3. [SOURCE: EN ISO 11139: 2018 section 3 definitions]

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

Implantable medical device - medical device which can only be removed by medical or surgical intervention and which is intended to:

- be totally or partially introduced into the human body or a natural orifice, or
- replace an epithelial surface or the surface of the eye, and
- remain after the procedure for at least 30 days

[*SOURCE: EN ISO 13485: 2016 section 3 definitions*]

Installation Qualification (IQ) - is the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification. [*SOURCE: EN 285: 2015*]

Instructions for use (IFU) - means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken. [*SOURCE: Regulation (EU) 2017/745 article 2 – (14)*]

Invasive device - means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. [*SOURCE: Regulation (EU) 2017/745 article 2 – (6)*]

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: 2015. 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 CDU cleanroom Room (17) and its Domestic Services Room (DSR) (19) are specified as ISO Class 8 in the 'operational' occupancy state. The CDU cleanroom Room: Gowning Room (18) and the CDU cleanroom Materials Transfer Room (20) are specified as ISO Class 9 in the 'operational' occupancy state.

Labelling - label, IFU, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents. [*SOURCE: EN ISO 13485: 2016 section 3 definitions*]

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Life-cycle - all phases in the life of a medical device, from the initial conception to final decommissioning and disposal. [SOURCE: EN ISO 13485: 2016 section 3 definitions] product, equipment, or materials to be processed together within an operating cycle. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

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

lumen device - item that consists of tube(s) or pipe(s). [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

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)

Manual cleaning - manual cleaning -removal of contaminants from an item to the extent necessary for further processing or for intended use without the use of an automated process. [*SOURCE: EN ISO 17664: 2017 section 3 definitions*]

Medical device - means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception
- products specifically intended for the cleaning, disinfection or sterilisation of

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devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. [*SOURCE: Regulation (EU) 2017/745 article 2 - (1)*]

Note 10: The term medical device as used in the SHTM 01-01 series only applies to those processed through a CDU.

Microbial barrier - property of a sterile barrier system to minimize the risk of ingress of microorganisms. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Microbial contamination - presence of unintended bacteria, fungi, protozoa, or viruses. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Microbe-carrying particle - particle on which a microorganism is carried, normally dispersed into room air by personnel as a skin cell, or fragment of skin cell, on which a skin microbe(s) is carried. [*SOURCE: BS EN ISO 14644-16: 2019*]

Moist heat - thermal energy in the presence of moisture released by gaseous or liquid water. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Microbial contamination - deposition of viable or potentially viable elements of bacteria, fungi or viruses onto or within articles previously rendered free of them.

Non-condensable gas - air and/ or other gas which will not liquefy under the conditions of saturated steam sterilization processes. [*SOURCE: EN 285: 2015*]

Non-unidirectional airflow - non-unidirectional airflow provides control of the environment through dilution of any airborne contamination by the introduction of clean supply air into the CDU cleanroom. The clean supply air mixes with contaminated room air and the mixed air is removed continuously. The clean air is supplied at a specific temperature and humidity to control thermal environmental conditions and comfort of occupants also by mixing. The number, location and type of supply air diffuser and distribution are critical in achieving the required CDU cleanroom performance. Similarly, the number and location of positions (return air or exhaust) where air exits the CDU cleanroom is also an important design consideration. Supply air diffusers protect any terminally mounted filters from damage during general operations and cleaning.

Non-unidirectional airflow (non-UDAF) - air distribution where the supply air entering the clean zone mixes with the internal air by means of induction. [*SOURCE: BS EN ISO 14644-16: 2019*]

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

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- **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

Operational Qualification (OQ) - is the process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures. [*SOURCE: EN 285: 2015*]

Overkill approach - method of defining a sterilization process that achieves a maximal sterility assurance level (SAL) for product substantially less than 10^{-6}. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

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.

Packaging system - combination of the sterile barrier system and protective packaging. [*SOURCE: EN 11607-1: 2017*]

Performance Qualification (PQ) - is defined as the process of obtaining and documenting PQ evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields products meeting its specification.

Periodic testing - is a series of tests carried out at daily, weekly, quarterly and yearly intervals.

Powered device - <washer-disinfector> surgical instrument which gives a rotating and/or oscillating movement to other surgical instruments. Note 1 to entry: The power applied to the driven instrument can be mechanical (from a motor, either through direct coupling, flexible axle, or belt) or by the flow of a pressurized fluid or compressed air. EXAMPLE Dental hand pieces, orthopaedic saws, drills. [*SOURCE: EN ISO 11139: 2018 section 3 definitions]*

Preconditioning - treatment of product, prior to the operating cycle, to attain specified values for temperature, relative humidity, and/or other process variables. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Process chemical - formulation of chemical compounds intended for use in a WD. Note: Process chemicals include for example detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners. [*SOURCE: EN ISO 15883-1: 2014 section 3 definitions*]

Processing - activity to prepare a new or used healthcare product for its intended use. Note processing includes cleaning, disinfection and sterilization (if necessary and applicable). A healthcare product refers to a medical device. [*SOURCE: EN ISO 17664: 2017 (published 25 October 2017*) *section 3 definitions*]

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Processor - organization and/or individual with the responsibility for carrying out actions necessary to prepare a new or reusable healthcare product for its intended use. Note a healthcare product refers to a medical device. [*SOURCE: EN ISO 17664:2017 section 3 definitions*]

Process challenge device PCD - item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process. [*SOURCE: EN ISO 11138-1: 2017 section 3 definitions*]

Product family - group or subgroup of product characterized by similar attributes determined to be equivalent for evaluation and processing purposes. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Protective packaging - configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of assembly until the point of use. [*SOURCE: EN 11607-1: 2017*]

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.

Reference load - specified load created to represent combinations of items that provide defined challenge(s) to a process. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Relative humidity - measure of water vapour in the air expressed as a percentage of the maximum for a given temperature. Note 1 to entry: It is expressed as a percent. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Reprocessing - means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device. [*SOURCE: Regulation (EU) 2017/745 article 2 – (39)]*

Reusable medical device - medical device designated or intended by the manufacturer as suitable for processing and reuse. Note: This is not a medical device that is designated or intended by the manufacturer for single-use only. [*SOURCE: EN ISO 17664: 2017 section 3 definitions*]

Reusable surgical instrument - means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out. [SOURCE: *Regulation (EU) 2017/745 Annex VIII chapter 1, 2.3*]

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

- design

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- finish
- mechanical and electrical
- equipment/ furniture/ fittings

Seal integrity - <packaging> characteristics of a seal to minimize the risk of ingress of microorganisms. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Self-contained biological indicator - biological indicator presented in such a way that the primary package, intended for incubation, contains the incubation medium required for recovery of the test organism [*SOURCE: EN ISO 11138-1: 2017 section 3 definitions*]

Service life - number of processing cycles and/or life-time that a medical device can be subjected to and remain suitable and safe for its intended use. [*SOURCE: EN ISO 17664: 2017 section 3 definitions*]

Single-use medical device - medical device designated or intended by the manufacturer for one-time use only. Note: A single-use medical device is not intended to be further processed and used again. [*SOURCE: EN ISO 17664: 2017 section 3 definitions*]

Single-use device - means a device that is intended to be used on one individual during a single procedure. [*SOURCE: Regulation (EU) 2017/745 article 2 – (8)]*

Single patient use - means the medical device may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use. [*SOURCE: Ref Page 14 - MHRA Single-use medical devices: implications and consequences of reuse December 2013*]

Source strength - rate describing the number of particles or colony-forming units emitted from an object per time unit. Note 1 to entry: A source can be a person, equipment or an object. [*SOURCE: BS EN ISO 14644-16: 2019 section 3 definitions*]

Sterilant - chemical or combination of chemicals used to generate a sterilizing agent. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Sterile - free from viable microorganisms. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Sterile barrier system - minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile product at the point of use. [*SOURCE: EN ISO 11737-1: 2018 section 3 definitions*]

Sterile field - area created by sterile surgical drape material where aseptic technique is practised NOTE A sterile field can be practised for example on a back table. [*SOURCE: EN ISO 13795: 2013 section 3 definitions*]

Sterile medical device - medical device intended to meet the requirements for sterility. [*SOURCE: EN ISO 13485: 2016 section 3 definitions*]

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Sterility assurance level SAL - probability of a single viable microorganism occurring on an item after sterilization. Note 1 to entry: It is expressed as the negative exponent to the base 10. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Sterilization - process used to render product free from viable microorganisms.

Note 11 to the above entry: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero [*SOURCE: EN ISO 17664: 2017 section 3 definitions*]

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.)

Turn-down - controlled reduction of ... airflow rates in non-UDAF cleanrooms in order to save energy during periods when the cleanroom is not in operation. [*SOURCE: BS EN ISO 14644-16: 2019 Energy efficiency in cleanrooms and separative devices]*

Type tests - is a series of tests conducted by the manufacturer to establish the working data for decontamination equipment. For example, type test in EN 285: 2015 is a series of checks and tests for a particular design of sterilizer and type test in EN 15883-1: 2014 is a test programme to verify conformity of a WD type to this standard and establish data for reference in subsequent tests.

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.

Unique Device Identifier (UDI) - means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market. [*SOURCE: Regulation (EU) 2017/745 article 2 – (15)]*

Usable chamber space - specified geometry within the chamber that is available to accept the load. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

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 (DQ).

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 (WDs) or sterilizers
- modification of the CDU cleanroom to increase packing table capacity

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- 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)

Validation - is the documented procedure required for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with a predetermined specification.

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

Washing - removal of adherent contamination from surfaces to be cleaned by means of an aqueous medium, with or without process chemicals, as necessary [*SOURCE: EN ISO 15883-1: 2014 section 3 definitions*].

Washer-disinfector (WD) - equipment designed to clean and disinfect product. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Works tests - series of tests performed during or after manufacture to demonstrate compliance of each equipment with the requirements of the test specified [*SOURCE: EN 285: 2015*].

Configuration - distribution and orientation of a load. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

Cycle - complete set of stages of a process that is carried out, in a specified sequence. Note 1 to entry: Loading and unloading are not part of the operating cycle. [*SOURCE: EN ISO 11139: 2018 section 3 definitions*]

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