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VCCN GUIDELINE 11 CENTRAL STERILE SERVICES DEPARTMENT- GUIDELINE FOR DESIGN, CONSTRUCTION AND STARTUP

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CENTRAL STERILE SERVICES DEPARTMENT –

GUIDELINE FOR DESIGN, CONSTRUCTION AND STARTUP

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This Guideline was prepared with the utmost care by a group of experts, following the most recent VCCN procedure. Although the utmost care was taken when preparing this publication, errors and omissions cannot be completely excluded. The various associations and experts involved, as well as the members of the project groups and committees therefore accept no liability whatsoever for direct or indirect damage caused by or in connection with the implementation of this Guideline.

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- Netherlands Federation of University Medical Centers (NFU)
- Dutch Hospital Association (NVZ)
- National Institute for Public Health and the Environment (RIVM)
- Federation of Medical Specialists

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1. Preface

This document has been published by VCCN (Netherlands Association for Contamination Control), SVN (Netherlands Sterilisation Association), vDSMH (Expert Association for Sterile Medical Devices) and VHIG (Association for Healthcare Hygiene & Infection Prevention) to promote suitable environmental conditions for the (re-)processing of medical devices within the Central Sterile Services Department into finished products that meet all relevant requirements.

Within various groups of professionals, there is a need for an update to the outdated CBZ Construction Standards, which were published in 2002. Institutions have been responsible for renovation and new construction since 2006, which is why we now have a Guideline. Renovating a sterilising department is a complicated process where many different responsibilities come into play. As such, the design process is emphasised in this Guideline, because this serves as the foundation of the proper construction of a Central Sterile Services Department (CSSD).

The work carried out by the task force included a literature study (Appendix 3), which did not lead to any evidence-based indications. However, there are indications that conditions during the evaporation phase of the steam sterilisation process may affect the quality of the sterilised medical devices. This, however, did not lead to the implementation of any enhanced measures in those phases of the process, other than the measures that already exist.

The authors of this guideline assume that all logistical and ventilation flows in the several areas of the Central Sterilising Department, as well as the links between the CSSD and all other areas, are based on compartmentalised zones. Access to all production-related areas within a zone must be controlled in order to safeguard and maintain specific ventilation conditions in all zones. This helps prevent the contamination of adjacent rooms that require higher levels of cleanliness. Persons working the production areas must at all times be aware of which area they are entering and which precautionary measures must be taken.

This includes, for example, wearing personal protective equipment in the cleaning area, or specific clothing that meets specific hygiene requirements when entering other areas. This includes, for example, wearing personal protective equipment in the cleaning area, or specific clothing that meets specific hygiene requirements when entering other areas. [1] Field Standard for Hygiene Policy and Dress Code :

In addition to coordinating internal and external logistics, the workflow, necessary equipment and building facilities, it is of great importance that the quality system of the CSSD be set up in such a way that the designed facilities correspond with the work and hygiene agreements made in the work units. Properly instructing and training employees plays a major role in this respect.

This Guideline assumes the presence of carefully monitored agreements and an approved CSSD quality system. As such, these elements are not addressed in the Guideline.

2. Terms and definitions

Aerosol: a mixture of liquid droplets or small solid particles in the air. The droplets and particles in an aerosol can vary in size from 0.001µm to up to 100µm.

Airlock: a passage between two rooms that prevents aerogenic contamination (particles and microorganisms) spreading from one room to other, cleaner, adjacent rooms. For an airlock to work properly, it must always feature an interlock system.
Note: In an airlock, the concentration of microorganisms and particles decreases over time.

Contamination: the presence of a chemical substance or microorganisms

Disinfection: reducing the initial contamination of microorganisms on the surfaces of medical devices to a contamination level of 10^{-5}.

Endoscope: a (flexible) instrument that you can use to look inside the body.

Smooth/even finish: the transition between two different types of material should show no height differences or seams, preventing the accumulation of dust and making the object in question easier to clean.

HEPA filter: High-Efficiency Particulate Air filter.

Recovery time: time required to reduce the initial concentration of airborne particles by a factor of 100.

IAP room: the Inspection, Assembly and Packing room. This is the room where reusable medical devices are inspected, assembled (put together) and packed.

Interlock: a technical system that prevents two or more linked doors in a certain room from being opened simultaneously.

Loan set: set of reusable medical devices owned by a third party and used temporarily.

Logistics lock: passage between two adjacent areas that forms a clear boundary between these spaces, in which logistical operations can take place. The lock is a transfer node for goods: packaging materials and transport equipment do not pass through the lock, but the goods in question do.
Note: A logistical lock features no special ventilation systems.

Medical device: an instrument, device or device, software, implant, reagent, material, or other item that is intended by the manufacturer to be used alone or in combination in humans for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or compensation of an injury or a disability;

- research into, replacement of, or modification of the anatomy, of a physiological or pathological process, or a physiological or pathological condition ;
- providing information through in-vitro research on specimens originating from the human body, including organ, blood and tissue donations;

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.

The following products are also classified as medical devices:

- devices intended for fertilisation control or support;
- products specially intended for cleaning, disinfecting or sterilising devices referred to in Article 1 (4) and those referred to in the first subparagraph of this point.

[Medical Device Regulation (2017/745 / EU)]

Monitoring: observations made by measurement in accordance with a defined method and plan to provide evidence of the performance of an installation.

Note 1: monitoring may be continuous, sequential or periodic; and if periodic, the frequency shall be specified.

Note 2: this information may be used to detect trends in operational state and to provide process support.

NEN-EN-ISO-14644-2.

Cleaning: removing all unwanted material from a device.

Sterilisation: a validated process to rid a medical device of all viable microorganisms, including spores.

Note: Note: Sterilisation involves eliminating microorganisms, with a process that gives microorganisms a chance of survival lower than 10^{-6}, or 1 in a million.

Steam steriliser: equipment that uses pressurised steam to sterilise materials.

Thermal Disinfector: equipment in which medical devices are both cleaned and disinfected automatically.

[B9100 'Basic information on cleaning and disinfecting medical devices']

Note: There are several terms for equipment (instrument washer, cleaner-disinfector, thermal disinfector) that serves the same purpose: adequately sterilising medical equipment.

Thermolabile: material or substance that cannot withstand temperatures higher than 60°C.

Validation: collecting and evaluating information that can demonstrate and prove whether a process is effective and reproducible.

Verification: the process of obtaining documented evidence that particular equipment has been delivered and installed in accordance with the established specifications.

[ISO/TS 11139]

3. Introduction

3.1 Scope and objective of the Guideline

This Guideline serves as a tool for anyone involved in defining requirements, designing, building and determining the layout and maintenance of the sterilising department.
This Guideline focuses on Central Sterilising Departments (CSSDs)

- in hospitals, independent treatment centres and organisations that sterilise reusable medical devices for these parties,
- where reusable medical devices for human use are cleaned, checked, packed, sterilised, released and stored.

This guideline does not contain any specific organisational models and/or process requirements. For process requirements, please refer to the relevant standards and guidelines.

The main aim of this Guideline is to:

Formulate requirements with regard to the necessary architectural and system & installation-related facilities to guarantee that the entire decontamination, packaging, sterilisation and storage process of reusable medical devices be carried out effectively and soundly.

3.2 Guideline development and implementation method

All requirements included in this Guideline serve, at the very least, as recommendations. A number of them are based on scientific evidence, as presented in peer-reviewed literature. These requirements are printed in **bold and underlined type,** because they are more important and should be interpreted strictly as mandatory requirements.

The requirements that can also be interpreted as recommendations are printed in standard type. They are based on guidelines adopted abroad, as well as the expert opinions of the members of the expert group. When it is necessary to deviate from the Guideline due to special circumstances, a well-founded alternative must be chosen.

It is recommended that you schedule a reasonable timeframe for the implementation of these requirements and recommendations.

- Recommendations involving (major) adjustments to buildings, areas and/or systems, or which necessitate the purchase of expensive equipment may be postponed until the next planned renovation. A timeframe of 5-10 years is deemed reasonable in this respect.
- For moderate adjustments (e.g. modifying doors, filters, finishing) an implementation timeframe of 1 to 2 years is more realistic.
- For minor adjustment (e.g. modifications to maintenance and management) 6 months is seen as a reasonable timeframe for implementation.

3.3 Key requirements and recommendations

Requirements:

- **Implement a clothing system that reduces particle emissions by staff members to a minimum.**
- **CSSDs must comply with the requirements stated in the hygiene and clothing protocol.**

Recommendations:

- Start each process by mapping the process in question (metro map). When designing an CSSD, future developments must also be taken into account. This does not just include scaled-up production, but also different process formats resulting from a shift to processing medical devices of a different nature.
- The department must be strictly and physically compartmentalised into several zones, in which processes can take place that require different levels of cleanliness. In addition, there must be a single, unidirectional air flow - leading from clean to dirty - throughout the entire department.
- Automatic thermal disinfectors should have a double-door layout and must be installed in the wall separating dirty and clean areas.
- Sterilisers should have a double-door layout and must be installed in the wall between the IAP room and the evaporation room.
- The IAP room and evaporation/discharge room must comply with ISO-7 classification “at rest” for particle sizes equal to or larger than 0.5µm, as well as featuring a unidirectional air flow from clean to dirty.
- The IAP room and the evaporation/discharge room must comply with a recovery time of no more than 20 minutes with a 100-fold concentration reduction of 0.5µm particles, in accordance with NEN-EN-ISO 14644-3.
- The requirements for the IAP room (ISO 7) are based on the prevention of contamination (sedimentation) of the instruments with particles in the period between cleaning and packaging. Literature shows that sterile particles on instruments can lead to Toxic Anterior Segment Syndrome (TASS), especially in ophthalmic procedures. It is therefore advisable to keep the time between the instruments are cleaned and packed as short as possible.

3.4 Design process, verification process, maintenance and management

The design of a CSSD is very important for the quality of sterilised medical devices and their applications in patient care.
It is essential to organise the design, realisation, verification and maintenance of this facility in a structured, process-based manner.

Table 1 shows a commonly used model for this process. It is recommended that this process be followed, so that all steps are taken in a structured manner.

Table1, Design, realisation and operational phase

Project phase	Project Step	Objective
Design phase (1)	Analysis (A)	Determine the current situation and lay the foundations for the project.

	List of Requirements (LoR)	Define project objectives in terms of system specifications, as well as the functional, operational and/or technical aspects required to achieve the desired results with minimal and manageable risks.
	Functional design (FD)	Translate the List of Requirements into the specific functions fulfilled by the various components of the system and the relationships between them. Formulate measures to minimise and manage risks at a functional level.
	Detailed design (DD)	Translate the requirements in the List of Requirements and the Functional Design into drawings, details, calculations and specifications that can be used to select specific components and build up the system.
	Design Verification (DV)	Ensure that the preliminary installation, system and equipment designs are suitable for the intended usage situation based on the List of Requirements. Make sure that the measures developed in previous phases succeed in minimising and managing risks.
Realisation phase (2)	Realisation	Realise a system that meets the set objectives (List of Requirements); Documenting the system; Monitor the measures formulated in the Risk Inventory.
Verification phase 3	Installation Verification (IV)	Ensure that all equipment has been delivered and installed, or has been modified in accordance with the approved, detailed design and the manufacturer's recommendations.
	Functional Verification (FV)	Ensure that the system's performance, as installed or modified, meets the requirements specified and recorded in the FD and DD.
	Performance Verification (PV)	Ensure that the system's performance in practice, as installed or modified, meets the requirements specified and recorded in the List of Requirements.
Operational maintenance phase 4	Operation and maintenance	Staff training; Adjusting the system and updating the corresponding documentation; Maintaining and managing facilities and equipment.
	Re-verification	Re-verification; System optimisation

Together, these phases form a sequence that can be abstracted to some extent and can be represented graphically, as shown in Figure 1.

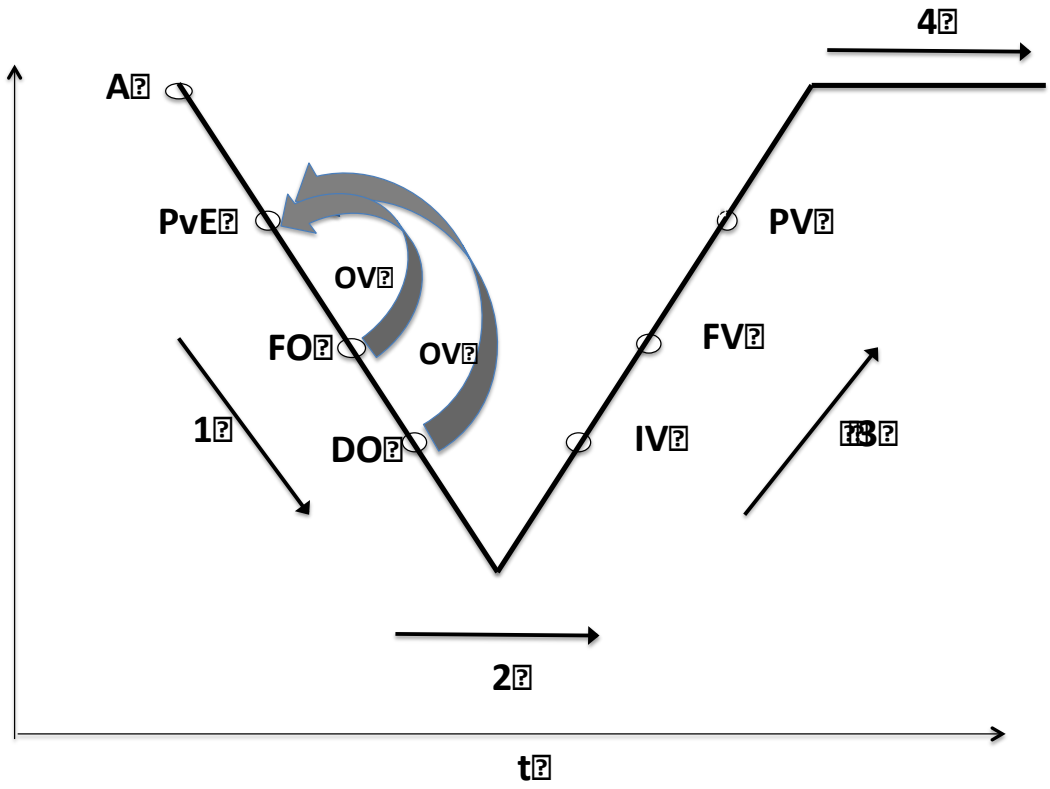

Figure 1, Graphic representation of the design process

1 Leu cine ratio	Design phase	FD	Functional Design
2	Realisation phase	DD	Detailed Design
3	Verification phase	DV	Design Verification
4	Maintenance phase	IV	Installation Verification
A	Analysis	FV	Functional Verification
LoR	List of Requirements	PV	Performance Verification

Note: The approach to the various steps shown in Table 1 and Figure 1 consists of:

- The steps that are defined by input, processing and output can be used as input for the next step.
- Level phases (in the abstract presentation) are related: it must be possible to check/measure/test the left-hand side of the V model (design) based on explicit, unambiguous criteria during the verification phase (right-hand side of the V model).

The various phases and steps are shown in greater detail in Table 1. Drawing up a List of Requirements (LoR) is an important aspect of this, which involves accurately and briefly describing the wishes and desired working method of the client, as well as indicating how it will be tested and verified in the Installation Verification (IV), Functional Verification (FV) and, optionally, the Performance Verification (PV) phase.

It is also important that the client ensures that the functional design - and subsequently the detailed design - result in a system that meets the criteria laid out in the List of Requirements (LoR). This step is also known as Design Verification (DV). The project cannot enter the execution phase before the final design, based on a document with a clear version history, has been approved.

Drawing up a risk list and defining which measures must be taken make up part of the List of Requirements (LoR), the Functional Design (FD) and the Detailed Design (DD). During the implementation phase, the system must be realised in accordance with the Detailed Design (DD), whilst ensuring that the measures set up to minimise risk are implemented. After the realisation phase, it is time for the verification phase, which involves clearly going through the Installation Verification (IV) and Functional Verification (FV) stages.

The model shows that the Detailed design (DD) is verified during the Installation Verification (IV). This involves clearly verifying that the system was built in line with the specifications included in the Detailed Design. During Functional Verification (FV), it is important to verify that the system's functionality corresponds with the Functional Design (FD).

Based on the Installation Verification (IV), the client can decide to approve the controlled commissioning of the system. The system can be delivered/accepted and released for use only after the entire Functional Verification (FV) process has been completed. After completion, the client can implement a Performance Verification (PV) phase to verify whether the system's performance is in line with the List of Requirements (LoR).

Drawing up a sound List of Requirements (LoR) and entering into clear contracts are foundational to a good project.

4. Applicability

This Guideline applies to Central Sterilising Departments in hospitals, independent treatment centres and organisations that sterilise reusable medical devices for these parties. The Guideline also applies to other healthcare institutions and clinics that carry out extensive sterilisation activities independently[1].

A Centralised Sterilising Department must consist of several, coordinated rooms in which various activities take place that together form the full sterilisation process, spanning from the influx of used, borrowed or new reusable medical devices to the delivery of checked, packed and sterilised medical devices.

The recommendations and requirements set out in this Guideline also apply in case of renovation or modification of existing buildings.

[1]According to the Healthcare Quality, Complaints and Disputes Act (Wkkgz), the professional/therapist is responsible for (the sterility of) the product used. In this context, healthcare providers are faced by a dilemma of sterilising their own devices or outsourcing these activities.

5. Applicable standards and references

- Medical Devices Act: Bulletin of Acts and Decrees (Stb) 1970, 53, Medical Devices Act, January 15, 1970;
- Sterilised Medical Devices in Hospitals Act: Stb 1993, 281, Decree on sterilised medical devices in hospitals, Ministry of Well-being, Health & Culture, 6 May, 1983;
- Healthcare Quality, Complaints and Disputes Act, Stb 2015, 407; Act containing rules to promote the quality of healthcare and the handling of healthcare complaints and disputes, 7 October 2015;
- WIP, Cleaning, disinfecting and sterilising reusable medical devices - non-critical, semi-critical or critical use, March 2017;
- Quality Handbook for Cleaning and Disinfecting Flexible Endoscopes, version 4.0, 2016;
- Central Sterile Services Department and Flexible Endoscope Cleaning & Disinfection, SVN, 2017;
- Sterilisation Guidelines: NEN, Sterilising and sterility total, approx. 81 standards and publications, via NEN-connect, 2014, Delft, Netherlands Standardisation Institute;
- NEN-EN-ISO 12464-1: 2014, Light and lighting - workplace lighting - Part 1: Indoor workplaces
- NEN-EN-ISO 13485:2012, Medical devices — Quality management systems — Requirements for regulatory purposes;
- NEN-EN-ISO 14644-1: 2016, Low-dust and germ-free rooms and environments - Part 1: Classification of air cleanliness based on particle concentrations;
- NEN-EN-ISO 14644-2: 2016, Low-dust and germ-free rooms and environments - Part 2: Monitor to demonstrate that air cleanliness in cleanrooms meets the specified particle concentration limit;
- NEN-EN-ISO 14644-3: 2010, Low-dust and germ-free rooms and environments - Part 3: Testing methods;
- NEN-EN-ISO 14644-4: 2010, Low-dust and germ-free rooms and environments - Part 4: Design, construction and startup;
- Decontamination and reprocessing of medical devices for health-care facilities, World Health Organisation, 2016;
- VCCN Guideline 4, Surface Cleanliness, 2004;
- VCCN Guideline 10, Guideline for the classification and testing of air permeability of the cleanroom shell and similar controlled environments, 2015;
- ISPE, Baseline volume 5, Commissioning and Qualification, 2001;
- NEN-EN 12599: 2012, Building Ventilation - Testing procedures and measuring methods for the delivery of installed ventilation and air treatment systems.

6. General description of the sterilisation process

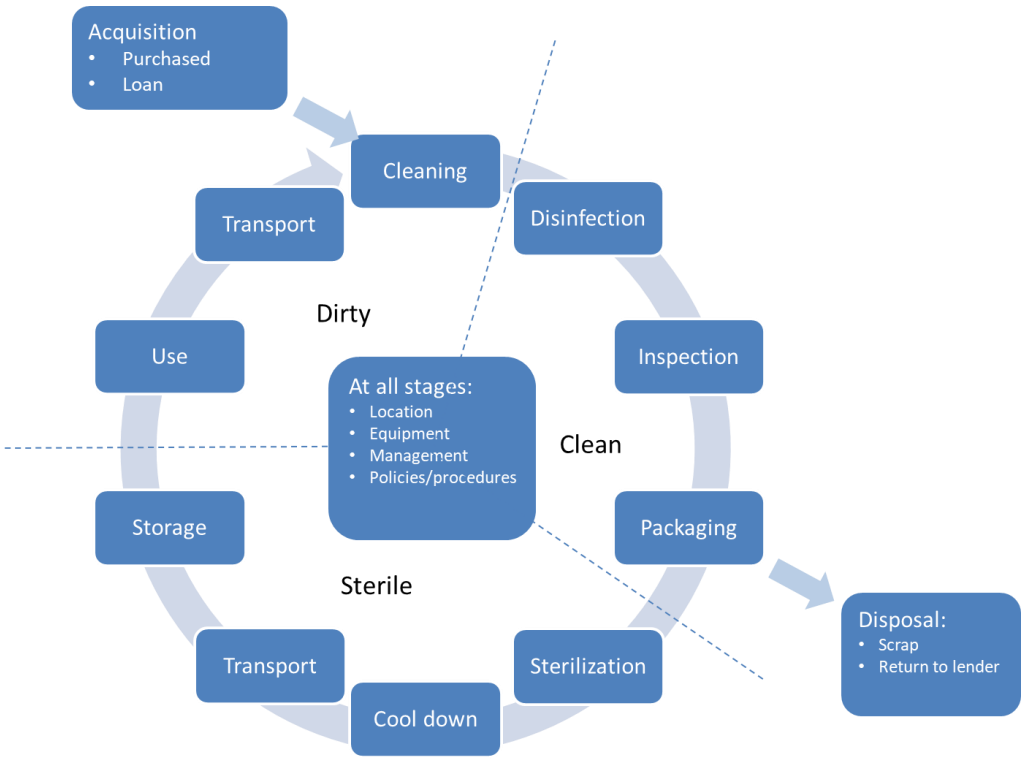

Figure 2, Schematic representation of the process phases

6.1 Introduction

Figure 2 shows the various process phases with regard to the processing of reusable medical devices. Each process step must be designed and executed in accordance with the applicable guidelines, requirements and standards.
The Sterile Medical Devices Expert (known as the DSMH in Dutch) is responsible for all quality of sterilisation-related aspects of all sterile medical devices, including the management, logistics and production of contaminated and sterilised medical devices.
The main activities that take place in the areas to which this Guideline applies are:

- disassembling, cleaning and disinfecting instruments, (medical) devices, containers and other reusable materials. Most objects will have been used in surgical procedures in operating rooms or other clinical environments, which means they should be treated as if they are contaminated;
- preparing, inspecting, assembling, and packing instrument sets and packages, including the required functional checks and safety tests;
- sterilising medical devices and providing disinfected, cleaned medical devices;
- storing materials and/or components before they are added to nets or instrument sets;

- storing sterilised or disinfected medical devices in the department until they are transported to the user;
- cleaning, disinfecting, drying and storing flexible endoscopes in such a way that the principles of cleaning and disinfection are applied properly[2];
- collecting used materials and distributing disinfected/sterilised medical devices.

Clean and dirty goods flows must be separated by means of strict compartmentalisation and may never come into contact with each other.

To end up with sterile medical devices, it is necessary that all cleaning and disinfection processes be carried out adequately. Before it has been sterilised, an instrument is subject to four major risks of contamination:

- insufficient cleaning and disinfection of the medical device in question;
- contamination via materials/means used in the production process;
- contamination via staff members;
- contamination via other environmental factors.

Four types of goods will be received in a CSSD:

- contaminated medical devices that have to be processed;
- sterile medical devices sterilised in an external facility;
- cleaned/expired reusable medical devices;
- consumables, including packing material.

The transport equipment used to accommodate the various goods flows is a separate subject. Depending on their nature and application, they must be treated (by means of cleaning, disinfection, storage) in such a way that they can always be available at the right time during the process.

If necessary, the CSSD can also be used for utensils required for medicine preparation.

Contamination can be reduced by ensuring proper control of architectural facilities and systems, the equipment and materials that are directly related to the process, staff members and the production environment. This includes:

- controlled physical conditions, proper separation of processes;
- a suitable production environment for sterile medical devices.

The medical devices go through a dirty - clean - sterile process. Within the architectural facilities and systems, all zones are either dirty or clean. All other rooms are considered public, see Table 2 for the layout. Figure3 displays the dirty and clean rooms and their position within the process.

[2] Quality Handbook for Cleaning and Disinfecting Flexible Endoscopes, SFERED, V 4.0, 2016.

Table 2, Layout of activities/rooms by zone: dirty, clean or public

Dirty	Clean[3]	Public
• Reception room for dirty medical devices • Cleaning and disinfection room • Decontamination room for transport equipment, baskets • Service area for cleaning	• Room for disinfected medical devices • IAP room • Evaporation/discharge room • Service area for cleaning	• Staff facilities, break room, administrative office • Service rooms for cleaning and waste • Room for the reception and storage of consumables • Room for transport materials (e.g. trolleys and carts)

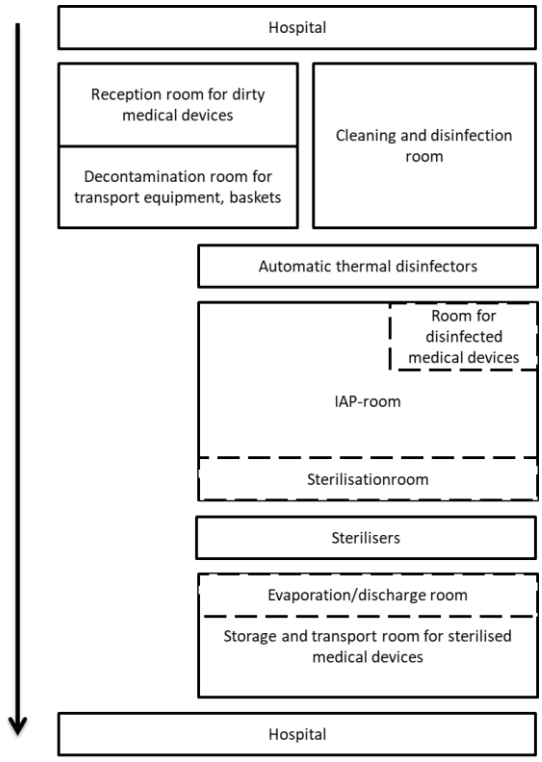

Figure3, Schematic representation of contaminated and clean rooms in CSSD. Spaces with a full border are separate rooms, spaces with a dotted border can also be considered to be part of another space.

[3] The storage and transport room for sterilised medical devices is not part of the clean zone. When storage and transport room for sterilised medical devices is within the clean zone (for example, in the same room as the evaporation / discharge space), the same same requirements apply.

7. Design phase (I)

In this phase, the foundations for the project are laid down by determining the List of Requirements (LoR), as well as the Functional design (FD) and Detailed design (DD).

7.1 Process flows (Metro map)

The so-called 'metro map' concept was developed as an answer to the variety of processes associated with the different streams within a CSSD, each of which come with their own specific requirements and practices. (Appendix 2). The basic principle of this concept is that materials must go through a specific, minimal process, determined by the nature of the actions that are to be performed. Once this process has been completed, the finished product must be sent to the usage location or be stored elsewhere.

The starting point for this approach is that it minimises the chance of damage to and/or (re-)contamination of the components or products. Transport equipment is one example of materials that are only needed in certain sub-processes that take place within a CSSD.

Examining and analysing the various goods flows separately in a metro map has the main advantage of clarifying the capacity and equipment needed for each sub-process. Mapping these requirements for sub-processes allows for a more accurate capacity estimate for the total process.

7.2 Size of the department

The size of the CSSD that is to be designed depends on the desired production capacity, the desired throughput time and peak load. When determining the size of a department, the designers must also take the potential use of loan sets into consideration. This requires specific attention and space, due to additional entry and exit checks and the storage of packaging materials.

The size of the department must be mapped as early as possible in the design process by drawing up a List of Requirements (LoR), also taking any potential future expansions into account. It is important that the design and layout of the apartment be tailored to local, long-term needs, whilst safeguarding the required levels of quality.

The capacity estimates used in the past, which were based simply on standard sterilisation unit counts (STE in Dutch) will no longer suffice, because they assumed a linear flow of medical devices.

The internal logistics and required capacity must be coordinated with the supply agreements made with the customers of the CSSD in question. In other words, the push principle is being replaced by the pull principle, or adjusting production based on demand.

7.3 Location of the department

When choosing a new location, accessibility is of key importance for effective inbound and outbound goods flows, which means the following aspects, among others, must be considered:

- accessibility of the location/ potential limiting conditions;
- distance to main users;
- revenues and investment costs;
- requirements/limitations of any particular mode of transport;
- security aspects.

Local aspects that must be considered by the design team include:

- building permits, including fire safety regulations: the department must be accessible for the fire services;
- environmental permits covering matter such as waste water disposal, waste processing and chemical permits;
- daylight access and views, in particular in staff rooms and workspaces that are used on a daily basis for long periods of time, such as the disinfection room and packing room.

7.4 General functional and spatial requirements/conditions

7.4.1 Indoor climate requirements

A pleasant working and living environment has a positive effect on the health, motivation and productivity of employees. Current rules and regulations, such as the Building Decree and Occupational Health and Safety Requirements, must be included in the LoR.

When determining the requirements pertaining to room temperature and humidity, the team must ensure that the equipment present in the room in question also meets the relevant requirements.

Temperature;

The indoor climate of all workspaces must comply with the relevant Health & Safety requirements. Pleasantness is subjective, but plays a role of key importance in working environments.
When specifying the required temperature band, the design team must consider the nature of the work to be performed, as well as the heat and humidity loads of the equipment present.

Recommendation:

- The minimum temperature in all rooms is 18°C, with the maximum temperature being 22°C.

Relative humidity

Humidity is an important factor in the various rooms and spaces within a CSSD. After sterilisation, the integrity of the packing is very important.
Indoor climate conditions must be such that no condensation can occur, which means that the dew point must never be reached. Surface temperatures that are too close to or below the dew point may result in high relative humidity or condensation. It is possible that fungi and bacteria might survive, or even grow on such surfaces.

Recommendation:

- A relative humidity of at least 40% is desirable in all rooms or spaces with an eye on comfort.
- A relative humidity of no higher than 70% is desirable in all rooms or spaces, to minimise the chance of condensation.
- Relative humidity levels may be anywhere between these two limits.

7.4.2 Ventilation and air quality

- All rooms require mechanical ventilation (inbound & outbound).
- Suction units must be installed at points where equipment or process units emit a lot of heat and/or moisture.
- Instrument washers, trolley washers and sterilisers produce considerable amounts of heat and moisture, which may affect the electronics needed to ensure that this equipment functions properly. Ventilation is of paramount importance in rooms that feature this equipment.

Room/Space requirements in the contaminated zone (in line with Table 2)

- Negative pressure prevents contaminated airflows passing from contaminated rooms to clean rooms.

Room/Space requirements in the clean zone (in line with Table 2)

- Air purity by particle concentration in the air in a clean room must comply with: ISO class 7, "at rest", 0.5 µm, 5.0 µm in accordance with NEN-EN-ISO 14644-1.
- The 100:1 recovery time must be within 20 minutes, 0.5 and 5.0 µm in accordance with NEN-EN-ISO 14644-3.
- Clean rooms must feature an positive pressure-based airflow from clean to dirty zones, in order to prevent contamination from an external source.
- To achieve the desired particle concentration levels, it is advisable to equip the inbound airflow system with HEPA filters.

Room/Space requirements in the dirty and clean zones (in line with Table 2)

- Rooms must be equipped with signs at the entrance door that display the correct, unidirectional airflow direction. If air flows deviate from the required standard for too long, an alarm must be triggered.

7.4.3 Lighting

Daylighting

- Daylighting in the cleaning and packing room promotes accurate visual inspection/checks, as well as having a positive effect on employees.
- Although it is desirable, daylighting will often be impossible in all rooms of a CSSD. Windows can aid communications, especially when supported by an intercom system. Windows are not desirable in storage rooms and changing rooms. Daylighting in storage rooms accelerates the aging process of the materials stored there.
- Curtains or any other types of indoor sun protection are not permitted.

Artificial light

- Light output/quality is crucial for all aspects of the cleaning and disinfection process and must be suitable for all work performed in any particular room. It must be possible to operate lighting systems with a high degree of accuracy, allowing for sufficient control over the light output at all workstations in all rooms.
- Special attention must be paid to the colour difference between daylight and artificial light, especially in rooms that are located far from the shell of the building. The goal should be to strike a harmonious colour balance at all workstations. Lighting in the workplace must comply with certain standards. The EU has developed a standard for what constitutes appropriate lighting in the workplace, as laid down in NEN 12464-1. This standard specifies an appropriate Lux level for safe, healthy working conditions in all workplaces. See Appendix 4 for more information.

7.4.4 Noise levels

Acoustics are of great importance in the various workspaces. The combination of smooth, hard finishes and the presence of a large number of machines can easily lead to high noise levels. To allow employees to work accurately, noise levels must comply with occupational health & safety requirements. Layout finishes must be considered carefully in the cleaning/disinfection rooms in particular, in order to strike a good balance between hygiene-related and acoustic requirements.

7.4.5 Architectural finishing

Requirements for dirty and clean rooms/spaces (in line with Table 2)

- Floor, wall and ceiling finishes must be smooth, seamless and closed.
- The ceiling must be of cleanroom quality and comply with NEN EN ISO 1644-4:2001, E2.1.2.
- The room may not have facade openings that can be opened.
- It must be possible to clean and disinfect the floor, ceiling and walls with agents permitted in hospitals.

Walls

- Walls in storage and production rooms/spaces and other spaces accessible to heavily laden carts must be resistant to or protected against impact caused by rolling/riding equipment. For this purpose, the following measures can be taken, among others: bumpers, risers, guide rails.
- Walls must be constructed in such a way as to prevent condensation in corners or construction beams, for instance.

Ceilings

- Ceilings in cleaning, packing and sterilising rooms/spaces must be able to withstand the high humidity levels produced by the process.

Doors

- For doors that are opened frequently, sliding doors are preferred with an eye on recovery time and the required air flow.
- Sliding doors wider than 1 meter must feature a walking setting.
- All other doors in a CSSD must close automatically (e.g. by installing door closers).
- In places where swing doors with an interlock system are required, the doors must swing towards the side with the highest pressure. Escape routes can also determine swing direction.
- Doors must remain open in case of emergency (fire, power failure).

Windows

- All windows must be easily accessible so that they can be cleaned.
- Windows and steel elements in the outdoor facade must be installed in such a way as to prevent condensation or thermal bridges.

7.4.6 Locks

Requirements for dirty and clean rooms/spaces (in line with Table 2)

- If a room provides access to a CSSD clean zone, it must feature a lock.
- Changing rooms can also serve as airlocks. In that case, they should be designed in such a way that the different sets of clothing are separated by a physical boundary. These rooms must also be sufficiently flushed with air. The final section of the changing room must be of the same class when “in rest” as the adjacent room.
- The two doors of the airlock may never be open at the same time. In order to prevent the simultaneous opening of more than one door at a time, an interlock or a visible and/or audible warning system must be installed.
- Airlocks can be intended and designed for people as well as goods. Employee and goods flows must be separated.
- Airlocks for people must feature at least one facility for cleaning and disinfecting one’s hands.

7.5 Rooms with equipment

The conditions in rooms that feature functioning equipment must be controlled in such a way that the materials will not be contaminated any further and that the equipment can function within the intended specifications. These conditions pertain to both dust and microorganisms. It is important to consider:

- the cleanliness of surfaces, connections and equipment, devices and accessories, edges and ridges, cleaning processes;
- air purity (filtration, airflow, humidity and atmospheric pressure ratios);
- cleanliness as a result of human behavior (clothing system, compliance).

Some equipment requires a mechanical room. These rooms are generally contaminated and form a source of contamination. It is recommended to enter mechanical rooms from outside the clean zone. If there is no other way to enter a mechanical room, it may only be entered when the CSSD is not in use. Afterwards, all necessary measures must be taken to reduce the potential risk of contaminating the clean zone.

7.6 Further room-specific requirements

This section specifies any additional requirements for each individual room, depending on the function of that room. The process requirements must be clearly identified at the start of the design process in order to shed light on which technical facilities will be necessary.

7.6.1 Reception room for dirty reusable medical devices

Process requirements

- It must be possible to receive inbound contaminated reusable medical devices.
- Determine how inbound reusable medical devices are transported.

Requirements for technical facilities

- The reception room is connected to the cleaning and disinfection rooms by means of a self-closing door.
- The reception room is separated from the rest of the building by means of a self-closing door.
- The door from the building to the reception room may only be operated by authorised personnel, avoiding unnecessary contamination risks (operation must not be manual).
- Unauthorised people must be able to deliver goods that require processing by means of a bell or intercom system.
- The reception room can be considered a logistics lock for goods or materials.

7.6.2 Cleaning and disinfection room

Process requirements

- The staff entrance to the cleaning room and cleaning room itself must feature a space where personal protective equipment can be replaced (masks, protective glasses, hair caps, etc.).
- Within the reception, cleaning and disinfection room, there must be a separate space for cleaning materials that are only used in these particular rooms.
- There must be hand washing and disinfecting facilities in the immediate vicinity of the cleaning room.

Requirements for technical facilities

- There must be sufficient space to disassemble and clean/disinfect medical devices.
- The ventilation system must provide sufficient fresh air to prevent excessive odour nuisance.
- There must be sufficient space to install and make efficient use of the equipment required for the pre-cleaning process.
- There must be a special facility for any necessary manual cleaning in accordance with Guideline B9100[4].
- There must be a local aerosol ventilation system in the rear wall or countertop of the rinsing system to protect employees.
- There must be sufficient space to create a workable logistics flow, even in case of peak loads.
- The room must be equipped with an emergency shower and eye shower or an alternative system to apply first aid in case of incidents.

7.6.3 Decontamination room for transport equipment, baskets

This room may be part of the cleaning and disinfection room (7.6.2.), provided that all requirements pertaining to both rooms are met.

Process requirements

- The room features a system that allows for automatic decontamination of transport equipment.
- The room is equipped with a system that allows for automatic decontamination of baskets.

Requirements for technical facilities

- The room is laid out in such a way that dirty and clean (contaminated) materials are clearly separated from each other.

[4] Basic information for Cleaning and disinfecting medical devices, NEN, B9100:2015.

- If the cleaning and disinfection room is combined with rooms in which other materials, such as baskets, are decontaminated, it must be laid out in such a way that these processes are clearly separated, eliminating any risk of recontamination.

7.6.4 Disinfected materials room

This room may be part of the IAP room (7.6.5), provided that all requirements pertaining to both rooms are met.

Process requirements

- This is the room where all materials end up immediately after the cleaning and disinfection phase and where, optionally, the materials are subjected to an additional drying process.
- If this room also features a location where disinfected devices are subjected to controls and a drying process with the aid of medical compressed air, it must also be equipped with an aerosol ventilation system or a physical boundary.
- This is where disinfected tools set for distribution are prepared for transport.
- Disinfected transport equipment (carts and bins) are collected here, or stored elsewhere, until they are used again.

7.6.5 IAP room (for the Inspection, Assembly, and Packing process)

Process requirements

- The IAP room serves as a place to inspect and re-assemble cleaned medical devices, before subjecting them to functional checks and tests, if required, and packing them for the following sterilisation process.
- Trolleys and other rolling equipment that are used outside the clean zone may not pass through the locks.

Requirements for technical facilities

- The IAP room must feature an air lock for clean packaging materials and all other tools and devices used in the IAP room.
- The IAP room must feature all connections required for checking and testing equipment.
- This room may not feature any taps or drains.
- The logistics lock must preferably feature a hand disinfection system.

7.6.6 Storage and transport room for sterilised medical devices

Process requirements

- After release and evaporation, the devices are ready for use or storage. In all cases, the sterilised devices must leave the clean zone through an airlock.
- Sterile medical devices must be transported under conditions that do not put either the sterility validity period or the integrity of the packaging at risk[5].
- All systems and facilities required for the release of goods must be present at the outbound side.

Requirements for technical facilities

[5] Sterilisation & Sterility Guidelines, R5402

- Storage space must comply with the requirements for sterile medical devices[6].

7.6.7 Public rooms/spaces

Process requirements

- If there is a separate training room in the premises, any teaching materials must be separated and distinguishable from the department's standard working materials.
- In spaces/rooms where extra protective clothing is required in addition to normal workwear, following the SVN Field Standard[7], this clothing must be donned and removed in the logistics lock at the "point of use".
- No food or beverages may be brought into or consumed in the dirty and clean zones. If necessary, a specific space or room can be designated for this purpose in the public zone.

Requirements for technical facilities

- Changing rooms must be large enough to allow employees to change clothes according to the required clothing system and protocol. There must be separate changing rooms for men and women that comply with all Occupational Health & Safety regulations.
- There must be a sufficient number of lockers in the cleaning room. The number of lockers required depends on the number of employees in the department and the maximum number of visitors.
- Toilets must be located in the public zone.
- Toilets must feature hand-washing facilities.
- All furniture, tables and chairs must be made of smooth material that is easy to clean.

7.6.8 Cleaning service rooms

Process requirements

- There are high standards for cleanliness throughout the department. In order to guarantee high levels of cleanliness, the various zones - dirty and clean - must feature their own storage space for cleaning equipment and materials used in that particular zone. Cleaning must always be done by progressing from the cleaner (part of a) room to a dirtier (part of a) room.
- Any handling and potential (interim) storage of waste must meet the relevant requirements set by the hospital.
- Within the clean zone, there must be a separate room for cleaning materials that are only used in the clean zone.

Requirements for technical facilities

- Ample storage space for cleaning equipment and materials, as well as personal protective equipment.
- Space for cleaning machine(s) and containers for temporary waste storage, if necessary.
- Water tap, water drain, sink and bucket sink.
- Hand-washing and disinfecting facility.

[6] Sterilisation & Sterility Guidelines, R5340

[7] Hygiene and Dress Code Guidelines: Central Sterilising Department and Flexible Endoscope Cleaning & Disinfection

7.6.9 Room for the reception and storage of consumables

Process requirements

- Only production equipment and materials set for processing may be stored in or pass through the department. The storage of processable goods includes items necessary for the production process.
- There must be facilities to dispose of waste and packaging material.
- If chemical agents/substances are stored, this room must comply with the relevant Occupational Health & Safety Regulations.

Requirements for technical facilities

- The design must reserve sufficient space for the inventory required.
- A CSSD requires rooms/spaces for at least two types of inventory:
  - space for the storage of processable materials,
  - space for the storage of processed materials.
- The space in question must be suitable for storing these goods.

7.6.10 Room for transport materials (e.g. trolleys and carts)

Process requirements

- The storage room for transport equipment must be in the immediate vicinity of the processed goods.
- It must be clear and unambiguous which medical devices are to be processed during the entire logistics flow.
- If the same transport equipment is used for clean and dirty devices, an effective cleaning system must be implemented before carts used to transport dirty devices can be used to transport clean devices. Even when goods flows are clearly separated, featuring dedicated carts for clean and dirty devices, these carts must be thoroughly cleaned.
- Transport carts go from the dirty reception room to the storage room and finally to the transport room for sterilised medical devices. This room is located on the outbound side of the sterilisers.
- Before the transport carts reach the transport room for sterilised medical devices, they must have been cleaned and sterilised. A dedicated system, such as a cart washing installation, must be present for this purpose.
- If other devices, such as baskets, are also treated, they must be processed separately.
- The transport equipment used for transport within the CSSD and to and from users must be fit for purpose and suitable for the process.
- All necessary facilities must safeguard the condition of the materials and eliminate any risk of recontamination during transport.
- Transport equipment may not be subjected to maintenance or repairs at the CSSD.

Requirements for technical facilities

- There must be a designated location for the inbound flow of dirty devices and transport equipment that cannot be processed right away.

7.7 Design verification (DV)

After determining the Functional Design (FD) and Detailed Design (DD), Design Verification (DV) should be carried out to ensure that the proposed installation, system and equipment design is suitable for the intended usage situation described in the List of Requirements (LoR) and that all measures succeed in minimising and managing risks.

8. Realisation phase (2)

During this phase, the elements specified in the design are implemented and documented.

8.1 Finishes

- In areas where devices are exposed to the environment, interior surfaces (walls, floors and ceilings) must be smooth and free from cracks or open joints and may not emit any particles. In these areas, floor, wall and ceiling finishes must be smooth, seamless and closed.
- Corners and transitions between floors and walls must be smooth and flowing in order to prevent the accumulation of dirt and to make them easy to clean.
- Pipes, ducts and any other facilities or systems must be installed in such a way that they have no corners, crevices or surfaces that are easy to clean and must preferably extend down from the ceiling. Finishes made to pipes and ducts require extra attention.
- Wall-mounted worktops, sinks, etc. must be fitted and finished seamlessly. Any unavoidable seams must be large enough for cleaning. All connections, links and transitions must be flat and smooth.
- The finished floor, screed and underlay must be able to withstand heavy, moving carts/trolleys.
- The floor covering must hug the wall, be installed in 1 piece and feature concave skirting, so it can be considered seamless: the wall finish that borders the skirting must be smooth and even.
- When working with “floor-standing” sterilisers, part of the floor on the outbound side of the sterilisers must also be heat-resistant (the wheels of transport equipment leaving the sterilisers can be hot).
- Additional attention must be paid to expansion joints in heavy-traffic areas, especially in places where carts/trolleys have to turn a corner.
- Passages from one room to an adjacent room are critical points when it comes to floor finishes.

8.2 Air permeability

Contamination control is very important in a CSSD and positive and negative pressure play a major role. Realising the desired airflows is a key issue that involves addressing air treatment and air permeability. In addition, saving on energy costs is an important issue when developing cleanrooms. For this reason, it is recommended to set requirements for the minimum and maximum air permeability of a particular room before starting the realisation phase, for which you can use VCCN Guideline 10.

8.2.1 Box-in-box construction

In order to minimise the influence of the wind pressure on the façade on the flow direction of the air within the CSSD, it is advisable to design the CSA as an independent construction with a low degree of air permeability. This type of construction is also known as a box-in-box construction.

To ensure that the shell has a low degree of air permeability, it is important to carefully consider all details (materials, feedthroughs, connections, etc.) in advance.
Equipment or connections of equipment to the shell of the room are a point of attention when it comes to air permeability.

8.3 Cleaning during realisation phase

It is important that the very first steps towards a qualified room or space be taken during the construction process. As such, cleaning is essential during this phase. VCCN Guideline 4, Surface Cleanliness and NEN-EN-ISO 14644-5 describes the general regulations and recommendations for cleaning work related to the construction, delivery, commissioning and operation of dust and germ-free rooms. This guideline specifies 10 distinct cleaning phases. These phases should also be implemented when building a CSSD.

8.4 Renovation

Work related to renovation, construction, maintenance and tests can also be detrimental to the integrity of the existing production environment. These types of activities may never disrupt any operational CSSD. Risk analysis is a systematic process of hazard identification, as well as the analysis and evaluation of risks associated with exposure to those hazards.
Solutions can be introduced in the basic design to mitigate the effects of these activities in the future.

9. Verification phase (3)

9.1 Testing Plan / Commissioning Plan

The Testing Plan/ Commissioning Plan must define the systems and equipment that will be used in the department, based on system limits.

There are many similar commissioning strategies, each of which depends on specific circumstances. Depending on the role played by the system, commissioning may be a precursor to process validation, but it may also be the final activity prior to the routine operational phase. If commissioning documentation is used to support the validation process,
it is of crucial importance to involve the head validating officer in the planning and coordination of the commissioning activities.
All deliverable documents for the project (such as the Validation Master Plan and the Testing Plan / Commissioning Plan) may contain cross references.

The Testing Plan must contain a description of all equipment and systems that will be commissioned, including the associated automation processes. All tests that have to be carried out and all associated testing protocols must be defined in a Testing Plan. This Testing Plan indicates which tests must be performed for each room, area or installation component, how these tests will be performed, and which acceptance criteria will be used. The Testing Plan must be approved and signed by the client, user and testing party before the start of the verification phase.

9.2 Testing

Tables 3 and 4 below provide an overview of which tests are to be performed, subdivided into mandatory and optional tests.

Table 3

Mandatory tests:	**Requirement:**	**Complies with standard/guideline:**
Particle measurements	ISO 7 at rest, 0.5 µm, 5.0 µm	NEN-EN-ISO 14644-1
Recovery time measurements	≤20 min with factor 0.01	NEN-EN-ISO 14644-3
Pressure hierarchy	In accordance with Appendix 1	NEN-EN-ISO 14644-3
Filter leak tests	n=0	NEN-EN-ISO 14644-3
Air quantities/ Circulation rates	Follows from LoR & Design	NEN-EN 12599

Table 4

Optional tests:	**Requirement:**	**Complies with standard/guideline:**
Light intensity measurements		In consultation
Sound measurements		In consultation
Microbiological measurements		NEN-EN-ISO 14698-1
Temperature/humidity measurements		NEN-EN-ISO 14644-3

Airflow profile	In accordance with Appendix 1	NEN-EN-ISO 14644-3
Air permeability test	E.g. Class L1, from 10 Pa to 50 Pa, positive & negative pressure	VCCN Guideline 10

10. Operational and maintenance phase (4)

10.1 CLEANING

In the CSSD, air treatment and filtration systems are used to create a suitable climate for the CSSD process. The presence of employees and the production process itself may contaminate surfaces. To ensure that the CSSD continues to meet the appropriate standards, it will have to be cleaned regularly.

Particles move along with airflows and are discharged via the air treatment installation in some cases. Any particles that are not caught in the airflow remain on surfaces. Due to the movement of air, some particles can be caught up by the airflow again and deposited on yet another surface. Heavier particles will end up on horizontal surfaces or the floor due to gravity.

Cleaning dust and germ-free areas is intended to remove all visible and invisible contamination on surfaces.

The following recommendations apply to daily and periodic cleaning:

- A work description must be drawn up for each individual room/space, specifying the cleaning programme, the machines, materials, cleaning agents and routing that must be used in careful detail. The description must also indicate which people are responsible and qualified for which actions and/or which parts of the CSSD. It is recommended that the proper cleaning of all rooms be checked with a checklist, especially in clean and dirty zones.
- Generally speaking, furniture and floors should be cleaned at least once a day. Ceilings and walls do not need to be cleaned as frequently. Critical work surfaces must be cleaned and/or disinfected prior to daily work and during work in case of visible dirt or dust.
- When using cleaning agents and disinfectants, those responsible for cleaning must ensure that all products are used for the right amount of time and in the right concentration, and that all surfaces are completely covered.

All the above is in accordance with VCCN, Guideline 4.

10.2 Monitoring

10.2.1 Monitoring plan

To ensure that the CSSD performs adequately, a monitoring plan that meets the specifications of NEN-EN-ISO 14644-2 must be drawn up, implemented and maintained. A monitoring plan takes the required levels of air purity into consideration, as well as critical locations and performance criteria of cleanrooms, airflows and installations that affect the department’s performance. The following steps must be taken into account when drawing up, implementing and maintaining the monitoring plan:

- develop a written monitoring plan;
- read and approve the plan;
- implement the plan by carrying out the monitoring activities it describes;
- analyse the data obtained by means of monitoring, perform a trend analysis where necessary and record the determined performance;

- implement and document any actions taken or any corrective actions that may be necessary;
- re-assess the monitoring plan in the event of maintenance and/or changes.

The concentration of airborne particles measured as part of a monitoring plan may exceed the concentration observed during the 'at rest' classification. The observed values can fluctuate considerably due to factors including, but not limited to, the number of people present, the airflow rate, the effectiveness of the ventilation system, instruments or machines and activities taking place in adjacent areas.

The requirements established in this Guideline are based on airborne particles.
Because sterility is of key importance in a CSSD, it is recommended that microbiological measurements be included in the monitoring plan, in accordance with NEN-EN-ISO 14698-1 and NEN-EN-ISO 14698-2.

10.2.2 Risk analysis

Risk analysis is a systematic process of hazard identification, as well as the analysis and evaluation of risks associated with exposure to those hazards.
A risk analysis is performed in order to:

- develop a monitoring plan by determining factors that may affect the ability to maintain the specified air purity levels by carrying out particle concentration analyses in the cleanroom or clean zone and establishing
- monitoring requirements to provide proof of performance.

10.2.3 Reclassification

The CSSD must be reclassified on a regular basis. This is done in accordance with the tests and testing plan described in section 9.

ISO 14644-1 stipulates that CSSDs must be reclassified every year. The
frequency of reclassification can be reduced based on the outcome of the risk analysis, the nature of the monitoring system and data that consistently fall within acceptance limits or levels defined in the monitoring plan.

Appendix 1. Schematic representation of zoning, airflow and workflow direction

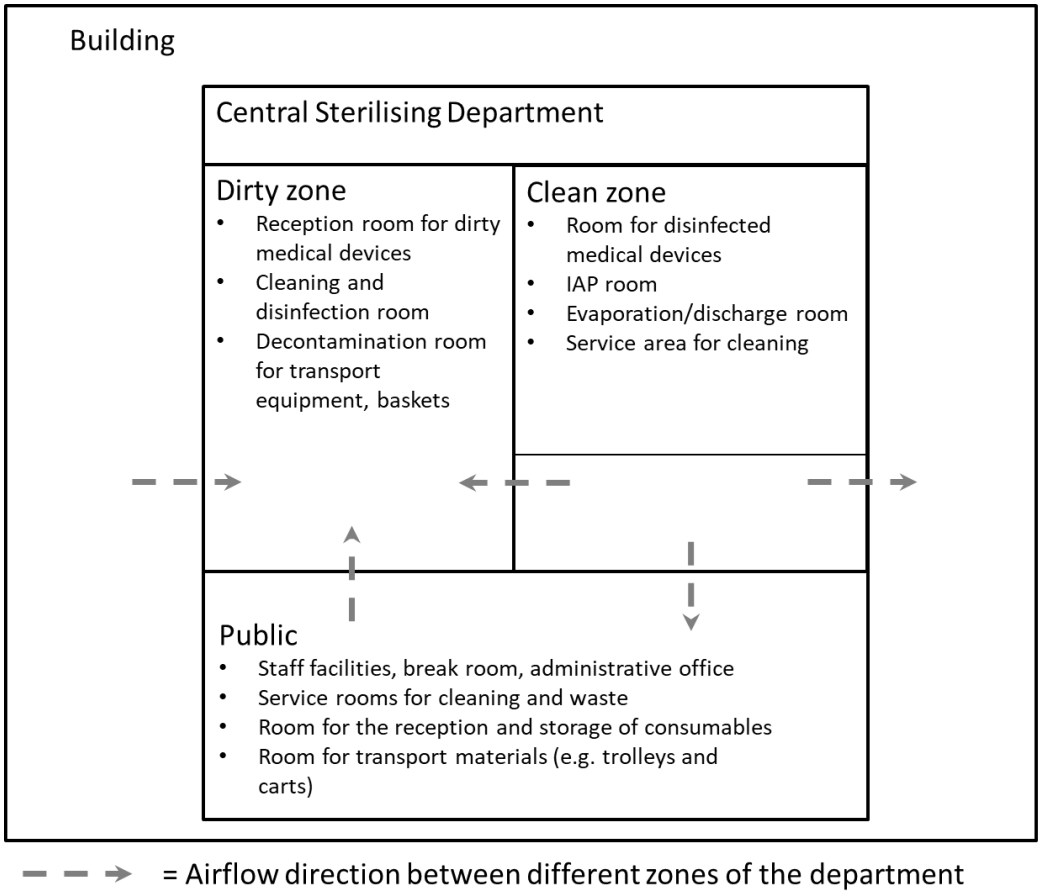

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Figure 4, Schematic representation of zoning, airflow and workflow direction

Appendix 2. Metromap: schematic representation of various flows in the CSSD

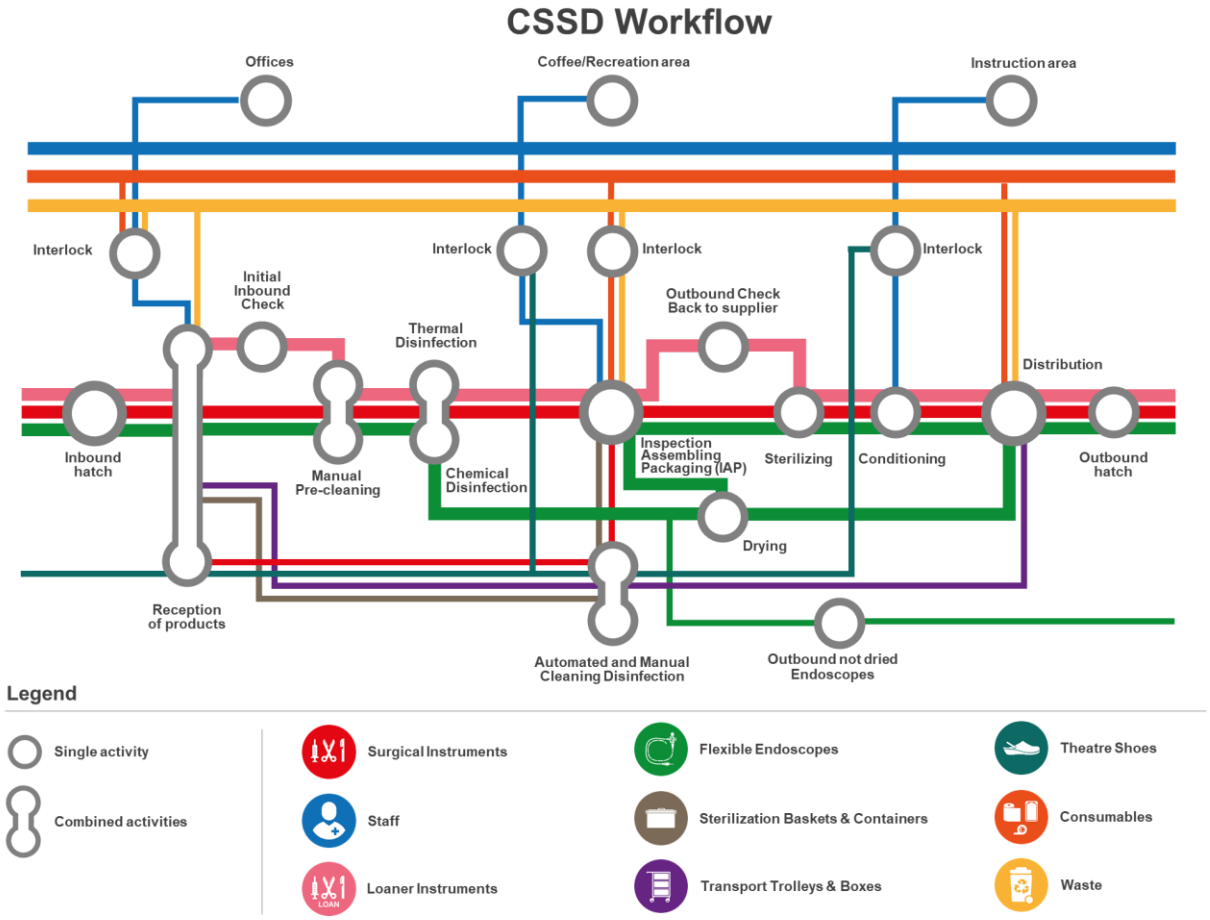

Figure 5, metro map example

Appendix 3. Summary of literature study

Reason

To date, many guidelines pertaining to CSSDs have been built on existing guidelines, although it has not always been clear whether they were based on scientific research.
A literature study was carried out to determine whether scientific evidence could be found that can be used in drawing up and underpinning this CSSD Guideline. This literature study was carried out as a systematic review (Assendelft et al. 1999[1)]. For more detailed results, please refer to the members of the task force.

Study design

Our study was based on the following research question:

1 How do air conditions influence contamination during the process steps in a CSSD?
2 The evaporation phase that follows after sterilisation is critical. Are there any known effects that influence the contamination of materials?
3 What role do pyrogens and/or sterile particles in potential complications, such as postoperative wound infections.
4 Are the chances of mixing up clean and dirty medical devices greater when working with processing rooms that are not separated by physical boundaries?

Results

Rec.1.: Two studies show that air contamination and air pressure fluctuations lead to increased levels of contamination in medical devices after sterilisation (during the cool-down and storage phases), but that these affects are negligible if the quality of the packaging material is high enough.
For the remaining process steps, up to and including sterilisation, no evidence was found of air conditions affecting the product result in any way.

Rec. 2. Only one study was found that cautiously points out that changing air pressure conditions could potentially have an affect on the permeability of packaging in the post-sterilisation phase.

Rec.3 .: A single study showed that endotoxins have no significant influence in opthalmology, with three other studies suggesting the same, but failing to demonstrate this clearly.
None of the studies found led to the conclusion that the presence of sterile particles might lead to an increased risk of Post-Operative Wound Infections. However, clothing was found to have an important affect on the presence of particles.

Rec.4.: The study provided no evidence for this.

In summary:

The task force has not found any hard scientific evidence that should necessarily lead to other construction-related requirements than those used to date.

Appendix 4. Lighting levels

The tables below were taken from NEN-EN-ISO 12464-1 (2014). For more information, please consult the full standard. We recommend always staying up to date with the latest version of the standard.

Table 5.37 - Healthcare - Rooms for general use

Ref. nr.	Soort ruimte, taak of activiteit	$\bar{E}_m$ lx	UGR_L –	U_o	R_a –	Specifieke eisen
						Te hoge luminanties in het blikveld van de patiënt moeten worden vermeden
5.37.1	Wachtkamers	200	22	0,40	80	
5.37.2	Gangen: overdag	100	22	0,40	80	Verlichtingssterkte op vloerhoogte
5.37.3	Gangen: schoonmaken	100	22	0,40	80	Verlichtingssterkte op vloerhoogte
5.37.4	Gangen: 's nachts	50	22	0,40	80	Verlichtingssterkte op vloerhoogte
5.37.5	Gangen voor multifunctioneel gebruik	200	22	0,60	80	Verlichtingssterkte op taak/-activiteitshoogte
5.37.6	Dagverblijven	200	22	0,60	80	
5.37.7	Liften voor personeel en bezoekers	100	22	0,60	80	Verlichtingssterkte op vloerhoogte
5.37.8	Serviceliften	200	22	0,60	80	Verlichtingssterkte op vloerhoogte

Table 5.38 - Healthcare - Staff rooms

Ref. nr.	Soort ruimte, taak of activiteit	$\bar{E}_m$ lx	UGR_L –	U_o	R_a –	Specifieke eisen
5.38.1	Kantoren	500	19	0,60	80	
5.38.2	Personeelsruimten	300	19	0,60	80	

Table 5.49 - Healthcare - Laboratories and pharmacies

Ref. nr.	Soort ruimte, taak of activiteit	$\bar{E}_m$ lx	UGR_L –	U_o	R_a –	Specifieke eisen
5.49.1	Algemene verlichting	500	19	0,60	80	
5.49.2	Kleurcontrole	1 000	19	0,70	90	6 000 K ≤ T_{CP} ≤ 6 500 K

Table 5.50 - Healthcare - Disinfection rooms

Ref. nr.	Soort ruimte, taak of activiteit	$\bar{E}_m$ lx	UGR_L –	U_o	R_a –	Specifieke eisen
5.50.1	Sterilisatieruimten	300	22	0,60	80	
5.50.2	Ontsmettingsruimten	300	22	0,60	80	

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