

Keywords

- sterilisation
- CSSD
- architecture

Architecture and Sterilisation Premises – Part 2

*AFS Working Group**

3. Description based on activity zone

3.1 Proposed method for determination of surface area based on the equipment

It is difficult to evaluate surface areas because of the heterogeneous nature of the tasks carried out in the Central Sterile Supply Departments (CSSDs) of healthcare institutions.

Activity indicators are indispensable elements for evaluation of surface areas.

An indirect approach may be considered and this entails quantifying the ground surface area occupied by the equipment needed to conduct sterilisation activities under optimal conditions, bearing in mind movement constraints around such equipment.

Healthcare establishments are increasingly using more disposable medical devices (MDs); generalisation of certain single-use medical-care sets, non-woven surgical drapes or disposable feeding bottles have considerably reduced the CSSD workload, enabling it to focus on reprocessing of supplies for the operating theatres.

This activity will depend on the type of surgery carried out in each institution and the volume of supplies to be reprocessed varies enormously according to the surgical speciality: orthopaedic, visceral, gynaecological ...

The architectural organisation and calculation of the surface area needed for the CSSD should take account of the volume of linen handled, of whether a greater or lesser number of disposable sterile MDs are in use, of whether the layout is as a single block or pavilion-style structures, or whether services are provided for external clients.

Estimation of surface areas some years ago produced the following ratios de-

pending on the number of beds: in Belgium 0.6 m²/bed, Netherlands: from 0.7 m²/bed for 200 beds to 0.45 m²/bed for 75 beds, in France depending on the "active" nature of the bed: 0.56 m²/bed for 300 beds to 0.45 m²/bed for 600 beds (24).

Thierry Hoët (23) has estimated the following ratios: 0.7 m²/bed from 0 to 300 beds; 0.6 m²/bed from 300 to 600 beds and 0.5 m²/bed for more than 600 beds, bearing in mind the different activities carried out in the CSSD.

To calculate the surface areas we propose that this be based on the number of beds used for Medical – Surgery – Obstetrics (MSO), using the following calculation basis:

- from 200 to 300 MSO beds: useful surface area of 1.5 m²/bed;
- from 300 to 400 beds MSO: useful surface area of 1.2 m²/bed;
- more than 400 beds for MSO: useful surface area of 1 m²/bed.

Since the CSSD has few internal corridors, the applicable conversion ratio between a useful surface area and net floor area is of the order of 1.3.

For establishments whose capacity is less than 200 MSO beds, a surface area threshold below which it is not possible to meet the sterilisation needs must be determined. This minimal surface area can be estimated as being 200 m² useful and 260 m² net floor area.

The surface area within the CSSD could be allocated in the following manner:

- reception: 10% of the surface area;
- sorting zone – cleaning: 25% of the surface area;
- packing: 35% of the surface area;
- spare sterilised MDs: 20% of the surface area;

– annex zones: 10% of the surface area. A 20% proportion allocated to spare MDs may appear excessive but, once more, the organisational structure within the establishment must be borne in mind. If no provision is made for spare sterilised MDs within the CSSD (with this being done in the patient-care units and operating theatres), this surface area must be reduced and use it only for storage prior to distribution. A greater proportion could then be allotted to the cleaning zone.

For CSSDs providing sterile supplies for medical departments, these surface areas may appear excessive and must be reviewed at base.

This method of defining surface areas and assigning them internally must be weighted in terms of the CSSD organisational form.

The costs estimated by architects for creating a new CSSD is 1830 euros per m²; these costs can be reduced by 30% if an existing structure is upgraded.

In the course of this study, once the different CSSD zones have been determined, architectural orientations will be proposed to provide for smooth workflow patterns and ensure that a sufficiently large area is available, bearing in mind the range of activities carried out therein. This surface area will depend on the number of beds in the establishments, on the nature and variety of surgical procedures, number of sterilisation assistants, etc.

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Each zone shall be defined and, depending on the regulations governing it, a layout shall be proposed.

3.2 The cleaning zone

Aim:

- to reprocess soiled MDs;
- to centralise and automate activities relating to the cleaning of MDs for the operating theatres and patient-care units;
- to reduce baseline microbial contamination to the very minimum;
- to protect personnel and the environment;
- to clean transport cabinets and basins, and possibly the clogs used in the operating theatres and/or CSSD.

Operations inherent to this zone:

- receipt of incoming instruments following pre-disinfection and collection of such instruments from the patient-care units and operating theatres;
- verification on the basis of the dispatch form that what has been dispatched (by patient-care units and operating theatres) has been received in the CSSD;
- setting up and checking a manual or computerised system for tracking MDs (including ancillary devices);
- cleaning per se.

The cleaning zone comprises:

- the reception zone – sorting – documentation of MDs;
- the zone for inspection of incoming MDs (including loaned ancillary devices);
- the cleaning zone per se (washer-disinfector, ultrasound basin, cleaning cabinet) comprising the technical wall with double-door washer-disinfector;
- the zone for manual cleaning of very delicate MDs;
- the zone for chemical inactivation as per Circular No. 100 of 11 December 1995 and No. 138 of 14 March 2001 (5);
- the zone for storage of trolleys and transport basins before cleaning;
- the zone for cleaning trolleys and transport basins.

Bear in mind that pre-disinfection, if carried out (as is generally the case) shall be performed within the department where the MD was used, while documenting the tasks conducted.

The cleaning zone shall be equipped with a zone for computerised tracking of MDs. This shall have two circuits:

- one circuit for cleaning MDs;
- one circuit for cleaning transport equipment.

A cleaning cabinet or, if this is not available, a pressure jet cleaner shall be used to clean transport trays and cabinets. This task shall be carried out within a watertight zone.

The cleaning cabinet must be provided with a connection for an incoming supply of compressed air to complete drying, if necessary.

The number of washer-disinfectors needed will depend on the usage turnaround. Whether a specific washer-disinfector or a cleaning cabinet is needed to clean and dry containers and their lids must be evaluated.

Once cleaned, the transport equipment is conveyed to the sterile supply distribution zone situated at the end of the sterilisation chain.

The washer-disinfector unloading zone shall serve as an intermediate zone between the cleaning and packaging zone where drying of the MDs can be completed after removal from the washer-disinfector (see Section 3.3).

It will be fitted with a connection for an incoming supply of compressed air to complete drying the MDs, and with water filters (water filters do not withstand a pressure above 3.5 bars).

This zone shall be separate from the packaging zone so as to avoid any form of humidity within this ISO Class 8 zone.

Materials for floors, walls, ceilings:

It is recommended that great care be taken when using tiles. If tiled floors are used, preference should be given to tiles with resin joints. The tiles must measure 300 x 300 mm and must be of a very good quality since broken tiles, because of falling objects, can serve as a source of microbial proliferation. The tiles must be laid by an approved company specialising in this field.

PVC floors composed of soldered strips rising to form a plinth should be used preferably in order to avoid the problems caused by tiles (see Section 2.3).

Reference source on which based:

The Permanent Working Group for Study of Markets (G.P.E.M./S.L.) (2)

3.2.1 The reception zone

Aim:

This zone is used to take charge of incoming transport cabinets and basins used to distribute the different MDs to be re-processed in the CSSD. The transport cabinets and basins shall follow a circuit whereby they are cleaned and then used to transport the sterilised MDs to the departments using them. The MDs shall follow a parallel circuit whereby they are cleaned, dried, inspected and packed before sterilisation.

Operations inherent to this zone:

- receipt of incoming supplies;
- manual inspection and manual or computerised recording of MD tracking.

Reference source on which based:

The Permanent Working Group for Study of Markets (G.P.E.M./S.L.) (2)

3.2.1.1 Equipment required

Entrance permitting access to the CSSD only from the external corridor. This entrance must comply with fire regulations.

A counter, made of a material that can be washed, easily disinfected and resistant to detergents and disinfectants and does not emit particles (Corian, resin, stainless steel, stratified mass) with enough space to accommodate and register incoming MDs, and, if necessary, serve as a barrier to restrict access to the cleaning zone.

A computer station, if possible close to the counter. This must be insulated to withstand any liquids that might be transported (depending on the organisational structure).

3.2.1.2 Optimal surface

Entrance with a front opening of at least 1.60 metres permitting circulation of the trolleys used to collect used MDs as well as for passage of heavy equipment. The same door width must be provided between the reception zone and cleaning zone.

Below are examples of the size of mobile trolleys, depending on the supplier, used to transport supplies between the CSSD and the departments in which they are used:

L = 930 or 1220 mm, w = 735 mm, h = 1400 mm;

L = 825 or 1155 mm, w = 675 mm, h = 1350 mm;

L = 1235 or 1400 mm, w = 630 or 720 mm, h = 1205 or 1750 mm;

L = 1200 to 1400 mm, w = 750 mm, h = 1200 to 1750 mm;

L = 1100 mm, w = 700 mm, h = 1100 to 1400 mm.

A minimum clearing of 3 metres must be left between the counter and the partition separating the cleaning zone (the counter could possibly serve as a partition between the reception and cleaning zones).

3.2.2 The cleaning zone per se

Aim:

The activities carried out in this zone must permit:

- elimination of organic and mineral soils;
- reduction of the baseline contamination on the MDs to be reprocessed;
- chemical inactivation of non-conventional transmissible agents (NCTAs).

Operations inherent to this zone:

- preparation of MDs for manual or automated cleaning;
- loading of washer-disinfectors;
- manual cleaning and cleaning in an ultrasound basin;
- cleaning of trolleys, containers, basins for collection of used supplies and mobile cabinets, using either a cleaning cabinet/tunnel washer or a pressure jet cleaner in a dedicated room;
- chemical inactivation treatment in bicarbonate or Javel water (5);
- drying of manually cleaned MDs.

Remark: the same basins used for pre-disinfection may also be used to collect the used supplies.

Trolleys enter on the cleaning side and may exit from the storage side to permit loading of the sterile supplies. In this case, a separation between the exit from the cleaning cabinet will help avoid residual humidity within the storage zone.

This cleaning cabinet can also be used to clean containers, pre-disinfection basins and surgical clogs; the latter must be secured to a rack designed to that effect.

If a cleaning cabinet is used, the use of a palliative solution and the possibility of needing an additional machine if this cabinet has to be serviced or repaired must be taken into account.

MDs must be inspected before being loaded into the double-door washer-disinfectors (allow enough space for automatic loading of the machines) or into a tunnel washer. Delicate MDs (microsur-

gical) must be kept separate from other MDs. To assure good cleaning results within the washer-disinfector, check that the various forceps and scissors are opened before being placed in the washer-disinfector.

Direct loading of the washer-disinfector may be recommended, depending on the type of pre-disinfection and in order to avoid handling or exposing sterilisation assistants to the risk of accidents involving blood-borne pathogens. To assure this, the trays used for the pre-disinfection basins must correspond to the standards (currently DIN) regulating the type of trays used in the washer-disinfectors. This also imposes stringent demands on the various departments serviced by the CSSD (no overloading of trays, differentiation between fragile and non-fragile instruments ...)

These different zones within the cleaning zone may be physically separated but total separation is not necessary. As far as possible, the zone used for chemical inactivation (bicarbonate or Javel water) must be insulated to protect staff.

Reference source on which based:

Blood-associated exposure accidents: Notice No. 666 of 28 October 1996 amended by Circular No. 98/228 of 9 April 1998 draws attention to the risk of transmission of the following viruses: HBV, HCV and HIV. Circular No. 98/228 stipulates that a method be devised to counter blood-associated exposure accidents, based on notification of such accidents, their management and maintenance of a register of accidents occurring during each procedure. Circular No 99/680 of 8 December 1999 points to the need for biological monitoring and early treatment of blood-associated exposure accidents as well as the importance of prevention.

Provision must be made to protect personnel against accidents: goggles, gloves, protective aprons must be made available.

An ocular fountain or a pack for rinsing the eye must be provided if there are ocular projections.

3.2.2.1 Equipment required

Gate:

A gate between the cleaning zone and packaging zone with an airtight double door that opens automatically to allow passage of containers and washer-disinfector trays (of a type that can be returned

if it does not conform to specifications). It must be assured that both doors of the gate may not be open at the same time and an electronic system should be able to block the opening of one door if the other one is already open.

Under no circumstances should this gate be a sluice permitting passage of sterilisation personnel.

Information technology:

Provision must be made in the reception of the cleaning zone for computerised registration of MDs.

Preparation of MDs:

Three or 4 mobile workstations for preparation of MDs. These workstations may be made of stainless steel but this material is easily scratched and reflects sunlight, in particular, hence we would prefer Corian or a synthetic resin compatible with the different detergents used in the cleaning zone.

A number of shelves shall be provided for storage of the various products used for the machines, to avoid these being placed at floor level.

Manual cleaning:

Make provision for a workstation for manual cleaning with two basins, side by side, for immersion and rinsing of MDs that do not fit into the washer-disinfector. These basins must be of an appropriate size.

Because of the large size of certain basins, "baby style" sinks as used in nurseries could be used for manual cleaning of pre-disinfection basins, preferably made of Corian.

The sinks must be of a scratchproof quality; Corian or a similar material is recommended.

- The cleaning zone workstations have the following dimensions, depending on the respective supplier:

L = 1200 or 1800 or 2400 mm, w = 700 mm, h = 900 mm;

L = 500 to 2650 mm, h = 850 or 900 mm.

- The cleaning basins have the following dimensions:

550 mm × 500 mm × 240 mm;

700 mm × 440 mm × 240 mm;

400 mm × 400 mm × 300 mm;

500 mm × 500 mm × 300 mm;

760 mm × 510 mm × 300 mm.

A compressed air connection will help complete drying.

Ultrasound basin:

For certain microsurgical or ophthalmologic MDs an ultrasound basin is needed to assure good cleaning of these devices.

If an ultrasound basin is needed, it should be big enough to accommodate the various devices used for coelioscopy (scissors, forceps, ...). It must be sufficiently soundproofed (dimensions 335 x 715 x 445 mm – capacity 25 litres – device 65 cm long), preferably fitted with a draining tap.

The zone with the ultrasound basin(s) must be equipped with a facility for direct drainage of the basin contents (or a flush-mounted or tabletop ultrasound basin).

A workstation close to the basin is needed for inspection of MDs.

Since the MDs need to be left in the ultrasound basin for 15 minutes once the basin has been degassed (degassing time of 15 min), a basin able to accommodate a volume of fragile MDs corresponding to the content of 4 sterilisers is recommended. This must be evaluated in accordance with the range of activities conducted in the CSSD and with the volume of fragile MDs to be reprocessed.

Cleaning cabinet:

Since cleaning is carried out very quickly in these cabinets (around 15 minutes), one single cabinet should be enough for sterilisation of 4 to 5 autoclaves.

Just as in the case of washer-disinfectors, so problems with drying can be encountered, in particular as regards wheels, so drying must be completed. It may therefore be necessary to provide a connection for an incoming supply of compressed air at the exit of the cleaning cabinet and to insulate this exit from the sterile exit zone as well as from the washer-disinfecter exits.

Washer-disinfectors or tunnel washers:

Double-door washer-disinfectors permitting loading on the cleaning side and unloading on the packaging zone are recommended.

The zone upstream of the washer-disinfecter loading area must be sufficiently big to position a transfer trolley so as to alleviate the workload for sterilisation assistants, in particular as regarding lifting heavy loads.

The recommended number of washer-disinfectors will depend on the load to be reprocessed and on the packing method used.

- It will depend on the number of containers to be reprocessed simultaneously. This must be determined following analysis of the CSSD activities and of flows between the CSSD and operating theatres (this can be calculated on the basis of the container dimensions: 600 mm x 300 mm or 300 mm x 300 mm);
- Likewise, what washer-disinfecter volume should be chosen (8, 10 or 12 trays)? This will be determined by analysing the CSSD activities;
- The number of MDs per tray must be evaluated (this could be calculated in accordance with the volume of MDs). The trays must not be overloaded to ensure a good cleaning result;
- Moreover, provision must be made for peak activities so as to have enough washer-disinfectors available during such periods.

The following ratios can be given by way of example:

- 1 washer-disinfecter containing 10 trays will accommodate the instruments generated by 2 visceral procedures or by 1.5 orthopaedic procedures;
- one cycle lasts 1 hour and 15 minutes;
- for a workload of 10 surgical procedures per day, one would have around 15 washer-disinfecter cycles, calling for an investment in 1 or 2 washer-disinfectors.

If the workload warrants it, a tunnel washer could be suggested as this would help achieve a better rentability threshold; each phase lasts around 15 min.

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If the workload warrants it, a tunnel washer could be suggested as this would help achieve a better rentability threshold; each phase lasts around 15 min.

Chemical inactivation zone:

A zone must be allotted to chemical inactivation of NCTAs. This must be equipped with basins for bicarbonate (1N. or 2N.) or Javel water. Provision must be made for a drainage system and for regulated elimination.

Chemical inactivation should be carried out in a basin fitted with a special drainage facility that allows for rinsing after inactivation. This procedure must be conducted within an enclosed area.

This area must be equipped with several basins:

- one for manual cleaning after pre-disinfection. This helps remove any protein materials present on the MDs and prepares them better for the ensuing chemical inactivation step;
- one for the immersion procedure of chemical inactivation;
- the MDs are then subjected, following thorough rinsing, to manual or automated cleaning before being transferred to the packaging zone.

3.2.2.2 Optimal surface area

The cleaning zone surface area will depend on:

- the distinctions made within this area;
- the number of washer-disinfectors;
- the number of MD containers.

Depending on the volume of activities (to cut back on personnel), a cleaning cabinet, preferably with a double opening (taking account of the principle of forward movement) may be needed for cleaning the trolleys as well as the transport and pre-disinfection basins. It is very important that the correct dimensions be used for this installation: length 4 m x width 2.5 m x height 3 m. To this must be added a free space of 2 m x 3 m at the entrance and exit to facilitate handling. The total length needed for installation of a cleaning cabinet with a double opening is therefore close to 10 metres.

3.2.3 Constraints imposed by the cleaning zone

A central evacuation plughole with a valve must be provided on the floor.

The following constraints apply:

- soundproofing;
- lighting: minimum 200 lux (occupational legislation);
- smooth walls and ceilings that can be washed;
- liquid-proof light fittings and electrical plugs;
- non-slip floors that are resistant to disinfectants with facilities for water drainage;
- air conditioning;
- differential pressure between the cleaning zone and packaging zone;
- criteria governing water quality (hardness, microbiological contamination, potability (8), ...);
- production of osmosed or demineralised water for rinsing MDs after manual and automated cleaning;
- connection for incoming supply of compressed air.

When designing the CSSD, the location of the washer-disinfectors marks the boundary between the "precleaning" and "post-cleaning" zones. There must be no direct passage of staff between the "precleaning" and "postcleaning" zones.

3.3 The packaging zone

Aim:

To pack the MDs to be sterilised in trays, packs, containers, individual pouches, etc.

This packaging zone shall comprise two separate parts:

- one zone for packing the MDs:
 - zone for functional testing of the cleaned MDs before they are packed;
 - packaging zone (ISO Class 8 of standard EN ISO 14644-1) with individual workstations for each type of activity (instrument pouches, instrument containers, ...) or for each type of operating theatre or for each dressings' nurse:
 - packaging zone for operating theatre containers;
 - packaging zone for different pouches;
 - temporary storage zone for packed MDs.
 - packaging zone for sterilisers;
 - computer workstation for tracking.
- If applicable, a zone for packing linen:
 - zone for incoming linen;
 - zone for inspection and folding of linen;
 - zone for packing linen (this must be separate from the zone used for linen folding and inspection).

Regulation on which based:

Good Hospital Pharmacy Practices (B.P.P.H.) (1)

There must not be any water outlet (the water outlet must be in the sluice).

If the drying performance of the double-door washer-disinfector is insufficient, drying can be completed within an enclosed area at the washer-disinfector exit to avoid the spread of humidity within the packaging zone. This area must be equipped with a draining board with a compressed air pistol. The MDs must be inspected before they are transferred to the packing side.

It must be remembered that the exhaust zone is a noisy zone.

This zone must conform to ISO Class 8 of standard EN ISO 14644-1 (1).

- To meet the performances specified by ISO Class 8 an appropriate filtration system is needed with an air renewal rate between 15 and 20 volumes/hour;
- The positive pressure in a "clean" area vs a contiguous "less clean" area must not be less than 15 pascals.

3.3.1 The zone for functional testing of medical devices before packing

Aim:

- to check the functional capabilities of MDs before assembly of different containers;
- to eliminate defective MDs, enabling them to be replaced by functional devices;
- to replace damaged or non-functional MDs by new devices (according to the organisational structure).

Regulation on which based:

Good Hospital Pharmacy Practices (B.P.P.H.) (1)

3.3.1.1 Equipment required

A modified workstation.

A magnifying glass must be available for microsurgical instruments (magnifying glass: $\times 3$ or 3 dioptries [2]).

The use of a microscope can also be recommended ($\times 3$ binoculars) to inspect the microsurgical instruments.

- The workstations have the following dimensions, depending on the respective supplier:

L = 1200 or 1800 or 2400 mm, w = 700 mm, h = 900 mm;

L = 500 to 2900 mm, h = 850 or 900 mm.

3.3.1.2 Optimal surface area

An adequate surface area to permit functional testing of MDs.

3.3.2 The linen packaging zone

While surgical linen is being used less and less, an area must nonetheless be allotted for this task to meet, if necessary, all specific needs of the various departments.

It is used primarily for linen sterilisation tasks, for example, for patients in the sterile zone (patient in a bubble for immunosuppressive chemotherapy).

Linen is packed in an area reserved to that effect, which is insulated from the

remainder of the zone devoted to packing MDs and enclosed to avoid the spread of textile particles generated at the time of linen inspection and folding. This area shall be under negative pressure vs the packing area.

Aim:

To reprocess clean linen for sterilisation for all patient-care activities calling for sterile linen.

Since handling of linen gives rise to pronounced generation of particles, it would be best to make provision for an area specially reserved for folding linen (inspection, fluff removal) and another for packing it. The zone shall therefore be divided into two parts to permit observance of the principle of "forward movement" and avoid recontamination of packed linen.

Hence the linen packaging zone shall be divided into two parts:

- one part of the zone for inspection and folding of linen which shall be at ambient pressure;
- another part of the zone for packing folded linen which shall be under positive pressure: Σ this zone will be under a positive pressure of 15 pascals vs to the preceding zone to prevent contamination of the MD packaging zone, which shall be under a maximum positive pressure of 30 pascals.

It must be borne in mind that the aim is to eliminate this zone and to switch over as soon as possible to non-woven surgical fabrics.

Operations inherent to this zone:

- receipt of incoming consumables;
- receipt of orders for linen from the laundry in closed trolleys;
- linen reprocessing: visual inspection (holes, soils), removal of fluff from cotton linen (with an adhesive brush), folding;
- packing linen in a pouch or double film;
- stocking and inspection of packed lined ready for sterilisation, constituting the stock of "packed linen to be sterilised";
- transfer of linen to the packaging zone to be autoclaved;
- preparation of orders before delivery to the steriliser-loading zone;
- tracking of incoming linen until the time of sterile storage or distribution.

This zone shall be separate from the MD packaging zone.

Sterilised linen shall be stored with sterile MDs.

Reference source on which based:

The Permanent Working Group for Study of Markets (G.P.E.M./S.L.) (2)

3.3.2.1 Equipment required

Clean linen coming from either the laundry or from an external reprocessor shall be transported in laundry cabinets whose content will be unloaded in an area reserved for that purpose and which allows the linen to be transferred on internal trolleys to the CSSD. This avoids direct entry from outside into the protected MD packaging zone (ISO Class 8 clean zone).

Communication with the steriliser-loading zone shall be effected, after packing and sealing, via a gate (if possible with a double door, otherwise transfer shall take place after having carried out all packing operations).

A zone for storage of pouches for packing, a workstation (its minimum surface area must be 10 m², apart from storage of the soldering machine, and will depend on the volume of linen sterilised), equipped with one or several soldering machines for sealing pouches as well as with a computer workstation for tracking.

3.3.2.2 Optimal surface area

The surface area will depend on what is packed and on the volume of linen to be sterilised.

3.3.3 The medical devices' packaging zone

Aim:

To pack the MDs to be sterilised so that the sterile state achieved in the steriliser can be preserved.

Operations inherent to this zone:

- provision of a supply of consumable products;
- receipt of incoming cleaned MDs;
- inspection;
- assembly of trays and containers and packing;
- specific preparatory tasks for certain types of packing;
- temporary storage of packed MDs:
 - containers;
 - the MDs are placed in mesh trays and then on supports to configure the loads in preparation for sterilisation

- loading of sterilisers;
- tracking of activities from receipt of incoming MDs to sterile storage or distribution.

The wrappers must be removed from the items needed for packing before they enter the packaging zone and these wrappers must be disposed of on the outside, without entering the protected zone.

Regulation on which based:

Good Hospital Pharmacy Practices (B.P.P.H.) (1) for the particulate contamination class and for microbiological contamination.

3.3.3.1 Equipment required

Adequate workstation.

- The workstations have the following dimensions, depending on the respective supplier:

L = 1200 or 1800 or 2400 mm, w = 700 mm, h = 900 mm;

L = 1450 mm, w = 750 mm, h = 900 mm;

L = 850 mm, w = 750 mm, h = 900 mm;

L = 750 or 1250 or 1500 mm, w = 600 mm, h = 900 mm;

L = 1250 or 1500 or 1800 mm, w = 750 mm, h = 900 mm;

L = 1000 to 2400 mm, w = 700 mm, h = 900 mm.

Zone for storage of sterilisation pouches, non-woven crêpe foil, sheaths without cartons.

- The supports used for non-woven crêpe foil will have the following dimensions, depending on the respective supplier:

L = 1200 mm, w = 640 mm, h = 800 mm;

L = 1270 mm, w = 650 mm, h = 995 mm;

L = 1360 mm, w = 570 mm, h = 990 mm.

The consumables required shall be restocked daily to allow for proper cleaning of surfaces apart from the floors. This will be done from the storage zone situated in the annexes and avoids having cartons enter the packaging zone.

Enough space shall be allotted for the soldering machines needed to seal the different sterilisation pouches.

- The tables used for the soldering machine have the following dimensions:

L = 1050 to 1280 mm, w = 630 mm, h = 900 mm.

The height of all this equipment is important because it shall be one of the chief determinants of ergonomic working practices.

3.3.3.2 Optimal surface area

This will depend on the activity carried out here and it must be sufficiently large

to enable a distinction to be made between the MDs coming from the various departments (so as to avoid errors, leading to claims), functional testing of medical devices and packaging under appropriate conditions.

3.3.4 The containers' packaging zone

Aim:

- to assemble the various containers after carrying out functional testing of the different MDs;
- to affix the different consumables (filter, label, safety seal, ...) providing for identification, tracking and preservation of the sterile state;
- to select the appropriate sterilisation cycle.

Reference source on which based:

The Permanent Working Group for Study of Markets (G.P.E.M./S.L.) (2)

It shall be equipped with:

- a sufficiently large workstation to enable assembly of the different containers.
- supports for the documents relating to container repairs, supports for filters, labels and safety seals for the containers. These supports must be placed on or affixed to the tables and preferably to the walls.

3.3.5 The steriliser-loading zone

Aim:

- to assure appropriate conditions for reprocessing the MDs to be sterilised;
- to prepare homogeneous loads for sterilisation;
- to distribute the MDs to be sterilised within the steriliser; this is done with the aid of loading trolleys.

If a computerised tracking system is used, a PC terminal must be provided.

To reduce noise and avoid heat diffusion, a technical wall must be installed to insulate the sterilisers.

3.3.5.1 Equipment required

Double-door sterilisers that are loaded on the packing side and unloaded on the sterile side. Make additional provision for:

- a further steriliser if required;
- another steriliser using a different sterilisation process (gas plasma, for example) governed by identical architectural constraints;

- make provision for installation of a new process able to tolerate the constraints inherent to steam sterilisation.

System for generation of osmosed water (preferably) needed for the sterilisers and washer-disinfectors. It shall be situated as close as possible to these machines and acoustically insulated (enclosed area that can be accessed by the engineering services from the outside without entering the CSSD itself).

The trolleys for loading the sterilisers have the following dimensions, depending on the respective supplier (the height is determined by the position of the steriliser door):

- 900 mm x 500 mm;
- 1200 mm x 500 mm;
- 900 mm x 700 mm;
- 1200 mm x 700 mm.

Enough space must be left for positioning and manoeuvring the loading trolleys (automatic loading trolleys occupy a large space).

3.3.5.2 Optimal surface area

Attention must be paid to this loading zone to assure easy movement of trolleys for loading/unloading of sterilisers and washer-disinfectors. Provision must be made for a zone that is free of any pillars that could impede manoeuvring of the trolleys.

3.4 The sterilised medical devices' exit zone

Aim:

- to allow the sterile load to cool down completely;
- to assure the integrity of all packaging following sterilisation and preserve the sterile state conferred by the sterilisation cycle;
- to verify the sterilisation cycle and validate the load sterilised;
- to record the validated loads and assure tracking.

This zone should be divided into two parts:

- a sterilised MD exit zone preferably ISO Class 8:
 - steriliser exit zone;
 - zone for verification of sterilisation and tracking;
 - computer workstation with a printer for tracking;
 - zone for storage of sterile MDs kept as stock within the CSSD.

- a storage zone before dispatch towards the intended department:

- if this zone is different from that of the steriliser exit and physically separate, ISO Class 8 not required.

Direct passage without a sluice is permitted between the packaging zone and unloading zone. In such a case, the surface area allotted to the unloading zone shall be reduced to its minimum so as not to increase the air treatment costs required for preservation of ISO Class 8.

This passage will allow return of the sterilisation trays for loading the sterilisers on the packaging side and will, in particular, permit easy circulation of the staff entrusted with loading, unloading and validating the loads because often the same persons are deployed to these different workstations.

It is advisable that ISO Class 8 conditions be maintained in the steriliser exit area because it has been proven that this area poses a risk of recontamination of the sterilised load during the cooling down phase. In view of the fact that the load is withdrawn from the autoclave at a temperature of 80 °C, the difference in temperature gives rise to a pressure differential and, in turn, to air flow (potentially with microorganisms) from within the room into the interior of the sterilised packaging (20).

Attention must be paid to the air vents (especially if the below-ceiling height is less than 2.80 m), something that should not happen in the steriliser exit area in view of the risk of abrupt cooling down of the load, giving rise to condensate formation and posing a risk of rupture of pouch seals.

Note: Special attention must be paid to the temperature and humidity (G.P.E.M./S.L. page 52) (2):

- the temperature must be maintained at around 20 °C + 5 – 2 ;
- the relative ambient humidity must be maintained between 40 and 75%.

Provision must be made for an air extraction system and for a central capacity able to cool down the hot air supply and vapour.

3.4.1 Equipment required

This zone shall allow cooling down of the load before verification. It shall be equipped with:

- trolleys for automated or non-automated loading;

- workstations;
- storage shelves;
- zone for tracking (computerised or manual, PC terminal).

3.4.2 Optimal surface area

The surface area shall be enough to:

- permit movement of the unloading trolleys (the unloading trolleys face the same impediments as the loading trolleys used in the packaging zone)
- assure verification of a successful sterilisation outcome for the various constituents of the load as well as their labelling and tracking.

This surface area shall be determined on the basis of the number of cabinets that can be stored therein during a defined period of time.

3.5 The sterilised medical devices' storage zone

Aim:

- to permit storage of sterilised MDs before they are distributed to the different departments;
- to permit preservation of sterility in the long term;
- to permit management of the stock of sterile supplies in series (patient-care sets, linen, ...);
- to permit loading of different transport cabinets;
- to assure distribution of the sterilised MDs to the users.

The "sterile storage" zone comprises:

- the zone for storage of the MD distribution basins;
- the zone for temporary storage of urgently needed supplies.

If the sterile storage zone is not a dedicated part of the steriliser exit zone, it will not be possible to circulate freely between the packaging zone, unloading zone and sterile storage zone. By paying careful attention and taking appropriate measures, the risk of recontamination while the supplies are cooling down can be averted.

3.5.1 Equipment required

This should be an enclosed zone providing for storage of sterilised MDs under conditions which must not have any impact on preservation of the sterile state conferred by the sterilisation process.

This zone shall be protected against sunlight, in particular against direct sunlight, heat and humidity. It shall be equipped with:

- hanging baskets or cabinets for storage of sterile MDs kept within the CSSD;
- a storage zone for dispatch of cabinets waiting to be loaded;
- tray supports with a ground base fitting having the following dimensions, depending on the respective supplier:

600 mm x 600 mm, h = 1030 or 1410 mm;

600 mm x 800 mm, h = 1030 or 1410 mm;

600 mm x 1200 mm, h = 1030 or 1410 mm;

800 mm x 1200 mm, h = 1030 or 1410 mm;

480 mm x 600 mm, h = 1030 or 1410 mm;

620 mm x 605 mm, h = 1060 mm;

675 mm x 605 mm, h = 1060 or 1460 or 1620 mm;

590 mm x 480 mm, h = 1460 mm;

630 mm x 515 mm, h = 1460 mm;

590 mm x 800 mm, h = 1460 mm;

630 mm x 840 mm, h = 1460 mm.

- the distribution trolleys have the following dimensions:

L = 950 mm, w = 530 to 720 mm, h = 1050 to 1850 mm ;

L = 680 to 1280 mm, w 430 to 630 mm, h = 900 to 1700 mm.

- the storage shelves have the following dimensions:

L = 680 mm, w = 430 mm, h = 1700 mm;

L = 980 mm, w = 430 or 630 mm, h = 1700 mm;

L = 1280 mm, w = 430 or 630 mm, h = 1700 mm;

L = 1000 or 1200 or 1400 mm, w = 500 or 600 mm, h = 1200 or 1400 or 1600 or 1800 or 2000 mm;

L = 600 or 800 or 900 or 1000 or 1200 or 1400 or 1500 mm, w = 300 or 400 or 500 or 600 mm, h = 1200 or 1400 or 1600 or 1800 or 2000 mm;

L = 700 or 1000 or 1300 mm, w = 500 or 600 mm, h = 1000 or 1700 or 2200 mm.

This zone shall also be the zone where trolleys and cabinets are loaded for distribution to the patient-care departments and operating theatres.

3.5.2 Optimal surface area

If there are no plans to store supplies within the CSSD, this will be used for storing transport trolleys before distribution and its surface area will be reduced accordingly.

3.6 Annex zones

One must try not to increase the number of rooms within any zone. All annex zones should have the following:

- changing room;
- recreation zone;
- offices.

- storage zone for various types of packaging and other consumables;
- zone for receipt and inspection of incoming ancillary items (in accordance with organisational structures within the specific establishment);
- zone for water treatment if using special osmosed water for the CSSD;
- zone for storage of specific maintenance tools used in the CSSD (stepladder, ...). The tools needed for maintenance shall be managed by the engineering department. They must be properly cleaned before use when first introduced into the CSSD;
- zone for storage of quarantined medical devices (5);
- zone for storage of housekeeping materials.

Attention must be paid to where the annex zones are located and integrated so as not to violate the critical conditions prevailing within the clean zones. Pressure and output systems, access and communication facilities (in particular the sluices, communication panels and interphones), airtightness of sheaths (especially of the junctions between the structural elements, the routes taken for equipment casings or constraints imposed by connections) must be designed such that there is no cross-contamination.

3.6.1 The changing room

Aim:

- to allow each CSSD employee to wear the clothing specific to the working zone to which he/she is assigned;
- to permit storage of personal belongings in a locker that can be locked with a key;
- to enable the various visitors or technicians, too, to change into clothing compatible with the different working zones (including to wear clogs that conform to safety standards and can be washed in a washer-disinfector).

The dressing room must separate incoming and outgoing staff. The entrance and exit must:

- use either spatially separated circuits;
- or entry and exit of persons must take place at different times.

Desirable layout:

Each staff member must dispose of a standard locker that can be locked with a key,

where he/she can place personal objects while present in the CSSD (a locker with separation of everyday/working clothing).

Occupational legislation stipulates that showers and toilets be provided for handicapped persons and that separate changing rooms be available for men and women.

To facilitate organisational structures within the CSSD and avoid infringement of the principle of forward movement, we propose the following:

- a changing room on the cleaning side (changing rooms for the "non-clean" zone);
- changing room on the packing side – sterile exit (changing room for the "clean" zone).

In this case, it is advisable that provision be made for the following:

- an organisational form or separation that allows for male and female changing rooms;
- double-access entrance with:
 - a direct entrance for staff into each of these changing rooms from the main entrance hall;
 - an entrance granting access into each of these two zones separate from the CSSD: "precleaning" and "postcleaning" zones;
 - division into an "everyday clothing" and "OR clothing" sectors; Σ the separation between these two "everyday clothing" and "OR clothing" sectors could be implemented by means of a ground marking or a bench permitting passage from one sector to another while changing overshoes or using appropriate clogs.
- a double-access exit based on the same principle as that used for entry;
- a system that prevents going backwards (door that opens only from one side).

Since different environmental constraints and requirements, as well as their implementation, apply for the "precleaning" and "postcleaning" zones, the changing rooms will be organised differently if we have two changing rooms as our disposal, i.e. one for the non-clean and one for the clean zone.

The changing rooms on the non-clean side, i.e. pre-cleaning zone, will not need a sluice since, in particular, the pressure

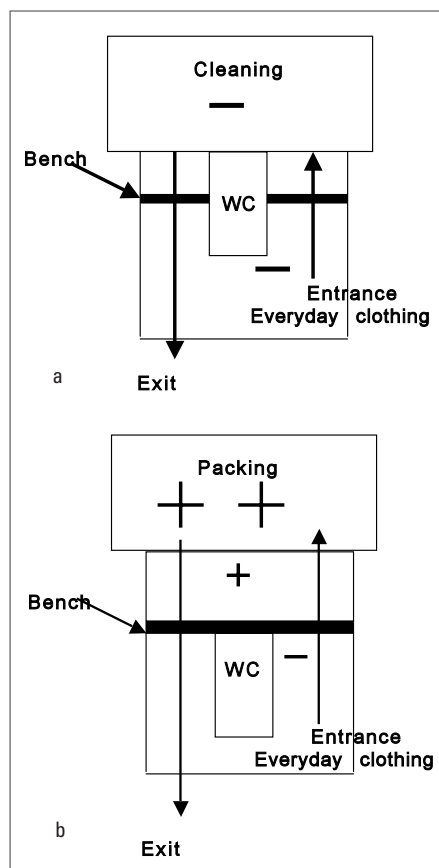


Fig. 5a: Changing room in non-clean or "precleaning" zone

Fig. 5b: Changing room in clean or "postcleaning" zones

conditions are identical in both sections of the changing room.

Above is a schematic drawing of a potential layout of two changing rooms (Fig. 5 a and b).

Changing room in non-clean or "precleaning" zone:

The toilets are accessed via the sluice so as to continue to observe the principle of forward movement.

The entrance side of the changing room:

- will allow every staff member to don the clothing specific to his/her working zone;
- shall be equipped with mobile supports for storage and provision of OR clothing, headgear, orofacial masks, protective apron, gloves;
- shall be equipped with enough sets of clothing to assure proper dress and fa-

ilities to change into the clothing prescribed for the following zones: cleaning, packaging and sterile exit zones, ...;

- shall be equipped with a non-manual handwashing facility, soap dispensers and disposable handtowels conforming to hygiene regulations.

The exit side of the changing room:

- shall be equipped with bags to collect used clothing before dispatch to the internal or external laundry;
- shall be equipped with bins to accommodate headdress and other disposable items (overshoes, ...) needed for clothing specific to the respective working zone.

Regulation on which based:

Good Hospital Pharmacy Practices (B.P.P.H.) (1)

3.6.1.1 Technical characteristics of the changing room

The changing room must be situated as close as possible to the entrance to the CSSD as well as to the zone in which the staff member concerned is going to work.

It must be situated in the final phase of the ventilation circuit. The following could be contemplated:

- separate male/female changing rooms;
 - unisex changing room with a separate undressing section in accordance with the composition of the CSSD personnel and the recommendations of the Committee for Hygiene, Safety and Occupational Conditions (C.H.S.C.T).
- The dressing room will be equipped with:
- standardised individual lockers for each sterilisation assistant;
 - shower and toilets;
 - mobile equipment with clothing and accessories;
 - clog supports specific to the CSSD (otherwise, overshoes provided).

3.6.1.2 Optimal surface area

Minimal surface area of 10 m² for a team of 6 persons.

An extra surface area of 1 m² for each additional sterilisation assistant could be considered.

3.6.2 The recreation zone

Aim:

The CSSD is an enclosed department in which conflicts can arise very quickly and

a recreation zone is absolutely indispensable.

Provision must be made for such a recreation zone to allow staff to take a coffee break during the working day. This zone must not be used for eating (self-service) but should be seen as being an administrative zone. It could also be used for staff training, with facilities for slides, films, etc. if the CSSD does not have a meeting room.

This zone is situated outside the actual working zone and must, under no circumstances, be entered wearing ISO Class 8 clothing.

Provision must be made for an air extraction system. This room must be ventilated and located in the terminal ventilation phase (tobacco odour, ...)

An organisational form shall be proposed in accordance with the internal structures of the healthcare establishment to enable staff to smoke during their breaks.

Regulation on which based:

Good Hospital Pharmacy Practices (B.P.P.H.) (1)

3.6.2.1 Equipment required

Tables, enough comfortable chairs, electric coffeemaker, ..., a white wall for slides whenever needed for staff training, power points and IT connections.

The surfaces and floors must be amenable to cleaning. If a carpet is desired in this recreation zone, a polypropylene carpet of good quality should be chosen.

A water outlet (sink with drain).

3.6.2.2 Optimal surface area

The minimum surface area of this room should be 10 m² for 6 staff members.

Beyond that, an additional surface area of 0.5 m² per CSSD staff member is needed.

If staff are trained here, the surface area must be increased to allow for appropriate projection of slides.

3.6.3 Offices

Aim:

They are allocated to the pharmacist and manager responsible for the CSSD. This zone is used to receive medical delegates and various clients. It is also a zone for administrative tasks, management of staff, processing of orders, analysis of activi-

ties and it must be equipped with computer facilities.

This room will also allow interim archival of ongoing data before they are transferred to the establishment's central archive.

Visitors and representatives must be able meet the pharmacist or CSSD manager without having to use the changing room, apart from those who come to visit the CSSD or to service equipment.

Desired layout:

They will be located at the entrance to the CSSD before the technical zones so as not to oblige the persons who do not need to enter the CSSD to don the prescribed clothing.

They must have the necessary connections for telephones, fax machines, computers and the internet.

Depending on the scope of the CSSD, 1 or several offices may be needed (head of department, manager ...)

The manager's office must have a direct view of the following: reception, sorting, cleaning and packaging zones.

However, it should not have a door with direct access to these zones, relying instead on free hands telephone contact.

The upper sections of the walls should be made of glass panels. A curtain or horizontal venetian blinds between two glass panels could provide for visual insulation of the office, if necessary.

Regulation on which based:

The legislation governing the archives is set out essentially in Act No. 79-18 of 3 January 1979. The conditions for application of this act are defined in Decrees No. 79-1037, No. 79-1038 and No. 79-1039 of 3 December 1979.

The Good Hospital Pharmacy Practices point out that the sterilisation documentation must be preserved for 5 years and must assure tracking of the process (1). This documentation shall be archived in a dedicated area or room.

3.6.3.1 Equipment required

Each office shall be equipped with a desk, chairs or armchairs, computer terminal (computer workstation that allows surveillance of different tracking activities as well as of interactions with other departments and the main switchboard.

3.6.3.2 Optimal surface area

The minimal surface shall be between 12 and 15 m² per office.

Attention must be paid to maintenance. PVC floors appear to be the preferred choice.

3.6.4 Zone for storage of various types of packaging

Aim:

- To permit storage of the different types of packaging and consumables needed for packing MDs in the CSSD (pouches, sheaths, non-woven crêpe foil, extra containers) before they are dispatched to the packaging zone.
- To assure receipt of deliveries and check that what is ordered is what is delivered, as well as management of stocks.
- To permit, if necessary, incoming deliveries of loaned ancillaries devices and their inspection before they are sent for cleaning, storage of cartons to be returned to the original supplier by the transport company (7).
- To permit, likewise, storage of non-sterile MDs to replace defective or implanted devices (screws, rods, ...). New MDs which must undergo reinforced cleaning processes must be identified before being placed in a container.

Locations:

This zone for storage of packaging may be located close to the cleaning zone but this calls for much discipline as regards the circuits used for personnel and transport of cartons between the storage zone and the place where waste is stored within the healthcare establishment.

It must be situated upstream of the zone used to clean the MDs to be sterilised so as to avoid the introduction of soils into the packaging and sterile exit zones by cartons that had been transported in various lorries which might have been used to transport soiled MDs.

Reference source on which based:

The Permanent Working Group for Study of Markets (G.P.E.M./S.L.) (2).

The convention and contract regulating loaned ancillary equipment and implants, respectively (7)

3.6.4.1 Equipment required

This zone shall be equipped with tables and shelves.

If the stocks of the various types of packaging are managed by the CSSD, a

computer workstation should be provided for management of incoming supplies.

A surface must be made available for management of stocks on a daily basis.

Different drawers shall be provided for accommodating and identifying new MDs (possibly with a list of minimum orders). This will constitute the stock of spare MDs.

3.6.4.2 Optimal surface area

This zone can be divided into three parts:

- one for storage of sterilisation packaging and of presdisinfectant and detergent products;
- one for receipt of new incoming MDs and for their inspection and storage;
- one for receipt and inspection of loaned ancillary devices.

Its surface will depend on the activities undertaken, on the type of surgery (orthopaedics, visceral, gynaecology, ...) as well as on the number of surgical procedures carried out:

- minimum of 6 m² for storage of sterilisation packaging:
 - with shelves to accommodate supplies.
- a surface area of 10 m² per steriliser could be recommended if the CSSD is not using containers:
 - this surface area could be reduced to 6 m² if the CSSD is using containers for the operating theatres.
- if loaned ancillary devices are used the surface area allotted for receipt and inspection of these ancillaries supplies should be a minimum of 8 m²:
 - a working surface (table) shall be made available for inspection;
 - depending on the turnaround of ancillary devices, a surface area of 3 m² per ancillary device per day.

This zone may also make provision for a zone for quarantining MDs, while awaiting implementation of the NCTA procedure (5). This shall be a dedicated zone because it relates to MDs that have been used and could be potentially contaminated.

3.6.5 Housekeeping zone

Aim:

To permit storage of the different materials needed for cleaning surfaces, apart from floors, within the CSSD.

As far as possible, there should be two housekeeping units (one for the clean

area and one for the non-clean area); otherwise one could have two different trolleys: one for the clean zone and one for the non-clean zone to avoid the risk of failure to comply with the circuits imposed.

Organisation:

To ensure observance of the principle of forward movement, this zone shall be composed of two parts:

- a housekeeping unit for the clean section:
 - this shall serve the packaging and sterile storage zones and shall therefore be situated in close proximity to these zones.
- a housekeeping unit for the non-clean section:
 - it will serve the cleaning zone and administrative zone.

Reference source on which based:

The Permanent Working Group for Study of Markets (G.P.E.M./S.L.) (2)

3.6.5.1 Equipment required

Each of these units shall be equipped with the material needed to carry out housekeeping tasks within the respective zone (housekeeping trolley, housekeeping equipment, ...) and with storage surfaces.

Each unit shall be equipped with a facility to drain waste water. This should measure 600 mm x 700 mm x 600 mm.

3.6.5.2 Optimal surface area

A useful surface area of 5 m² for storage of cleaning materials (trolley, ...), detergents and disinfectants could be considered.

3.6.6 Archival zone

Aim:

- to facilitate review of the sterilisation activities over the past months;
- to assure archival of tracking documentation which must now be archived for 5 years.

Regulation on which based:

Good Hospital Pharmacy Practices (B.P.P.H.) (1)

3.6.6.1 Equipment required

This zone shall be equipped with shelves and cabinets for accommodation and storage of archives.

200 or fewer MSO beds	200 to 300 MSO beds	300 to 400 MSO beds	More than 400 MSO beds
200 m ² useful	Useful area of 1.5 m ² /bed	Useful area of 1.2 m ² /bed	Useful area of 1 m ² /bed
260 m ² net	Net surface area of 1.95 m ² /bed	Net surface area of 1.56 m ² /bed	Net surface area of 1.3 m ² /bed

Table 1: Surface areas proposed based on number of MSO beds

Reception	Sorting – Cleaning	Packing	Spare sterile supplies	Annex zones
10% of the surface area	25% of the surface area	35% of the surface area	20% of the surface area	10% of the surface area

Table 2: Distribution of surface areas within the CSSD

A network installation could be contemplated so as to be able to avail of an archival system for the entire establishment. The CSSD could then confine itself to one-year archival of its activities.

3.6.6.2 Optimal surface area

This surface area must be able to accommodate the activities unfolding over a one-year period, with provision made for sufficient shelves.

3.6.7 The sluices between the different zones
Aim:

- to permit changing of clothes and hand-washing when passing from one zone of activity to another;
- to permit, likewise, maintenance of pressure differences between the different zones;
- to guarantee the integrity of the clean zone at the time of entry and exit.

Measures must be taken to ensure that the sluice entrance and exit doors are not open at the same time.

The sluices shall represent an organisational constraint and should be kept to a minimum. It would be better to reflect on how to ensure good organisation of staff and circuits so as not to infringe the principle of forward movement.

Reference source on which based:

The Permanent Working Group for Study of Markets (G.P.E.M./S.L.) (2)

3.6.7.1 Equipment required

Sluice between the different zones with a facility for manual cleaning identical to those in the changing rooms.

Equipped with a washbasin, wastebin (for handtowels, facility for clogs, if clogs

of a different colour are prescribed for each zone

They are also equipped with overblouses, overshoes, headdress and orofacial masks.

3.6.7.2 Optimal surface area

A surface area of between 2 and 3 m² might suffice to properly equip a sluice.

3.6.8 Technical premises

These premises can be used to insulate all technical areas, enabling smooth functioning of the CSSD.

Access to these premises by the establishment's engineering departments must be from the outside the CSSD so as not to give rise to contamination while work is being carried out in the CSSD. As far as possible, engineering services' access should be avoided in the packaging zone and sterile exit zone, preferably granting access in a "neutral" zone.

These contain electrical fittings, zones for the connections for incoming compressed air, technical premises for osmosis equipment, ...

4. Summary of surface areas and pressure values

Surface areas:

Based on the number of MSO beds, the following surface areas are proposed (Table 1). Hence surface areas within the CSSD itself shall be distributed as follows (Table 2).

Conditions for obtaining Class 8 of standard EN ISO 14644-1:

Adequate filtration:

- minimum 95% DOP

Air renewal rate in the packaging zone and sterile exit zone:

- minimum 15 volumes/hour;
- preferably 20 volumes/hour.

A pressure gradient must be created between the different zones; pressure values will be distributed as lined out in Table 3.

The maximum positive pressure between the "clean" and "non-clean" zones shall be 30 pascals.

The positive pressure between the "clean" and an "intermediate" zone shall be 15 pascals.

Positive pressure is legally mandated only in the packaging zone.

Limitations of ISO Class 8 of standard EN ISO 14644-1 "at rest": Table 4

Recommendations for microbiological surveillance "during working periods": Table 5

Maximum positive pressure	Positive pressure	Atmospheric pressure
Packaging	Linen packaging	Reception, Laundry sorting
Autoclave exit	Storage	Cleaning
	Sluice	Changing room
		Annex zones

Table 3: Pressure values in different areas

Max number of particles authorised per m ³ air	Particles measuring or more than 0.5 µm: 3 520 000
	Particles measuring or more than 1 µm: 832 000
	Particles measuring or more than 5 µm: 29 300

Table 4: Limitations of ISO Class 8

Recommended limit of microbiological contamination	Air sample cfu/m ³ : 200
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Table 5: Recommendations for microbiological surveillance "during working periods"

5. Organisational schema for a CSSD

In view of the diverse nature of CSSDs, we did not wish to propose a uniform CSSD policy, opting instead for an organisational schema that should enable each department to incorporate the essential elements needed. This schema comprises two circuits (see Section 2.3, Figure 6):

- a circuit for cleaning the MDs to be re-processed, thus being a "non-clean" zone;
- a long circuit for sterilisation per se of these MDs, thus being a "clean" zone

The annex zones shall be distributed within the CSSD so that they are close to the zone to which they are allocated and, also, so as not to interrupt the environmental classes. *

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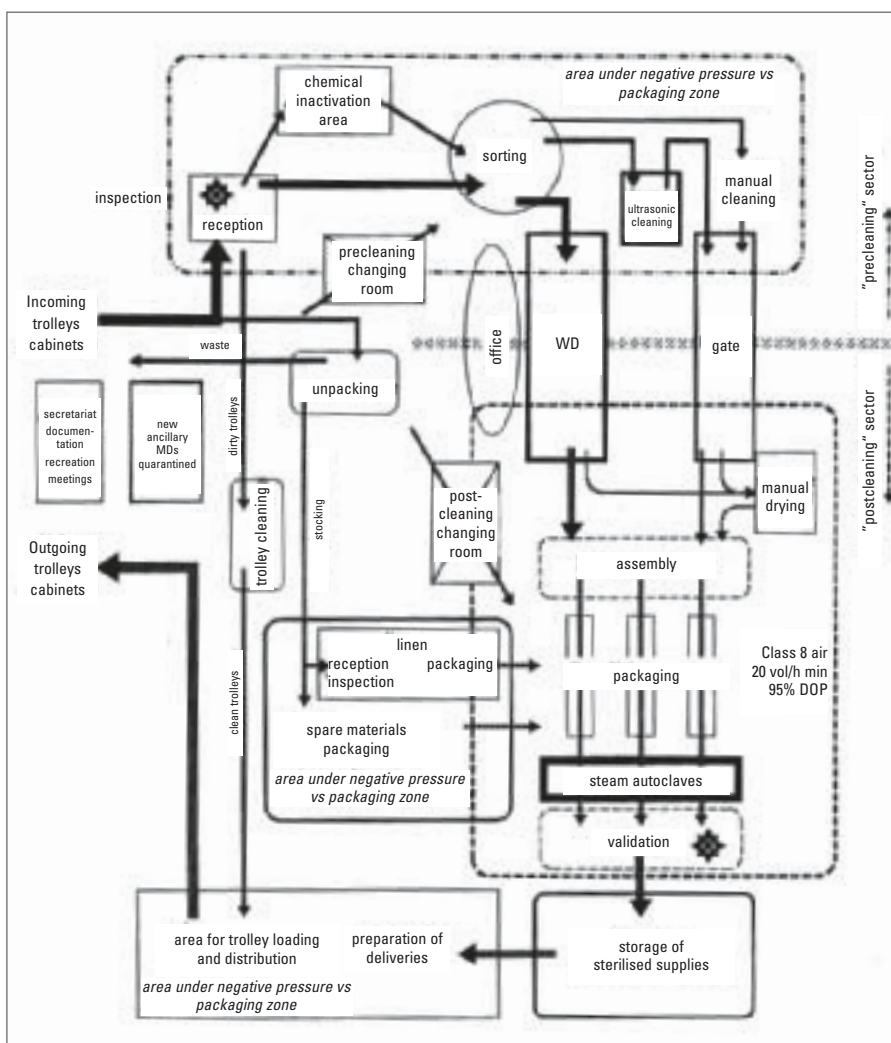


Fig. 6: Organisational schema for a CSSD

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