ZENTRAL STERILISATION 3

Keywords
- sterilisation
- CSSD
- architecture

Architecture and Sterilisation Premises

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This document is the fruit of a joint collaboration between members of the French Sterilisation Association (AFS) whose goal was to find answers to questions about architectural organisation which anyone in charge of, or employed in, the Central Sterile Supply Department (CSSD) could ask themselves. It is a proposal for rational organisation of sterilisation in the light of regulatory constraints.

This study aims to enhance the sterilisation environment, while making provision for "forward movement" and for tracking of the medical devices (MDs) to be sterilised. Our study is confined to steam sterilisation.

This document is not a review of sterilisation procedures but rather is intended as a guide to organising the CSSD in respect of the different architectural constraints that can be encountered. Nor is it a list of suppliers or manufacturers.

1. General principles governing architecture and sterilisation premises

The architecture of the CSSD premises must as far as possible permit the principle of forward movement (2), i.e. to proceed from the dirtiest towards the cleanest area so as to minimise the risks of contamination and confusion.

The design and layout of the premises must take this into account and be rational and tailored to the quality demands of the tasks carried out. The different stages of working procedures must unfold within premises that are linked to each other in a rational order that corresponds to the progression of activities.

As such, the MDs shall embark on a pathway that renders going backwards impossible such that contamination of the clean devices through passage through a dirty zone is ruled out.

Moreover, it must take into consideration the possibility of expanding working activities.

The Good Sterilisation Practices (B.P.S.) (2) as well as the Good Hospital Pharmacy Practices (B.P.P.H.) (1) refer to different sectors within the CSSD but we prefer to use the term "zone": cleaning zone, packaging zone and sterile exit zone. Each of these zones may comprise different elements but each zone will enable tracking of a MD within the CSSD, the aim being to provide for its trajectory from a "contaminated" towards a "sterile packaged" area.

Each zone (wash, packaging and sterile exit) will be studied separately in order to identify the requirements of each of them: design, functionality, environment and control measures.

We are now going to:

– Define each task per zone;
– Identify the activities carried out;
– Define the layout of each room with respect to its compliance with forward movement (i.e. the different points of access);
– Estimate the surface areas needed;
– Define the equipment needed;
– Examine special constraints.

It must be borne in mind that CSSD staff should observe hygiene requirements and the circuits defined within that department, so as to take account of organisation of the procedures carried out therein.

For example, a specific type of dress shall be designated for each zone and movement from a dirty zone to a clean zone in the same clothing shall be avoided.

Likewise, those staff members recruited must be qualified, interested and motivated and accept the constraints imposed by hospital hygiene as well as those relating to the quality assurance of the process.

The activities of the CSSD are linked to the inhouse pharmacy (1) of a healthcare establishment. Hence, they are carried out under the supervision of the head pharmacist of the inhouse pharmacy (pursuant to a notice by the Medical Commission of the Establishment (Commission Médicale d'Etablissement – C.M.E.) and of the Board of Governors (Conseil d'Administration – C.A.). The quality assurance officer is appointed by the director of the establishment (9).

In its capacity of healthcare service provider, the CSSD must provide its clients with sterile MDs and must therefore dispose of a transport system that provides for achieving and maintaining this sterile state during transport.

To reach this goal of creating sterile MDs, the CSSD must at times meet conflicting requirements:

– The principle of "forward movement" and the direction of movement of CSSD staff could favour unidirectional doors or sluices (within the confines imposed by fire safety regulations);

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– The premises must be properly lit and ventilated, and kept at a controlled temperature, yet no opening towards the outside is desirable.

To facilitate environmental control, one could recommend opting for different colour dress tailored to the respective working zone, installation of an ergonomic interphone system between the various zones, selection of furniture on wheels and of surfaces that lend themselves to biocleaning.

The CSSD shall be designed to take account of the general tasks performed therein and of the establishment's needs on the basis of an analysis of the demands of the respective site and of the services to be rendered (establishment project, client-supplier contracts).

2. Study of constraints

2.1 Description of sterilisation

2.1.1 Tasks carried out by a Central Sterile Supply Department

Tasks carried out by a CSSD (1):

MDs are reprocessed to render them sterile and thus rule out any risk of infection arising from them. Sterility denotes the absence of all viable microorganisms. In order for a MD that has undergone sterilisation to be labelled as "sterile", the theoretical probability that a viable microorganism is present must be less than or equal to 1 per 10^6.

The decontamination stages preceding sterilisation are aimed at reducing all forms of microbial, chemical and particulate contamination.

Inactivation of non-conventional transmissible agents (NCTAs) calls for specific treatment.

The sterility of a MD is determined by the sum of the procedures needed to achieve and maintain the sterile state of this MD.

2.1.1.1 Activities of the Central Sterile Supply Department

The supplies sterilised include containers, patient-care trays, surgical instruments, laundry and dressings. As far as possible efforts must be made to opt for single use if the technical performances assured are identical.

Successful implementation of these important services rendered by the CSSD entails both presterilisation (purchases, receipt of predisinfected supplies, manual or automated cleaning, packing, …) and poststerilisation tasks (batch validation, storage, dispensation, management analysis …). This activity is directed exclusively towards the surgical department and the care of inpatients. However, it may in the future be made available to other healthcare establishments that do not have a CSSD of their own, or also at a future date to independent professions (provided that the legislation will permit this), based on an agreement authorised by the regional prefect (préfet du département).

It is advisable to reach an agreement with neighbouring healthcare establishments so as to offset the adverse impact of any malfunctioning of one's own CSSD (pursuant to the Universal Medical Insurance Act) (11)).

Provision must be made for tracking of sterile supplies from the time of predisinfection until their use in the operating theatre or for patient care.

When organising sterilisation activities, the flow of persons / materials entering and exiting the CSSD as well as peaks in activity, which are often seen at irregular intervals throughout the day, must be taken into consideration.

In its capacity of service provider, the CSSD should draw up a contract with each of its different clients (operating theatres, patient care services, external clients …). This contract should specify, inter alia, how services are to be organised and feature a list of the various MDs to be sterilised (this topic shall be addressed in the AFS document entitled "Organisation and Circuits".

2.1.1.2 Reprocessing of a sterile medical device

Sterilisation procedures are regulated by the Good Hospital Pharmacy Practices (B.P.P.H. [1]) and by valid regulations. It comprises two streams of activities:

– The first relates to quality assurance, general organisation, personnel, premises and equipment;
– The second refers to the procedures needed to achieve sterile supplies.

Sterilisation procedures comprise:

– Predisinfection: This is carried out in the operating theatre or on the wards after use or before transporting the supplies to the CSSD. It must be pointed out that this activity may be omitted if the MDs are treated immediately in a qualified washer-disinfector (proposed interval until reprocessing: 1 hour after use);
– The chemical process used for inactivation of NCTAs (5), based on risk assessment;
– Manual cleaning, or automated or ultrasonic cleaning;
– Drying;
– MD inspection;
– Packaging: Packaging is conducted in an ISO Class 8 controlled environment pursuant to standard NF EN ISO 14644-1 (1). Supplies can be packed using containers, sachets or peelable sheaths or wrapping foils;
– The sterilisation process itself: The reference sterilant used in healthcare establishments is moist heat (steam steriliser or autoclave) but other types of sterilants may be encountered such as ethylene oxide or gas plasma;
– Verification of the sterilisation process;
– Storage and distribution of the sterile supplies: Special precautions must be taken during storage and distribution in order to preserve the sterile state.

The aim is to uphold quality assurance in the CSSD (9) and ensure tracking of the sterile supplies.

2.1.1.3 Information on sterilisation

This entails several aspects and is intended primarily for all pharmaceutical, medical, paramedical or administrative staff who are involved in any way with sterilisation.

It grants administrative and legislative insights into sterilisation functions and implementation (accountancy and management), as well as technical and scientific information.

It is based on the assumption that documentary sources are in place and that the technical and scientific competences of the sterilisation team are kept up to date and shall serve as a base for the initial training required.

2.1.1.4 Economic aspects

This is broken down into the following activities:

– *Purchasing:*
Purchasing entails placement of orders for the devices needed for sterilisation, monitoring of deliveries and claims as well as procurement based on the procedures governing the public procurement code or the healthcare establishment's statutes.

– *Management and management analysis:*
This involves supervision of incoming and outgoing supplies, administration of the budgets earmarked for sterilisation while comparing set targets with the goals achieved as well monitoring of sterile supply consumption for the different service providers.

It may take charge of management of the MDs to be repaired or replaced.

– *Activity indicators:*
This constitutes implementation of reference systems and of activity indicators to reconcile effective procedures with the standards in practice.

– *Regulatory and safety aspects:*
This involves compliance with the regulations and good practices.

2.1.2 Organisation of sterilisation

Before contemplating rational organisation of the CSSD the activities of this department must be analysed, and the different points outlined in the chapter will help carry out such an evaluation.

2.1.2.1 The CSSD as service provider

In order to evaluate the CSSD activities, the following information must be provided:

– Name of the healthcare establishment:
– Description of the structure of the healthcare establishment and of its geographic location within the healthcare setting:
  - total number of beds;
  - numbers of beds allotted to medical care, surgery and obstetrics;
  - number of surgical beds.
– Surgical activities:
  - surgical specialities;
  - outpatient surgical activities;
  - number of operating theatres and surgical procedures;
  - number of interventions per year;
  - number of operations (in thousands) per year;
  - number of days and hours each theatre is open.
– Sterilisation activities:
  - number of sterilisers;
  - steriliser capacity;
  - number of cycles per year;
  - evaluation in m^3.
– Medicotechnical services:
– Geographic location of sterilisation:

2.1.2.2 Opening hours

From Monday to Friday:

Description of how sterilisation is organised at the weekends, nights and on public holidays: This form of organisation may be reviewed at the time of starting a sterilisation activity, in particular when including a new operating theatre. The working hours and requirements of this theatre must then be taken into account.

2.1.2.3 Personnel

Number of pharmacists:

Number of interns or students in the pharmacy:

Number of managers:

Number of state registered theatre nurses entrusted exclusively with the task of sterilisation:

Number of state registered theatre nurses engaged in assembling the containers:

Number of state registered nurses:

Number of staff engaged in preparatory tasks in the pharmacy:

Number of assistants engaged in preparatory tasks in the pharmacy:

Number of auxiliary nurses:

Number of hospital sterilisation staff:

Number of packers:

Others:

2. 1.2.4 Circuit embarked upon by medical devices to be sterilised

– *Collection or receipt of the devices to be sterilised:*
Describe the circuit comprising collection and receipt of MDs to be reprocessed.

Depending of the inhouse organisation of the respective establishment, the MDs to be sterilised may be collected by the CSSD staff or by logistical personnel. Collection may mean that staff deposit the supplies in the reception area of the CSSD cleaning zone.

Procedures will be formulated, while highlighting the requirements and forms of collection and distribution of sterile MDs.

– *Transport methods:*
Describe the means of transport in use.

Supplies are transported in clean basins or cabinets that are carefully maintained, hermetically sealed so as to guarantee the integrity of the packaging (1).

There is a broad range of options available for transport of soiled medical devices:

– If the MDs are not reprocessed immediately in a washer-disinfector in the CSSD (transport of non-reprocessed instruments), they will be transported after predisinfection. Each establishment must decide (following verification of the condition of these MDs) whether transportation is to be conducted in a "moist" or "dry" environment;
– If this is done under "moist" conditions, only a closed, sealed basin may be used, while ensuring that the basin cannot be overturned;
– If this is done under "dry" conditions, it can be effected only after rinsing with non-chlorinated water. Indeed, rinsing before transportation is of paramount importance to avoid corrosion due to the presence of the predisinfectant. If the interval between predisinfection and reprocessing in the CSSD is more than one day, the device must be stored in pure non-chlorinated water (pure water for injection or osmosed water) (see AFS recommendations);

Bear in mind that the interval between predisinfection and arrival in the CSSD must be as short as possible to avoid drying of protein-based substances and thus facilitate reprocessing of the MDs to be sterilised.

This topic will be elaborated on further in the document entitled "Organisation and Circuits".

– *Frequency:*
Describe the methods used to distribute the sterile supplies on weekdays, at the weekend and on public holidays.

2.1.2.5 Purchases and deliveries

Describe briefly how purchases and deliveries are dealt with (for example the intervals and volumes involved).

2.1.2.6 Documentation for sterilisation

Documentation is a means of transmitting and preserving information (1). All the documents needed and tailored to smooth running of the quality system shall be administered in a coherent manner using appropriate procedures.

While they are different, the internal and external documents which are based on different sources are administered as sterilisation documentation:

- Internal documentation:
  - procedures' file;
  - container contents;
  - tracking documents;
  - qualification, requalification and maintenance files;
  - administrative files;
  - patient data (risk of NCTAs).
- External documentation:
  - catalogues of suppliers;
  - technical specifications for the MDs to be sterilised;
  - books;
  - magazines and periodicals;
  - technical and scientific dossiers (product files);
  - databanks (Minitel, CD ROMs etc.).

The documentation shall also include all matters related to the quality system:

- prescribed reference systems and preserved reference systems;
- contracts and agreements;
- reports and records for validation, operational qualification, requalification and maintenance control;
- records relating to cases of non-conformity and of remedial measures;
- reports on internal and external audits;
- inspection reports.

Each sterilisation zone needs to be close to the information sources specific to it. However, the head pharmacists and managers will continue to be the main persons using these documents (journals, files, dossiers, …) which will be classified and easily accessible to all CSSD staff. The installation of an information technology (IT) network will facilitate data exchange between different computers. This calls for purchase of software for databases, data processing and spreadsheets.

2.1.2.7 Information technology for the CSSD

The Sterilisation Information System (SIS) makes it easier to organise procedures and obtain results, and may call for purchase of special software.

SIS will organise management of information, data and documents relating to the CSSD.

It is an integral part of the Pharmaceutical and Hospital information System (S.I.H.).

The network needed for propagation of data and documents on sterilisation operations is managed by the hospital pharmacy.

SIS will process the data relating to working procedures (management of supplies entering and exiting the decontamination system); it is thus linked to the economic management and financial software applications used within the healthcare establishment. It also processes the standard data on the decontamination procedures to which the MDs have been subjected or the MDs in their entirety to assure tracking.

SIS may also be used to set up the sterilisation quality system, ranging from compilation of documents to the final records.

All hardware and software items will be described in an organisational document, so as to provide for management of the premises, circuits and equipment and thus optimise utilisation of information technology tools.

If this tool is unable to process all data required for sterile MD reprocessing and distribution, hardcopy documents shall be used to supplement the IT system.

It must be remembered that information technology will facilitate follow up and tracking but it does not constitute a prerequisite: good manual tracking is also possible.

This IT-based tracking helps monitor stocks of different MDs in various departments and can serve as a point of reference for managing expiry dates.

2.1.3 The geography of the CSSD

2.1.3.1 Localisation within the establishment

CSSD localisation within, or close to, the healthcare establishment, is of paramount importance because this is the source of the flow of persons/materials that must be controlled in order to assure an unchanging level of sterilisation quality regardless of the type of organisation used. This control may be more or less complex depending on the localisation envisaged.

If possible, the CSSD shall be located close to the operating theatres and to the pharmacy (1).

The sterilisation unit needs the most direct access possible to the outside, and in the case of a central sterile supply unit or of inter-establishment cooperation (or in the case of linen sterilisation too), possibly an external platform for unloading; this must be assured while still having direct access to the operating theatres and wards.

The flow of persons/materials will converge towards the sterilisation unit, while others emanate from it. These flows will be described in detail in section 2.2.

2.1.3.2 The internal structure of the CSSD

The CSSD can be divided into activity zones which, in turn, are divided into specific zones and places. The following zones are distinguished:

- *The cleaning zone:*
  - receipt of devices to be reprocessed;
  - manual cleaning;
  - ultrasound basins;
  - technical wall for cleaning in two-door machine and/or cleaning cabinet or tunnel washer;
  - storage of trolleys and transport basins;
  - place for general "housekeeping" tasks.

If there is no cleaning room, pressurised cleaning equipment with connection for incoming compressed air must be provided in a dedicated zone for cleaning trolleys and transport basins.

- *Packaging zone* (ISO Class 8 of standard NF EN ISO 14644-1, applicable [1]):

It is divided into:

- Place for the equipment needed for drying with compressed air (see 3.2): it is desirable that this be a separate zone as the following problems arise:
  - moisture at the exit from the washer-disinfector;
  - noise: soundproofing;
  - dispersion of moist particles due to air turbulence.

Attention must be paid to the quality of the compressed air which must be free of contamination (dry air, deoiled, filtered) because this serves as an effective medium for dispersal of solid or liquid particles that become detached from surfaces. Hence what is needed here is propulsion of "clean" air onto "clean" surfaces.

- place for textiles:
  - reception;
  - verification;
  - linen folding.
  - storage of consumables;
  - place for general "housekeeping" tasks;
  - place for packing;
  - technical wall with two-door sterilisers;
  - communication with sterile zone;
  - the sluice between the packaging zone and sterile exit zone. This is obligatory only if the environmental dust class is not the same between both zones (this would eliminate the problem of doors remaining open):
- by controlling this, attention is paid to ensuring compliance with the dust class for activities in the packaging zone;
- and the surface area of the sterile exit zone can be limited for reasons relating to costs and to control of the environmental class (the storage zone will therefore be separate).
- The autoclave exit zone for sterile supplies (ISO Class 8 of standard EN ISO 14644-1, recommended):
  - unloading of sterilisers;
  - cooling down and validation of batches.
- *Zone for storage of sterilised MDs:*
  - storage of validated sterile supplies;
  - storage of trolleys and transport basins;
  - emergency dispensation.
- *Ancillary zones:*
  - offices;
  - changing room;
  - toilet;
  - recreation room;
  - meeting room;
  - archive;
  - place for storage of consumables;
  - place for incoming ancillary items based on the hospital organisational structure;

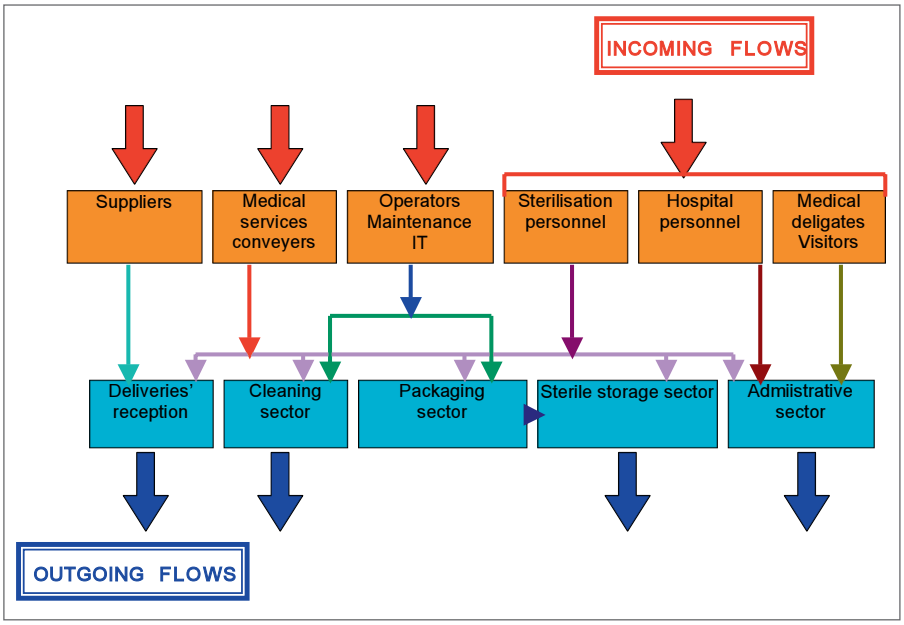

Fig. 1: Interrelationships between the CSSD and external flows

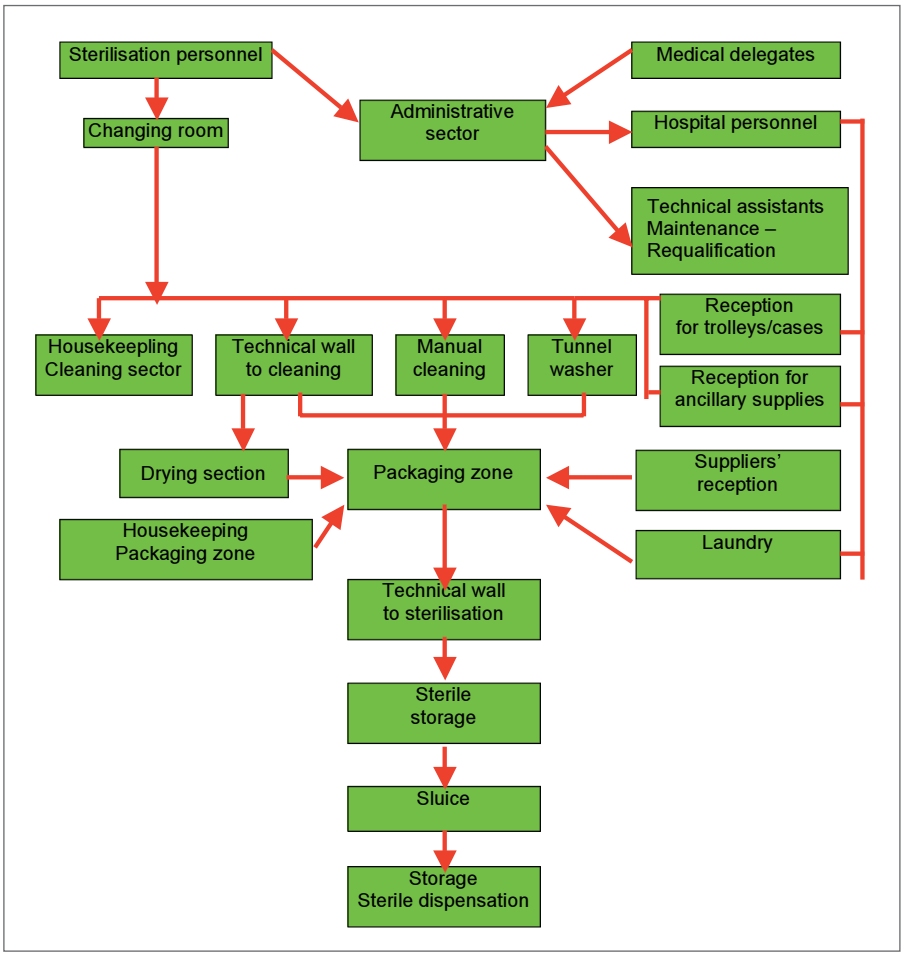

Fig. 2: Interrelationships between the sterilisation sectors

- place for spare MDs to replace defective MDs;
- technical premises (water generation, central air supply …).

This is not a comprehensive list; depending on the size of the hospital or CSSD, this sector may also have a library and a dedicated training room for the CSSD.

The cleaning zone and packaging zones are separated by a technical wall reserved for installation of two-door washer-disinfectors.

The packaging zone and steriliser exit zone are partially separated by a technical wall reserved for installation of two-door sterilisers.

Each of these technical walls will provide for thermal insulation and soundproofing to assure compliance with particle contamination classes..

This architecture is aimed at assuring compliance with the principle of forward movement.

Each of these different zones will be described in detail in the following chapter (description of each activity zone).

It is desirable that, at most glass, partitions be installed to permit passage of daylight and also enable rapid inspection of the different activity zones by management staff. At most, provision must be made for natural illumination in all zones apart from the storage zones.

Since the packaging zone, as well as if possible the sterile exit zone, is governed by ISO Class, a technical room with soundproofing must be provided for the central air supply and osmosis unit as close as possible to the sterilisers and washer-disinfectors (using the shortest circuit possible to avoid dead arms and stagnation of contamination sources).

2.2 Examination of flows

Sterilisation activities give rise to incoming and outgoing flows (Fig .1).

A study of these flows will help devise a methodology for evaluation of the CSSD activities; such an evaluation is needed to determine the scope of the machine park in the CSSD, as well as the number of staff and surface areas conductive to orderly functioning of the department.

Incoming flows:

These flows may be obstacles to compliance with the following:

– forward movement
– hygiene regulations.

These include:

– flow of persons:
  - sterilisation personnel;
  - hospital personnel;
  - medicotechnical service personnel;
  - operators engaged in maintenance and requalification of equipment; operators conducting environmental sampling;
  - visitors, interns;
  - medical delegates;
– flow of raw materials:
  - deliveries of MDs to be sterilised originating from the operating theatres and wards or from outside if subcontracted;
  - deliveries from internal or external suppliers;
  - deliveries of new MDs or of loaned instruments.

Outgoing flows:

These include flows:

– towards the wards and operating theatres:
  - sterile supplies destined for the operating theatres;
  - sterile supplies destined for the wards;
  - sterile supplies for external clients (if subcontracted).
– Towards the suppliers' laboratories:
  - return of defective MDs dispatched for repair;
  - return of sterilised loaned instruments (7).

As far as possible, the flow of persons from outside the CSSD should be confined to the administrative zone.

When persons from the outside visit the CSSD they must be asked to don appropriate clothing and the number of persons must not adversely affect smooth operations within the department. Mixing of air must be avoided in the packaging zone when assembling containers and trays. Visits should be preferably paid during periods of least activity (end of the day).

Whenever possible, preference should be given to visits "from the outside", taking advantage of the windows installed in the partitions.

Evaluation of these flows will help to refine organisation of the CSSD, to define the days and hours of service and determine the periods of peak activity.

This qualitative analysis of the type of organisation chosen for the CSSD can serve as the base for enhancing workflow patterns within this department.

To estimate these flows, the activities of the CSSD must be evaluated first of all:

– by counting the number of sachets, number of containers, number of standardised autoclave trays (600 x 300 x 300 mm) it is possible to calculate the number of steriliser batches per day. This investigation can be carried out over a defined and representative period of time to assure reproducibility and estimate the number of sterilisers needed in the department. This will also help identify periods of inactivity.
– To evaluate cleaning activities, an analysis could be carried out for the operating theatre:
  - investigation over a period of one month;
  - number of containers and trays supplied per procedure in the operating theatre;
  - number of MDs to be reprocessed per procedure in the operating theatre, while analysing what had been supplied and what been actually used during the procedure (make provision for dividing the contents of containers into two);
  - duration of procedure;
  - calculate the number of DIN trays (240 x 240 x 40 mm – 240 x 240 x 65 mm – 240 x 480 x 40 mm – 240 x 480 x 65 mm) for a washer-disinfector;
  - calculate the number of trays and rate at which washers-disinfectors are filled as a function of the number of hours (filling rate as 8/8 or 12/12 depending on the type of machine used);
  - identify the periods of lowest and peak activity;
  - then calculate the number of persons needed for each zone.

This qualitative analysis shall serve as the basis for a quantitative study which will help calculate the number and capacity

of washer-disinfectors needed in the CSSD, while taking account of their output capacity (volume of supplies reprocessed/cycle duration).

To enhance organisation of the CSSD, an IT link between this department and the operating theatres could be contemplated. This would enable the CSSD to identify the containers entering the operating theatre for a surgical procedure and plan how to reprocess them once they have returned to that department.

2.3 General characteristics of the premises

Height:

A below-ceiling height of 2.80 m (2) is recommended. If ceilings are lower, precautions must be taken with respect to the arrangement and number of air vents as well as to the temperature of the air circulated. This below-ceiling height will have implications for the noise level prevailing within the CSSD.

Floors:

Floors must be:

- resistant to pressure and impact, in particular to the imprints left by trolley wheels;
- joined to the walls to facilitate cleaning (curved plinth) and if they contain joints, these must be easy to maintain and clean;
- easy to clean and decontaminate;
- resistant to the different products used, especially to detergent disinfectants, regardless of whether they are alkaline or not, as well as to bicarbonate and Javel water (at least within the dedicated zone);
- equipped with facilities for removing or suctioning off water within the cleaning zone.

It must be possible to access, dismantle, clean and disinfect the floor siphons. Attention must be paid to the levels of positive pressure used for automatic flushing of the siphons.

One could also recommend that floors be non-slip, without impeding the operation of trolleys. Rugged floors that are very difficult to decontaminate must be avoided.

It is preferable to have a continuous floor without any joints.

However, the materials used in continuous, cast floors are not without their drawbacks: installing such floors is a very delicate task and this must be done perfectly, hence the firm entrusted with such a task must be carefully chosen.

Furthermore, if such floors are smooth, they will also be slippery. They can be rendered non-slip by incorporating a quartz surface, but these types of floors are difficult to maintain in terms of hygiene.

PVC coverings in the form of soldered strips rising to form a plinth assure good continuity.

For technical and economical reasons, there is no need to provide for antistatic floors within the CSSD because there appears to be few problems with static electricity in that setting and, moreover, such floors are very onerous. Essentially, electrostatic risks are posed by the users and are virtually non-existent in the case of PVC floors.

One solution here would be to opt for an electrotechnical floor made of special PVC that lends itself to high volumes of circulation, is very hard and a good conductor of electricity (if one wishes to avoid discharge of static electricity). Another possibility would be a soldered thermoreticule PVC floor since porosity problems could be a problem for maintenance of electrotechnical PVC floors.

IT equipment as well as the computerised parts of sterilisers or washer-disinfectors must be protected against all such types of effects. One way of doing so would be to connect the various apparatuses to an earth ground so as to avoid electrostatic discharges.

If there is a risk of static electricity, one could consider installing IT equipment on insulated rubber pedestals.

A tile covering could also be contemplated. In such a case, the following would be needed:

- large-sized ceramic tiles to minimise the number of joints (300x300 mm) but such a form of tiling is more fragile;
- resin-treated or metallic joints to avoid porosity and shrinkage. This would have to be done by a trained craftsman;
- attention must be paid to using good quality tiles to minimise, in the event of any impact, damage that could cause the tiles to break or become porous, thus acting as a source of moisture and of environmental contamination;
- curved plinths are indispensable.

Walls, partitions and ceilings:

These surfaces must be designed in such a way as to counter microbial growth.

Hence the walls and ceilings must be smooth, without any cracks, impermeable, easy to clean/disinfect and amenable to biocleaning.

All forms of naked wood surfaces are prohibited. Stainless steel is difficult to maintain, has an adverse effect on the eyes and attention should be paid to the quality of the finish used.

Horizontal pipework must not be visible.

Other pipes must not form any recesses that are difficult to access for cleaning purposes.

As far as possible, installation of pipes and sheaths should be avoided in the packaging and sterile exit zones. Otherwise, they should be placed either on the edges of zones (corridor) or in false ceilings in a manner that facilitates upkeep and maintenance without causing any disruption of the ISO Class 8 characteristics conferred.

The false ceilings must be made of rigid panels that are washable and waterproof, mounted on aluminium-reinforced profiles. They may be made of enamel sheet metal or be laminated:

- they may be metallic packs with silicone waterproof joints. One must therefore be very careful when installing them because these are slabs which are firmly soldered to each other;
- they must be waterproof and may be made of antidamp plaster slabs whose joints must be completely waterproof (there are problems accessing such ceilings for maintenance purposes and they would therefore have to be broken).

They must remain accessible for maintenance of air conduits and pipes.

False ceilings made of small slabs must be avoided, opting instead for bigger panels (for example 600x1200 mm).

Top priority shall be paid to continuity of walls, finished off with a coat of paint (resistant to chemical detergents and disinfectants or with a PVC covering).

Partitions must be reinforced in the zones where there is circulation of trolleys and must be protected by handrails.

The walls and partitions must feature as many glass panels as possible apart from the zone used for storage of sterilised MDs.

Lighting:

Natural daylight should be used wherever possible and is needed in the cleaning and packaging zones. Conversely, the zone used for storage of sterilised MDs must be protected against direct sunlight and humidity; the windows must be protected to prevent adverse effects caused by sunlight.

Low-luminance devices must be used for artificial lighting.

The circular dated 11 April 1984 relating to the technical commentary on Decree Nos. 83-721 and No. 83-722 of 2 August 1983 on lighting in the workplace makes some references to minimal illumination values.

The Permanent Workgroup for Study of Markets (G.P.E.M./S.L) (2) recommends:

– at least 200 Lux en general;
– 400 to 500 Lux in the workplace.

Standard NF X 35-103 recommends the following illumination values (19):

– office work: 400 Lux;
– steriliser loading and unloading zone: 600 to 800 Lux;
– visual inspection of MDs: 1000 Lux.

The luminous environment should not be either too strong as to cause dazzle, nor too weak as to strain one's eyes and must vary in accordance with the different activities carried out in the CSSD (19).

The following points must be borne in mind:

– the nature of the lighting itself;
– the colour of coverings used for floors, walls and ceilings;
– the (colour) shades used for draining boards or work tables

Pastel tones provide for a more harmonious luminous environment, especially for large zones. White should be avoided in view of its strong reflection. Draining boards or tables in a light shade, not white, such as ivory or light beige facilitate visual inspection of MDs.

Stainless steel should be avoided as it is mainly reflective (or one opts for a non-reflecting quality), giving preference to Corian or synthetic resins.

Low-luminance tubes with reinforced halogen above the zones subject to specific control help to rest the eyes and are an acceptable compromise.

Light fittings must not feature any projections that collect dust.

Lights should be integrated into the false ceiling, flush mounted and rendered waterproof.

Temperature and humidity prevailing in the premises: Air conditioning must be provided in all premises.

The temperature must be kept at around 20 °C + 5 – 2 .

The relative humidity must be between 40% and 75%.

The air conditioning system need not necessarily be rounded off by a rehydration system since this is not beneficial in all areas and gives rise to technical (malfunctioning, maintenance, energy costs) and health complications (legionellosis). Care must be taken in choosing a rehydration system, giving preference to steam over liquid systems.

Noise level:

Noise must be controlled. Indeed, the working code (directive EEC/86/188) states that hearing faculties are endangered above 85 decibels (dB). However, the ear perceives sounds according to their intensity (decibels) in association with their frequency (hertz). The decibel value corresponding to a physical measurement is not enough and a weighting coefficient must be added to obtain the physiological decibel characterising the noise perceived by the ear.

A threshold of 60 dBA (physiological decibel) must not be exceeded (2).

The walls and ceilings should be made of absorbent materials that do not reflect sound (2). But this would imply non-even surfaces which would not be compatible with the hygiene requirements prevailing in the CSSD.

Soundproofing should be provided for the various machines so as to control the noise level within the CSSD.

To avoid echo phenomena, the distance between two walls must not be a multiple of 7.

The following is recommended to reduce noise-mediated disturbances:

– insulation of the compressed air circulation gradient within an acoustic box in conjunction with the wearing of ear protectors by the staff members entrusted with this task;
– insulation of sterilisers and washer-disinfectors in technical walls so as to reduce the noise level;
– insulation of autoclaves by means of a rubber base to reduce low-frequency noises (19);
– installation of generators and vacuum pumps in technical zones;
– installation of a system comprising two rows of absorbent panels, fixed to the ceiling and positioned a few metres from and facing the area used for loading autoclaves (19).

Miscellaneous:

Electrical installations and water pipes must be equipped with a circuit breaker (blow switch type).

Attention must be paid to where the washer-disinfectors and sterilisers are positioned within the cleaning, packaging and sterile exit zones, a avoiding placing them close to weight-bearing pillars so as not to impede loading and unloading trolleys. Moreover, easy access must be provided for washer-disinfectors or sterilisers (and for maintenance equipment) when replacing these or installing an additional steriliser (pay particular attention to the size of doors).

Provision must be made for communication systems to minimise entry and exit of staff to and from the clean zone. Glass partitions, communication panels, IT and video links for data transfer, interphones and telephones can serve as an appropriate means of communication. They must be chosen in terms of their compatibility with the dictates of a clean zone class, while bearing in mind the intended application.

If there are glass partitions towards the outside, they must be carefully examined and installed. One should try to use glass partitions to permit observance of the activities within the clean zone (from the outside) without having to enter it. The glass panels must be of a non-opening design and must be waterproof and flush mounted.

Control of aerobiocontamination:

The environment must be controlled so as to limit:

– baseline contamination of the devices to be sterilised;
– contamination of the entire complement of stored and packaged devices.

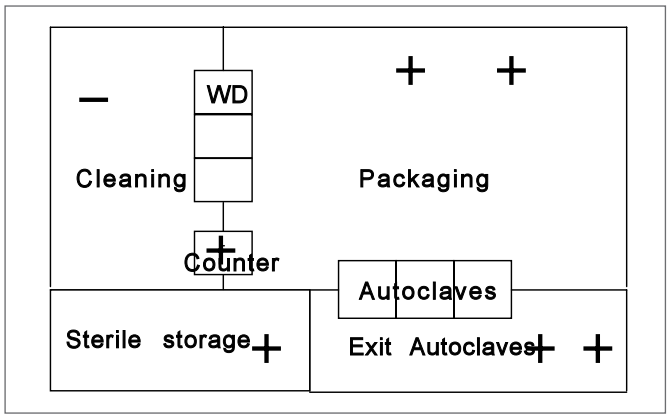

Fig. 3: Distribution of pressure gradients
Legend: + + : maximum positive pressure (30 pascals)
+ : positive pressure (15 pascals)
– : atmospheric pressure

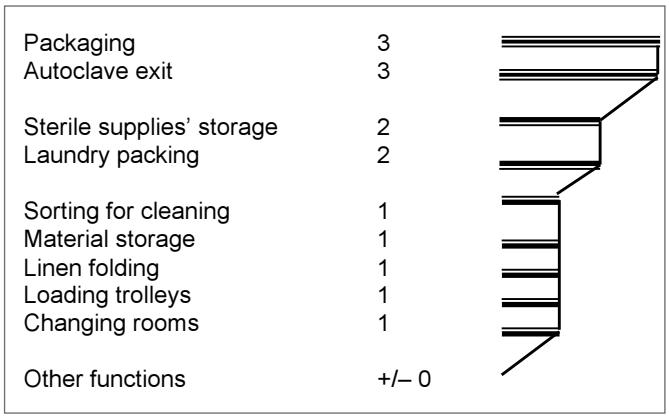

Fig. 4: Distribution of pressure gradients

Pressure levels must be distributed such that ISO Class 8 can be maintained wherever recommended (Fig. 3 and 4) (1).

To assure ISO Class 8, provision must be made for appropriate air renewal.

Non-unidirectional airflow must be used for the protected zone (standard NF S 90-351).

The air is renewed so as to maintain the desired dust class, while diluting and eliminating the contaminants shed into the air by:

– the manufacturing process;
– personnel.

The air renewal rate determines the self-purification ability of the room, i.e. its efficiency at eliminating the contamination generated on site by the activities taking place.

It must be brought into line with the climatic conditions and the furnishings used in the premises. It must be between 15 and 20 volumes/hour; the minimum being 15 volumes/hour. The percentage of new air providing for positive pressure of the premises is calculated on the basis of the degree of airtightness observed therein. This calculation can be based on standard NF S 90-351 (the 1987 standard is being currently updated).

Terminal filtration of the circulated air is assured by THE and HEPA filters endowed with a minimum capacity of 95% dioctyl phtalate (DOP).

Preliminary filtration with G or F series of filters (based on standard EN 779) will permit:

– protection of the air distribution network;
– guarantee air salubriousness;
– protect the absolute filters.

A value of 95% is optimal and the expected minimum service life of terminal filters is between 2 and 3 years and can even be between 5 and 7 if one uses good preliminary filtration.

Based on Good Hospital Pharmacy Practices (1), the packaging zone must comply with ISO Class 8 during periods of inactivity. Furthermore, microbiological contamination must be monitored here during periods of activity and must be less than 200 cfu/m^3.

To protect a clean area against any contamination from neighbouring zones, static positive pressure must be maintained within these clean premises with respect to the adjoining zone. This positive pressure must be of a sufficiently high level and stable, with a minimum of 15 pascals in the desired direction (standard NF S 90-351).

The positive pressure value prevailing in "clean" premises compared with "less clean" adjacent areas must not be less than 15 pascals. The dfferent pressure levels within the CSSD shall be distributed as follows (Fig. 4):

– maximum positive pressure (30 pascal) in the instruments' packaging zone and at the autoclave exit;
– positive pressure (15 pascals) in the laundry packaging zone, storage zone and sluice;
– atmospheric pressure in the zone used for incoming linen and linen sorting, cleaning zone, changing rooms and adjacent zones.

If the MDs arrive in the CSSD without having been predisinfected (see § 2.1.1.2 and 2.1.2.4), the zone allotted for receiving and sorting these contaminated MDs will be at negative pressure compared with the neighbouring zones.

Distribution of the pressure gradients can be illustrated as shown in Fig. 3.

The heat generated by the sterilisers shall be offset by thermal treatment of the air and compensation.

Circuits:

The principle of forward movement shall be systematically applied so that the activity flows do not overlap and that the safety of staff and of the devices to be reprocessed is assured.

It is imperative that direct passage of personnel between the "precleaning" and "postcleaning" zone be avoided.

Two circuits are identified in the CSSD:

– a short circuit for cleaning the MDs and transport equipment;
– a long circuit used for sterilisation activities per se, including packaging, sterilisation, verification of the sterilisation process, storage and distribution.

Part 2 of this publication will appear in Central Service *issue no. 4/2008.*

Keywords
- sterilisation
- CSSD
- architecture

ZENTRAL STERILISATION 4

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 depending on the number of beds: in Belgium 0.6 m^2/bed, Netherlands: from 0.7 m^2/bed for 200 beds to 0.45 m^2/bed for 75 beds, in France depending on the "active" nature of the bed: 0.56 m^2/bed for 300 beds to 0.45 m^2/bed for 600 beds (24).

Thierry Hoët (23) has estimated the following ratios: 0.7 m^2/bed from 0 to 300 beds; 0.6 m^2/bed from 300 to 600 beds and 0.5 m^2/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 m^2/bed;
- from 300 to 400 beds beds MSO: useful surface area of 1.2 m^2/bed;
- more than 400 beds for beds MSO: useful surface area of 1 m^2/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 m^2 useful and 260 m^2 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 m^2; 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 predisinfection 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 predisinfection, 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 reprocessed 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 predisinfection 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, predisinfection 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 (microsurgical) 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 predisinfection 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 predisinfection 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 predisinfection 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 cœlioscopy (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-disinfector 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-disinfector 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-disinfector 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-disinfector 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-disinfector 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.

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 predisinfection. 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 predisinfection 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 "postcleaning" zones. There must be no direct passage of staff between the "precleaning cleaning" 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: × 3 or 3 dioptres [2]).

The use of a microscope can also be recommended (× 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: ∑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 m^2, 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 than 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 to1280 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; ∑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 are 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

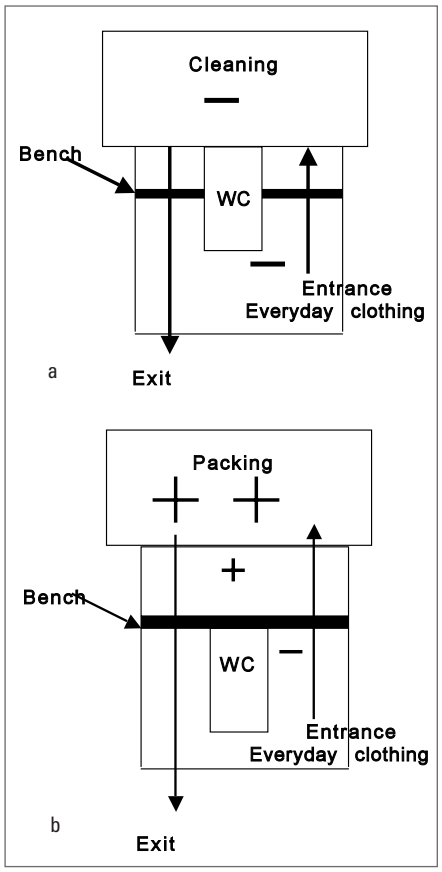

Fig. 5a: Changing room in non-clean or "precleaning" zone

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 facilities 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 m^2 for a team of 6 persons.

An extra surface area of 1 m^2 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 m^2 for 6 staff members.

Beyond that, an additional surface area of de 0.5 m^2 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 m^2 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 m^2 for storage of sterilisation packaging:
  - with shelves to accommodate supplies.
- a surface area of 10 m^2 per steriliser could be recommended if the CSSD is not using containers:
  - this surface area could be reduced to 6 m^2 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 m^2:
  - a working surface (table) shall be made available for inspection;
  - depending on the turnaround of ancillary devices, a surface area of 3 m^2 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 m^2 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 handwashing 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 m^2 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.

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

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

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

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

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 reprocessed, 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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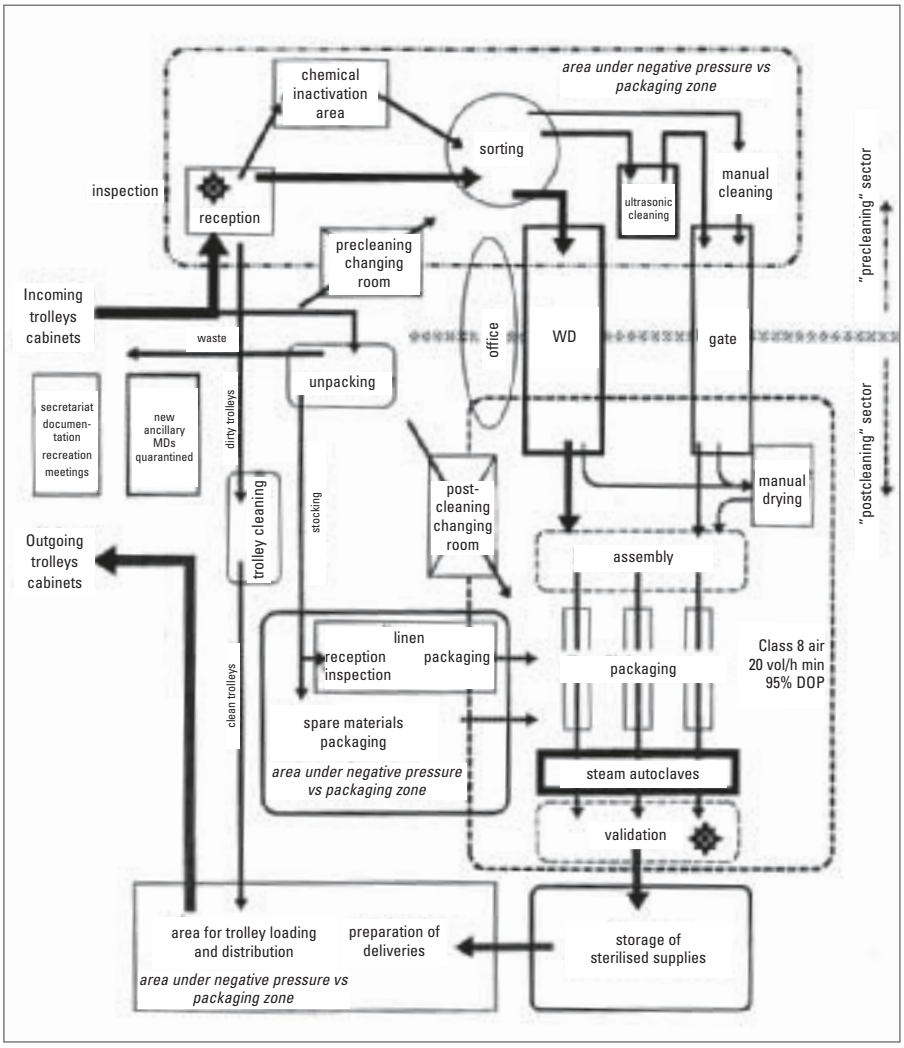

Fig. 6: Organisational schema for a CSSD

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References

Official texts and documents

1. Bonnes pratiques de pharmacie hospitalière, 1er édition, juin 2001
2. Bonnes pratiques de stérilisation, stérilisateurs à la vapeur d'eau pour charges à protection perméable, Commission centrale des marchés, G.P.E.M./S.L., 1993
3. Circulaire n° 51 du 29 décembre 1994 relative à l'utilisation des dispositifs médicaux stériles à usage unique dans les établissements de santé publics et privés
4. Circulaire n° 672 du 20 octobre 1997 relative à la stérilisation des dispositifs médicaux dans les établissements de santé
5. Circulaire n° 138 du 14 mars 2001 relative aux précautions à observer lors de soins en vue de réduire les risques de transmission d'agents transmissibles non conventionnels (abroge la circulaire n° 100 du 11 décembre 1995 et la circulaire n° 236 du 2 avril 1996)
6. Circulaire n° 139 du 14 mars 2001 relative à la prise en charge des personnes atteintes d'encéphalopathies subaiguës spongiformes transmissibles
7. Convention de prêt et contrat de dépôt pour le matériel ancillaire et les implants : Snitem, Synprefh, Euro Pharmat, Unaibode, Syndicat National des Chirurgiens Orthopédistes, Commission des Directeurs des Services Economiques de CHU, 4 mars 1999
8. Décret n° 89-3 du 3 janvier 1989 relatif aux eaux destinées à la consommation humaine à l'exclusion des eaux minérales naturelles, Journal Officiel de la République Française 04/01/1989, 125-131
9. Décret n°2002-587 du 23 avril 2002 relatif au système permettant d'assurer la qualité de la stérilisation des dispositifs médicaux dans les établissements de santé et les syndicats interhospitaliers
10. Guide du bionettoyage, Commission centrale des marchés, G.P.E.M./S.L., Fascicule n° 5670, Journal Officiel Editeur, 1991
11. Loi portant création d'une couverture médicale universelle : Décision n° 99-416 DC du 23 juillet 1999, Journal Officiel de la République Française n° 172 du 28/07/1999 p 11250
12. Norme NF EN 554 d'octobre 1994 : Stérilisation de dispositifs médicaux – validation et contrôle de routine pour la stérilisation à la vapeur d'eau
13. Norme NF EN 285 de février 1997 : Stérilisation – stérilisateurs à la vapeur d'eau – grands stérilisateurs
14. Norme NF EN 556 : Stérilisation de dispositifs médicaux – exigences pour les dispositifs médicaux étiquetés «stérile»
15. Note d'information n° 226 du 23 mars 1998 concernant la circulaire n° 672 du 20 octobre 1997 relative à la stérilisation des dispositifs médicaux dans les établissements de santé
16. Recommandations pour les contrôles d'environnement dans les établissements de santé, C. CLIN Ouest, octobre 1999

Articles

17. Aupée M. Entretien des locaux et des équipements en stérilisation centrale. Revue de l'ADPHSO, 1997, Tome 22 n° 3: 59–64.
18. Benoît F. L'eau et la stérilisation. Revue de l'ADPHSO, 1997, Tome 22 n° 3: 65–68.
19. Collard Ch. Ergonomie en stérilisation, grands travaux au CHU de Poitiers. Le Moniteur Hospitalier, janvier 2002, n° 29: 29–38.
20. De Brujin A.C.P et Kastelein J. Simple emballage ou emballage multiple des DMS : évaluation des protocoles au travers de la recherche. Zentr Steril, 1999∞ 7: 292–303
21. Goetz M.L. Hygiène du personnel en stérilisation. Revue de l'ADPHSO, 1997, Tome 22 n° 3: 55–57.
22. Grandgeorge E. Concevoir et organiser une stérilisation centrale en 1995. T.H., septembre 1995, n° 599: 39–44.
23. Hoët Th. Le service de stérilisation centrale dans les hôpitaux : évaluation – organisation – réalisation. Edition des Etudes Hospitalières, 1989.
24. Thiveaud D. Du nettoyage à la stérilisation : Les locaux. Hygiène en Milieu Hospitalier, février 2000, n°25: 19–24.