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;

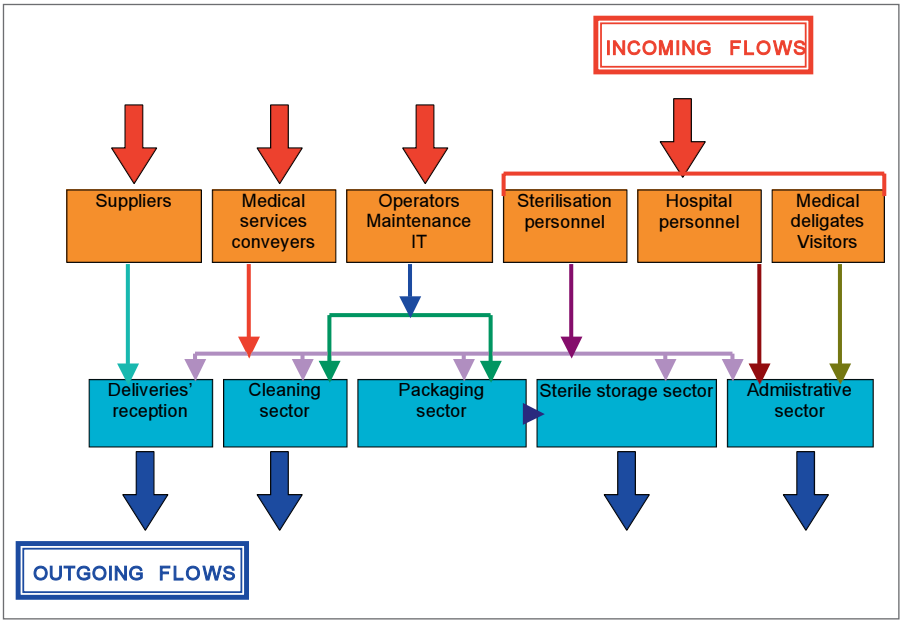

Fig. 1: Interrelationships between the CSSD and external flows

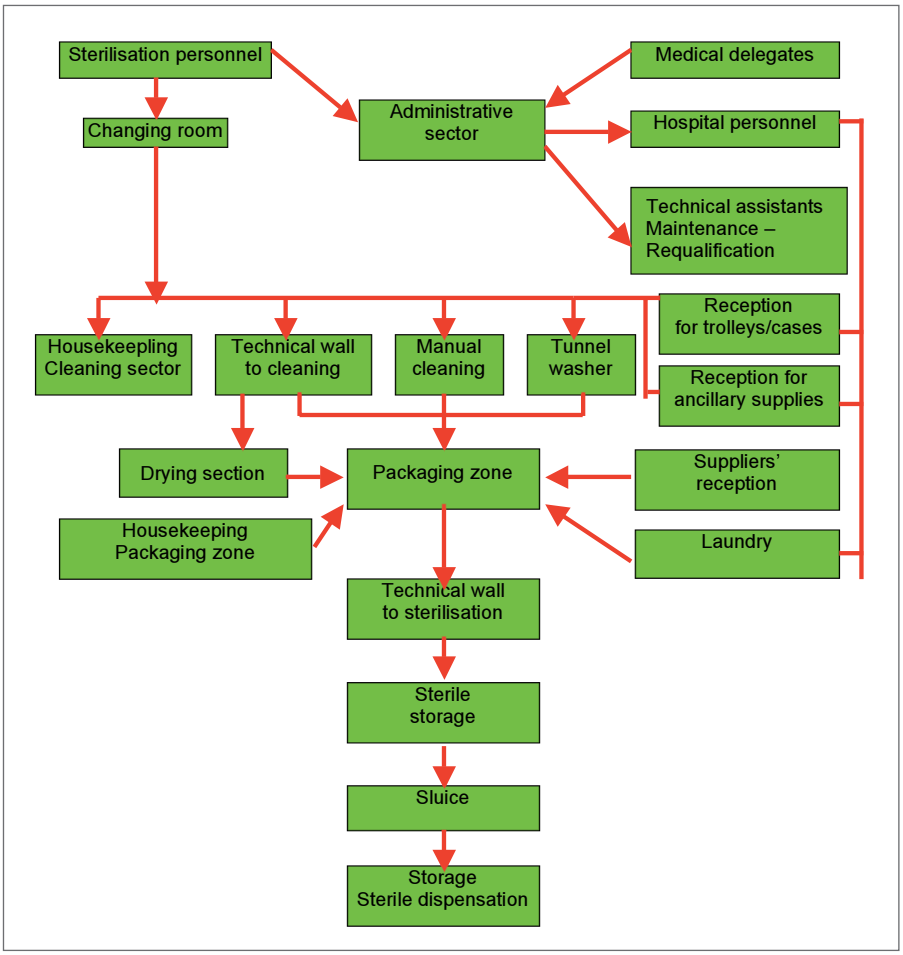

Fig. 2: Interrelationships between the sterilisation sectors

- 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.

ZENTRAL STERILISATION 3

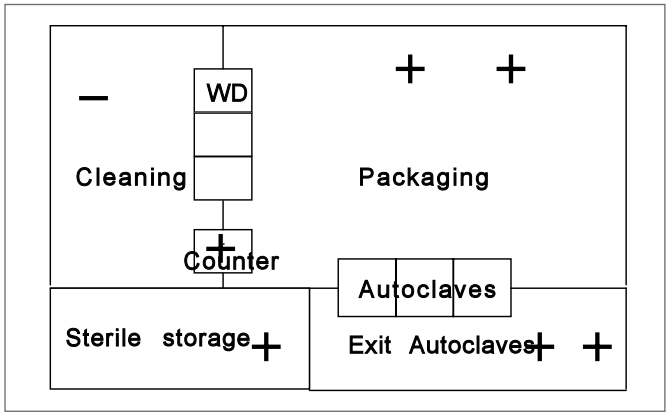

Fig. 3: Distribution of pressure gradients
Legend: + + : maximum positive pressure (30 pascals)
+ : positive pressure (15 pascals)
– : atmospheric pressure

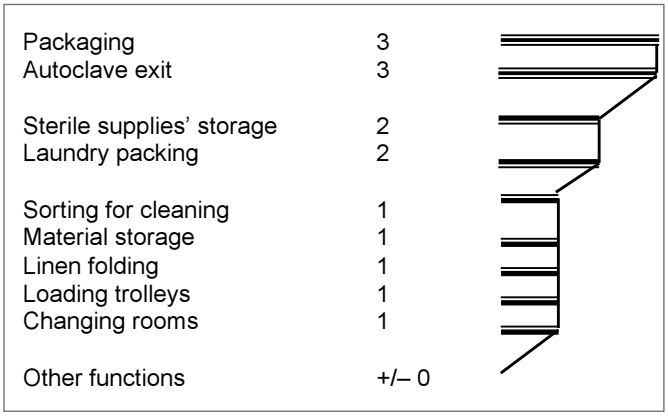

Fig. 4: Distribution of pressure gradients

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.*