

Department: Central Sterilization Department

Guidelines

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The centralized sterilizing department (CSD) provides disinfection and sterilization of items for the hospital. A centralized department within the hospital is one way of providing a more efficient service. Some hospitals may choose to have an external provider for this service however; they are still obliged to comply with the relevant standards. Collection, sterilization/disinfection and distribution of surgical items is the prime function of the service. However, it must also be ensured that the quantity of items required for daily usage is sufficient to meet the needs of the hospital. Storage of sterile items may also be a function of the department.

Ideally, the manager of this department should have at minimum a Bachelor of Science degree in a health related field. All staff working within the department must have a thoroughly documented orientation to all specialized equipment for which they are responsible. Those working in the department must show competency in all skills and tasks expected of them as described in their job descriptions. On-going competency testing with respect to asepsis and sterilization is expected to be in evidence. When gaps in staff competencies are identified, there should be evidence that deficiencies have been corrected and all education be documented.

The physical structure of the department can greatly affect the efficiency and effectiveness of the CSD department. The traffic flow of the entire department should proceed from dirty to clean with two distinct areas and entrance/exits. Internationally, facilities are now being penalized for not having the design of the department to permit this. It is therefore prudent for this to be considered when renovations are being carried out or planned. Separate hand washing facilities must be provided (a) one in the dirty area and (b) another in the clean area, at minimum. Where the CSD is contained within the operating room complex, the scrub area or toilet facilities are not acceptable as the hand washing facility.

When building or renovating a CSD department it would be prudent to consider international standards which demand that air flow within a CSD meet the requirements of each specific area. Thus decontamination areas need negative air flow (to keep contaminants in the room) whereas the “clean” workroom areas would be expected to have a positive airflow (to blow possible contaminants and keep them from entering the room). All areas (decontamination, clean processing and sterilizer equipment rooms) should have direct exhausting of all air to the outdoors. Sterile storage areas should also have positive pressure ventilation (to keep contaminants out) and should be used exclusively for sterile packs not other general stores / equipment. Another move internationally and one to be considered is that storage of sterile packs and general supplies are kept in separate storage areas. Storage areas must be adjacent to the processing areas with shelf storage to maintain sterilized items off the floor and have appropriate air circulation. Distribution carts are expected to be closed containers that are clean and kept outside but near the storage area for transporting items back to their respective units or the operating rooms.

It is important that personnel who are working in the decontamination areas have barrier protection equipment. This would include rubber gloves, waterproof aprons, a supply of facemasks that have face shields and safety goggles. Disposable gloves should be used in all contact with soiled or used items. Ideally, staff designated to work in the decontamination area would not cross over to the sterilization area. In situations where division of labor is impossible, it is imperative that precautions are taken to avoid contamination of the clean areas. Staff should wash their hands and ideally, put on a clean cover gown prior to entering the clean areas.

It is suggested that linen inspection and packing be performed before or after the processing of solid instruments in order to decrease the incidence of lint or fiber contamination. A specified amount of time should be allowed between linen packing and instrument processing.

If possible, all sterilizers should be secluded from the processing areas. It is imperative that ETO sterilizers if used have air exhaust directly to the outdoors and negative pressure ventilation (to keep the ETO from leaking into the general processing area). Evidence must be available that the hospital adheres to specific ventilation requirements and drainage requirements as suggested by the manufacturer. Policies and procedures must be available outlining all procedures in the event of an emergency, such as a gas leak. Where ETO sterilizers are in use, the hospital must ensure that staff working in the department have the required competencies regarding operation of such sterilizers and their safety requirements and emergency procedures. An alarm system should be installed in the area to alert staff of any ETO gas leak. In this area, the exhaust system should be on UPS emergency back up to ensure no accidental buildup of toxic gas.

In the event a hospital does not have an ETO sterilizer, policies and procedure should exist outlining the hospital's practice for sterilizing heat sensitive equipment. This may include subcontracting the service to an external provider. In this case a clear tracking system must exist for each item. Departments that use glutaraldehyde based terminal disinfection (sterilization is not possible) processes for heat sensitive equipment should ensure that adequate ventilation is provided. Ideally a fume cabinet must be present when using these toxic agents.

Documentation / manuals outlining the sterilization and safety parameters provided by the manufacturer of each sterilizer / equipment in the department should be available. Evidence must be available that these parameters are adhered to.

In a case that hospitals use other international parameter standards these must be clearly documented. Following are examples of international standards:

- Pre-or HiVacuum Sterilizer cycles and sterilizing times are suggested to be: 133-135°C for 3-4 minutes.
- Gravity Steam Sterilizer cycles and sterilizing times are suggested to be: either 133-135° C for 10-15 minutes or 121°C for 15-30 minutes.
- Dry Heat Sterilizer cycle times and temperatures are suggested to be:
 - ▶ 170°C for 1 hour
 - ▶ Or, 160°C for 2 hours
 - ▶ Or, 150°C for 2 ½ hours

Whether the hospital follows manufacturer recommendations or parameters set by another established entity, there must be evidence that a set of established parameters guide the cycle time and temperature of the sterilizers in use.

If flash sterilizers are used within the hospital or the department, all policies and procedures including indications for flash sterilization and appropriate cycle times and temperatures need to be readily available in that department. The following are suggested temperature guidelines for flash sterilization:

- Pre or HiVacuum Units:
 - ▶ Routine metal instruments 132° C for 3 minutes
 - ▶ Mixed load 132°C for 4 minutes
- Gravity Steam Units:

- ▶ Routine metal instruments 132° C for 3 minutes
- ▶ Cannulated instruments or loads with an excess of 10 instruments 132° C for 10 minutes

It is important that the processes, monitoring, verification of sterilization, be meticulously recorded for all methods. Equipment must have daily function tests performed and recorded. It is important to note that a chemical indicator does not in itself ensure sterility post processing. It only verifies that certain processing conditions have been met. An example is, if the chemical indicator has changed color appropriately but the pack is wet. The process has achieved the conditions to change the chemical indicator but the fact that the pack is wet negates any sterilization activity. The same applies for external indicator tapes. It is expected that each individual sterilizer will have function testing records retained for at least one year. These should include but not limited to: results of spore testing; printouts recording exposure time/temperature/pressure; and the contents of each load along with the initials of the operator who loaded the sterilizer. Each sterilizer log should record all preventative maintenance performed. These documents are crucial as part of an audit trail in the event of an untoward incident involving a patient and a sterilized item.

A tracking system is needed to identify each item sterilized; either an identity number or bar code that can be traced from the patient to the sterilizing load. It should indicate which sterilizer was used for that particular item (if there are more than one), the date it was sterilized and in which load. All sterilized items are expected to have an expiry date clearly written on the wrapping. Ideally, all sterile items used during surgery will have their identity number or bar code documented in the patient's medical record (especially when providing implants)

Re-processing of single use items (including but not limited to: used endotracheal tubes, used disposable tracheostomy cannulas, used oral airways, used invasive cardiac catheters, used Swan-Ganz catheters, used suction catheters) is unacceptable. Items that are labeled "single use" by the manufacturer should be disposed of after use. If sterile single use item packaging has been opened and the item not used or accidentally contaminated without damaging its integrity there should be evidence from the manufacturer on file that an item that falls under this category can be re-sterilized. The manufacturer should stipulate the conditions under which the item can be re-sterilized and the method of re-sterilization. Most manufacturers allow for expired, unopened, single use items to be re-sterilized. However, care must be taken that the facility only acts on the advice of documented instructions by the manufacturer.

Data collection is essential to provide the information for the purposes of continuous quality improvement. One of the mandatory quality activities is that external validation of the department's sterilization processes should occur on a regular basis.

It would be expected that auditing tools are in evidence and any resulting change in practice is fully documented. The above information is not intended to be all inclusive. Thus individual hospitals and each department have a responsibility to research and source information that allows them to comply with the standards below.

Standards	
CS 1	The supervisor of CSD is a qualified person with a university degree in health science

Standards	
CS 2	A list of staff with contact details and designation is available with the supervisor

Standards	
CS 3	<p>3.1 ● In a decentralized management system where the CSD holds personnel files for each individual staff member the file must contain a signed job description</p> <p>OR</p> <p>3.2 ● In a centralized management system the head of each department must retain master copies of all job descriptions relevant to the staff in their departments</p> <p>3.3 ● In both cases personnel files must contain evidence of educational qualifications</p> <p>3.4 ● Evidence must be provided that formal performance appraisals have been conducted</p> <p>3.5 ● Job descriptions are reviewed regularly</p> <p>3.6 ● A documented performance appraisal is conducted in line with the job descriptions</p>

Standards	
CS 4	Department holds an orientation manual which includes: <ul style="list-style-type: none">4.1 • Section for general hospital issues4.2 • Subsection for CSD department4.3 • A checklist to verify that all sections of the orientation program has been completed (this must be signed and retained in the individual's personnel file)

Standards	
CS 5	<ul style="list-style-type: none">5.1 • Documented evidence of regular testing of staff competencies specific to roles and responsibilities in the unit5.2 • Evidence of all staff in the unit having completed competency testing5.3 • Evidence of corrective action to ameliorate deficiencies identified following competency testing

Standards	
CS 6	<ul style="list-style-type: none">6.1 • Entrance into the CSD is restricted to authorized personnel only6.2 • Traffic within the department flows from soiled through to clean areas with clear demarcation zones6.3 • Decontamination area is physically separated from the packing, sterilizing and storage areas6.4 • Instruments processed by the department flow from "dirty" to "clean"6.5 • The autoclave / sterilizers are housed in a separate area from the processing sections6.6 • Air from the decontamination area is exhausted to the outdoors6.7 • Air from the area designated for packing and folding linen and related materials is exhausted to the outdoors <p>OR</p> <ul style="list-style-type: none">6.8 • A policy and procedure is in place to ensure that a sufficient amount of time is allowed between packing of linen and related materials and instruments

Standards	
CS 7	<p>Designated and separate hand washing facilities are available within the areas used for:</p> <ul style="list-style-type: none">7.1 • Decontamination7.2 • Sterilization7.3 • Toilet Facilities

Standards	
CS 8	<p>Barrier protective equipment is available for each staff member working within the CSD</p> <ul style="list-style-type: none">8.1 ● Puncture resistant rubber gloves and disposable latex gloves8.2 ● Gloves are worn during every decontamination processes8.3 ● Face masks which cover the mouth and nose & safety goggles or full face shield8.4 ● Waterproof aprons8.5 ● Hospital approved sharps container

Standards	
CS 9	<ul style="list-style-type: none">9.1 ● Specialized equipment for cleaning, disinfection, drying, packaging and sterilization is available9.2 ● Ultrasound machine9.3 ● Pressure water jet at decontamination sink9.4 ● Air pressure gun for drying9.5 ● Instrument washing machine9.6 ● Approved autoclave packing paper/ material

Standards

CS 10

All sterilizing activities are monitored as follows:

- 10.1** ● Evidence that testing (Bowie-Dick) is performed daily on high-speed pre-vacuum sterilizers.
- 10.2** ● Evidence that spore tests (live bacterial spores) are performed weekly (1 point), daily (2 points)
- 10.3** ● Evidence that spore testing is/was performed when the sterilizer was installed and after each major repair
- 10.4** ● Evidence that biological indicators are present in each load containing implants
- 10.5** ● Evidence that chemical indicators are placed inside each item or pack to be sterilized
- 10.6** ● Evidence that appropriately sensitive chemical indicators are used within the appropriate sterilizers
- 10.7** ● Evidence of external validation of sterilization process is performed at appropriate intervals

A log is provided for each sterilizer within the department. Contents of the log should include but not be limited to:

- 10.8** ● Each sterilizer has a unique number or code
- 10.9** ● Results of daily function tests (as above)
- 10.10** ● Result of spore tests
- 10.11** ● Contents of each load
- 10.12** ● Any graph or machine generated printout that records exposure time and temperatures
- 10.13** ● Name of operator performing each load
- 10.14** ● All preventative maintenance provided
- 10.15** ● Log records to be held for a one year period for each sterilizer

Each item or pack to be sterilized is labeled with:

- 10.16** ● Lot number which identifies the sterilizer
- 10.17** ● Date of sterilization
- 10.18** ● Sterilizer cycle number
- 10.19** ● Initials of person who assembled the pack
- 10.20** ● Expiration date
- 10.21** ● Audit of randomized packs to provide evidence of compliance with above standards

Standards

CS 11

A policy and procedure manual exists which describes the central sterilization department and management issues relevant to the department

- 11.1** ● Policies are clearly identified
 - 11.2** ● Procedures are clearly identified
 - 11.3** ● Policies and procedures are presented in a hospital wide uniform manner
 - 11.4** ● The index for the policy and procedure manual is accurate
 - 11.5** ● Policies and procedures are regularly reviewed
- Policies and procedures are provided and include but are not limited to:**
- 11.6** ● Parameters for cycle time, temperature and pressure for sterilizers
 - 11.7** ● Employee safety
 - 11.8** ● Infection control
 - 11.9** ● Instrument cleaning
 - 11.10** ● Instrument disinfection
 - 11.12** ● Treatment of heat sensitive items
 - 11.13** ● Non re sterilization of single use items previously used
 - 11.14** ● Recall of commercially prepared and/or in-house sterilized items
 - 11.15** ● Retrieval and reprocessing of supplies when sterilization procedures have failed
 - 11.16** ● Handling and storing sterile medical supplies
 - 11.17** ● A system which identifies a serial number or other identifying factor of critical single use items and the fact that they have been disposed following single useage

Standards	
CS 12	<ul style="list-style-type: none">12.1 • All sterilized items are stored at a distance off the floor12.2 • Sterilized products are stored independently of other equipment/products12.3 • Shelving and containers have smooth, non-porous surfaces to facilitate thorough cleaning12.4 • All sterile items are transported in closed containers

Standards	
CS 13	A tracking system exists for the sterilization process which links the sterile products used to the patient medical record

Standards

CS 14

- 14.1** • Gas sterilization equipment using ethylene oxide (EOH) is installed
 - 14.2** • The EOH sterilizer is installed to manufacturer’s instructions with evidence of appropriate ventilation
 - 14.3** • EOH sterilizer is placed within a designated room away from other sterilizers and processing areas
 - 14.4** • Documented evidence of orientation and in-service training for those staff working with the ethylene oxide sterilizer, (this also includes pertinent maintenance staff)
 - 14.5** • Documented evidence that all staff who come in work with the EOH sterilizer have received complete pertinent occupational health & safety education
 - 14.6** • Exhaust ventilation for EOH sterilizers is directly to the outside or to a sanitary drain according to manufacturers’ instructions
 - 14.7** • An alarm system is provided to alert staff if there is EOH gas leakage
 - 14.8** • The exhaust ventilation system is connected to a UPS power supply
 - 14.9** • A policy and procedure is in place that dictates the emergency response to an ethylene oxide gas leakage
- OR**
- 14.10** • There is evidence that this service has been contracted to an external provider
 - 14.11** • There is evidence that this contractual service has been operational for at least 12 months
 - 14.12** • A cold sterilant/terminal disinfection system (e.g. liquid sterilant) is provided within the hospital
 - 14.13** • This system provides full documentation of process to achieve terminal disinfection for heat sensitive items
 - 14.14** • Evidence that the terminal disinfection/liquid sterilant is utilized as per manufacturers recommendation:
 - 14.15** • The system is housed in clearly marked, purpose specific sealed/closed containers
 - 14.16** • There is a clear process of determining the integrity/validity of the liquid sterilant
 - 14.17** • The dates of preparation of the solution and the expiration date of the present solution are clearly marked on the container(s)
 - 14.18** • Staff can demonstrate education in the mixing and use of the cold sterilant/terminal disinfection system
 - 14.19** • Evidence that the liquid sterilant dilution/mixing is done within appropriate ventilation safety condition

Standards	
CS 15	<ul style="list-style-type: none">15.1 • Documented evidence of regular testing of staff competencies specific to roles and responsibilities in the unit15.2 • Evidence of all staff in the unit having completed competency testing15.3 • Regular testing of staff competencies15.4 • Evidence of corrective action to ameliorate deficiencies identified following competency testing15.4 • Evidence of regular in-service education occurs on a regular basis for staff working in this area
Standards	
CS 16	<ul style="list-style-type: none">16.1 • Data has been collected and computerized for sterilization services activities16.2 • Rationale for data collection has been documented16.3 • Audit tools established for this specific area16.4 • Audits have been conducted16.5 • Analysis and planned intervention resulting from audits is documented
Standards	
CS 17	<ul style="list-style-type: none">• Document evidence supports that staff have been educated on occupational health and safety issues relating specifically to this department/service

Standards	
CS 18	Documented orientation program for all new staff which includes:
18.1	● General hospital issues
18.2	● Sub section for this department
18.3	● Check list to verify that all section of the orientation program has been completed

Standards	
CS 19	● Dedicated bucket(s) mop(s) and cleaning supplies are utilized for the decontamination area and the clean area