



C.S.S.D



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2015

State of KUWAIT

Ministry of health

Infection control directorate

Section location	Central sterile department (C.S.S.D)
Effective Date	May 2015
Applied to	All workers in C.S.S.D

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Standard Operation Policy No. SOP1	Policy Title : CSSD function & Layout
Issue Date :	Section : Central sterile supply department

Responsibilities of Main CSSD

1-The CSSD provides support to all patient care services and responsible for :

- a. Collection.
- b. Decontamination.
- c. Disinfection.
- d. Inspection.
- e. Assembly
- f. Packaging.
- g. Sterilization.
- h. Storing.
- i. Distribution of all instruments and medical devices.

2- Providing Sterile supplies to all hospitals, clinics and polyclinics -ministry of Health.

3-Planning and approval for the design of any CSSD in the Ministry's or private hospitals.

4- Providing policies / procedures and supervising the implementation of the same in MOH.

5-Technical Supervision on central sterile supply department (CSSD) .

6-Communicate with the end users to improve the quality of the service.

7-Participating in committees to outline specifications of purchased equipment and raw materials.

- 8-Specifying criterion for quality control of all items produced by CSSD's.**
- 9-Providing two years training program in the field of sterilization for the Public Authority for Applied Education .**
- 10-Training technical staff prior to employment in private hospitals.**
- 11-Providing consultancy and technical advice to enquiries related to sterilization from both Ministry of Health or private hospitals.**
- 12-Providing on job training program, refreshment courses and continuous updating of technical staff**

Progress towards Quality Systems Accreditation

- 1-The Directorate of Infection Control is intending to obtain the Quality Systems Accreditation (ISO). On this regard and impressive progress was achieved to fulfill the requirements of the Quality Systems.**
- 2-Continuous training programs are in progress to increase awareness of technical staff about Quality Systems.**
- 3-Quality Manual, Quality Procedures and Quality Control Records were prepared and implemented.**

II- LAYOUT

- 1-The department should be designed so that it is physically separated from all other work areas.**
- 2-The department should be designed to facilitate a unidirectional flow from the 'dirty' area to the 'clean' area**
- 3-There should be a changing area for workers including toilet facilities and lockers in proximity to the decontamination area.**
- 4-Access to the wash room and to the clean room should be through dedicated gowning rooms provided with hand hygiene facilities.**

5-The wash room, clean room and sterilizer unloading area should be free from 'opening' windows, and unclean areas

6-All rooms in the department should be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures should be controlled between 18-22°Celsius and relative humidity should be controlled within the range 35-60%).

7- Staff movement between dirty and clean areas should not be possible without passing through a clothing change and wash-up area

8-Storage facilities for bulk items should be provided external to the clean room and the wash room

Standard Operation Policy No. SOP2	Policy Title : CSSD Health & safety
Issue Date :	Section : Central sterile supply department

- 1-All personnel must follow traffic flow patterns.
- 2- Material Safety Data Sheets (MSDS) for all chemicals used in the sterile service department must be available
- 3- All employees must be trained in appropriate personnel protective equipment designated for each area
- 4- Employees must follow and practice hand washing guidelines (before and after each tasks)
- 5-Eating and drinking is prohibited in all workspaces including supply storage, processing and decontamination sections
- 6- Work spaces must be free from clutter and have un-obstructed entrances and exits.
- 7-Visitors are not allowed to enter without permission. If visitors must enter restricted areas, appropriate attire is required and they should be escorted by CSSD staff
- 8- Safe keeping of all items by ensuring that storage areas are kept clean,
- 9- Prevent burn injuries when loading or unloading steam sterilizers and washer disinfectors by following procedure and wearing appropriate PPE.

10- Employees must use proper body mechanics when carrying or handling heavy items.

11- On entering the Sterile Service Department, all staff will change into departmental uniform provided in the changing area including shoes.

12- Staff moving into the wash area, who will be engaged in the handling and processing of incoming equipment, will put on an extra protection gown, gloves and protective goggles(when splashing is anticipated)

13- When leaving the wash area staff will remove and discard the gown and gloves and wash their hands.

Standard Operation Policy No. SOP3	Policy Title : PPE (personal protective equipment)
Issue Date :	Section : Central sterile supply department

- 1- When handling contaminated items, wearing personal protective equipment (PPE) is required.
- 2- PPE's include: eye protection, gloves, surgical mask, moisture resistant gown, shoe covers and hair covering. After task is completed, remove and discard all PPE's and thoroughly wash hands
- 3- All head and facial hair should be completely covered with surgical cap in restricted areas.
- 4-Finger nails must be kept short, clean and healthy, nail polish is not allowed.
- 5- Hand jewelry and wrist watch is not allowed to wear in decontamination area.
- 6- Vaccination is mandatory for hepatitis B for workers .

Standard Operation Policy No. SOP4	Policy title : Job descriptions
Issue date	Section Central sterile supply department

Head of CSSD

- 1- Run CSSD according to the goals and objectives of infection control Directorate and ensuring its implementation and follow up.
- 2- Supervising, directing and follow up of CSSD staff ,suggesting the best motivation approach .
- 3-ensuring covering the hospital' requirements of sterile supply.
- 4- Yearly assessment of the employee .
- 5-preparing & writing reports for infection control directorate.
- 6- keep accurate records for all CSSD activities including the repair programs for CSSD equipments & machines .
- 7-Taking part in emergency plan for CSSD and regular check up .
- 8- participate in training the staff by giving lectures during courses or scientific days .

9- Planning & consultation regard CSSD design & layout in government & private sector .

10-Performing other tasks entrusted by infection control manager

Training supervisor

1-Ensuring that all CSSD workers have both the efficiency & the skill to perform their jobs according to their job descriptions.

2 -Participate in the implementation of continuous training programs , scientific activities, according to the selected program .

3- observations of the the CSSD supervisory inspection reports and suggest appropriate program to evaluate the outcomes.

4-Participate in the evaluation of the technical performance of workers in the field of training and for new employees during the training period.

5-Follow developments in the field of sterilization to prepare the necessary reports to discuss the possibility of their application .

6-Prepare operating instructions manuals for the CSSD equipments .

7- Performing other tasks entrusted by infection control manager.

Senior sterilization technician

10 years working in CSSD

Updated on 2014 maximum 7 years required currently

- 1- knowledge of CSSD tasks and participate in the training of new employees according to the plan and in evaluating their performance .
- 2-participation in the organization & distribution of work in the assigned region in accordance with the approved program .knowledge of quality control .
- 3- Ensure the availability of all raw materials and equipment needed to ensure the regularity of the workflow
- 4- Good planning to increase daily production in their group according to the operating instruction manual . and contribute in solving problems relating to work.
- 5-performing the assigned statistics according to planned program .
- 6-Ensuring the validity of the CSSD equipments in the assigned area,recording the results and contacting repair technicians .
- 7- ensure to follow the correct procedure of cleaning and disinfection of the surfaces before handing the area to the following shift.

8- Committed to work in the holidays century duty according to planned time table .

9-performig other tasks entrusted by head of CSSD .

Sterilization technician (5 years working years)

1- Follow the correct procedure in the decontamination area of reception ,segregation and loading the soiled instruments in the trays

2- Assembly & packing of the instruments is performed according to operation manual.

3- Packaging of single use packages according to the planned program.

4- Regular performance of validation tests of the instruments

5- Operating all the equipments & devices in CSSD according to operating manual .

6- Arranging the packages in the sterile store according to the expiry date ,preparing the orders for hospital wards

7- Should have enough knowledge regard quality assurance in each area of the CSSD and participate in the statistics collection .

8- Using the electrical cutter to cut sterilization papers and gauze.

9- Committed to work in the holidays century duty according to planned time table .

10- performing other tasks entrusted by head of CSSD.

Sterilization technician Assistant

- 1- Assisting the sterilization technician of following the correct procedure in the decontamination area in sorting ,segregation and loading the soiled instruments in the trays before cleaning and disinfection .in addition ensuring the validity of CSSD washer disinfectors.
- 2- After ensuring cleanliness and disinfection of the working surfaces assembly of the instruments is performed according to operation manual.
- 3- Packaging of single use packages according to the planned program.
- 4- Assist in Regular performance of validation tests of the instruments
- 5- Operating all the equipments & devices in CSSD according to operating manual under supervision .
- 6- Arranging the packages in the sterile store according to the expiry date ,preparing the orders for hospital wards
- 7- Should have enough knowledge regard quality assurance in each area of the CSSD and participate in the statistics collection .
- 8 -Using the electrical cutter to cut sterilization papers and gauze.
- 9- Committed to work in the holidays century duty according to planned time table
- 10- performing other tasks entrusted by CSSD manager.

Assistant Sterilization technician

(6 months course) MOH stopped these courses since 1992

Job description

- 1- Assistance of the sterilization technician in decontamination area including reception ,segregation and loading of soiled instruments prior to cleaning & disinfection.
- 2- Assistance in cleaning & disinfection procedure according to guideline manual procedure
- 3- Cleaning & disinfection of the working surface in packaging area .
- 4- Operating the decontamination area equipments under supervision of sterilization technician .
- 5- Packing single use packages of all kinds .
- 6- Assistance in assembly & packing instruments trays and labeling under sterilization technician supervision
- 7- Assistance in operating & loading the sterilization machines .
- 8- Assistance in storage work (unsterile & sterile) in preparing & organizing the packages .
- 9- performing other tasks entrusted by CSSD manager

Sterilization Nurse

Nursing Diploma

Job description

- 1- Assistance of the sterilization technician in decontamination area including reception ,segregation and loading of soiled instruments prior to cleaning & disinfection.**
- 2- Assistance in cleaning & disinfection procedure according to guideline manual procedure**
- 3- Cleaning & disinfection of the working surface in packaging area .**
- 4- Operating the decontamination area equipments under supervision of sterilization technician .**
- 5- Packing single use packages of all kinds .**

- 6- Assistance in assembly & packing instruments trays and labeling under sterilization technician supervision
- 7- Assistance in operating & loading the sterilization machines .
- 8- Assistance in storage work (unsterile & sterile) in preparing & organizing the packages .
- 9- Performing any other tasks assigned by CSSD manager

Standard Operation Policy No. SOP5	Policy title : Cleaning of CSSD building
Issue date	Section Central sterile supply department

- 1- The CSSD must be cleaned on a daily basis at the beginning and at the end of each shift.
- 2- Cleaning equipment must be stored in a designated area for CSSD use only.
- 3- Cleaning of the department must be undertaken by CSSD staff with the assistance of a cleaner
- 4- Daily cleaning of the area includes damp mopping floors, storage shelves and other work surfaces /empty trash containers. high cleaning is performed as required.

5- CSSD staff is responsible for ensuring that all surfaces are cleaned in accordance with the cleaning schedule

6- All counter surfaces and floors must be disinfected at least daily

7- The disinfectant must be freshly prepared on a daily basis and discarded at the end of the work day .

8- Cleaning and disinfectants agent must be approved by ministry of health

10- Storage of raw material in production areas must be minimal. only sufficient raw material for one days production must be kept.

11- Outer packaging must be removed from raw material before they enter the assembly and packaging area to avoid environmental contamination .

12- Vacuuming the air vents and cleaning out the light fixtures is recommended at least twice per year to prevent build up of dust and lint .

Standard Operation Policy No. SOP6	Policy title : Water Quality
Issue date	Section Central sterile supply department

- 1- water used for the cleaning of instruments should meet specific quality it should not cause damage to instruments and equipment.
- 2- Water hardness is determined by the amount of calcium and magnesium ions present. High levels of mineral content will result in surface staining and shorten surgical instruments life span .
- 3- Chlorides are the most corrosive of water contaminants.
- 4- Water with high mineral content is unsuitable for the final rinsing of instruments due to mineral deposits permanently damaging and shortening the life span of the item.high mineral content may also interfere with the efficacy of the cleaning agents.
- 5- Hardness can affect the activity of the detergent used for cleaning and may require increased concentrations of detergent

6- Water testing can either be conducted by biomedical engineering department or by chemical distribution representative from the public health authority .

7- Ph levels ,water quality and chemical compatibility tests are carried out and recorded

8- Report any residue left on instruments to the supervisor and biomedical engineering department .

Standard Operation Policy No. SOP7	Policy title : Collection of soiled/contaminated equipment
Issue date	Section Central sterile supply department

1- Non-sterile gloves must be worn for the collection of soiled instruments

2- Wash hands in accordance with departmental procedures.

3- Wear protective clothing / attire in compliance with standard precaution guidelines.

4- Use allocated trolleys.

5- Follow designated collection routine and time table in accordance with department Guidelines

6- Linen and waste must be separated from reusable medical devices at the point of use.

- 7- Gross contaminants such as large amount of blood & body waste must be removed at the point of use before collection by CSSD staff
- 8- Collect used items in puncture resistant closed containers; do not overload.
- 9- Place heavy instrument containers at the bottom of trolleys.
- 10- Secure contaminated items and cover prior to transportation.
- 11- Transport / Deliver used items and equipment to the cleaning area
- 12- Clean and disinfect collection trolleys and bins and store appropriately.
- 13- Use allocated vehicle for transport. regular cleaning is required .

Standard Operation Policy No. SOP8	Policy title : Dealing with known infectious cases (soiled instrumentation with labeled infectious)
Issue date	Section Central sterile supply department

- 1- Consider every item collected and received to C.S.S.D infectious either labeled or not .(some pt. don't inform / virus incubation period with no symptoms)
- 2- Ensure proper handling for instruments with complete P.P.A.
- 3- Avoid Manual wash or Ultrasonic .
- 4- Use washer disinfector with load/ recommendation to use lower shelf
- 5- Run the cycle according to temperature recommended
(90 C or 85 C)

- 6- The specification of the washer includes self disinfection cycle therefore no need to run the washer twice .
- 7- Most viruses can be killed in the temperature selected .no need to run the washer twice .
- 8- Report the instruments with detailed
- 9- Report any injury – incident report
- 10- Disinfect the transport container using washer disinfectant or trolley washer if available (bottom shelf)

Standard Operation Policy No. SOP9	Policy title Instrument segregation & loading the trays
Issue date	Section Central sterile supply department

- 1- Handle contaminated devices as little as possible.
- 2- All equipment is transferred from the boxes to the work surface.
- 3- Identify if the process of cleaning & disinfection (manual/machinery)
- 4- Identify items requiring special attention and handle in accordance with documented manufacturers' instructions
- 5- Each instrument will be prepared for decontamination as follows
 - Avoid contaminating hands wear PPE

- Separate baskets, container and instruments.
- Check degree of soil, sort and discard any disposable material.
- Sort Cannulated and solid devices.
- Open all hinged instruments
- Flush all Cannulated instruments with the pressure jet gun

Disassemble all multi part instruments

- Handle and process all devices in accordance with the manufacture instructions .
- If an instrument is broken, any broken piece is reported immediately
- the missing instrument should be reported & recorded.

When loading the washer disinfector:

- Choose the relevant washer rack
- Place instruments into a wash basket and check to ensure all items and parts are present.
- Load items to be decontaminated in the correct position in baskets so that maximum exposure to the decontamination process is achieved on all surfaces of the instrument

CSSDORUM STANARD OPERATING PROCEDURE

- Connect all tubes to the appropriate connector on the basket union. And position tray into the chamber
- Place heavier items at the bottom making sure that all surfaces can be reached by the spray jets .
- jets
- Do not pack too densely, all surfaces must be reached by the spray jets.

- Use detergents according to washer manufacturers' instructions
- A full-automated process should be According to A □ 3000.
- Maintain records of all items received and prepared for processing

Standard Operation Policy No. SOP10	Policy title : Manual cleaning of medical devices
Issue date	Section Central sterile supply department

- 1 - Identify the correct process for the items to be decontaminated according to manufacturer's instructions.(with immersion /without immersion)
- 2 - Staff working in this area will wear protective clothing at all times in compliance with the standard precautions dress.
- 3 -Two dedicated deep sinks must be available with a dedicated drying surface
Sinks and accessories must be cleaned at each water change. The sinks should only be used for washing instruments, not for hand washing or anything else

4 -When cleaning manually, a pre-rinse, wash, rinse and drying process must be followed.

5- Water and detergent should be measured according to manufacturers' instructions and have the correct chemical mixture

6 - If the water, is visibly stained at any stage it must be replaced

7 - All devices being manually cleaned must be fully immersed in the washing water while being scrubbed

8 - Special attention must be paid to the joints of any jointed instrument and meticulous attention paid to the tips or crevices.

9 - A clean soft brush or soft cloth is required to clean the surfaces.

10- After decontamination, all devices must be visually inspected for soil, damage and Functionality tested.

11- Dry items using a lint free cloth or the dryer.

Standard Operation Policy No. SOP11	Title policy : Assembling Trays
Issue date	Section Central sterile supply department

- 1-After decontamination, all clean items are received into the packing area
- 2- Any item that is rejected due to evidence of residual blood, body fluid, stains or water are returned by window dispatch.
- 3- Any item that is damaged or broken should be documented
- 4-Make sure that all work surfaces are clean and disinfected . according to department procedure
- 5- cleanliness & functional test should be performed..

- 6- Trays should be perforated to allow penetration of the sterilizing agent and efficient drying.**
- 7-Instruments must be laid out according to the order on the check list should be signed.**
- 8-The contents of instrument sets are usually decided by the surgical team.**
- 9- Place an in-pack chemical indicator into most challenging part of the tray. This indicator will only change colour if the in pack sterilization parameters have been reached**
- 10- Ensure that the tray checklist is dated and signed by the packer and checked.**
- 11- The weight of packs must be taken into consideration when assembling trays. (MAX.8 kilos)**
- 12- Overloaded and heavy trays/sets may some cases remain wet**
- 13- Place a tray liner (where indicated) on the bottom of the tray.**
- 14- Check instruments visually for cleanliness and missing parts /functional test (tips, screws, free movement, sharpness and overall condition).**
- 15- Instruments with ratchets or hinges should be held in an open and unlocked position;**
- 16- Instrument should be left slightly open to allow for sterilant penetration, rings should be slightly separated**
- 17- Tips of instruments should all be facing the same direction the use of tip protectors is often advised by the manufacturer**
- 18-Always make sure that all parts of the instruments are present**
- 19- Items (bowl/basins/receivers) that could hold water during steam sterilization must be placed in a way that allows easy drainage.**
- 20- Heavy instruments should be placed at the bottom of the tray as the weight of heavy instruments or retractors lying on top or over other instruments can cause the instruments at the bottom to bend and become misaligned.**

Standard Operation Policy No. SOP12	Policy title : Packing and wrapping
Issue date	Section Central sterile supply department

- 1- Instruments and other items that are prepared for sterilization must be packaged so that their sterility can be maintained to the point of use .
- 2- Access to CSSD sterile packaging area must be restricted
- 3- All staff are responsible for keeping the preparation room entry / exit neat and tidy
- 4- Everybody entering the preparation area must be correctly dressed and conform to policy
- 5- No personal possessions other than locker keys are allowed to be taken into the preparation area
- 6- No jewelry is allowed other than stud like ear ring , and the must be completely covered with head wear
- 7- No food or drinks of any kind may be taken into any area of the department
- 8- Before entry to the preparation room area all personnel will put on suitable head covering and clean room gown
- 9- Personnel will wash and dry hand before entering the area
- 10- Head covering must be worn at all times and only discarded at the end of the shift
- 11- Quality of packing materials .

12-Packaging materials should fulfill the following aspects :

- effective barrier
- easy to use
- puncture resistance
- resistant to tearing
- non- linting
- non reactive
- heat compatible
- non toxic
- non odorous
- flexible sizing

12- All wraps shall be single used.

PAPER-PLASTIC POUCHES

- 1- Select a package of appropriate size to accommodate the item(s) that is being packaged. Allow enough room for securely sealing the package.**
- 2- Cover all sharp pointed items with protectors to prevent tips from puncturing The package.**
- 3- Place item(s) in package with the “handle end” of the instrument toward the end of the Package that will be opened by the user**
- 4- When double peel packaging; select a larger size outer package to allow the inner Package to remain unfolded. Folding the inner package may hinder the steril-ant from Penetrating the packaging**
- 5- must use standardized heat sealing machine .**

WRAPPED ITEMS (Crepe OR NON-WOVEN)

- 1- Select the appropriate sized wrappers to adequately cover the item being wrapped. **NOTE: All Items will be wrapped in two layers of wrapping material.**
- 2-Place item on wrapper and wrap the item with either the envelope or parcel method. (use specific packaging materials –TYVEK)
- 3- Seal the package using appropriate sterilization indicator tape, depending upon the method of Sterilization being used
- 4-Check if the instruments set tray is complete with indicator strip and check list signed and double-checked by senior technician
- 8- For instrument sterilized by plasma sterilizers manufacturer’s recommendations should be followed

Standard Operation Policy No. SOP13	Policy title : Steam sterilizer
Issue date	Section Central sterile supply department

- 1- For an autoclave with a manual recording chart, replace chart identifying autoclave, date and initial in place provided
- 2- The first cycle will be a “warm up “cycle.
- 3- On the second cycle place a Bowie & Dick Test Pack, Run the test according to manufacturers’ instructions
- 4-Once the cycle has run record the Bowie & Dick according to procedure
- 5- If the Bowie Dick result is a fail repeat the test with a new Bowie Dick Test pack. If the Bowie Dick is still a fail shut down the autoclave for repair and recall all sterile packs
- 6-after the last Positive Bowie Dick Test result Run a daily Biological, according to manufacturers’ instructions

- 7- Record contents of load, information must be detailed enough to allow for tracking and recall if necessary.**
- 8- Label Package according to policy**
- 9- Packaging manufacturers must validate that the product contained can be satisfactorily sterilized within the wrap, pouch, container etc.**
- 10- Process full loads – not overloaded- to limit the number of cycles you need to run**
- 11- Load the autoclave according to manufacturers' instructions, make sure the door to the chamber is locked, and the appropriate cycle is selected based on the types of devices being processed.**
- 12- Load baskets and carts so hands won't touch packs when removing the hot trolley.**
- 13-On completion of cycle, cycle complete indicator will appear, visually check the graph / printer to determine that all parameters have been met.**
- 14- In the event of a cycle failure / cycle aborted, the entire load will need to go through the full reprocessing cycle.**
- 15- Put on heat resistant gloves and remove carrier from steam sterilizer .**
- 16- Allow to cool for 10 – 20 minutes before storage or dispensing.**
- 17-Inspect packages to ensure integrity and external chemical indicators have changed.**

I-Loading steam sterilizer :

- 1- Wear relevant protective clothing
- 2-Load instruments sets flat in single layer
- 3- Load soft packages on their sides with a hands width between items
- 4- Load soft packs on top shelf and large instrument trays on lower shelf
- 5- Load containers according to manufacturers instructions some may be stacked
- 6- Do not allow packs to touch top, bottom or sides of autoclave
- 7- Do not compress packs
- 8-Position peel packs on sides
- 9- Do not overload

II- Unloading steam sterilizer

- 1- On completion of cycle record according to policy
- 2- Allow autoclave and packs to cool before handling
- 3- Do not touch packs until completely cooled
- 4- DO NOT TOUCH HOT RACKS WITHOUT HEAT RESISTANT GLOVES
- 5- Once cooled check for wet packs, tears, indicator changes etc.

Monitoring steam sterilizer :

- 1- Monitoring includes all sterilizer components that track and record time, temperature and pressure during each cycle, Printouts, gauges, round charts, etc.
- 2- Documentation of critical cycle parameters permits the earliest detection of equipment malfunctions since they can be evaluated when the cycle is in progress

Sterilization failure can be identified at a number of stages:

- Autoclave parameters are not met
- Biological Test shows growth
- Bowie Dick Test Failure
- Process Challenge Device or Load Control Failure
- External Process Indicator Failure
- Internal Chemical Test Failure

Wet Packs

-Chemical Indicators

-Chemical Indicators are used in combination with physical parameter to monitor the effectiveness of the sterilizer

- They monitor conditions in the sterilizer chamber or from within the load as part of a total system of sterilization monitoring.

The following main types of chemical indicators are available

- Process indicators

- In-Pack indicators

- Load controls or Process Challenge Devices

Standard Operation Policy No. SOP14	Policy title : Ethylene Oxide Sterilization
Issue date	Section Central sterile supply department

Instructions

5- It is important that all staff members are aware of the policy and procedures that relate to EtO sterilization (refer to room specification)

6-Operators must know how to operate the ETO sterilizer safely as well as the importance of adequate aeration

7-Operators need to understand the environment requirements and safe work practices

8- Operators must know what the emergency procedures are in case of a leak or accident

9- The ETO sterilizer must be operated accordance with the manufacturer's instructions

10- The ETO sterilizer must be used in a well ventilated controlled room with dedicated exhausts, emission control, enclosed ETO sterilizer/aerator room, ventilation, air exchanges and environmental monitoring provided

11- Single-use cartridge delivers the appropriate volume/concentration of ETO

12- Check with gas manufacturer/supplier for storage recommendations and MSDS sheet.

13- ETO gas must be stored at the prescribed temperature in a well ventilated area in a cupboard marked with Hazardous materials label

14-The sterilizer operating temperature is usually preset by the sterilizer manufacturer; there are usually two options: 37 C (cold cycle) 55C (warm cycle)

15-The manufacturer of a device is responsible for providing validated information regarding proper sterilization and aeration of their products, depending on

the concentration, humidity, temperature parameters, and the type of sterilizer

16- The ETO cartridge must be discarded in a safe manner according gas manufacturer/supplier and hospital policies

16- Packaging manufacturers must validate that the product contained can be satisfactorily sterilized within the wrap, pouch, container etc. and can release EO upon aeration in a reasonable amount of time; not only from the device but the packaging material too

Standard operation policy	Policy title
No.15	Plasma sterilizer
Staff/area	Sterilization area

1-Used for heat sensitive items with specific diameter and tube length .

- Any item that is not completely dry.
- Items or materials that absorb liquids.
- Items made from materials containing cellulose e.g., Cotton, paper, cardboard, linens, gauze or items that contain wood pulp

- 2- Do not remove cassette from plastic wrapper if indicator strip is red (Sterrad) this indicates That the cassette might have been damaged**
- 3- Use manufacturer approved biological indicators) biological monitoring is recommended to be performed with every load.**
- 4- Place biological monitor into a Tyvek pouch then put it with load in sterilizer as per manufacturer's recommendation (Sterrad: Back of the chamber on the bottom shelf with the opening toward the back of the chamber).**
- 5-Incubate Biological indicator at temperature as recommended by manufacturer.**
- 6- Preparing Items for loading & Loading sterilizer.**
- 7- All items must be thoroughly cleaned and dried before packaging.**
- 8- Use packaging and containers recommended by the manufacture.**
- 9- Place chemical indicator in each packaged item.**
- 10-Arrange items in such a way as to ensure sterilant will come into contact with all surfaces.**

Standard Operation Policy No. SOP16	Policy title: The Delivery and Distribution of Processed Items
Issue date	Section Central sterile supply department

- 1-All items will be checked for sterility before they are released
- 2- The following should be checked when deciding if the pack is still sterile:
 - Holes or tears
 - Wetness or stains
 - Broken seals
 - Dust
- 3- All damage items are returned to the CSSD
- 4- All items issued will be recorded so that a tracking system is effected
- 5- Various methods can be used in the transport of sterile packaged items to their point of use.

6- Sterile supplies should be transported in covered or enclosed trolleys with a solid bottom shelf. The solid bottom shelf prevents microorganism on the floor being picked up by the wheels of the trolley and then spun upwards onto the sterile packs

7- If items are placed inside plastic or paper bags, they should be arranged to prevent them from being crushed or damaged during transport. They all protect medical devices from damage

9- Items must be placed onto a clean trolley that can be covered

10-Trolleys must not be overloaded

11-Soiled items must NOT be loaded onto the same trolley

Standard operation policy No 17	Policy title : Equipment maintenance
Issue date	Section Central sterile supply department

1- Equipment must be maintained according to manufacturers specification .

2- Records of the repair made to each piece of equipment must be maintained within the CSSD and recorded in the maintenance log,

3- Copies of the maintenance log from the manufacturing company must be kept in biomedical department and CSSD respectively .

4- After any major repairs or modifications are made to satirizing equipment a validation test must take place before the equipment is placed back to service .

5- CSSD staff must inform the department manager when any maintenance has been performed.

Standard operation policy No 18	Policy title : Single use
Issue date	Section Central sterile supply department

1- Correct use of ‘ single use ‘ equipment is essential to ensure that all risks from medical devices are minimized for the control of infections.

2- Possible consequences and legal implication of reusing single use devices :

- **Re-use of a single medical device can expose the patient and the re-processor to unnecessary risks.**

- **Reprocessing a single use device may alter its characteristics so that it may no longer comply with the manufacturer's specifications and the device may not work properly .**

- **Most problems associated by inappropriate reuse of a single device fall into one or more of the categories.**

- Potential for cross infection .**

- Inability to clean and decontaminate .**

- Residues from chemical decontamination agents.**

- Mechanical failure.**

- Sufficient stocks of single – use device are available so that staff do not consider their re-use .**

- Staff are aware of the risks associated with reprocessing single-use devices,i.e all staff are aware that they report all incidents relating to single-use and single patient use devices in accordance with the adverse event reporting procedure .**

Standard operation policy No.19	Sterile Storage
Issue Date :	Section : Central sterile supply department

**1 - All sterile must be cooled before storing and shall be stored in a secure location
This maintains the Integrity of the sterile item.**

2 - All storage areas shall be clean, dry, protected from moisture.

3- Before storage, all sterile items shall be checked for the following:

- Items are completely dry
- Integrity of the outer wrap
- Coloring of sterile indicator tape, date prepared, initialed
- Lot number labels.

- 4- Any sterile item that has been dropped on the floor is considered unsterile.
- 5- Stock sterile items on shelves 8-10 cm from the floor and 20 -25 cm from ceiling.
- 6- Unauthorized personnel, patients, or visitors are prohibited to enter the sterile storage area. Ensure the proper signs and labels are posted in the storage shelves.
- 7- Items will be labeled (Sterile unless package is opened or damaged and checked Before use).
- 8-Damage of sterile items includes: Hole or torn wrapper, broken seal in peel Pouches, items dropped, securing tape or lock that shows sign of tampering or having been removed, exposure to contaminants of unsafe environment and exposure to any type of moisture will be considered un-sterile.
- 9- Temperature should be controlled in range of. Relative humidity 35%-50% to prevent drying out or premature breakdown of material of seal.

Standard operation policy No.20	Textile -Green laundry
Issue Date :	Section : Central sterile supply department

-Clean textiles must be stored in a clean storage area shelving units and transported in a closed container to prevent cross contamination

- Textiles should be visually inspected between drying and packing, with the assistance of a light table, for stains, physical defects, foreign debris, labels/tape, against written quality standards.

- Quality assurance measures need to be in place to ensure that every step in the process i.e. collecting, cleaning, disinfecting, drying, storage and transporting of textiles meet validated process specifications. Acceptable standards can be met if reusable textiles are treated as medical devices and are professionally processed accordingly.
- The drying cycle is an important part of the cleaning process as it assists in killing any remaining microorganisms that may be left after the laundry machine has done its work
- Linen to be sterilized must be appropriately checked and wrapped before being sent to the sterile processing department. Linen must not be placed or stored on the floor.
- Linen must be stored in a dedicated clean storage area

Standard Operation Policy No. SOP21	Policy title : Shelf life
Issue date	Section Central sterile supply department

1-The shelf life of a pack is dependent on packaging, handling and storage conditions.

2- The date on a sterile package indicates the date the item was sterilized or manufactured. Sterility is maintained as long as the integrity of all barrier properties and seals are maintained

3-Expiration date is a reminder “Use Before” /”Use First”

3 months for wrapping papers/sterilization bags / 6 months for flat reels.

4- Storage conditions will be such that product integrity is not compromised by moisture or any other means which breach the wrapping materials

5- The probability of a contaminating event happening increases over time.You can maintain a product’s shelf life by:

-reducing its exposure to direct sunlight, excessive temperatures and humidity

- reducing handling and transportation as much as possible

- Holes or torn wrappers

- Broken or incomplete seals on laminated pouches

- Items that have been dropped on a dirty surface

- Exposure to blood, body fluids or any type of moisture.

-Cardboard boxes are not to be used except where supplied by the manufacturer

9-Items should be decanted from large outer (shipping) boxes prior to being brought into the sterile storage area

10- Elastic bands or tapes should not be used to bundle items

Standard Operation Policy No. SOP22	Policy title : Tracking system
Issue date	Section Central sterile supply department

1-To ensure that surgical instruments can be tracked through decontamination processes .

2- Labels are applied to the external packaging, prior to sterilization to allow ease of identification of the contents of a package and the process

3- Packaging should be labeled prior to sterilization in a way that does not compromise the integrity of the pack.

4-Labeling must not:

- Affect the sterility or integrity of the pack**
- Transfer to pack content**
- Interfere with the decontamination process**
- Become detached after sterilization or subsequent storage**

5- An electronic system allows the items to be scanned by a hand held scanner with the information downloaded to produce a batch report.

6- A common method involves the use of bar codes that are used to identify packs and device locations by a scanning process

7-Packaging systems should be labeled with;

- a description of the package contents**
- identification of the person receiving, cleaning, checking, assembling, sterilising, storing, dispatching the package**
- a lot control number**
- any expiration date/shelf life statement applicable to the facility**
- dispatch information**

8- All affected trays can be recalled in the event of failed quality management or in the event of a contagious disease or infection, if an effective tracking system is available

Standard Operation Policy No. SOP23	Policy title : Wast management
Issue date	Section Central sterile supply department

1- The arrangements for the handling and temporary storage of waste awaiting collection within the CSSD should be part of the hospital's waste management programme and should conform to current legislation and guidance.

2- Categories of health-care waste

Descriptions and examples

Waste category

Hazardous health-care waste

Sharps waste

Used or unused sharps (e.g. hypodermic, intravenous or other needles; auto-disable syringes; syringes with attached needles; infusion sets; scalpels; pipettes; knives; blades; broken glass)

Infectious waste

Waste suspected to contain pathogens and that poses a risk of disease transmission (see section 2.1.2) (e.g. waste contaminated with blood and other body fluids; laboratory cultures and microbiological stocks; waste including excreta and other materials that have been in contact with patients infected with highly infectious diseases in isolation wards)

Non-hazardous or general health-care waste

Waste that does not pose any particular biological, chemical, radioactive or physical hazard

3- Colour code:

- Yellow bags : infectious waste – incineration
- Blue/ black bags : domestic waste
- Red bags : microbiological/solid waste

Standard Operation Policy No. SOP24	Policy title : Reprocessing Endoscope
Issue date	Section Central sterile supply department

A. Recommended reprocessing of flexible endoscopes

- **As a rule: Endoscopes or accessories that contact sterile tissue (e.g., laparoscopes, arthroscopes and other scopes) should be sterilized and endoscopes that contact intact mucous membranes (e.g., the respiratory and gastrointestinal tracts) undergo at least high-level disinfection before each use.**
- **All heat-sensitive endoscopes (e.g. gastrointestinal endoscope, bronchoscope, nasopharyngoscope) must be at a minimum, subjected to high-level disinfection after each use.**
- **Sterilization with a liquid chemical sterilant may not convey the same sterility assurance as sterilization achieved using thermal or low temperature chemical gas/ plasma/vapor sterilization.**

B. Training

- All health care personnel in the endoscopy suite should be trained in and adhere to standard precautions and safety measures regarding the biological and chemical hazards.
- Personnel assigned to reprocess endoscopes should receive device-specific reprocessing instructions ie, endoscope and/or automatic endoscope reprocessor (AER).

C. PPE

- Personal protective equipment PPE (eg, gloves, gowns not water permeable, mask, eyewear, respiratory protection devices) should be readily available and should be used during handling of the endoscopes, as appropriate, to protect workers from exposure to chemicals and blood or other potentially infectious material.

D. Recommended disinfectant

- Select a liquid disinfectant or sterilization technology that is compatible with the endoscope.
- FDA maintains a list of cleared liquid chemical sterilants and high-level disinfectants with the exposure time and temperature that can be used (<http://www.fda.gov/cdrh/ode/germlab.html>)
- At this time, the FDA-cleared and marketed formulations include:
 - >2.4% glutaraldehyde at 25°C range from 20-90 minutes (professional organizations support the efficacy of >2% glutaraldehyde for 20 minutes at 20°C),
 - 0.55% ortho-phthalaldehyde (OPA) for 12 minutes at 20°C,
 - 0.95% glutaraldehyde with 1.64% phenol/phenate,
 - 7.35% hydrogen peroxide with 0.23% peracetic acid for 15 minutes at 20°C,
 - 7.5% hydrogen peroxide .
- Disinfectants that are not FDA-cleared and should be strongly discouraged because of lack of proven efficacy against all microorganisms or materials incompatibility are:
 - iodophors
 - alcohols
 - chlorine solutions
 - phenolic
 - quaternary ammonium compounds

E. Steps of reprocessing of flexible endoscopes

Step 1: Precleaning

- Precleaning should be performed at the point of use by wiping the exterior of the endoscope with soft cloth/sponge soaked in freshly prepared enzymatic detergent .
- Flush suction/biopsy and air/water channels with enzymatic detergent. Other channels should be cleaned per manufacturer's instructions.
- Remove all detachable parts e.g., valves/buttons/caps and clean with enzymatic detergent.
- Correctly dispose of parts designated as single use.

Step 2: transportation

- Transport the soiled endoscope and accessories to the reprocessing area immediately before remaining soil dries.
- An open container can suffice for transport to immediately adjacent reprocessing rooms, but fully enclosed and labeled containers should be used for transportation to distant areas.

Step 3: Leak testing

- Perform pressure/leak testing after each use and before reprocessing, according to manufacturer guidelines to verify the integrity of the endoscope.
- If AER is used, this step should be part of the machine cycle.
- If leak detected, send for repair.

Step 4: Manual Washing

- Disassemble removable parts e.g. all buttons/valves/caps and other removable parts and reprocess (step5)
- Completely immerse the Endoscope in enzymatic detergent solution. Wipe exterior of the endoscope with a soft brush.
- Brush all channels until there is no debris visible. Discard brush appropriately after use.
- Drain water from the sink.
- Curl endoscope for transfer to a separate sink.
- Immerse endoscope in another sink full of water for rinsing to remove residual detergent.
- Flush all channels with water.
- Discard enzymatic detergents after each use.

Step 5: Disinfection/sterilization of endoscopic accessories and removable parts

- Reusable endoscopic accessories (eg, biopsy forceps, snares, sphincterotomes, and other cutting instruments) and endoscopes removable parts e.g. buttons/valves/caps should be mechanically cleaned and then sterilized between each patient use (high-level disinfection is not appropriate).
- Ultrasonic cleaning of reusable endoscopic accessories and endoscope components may be used to remove soil and organic material from hard-to-clean areas.
- High-level disinfect or sterilize the water bottle (used for cleaning the lens and irrigation during the procedure) and its connecting tube at least daily. Sterile water should be used to fill the water bottle.

Step 6: Disinfection/sterilization of endoscopes

A. Automated disinfection

- Automated endoscope reprocessors (AERs) are of two principle types; endoscope washer-disinfectors (EWD) and liquid chemical disinfectors (LCD).
- The use of an endoscope washer-disinfector (EWD) is strongly recommended as the best method.
- EWD can be used for all types of endoscopes while LCD can not be used for gastroendoscopes or any endoscope with three and more channels.
- Both EWDs and LCDs should provide:
 - A leak test facility
 - A purging stage after the post-disinfection rinse to ensure that channels are cleared of water.
 - A drying stage to dry the channels and the outer surfaces of the endoscopes.
- Ensure that the endoscope and endoscope components can be effectively reprocessed with the AER (eg, the elevator wire channel of duodenoscopes is not effectively disinfected by most AERs and this step should be performed manually). Users should obtain and review model-specific reprocessing protocols from both the endoscope and the AER manufacturers and check for compatibility
- If an AER cycle is interrupted, the cycle should be repeated.
- Maintain a log for each procedure indicating the patient's name and ID of the endoscope and AER to assist in an outbreak investigation.

B. Sterilization

- After the previous step of automated disinfection, flexible endoscope that contact sterile tissue should undergo sterilization by: Gas plasma, Ethylene oxide (ETO), low temperature steam or formaldehyde (LTSF).
- After this step proceed directly to step 9.

Step 7: rinsing

- AER cycle should include rinsing the endoscope and flushing the channels with sterile, filtered or tap water to remove the disinfectant solution.

Step 8: Drying

- AER cycle should include drying by flushing the channels with 70% to 90% ethyl or isopropyl alcohol and dry by using forced air.

Step 9: Visual inspection

- Visually inspect both endoscopes and reusable accessories frequently in the course of their use and reprocessing, before, during and after use, as well after cleaning and before disinfection.
- Damaged endoscopes and accessories should be removed from use for repair or disposal.

Step 10: Storage

- When storing the disinfected endoscope, hang it in a vertical position to facilitate drying with caps, valves and other detachable components removed, per manufacturer's instructions.
- Reuse of endoscopes within 10 to 14 days of high-level disinfection appears to be safe although shorter period is recommended.
- Sterilized endoscopes must be stored sealed in the container or packaging in which they were sterilized.

