# CENTRAL STERILE SUPPLY DEPARTMENT

(DEC.2017-2018)

## VERSION 1.0

<table>
<thead>
<tr>
<th>Document Name</th>
<th>CSSD Manual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document No</td>
<td>SKNMC &amp; GH / CSSD Version 01</td>
</tr>
<tr>
<td>No. of Pages</td>
<td>47</td>
</tr>
<tr>
<td>Date of Preparation</td>
<td>15/11/2017</td>
</tr>
<tr>
<td>Date of Implementation</td>
<td>15/12/2017</td>
</tr>
<tr>
<td>Next Review Date</td>
<td>15/11/2018</td>
</tr>
<tr>
<td>Valid Till</td>
<td>15/12/2018</td>
</tr>
</tbody>
</table>

| Prepared By                 | Name: Dr. Kavita Adate  
CSSD In charge  
Designation: Professor  
Department of Anaesthesiology |
|-----------------------------|-----------------------------|
| Approved By                 | Name: Dr. Shalini Sardesai  
Safe – I Co-ordinator  
Designation: Professor  
Department of Anaesthesiology |
|                             | Name: Dr. (Col) Girish Saundattikar  
Designation: Professor & HOD  
Department of Anaesthesiology |
|                             | Name: Dr. R.S. Bangal  
Dean  
SKNMC & GH |

Source: [http://www.cdc.gov/nchs](http://www.cdc.gov/nchs)  
NABH guidelines
INTRODUCTION

VISION OF SKNMC&GH

Smt. Kashibai Navale Medical College & General Hospital envisions to be recognized as a centre for excellence in medical education and research with a teaching hospital of global standards to serve the people in the region of Pune and neighboring districts with advanced and modern medical facilities at an affordable cost, with special locus on rural population and to be renowned for innovations in curriculum, science based patient care and need based community service, thereby becoming the preferred destination for aspiring students.

MISSION OF SKNMC&GH

“Holistic development of students and teachers is what we believe in and work for. We strive to achieve this by imbibing a unique value system, transparent work culture, excellent academic and physical environment conducive to learning, creativity & technology transfer. Our mandate is to generate, preserve and share knowledge for developing a vibrant Society.”

QUALITY POLICY OF SKNMC & GH

Our team of SKNMC&GH aims toward achieving utmost patients’ satisfaction and positive health, through Continuous Quality improvement, adhering to Safety standards and legal norms.
INTRODUCTION OF CSSD

SKNMC&GH is a multispecialty hospital located in Pune with bed strength of 1094 beds. The Central Sterile and Supply Department (CSSD) forms the heart of the sterilization activities carried out at SKNMC&GH. The CSSD provides and supplies sterile instruments, linen and other items used for operations & sterile procedure. It receives Checks & Cleans the instruments & maintain inventory. CSSD Monitors and ensures sterility necessary to prevent cross infection control policy. It maintains record of all cycles & their sterility indicators daily.

LOCATION

- We have two CSSD set up
- CSSD I is situating on the 2nd Floor of OT complex one.
- CSSD II is situated on 3rd Floor of OT complex two.

ZONING IN THE CSSD

<table>
<thead>
<tr>
<th></th>
<th>CSSD I</th>
<th>CSSD II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving area</td>
<td>4X3 Sq. M</td>
<td>6.3 X 1.90 Sq. M</td>
</tr>
<tr>
<td>Instruments cleaning area</td>
<td>3.95 X 2.80 Sq.M</td>
<td>3.95 X 2.80 Sq.M</td>
</tr>
<tr>
<td>Assemble and packing area</td>
<td>2.7 X 2.00 Sq. M</td>
<td>3.30 X 3.70 Sq.M</td>
</tr>
<tr>
<td>Working area</td>
<td>7.10 X 2.2 Sq. M</td>
<td>6.65 X 6.00 Sq. M</td>
</tr>
<tr>
<td>Sterile storage area</td>
<td>7.00X4.55 Sq. M</td>
<td>16.09X 30.21 Sq. M</td>
</tr>
</tbody>
</table>

- All the sterile material issued to OT
- Sterile storage area of the sterile instruments & linen
- Very limited access.
- Special precautions like PPE to be worn, Antiseptic hand rub to be applied before entering the sterile storage room.
SCOPE

1. Receives the instruments & linen which is required for the operation theater & other procedures in the Hospital.
2. Cleaning is done with the prescribed solution by following the cleaning procedure before packing.
3. After cleaning the instruments it is inspected for the good working condition of the instruments before packing in the tray.
4. Assembling of the instruments is assembled in trays according to the list of set.
5. Packing of sets is done in double wrap as per the procedures.
6. Sterilization is done according to the procedure either autoclaving or ETO sterilization.
7. Storage of sterile sets is done in a sterile storage room. The temperature of sterile storage maintained & monitored periodically.
8. The respective trays are supplied to the respective departments on request.

RESOURCE AVAILABLE

MAN POWER

<table>
<thead>
<tr>
<th></th>
<th>CSSD I</th>
<th>CSSD II</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSSD supervisor</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Technicians</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Helpers</td>
<td>6</td>
<td>5</td>
</tr>
</tbody>
</table>

EQUIPMENTS

<table>
<thead>
<tr>
<th></th>
<th>CSSD I</th>
<th>CSSD II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam sterilizer with Double door system</td>
<td>01</td>
<td>01</td>
</tr>
<tr>
<td>Ultrasonic Cleaner</td>
<td>01</td>
<td>01</td>
</tr>
<tr>
<td>Instruments Dryer</td>
<td>01</td>
<td>01</td>
</tr>
<tr>
<td>Ethylene oxide machine</td>
<td>01</td>
<td>01</td>
</tr>
<tr>
<td>Sealing machine (rolling)</td>
<td>01</td>
<td>01</td>
</tr>
<tr>
<td>Water gun &amp; air gun</td>
<td>01</td>
<td>01</td>
</tr>
<tr>
<td>Assembling tables</td>
<td>02</td>
<td>06</td>
</tr>
<tr>
<td>Racks</td>
<td>04</td>
<td>09</td>
</tr>
</tbody>
</table>
QUALITY OBJECTIVE

- To ensure effective and quality assured sterilization practice of all material.
- To get regularly updated with latest technologies in Sterilization and disinfection.

JOB DESCRIPTION

Job title: CSSD SUPERVISOR
Reporting to: Incharge CSSD
Shifts: General shift

JOB DESCRIPTION

- Takes the responsibility of all the equipments used in CSSD.
- Responsible all the activities of CSSD.
- To maintain all equipments in good condition to ensure uninterrupted services to all the areas of the Hospital.
- Coordinating with wards, OT and other departments.
- Ensure that the staffs are following all the Procedures according to the manual.
- Monitor and ensure all materials are available for procedure & surgeries.
- Supervise Sterilization cycle achieved or not by monitoring biological indicators.
- Co-ordinate with biomedical dept for repairs & AMC of equipments.
- Training and education to the staff and maintain the record of it.
- Maintain all registers & all record pertaining to CSSD.
- Prepare indents as and when required
- Implementation of organization and departments policies & procedures.
- Ensure implementation of all infection control Measures.

CSSD TECHNICIANS:

Job title: CSSD Technicians
Reporting to: CSSD Supervision
Shifts: Three shifts (Morning, Evening, Nights)
JOB DESCRIPTION:

- Keep records of all material receiving for sterilization from OT and Other Dept.
- Sterilizing instruments packs, linen, OT dresses etc issuing to OT and other Dept.
- Keep Record of all material returned & issued.
- Provide sterile packs on time to all surgeries.
- Receiving and packing of instruments.
- Receive the instruments form the staff after surgery / procedure.
- Ensure supply and sterile packs to OT, wards and other departments as per their requirement.
- Supervise cleaning of instruments.
- Packing the instruments as per checklist
- Ensure that minimum stock is always maintained.
- Monitor that minimum stock is always maintained.
- Monitor the condition of the instrument regularly and maintain it
- Help the CSSD in charge in stock taking and any other job as per requirements.
- Check all instruments meticulously before packing.
- Ensure all sterility check indicators before loading the pack.
- Ensure Bowie Dick's test every day before the beginning of cycle, Time Steam temperature (TST) every load, Biological Indicators (BI) test once a month for autoclave, and each load for Ethylene Oxide.
- He should be trained for operating the autoclaved machine, ETO machine, Ultrasonic cleaner & dryer.
- Maintain all records & documents in prescribed registers & forms.
- Ensure the CSSD area is always clean and daily surface cleaning is done as per protocol.
- Maintenance of autoclave machine as per portal prescribed by the company.
- Proper handing over and taking over after each shift.
JOB TITLE: CSSD HELPER  
Reporting to: CSSD supervisor  
Shifts: Three shifts (Morning, Evening, Night)  

JOB DESCRIPTION:  
- Receive the instruments form all wards including OT as per checklist.  
- Washing and drying the instruments as per protocol  
- Help the CSSD technicians for packing Instruments for Autoclave and ETO machine.  
- Help the CSSD technicians for packing Instruments for Autoclave and ETO  
- Ensure proper storage of sterile items.  
- Perform any other task as instructed by the CSSD Technician or Supervisor.  
- Ensure CSSD area is always neat, clean and dry.  
- Filing the documents systematically.  
- Disinfect as per protocol.  

TRAINING  
Training in CSSD is carried out on the following topics.  
- Introduction to the department, work flow, SOPs and policies.  
- Training on biological indicators and validation of sterilization CSSD  
- Infection control practices  
- Safety practices to be followed in CSSD.  
- Personal hygiene and grooming of Technicians.  
- Training is also carried out to helpers and technicians.  
- Training is given by Power Point, handouts, hands on training.  
- Skill assessment done by CSSD Incharge.
## INDEX

<table>
<thead>
<tr>
<th>Sr.No</th>
<th>Name of SOP</th>
<th>Page.No</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOP 1</td>
<td>CSSD function &amp; Layout</td>
<td>10</td>
</tr>
<tr>
<td>SOP 2</td>
<td>CSSD Health &amp; safety</td>
<td>12</td>
</tr>
<tr>
<td>SOP 3</td>
<td>Personal protective equipment’s</td>
<td>13</td>
</tr>
<tr>
<td>SOP 4</td>
<td>Cleaning of CSSD</td>
<td>14</td>
</tr>
<tr>
<td>SOP 5</td>
<td>Water Quality</td>
<td>15</td>
</tr>
<tr>
<td>SOP 6</td>
<td>Collection of soiled/contaminated equipment</td>
<td>16</td>
</tr>
<tr>
<td>SOP 7</td>
<td>Collection of known infectious instruments</td>
<td>17</td>
</tr>
<tr>
<td>SOP 8</td>
<td>Instrument segregation &amp; loading the trays</td>
<td>18</td>
</tr>
<tr>
<td>SOP 9</td>
<td>Cleaning of medical devices</td>
<td>19</td>
</tr>
<tr>
<td>SOP 10</td>
<td>Assembling Trays</td>
<td>20</td>
</tr>
<tr>
<td>SOP 11</td>
<td>Packing and wrapping</td>
<td>21</td>
</tr>
<tr>
<td>SOP 12</td>
<td>Steam sterilizer</td>
<td>22</td>
</tr>
<tr>
<td>SOP 13</td>
<td>EtO sterilizer</td>
<td>28</td>
</tr>
<tr>
<td>SOP 14</td>
<td>Storage of sterile goods</td>
<td>29</td>
</tr>
<tr>
<td>SOP 15</td>
<td>Delivery and distribution of processed items</td>
<td>30</td>
</tr>
<tr>
<td>SOP 16</td>
<td>Equipment maintenance</td>
<td>31</td>
</tr>
<tr>
<td>SOP 17</td>
<td>Tracking system</td>
<td>32</td>
</tr>
<tr>
<td>SOP 18</td>
<td>Record Keeping</td>
<td>33</td>
</tr>
<tr>
<td>SOP 19</td>
<td>Recall policy for sterilization</td>
<td>34</td>
</tr>
<tr>
<td>SOP 20</td>
<td>Shelf life for sterilized items</td>
<td>36</td>
</tr>
<tr>
<td>SOP 21</td>
<td>Endoscope Reprocessing</td>
<td>37</td>
</tr>
<tr>
<td>SOP 22</td>
<td>Bio-logical waste</td>
<td>41</td>
</tr>
</tbody>
</table>

CSSD IMAGES
OBJECTIVES OF 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. Storage.
   i. Distribution of all instruments and medical devices.

2. Providing Sterile supplies to all wards, OPD’S, and operation theatre.
3. Planning and approval for the design of CSSD
4. Providing policies / procedures and supervising the implementation of the same.
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 job training program, refreshment courses and continuous updating of technical staff progress to increase awareness of technical staff about Quality Systems.
10. Quality Manual, Quality Procedures and Quality Control Records are prepared and implemented.

II- LAYOUT

1. The department is designed so that it is physically separated from all other work areas.
2. The department is designed to facilitate a unidirectional flow from the ‘dirty’ area to the ‘clean’ area.
3. There is 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 is through dedicated gowning rooms provided with hand hygiene facilities.
5. The wash room, clean room and sterilizer unloading area is free from ‘Opening’ windows, and unclean areas.
6. Staff movement between dirty and clean areas is not possible without passing through a clothing change and wash-up area.
7. Storage facilities for bulk items is provided external to the clean room and the wash room.
SOP 2 - CSSD HEALTH AND SAFETY

1. All personnel must follow traffic flow patterns.
2. Material Safety Data Sheets (MSDS) for all chemicals used in the sterile service department is available.
3. All employees are trained in appropriate personnel protective equipment designated for each area.
4. Employees must follow and practice hand washing guidelines (before and after each task).
5. Eating and drinking is prohibited in all workspaces including supply storage, processing and decontamination sections.
6. Work spaces are 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.
14. Heat resistant gloves and N95 mask are provided to autoclave and ETO worker.
SOP 3 - PERSONAL PROTECTIVE EQUIPMENTS FOR CSSD STAFF

1. When handling contaminated items, wearing personal protective equipment (PPE) is mandatory for all the staff.

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. Hepatitis B vaccination is mandatory for all workers.
SOP 4  - CLEANING OF CSSD

1. The CSSD is cleaned on a daily basis at the beginning and at the end of each shift.

2. Cleaning equipment’s is stored in a designated area, for CSSD use only.

3. Cleaning of the department must be undertaken by CSSD staff with the assistance of helper.

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 are disinfected daily

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

8. Outer packaging is removed from raw material before they enter the assembly and packaging area to avoid environmental contamination.

9. Vacuuming the air vents and cleaning out the light fixtures is recommended at least twice per year to prevent buildup of dust and lint.
SOP 5 - WATER QUALITY

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. 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.

IN OUR HOSPITAL TAP WATER USED FOR ALL PUPOSE IS SOFT IN NATURE.

Water testing is done at regular interval by housekeeping department.

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

Staffs are informed to report any residue left on instruments to the supervisor and biomedical engineering department.
SOP 6 - COLLECTION OF SOILED / CONTAMINATED EQUIPMENT

1. Non-sterile gloves are worn for the collection of soiled instruments
2. Hand wash is performed in accordance with departmental procedures
3. Protective clothing / attire are used in compliance with standard precaution guidelines
4. Allocated trolleys are used.
5. Follow designated collection routine and time table in accordance with department Guidelines.
6. Linen and waste are separated from reusable medical devices at the point of use.
7. Gross contaminants such as large amount of blood & body waste is removed at the point of use before collection by CSSD staff.
8. Used items are collected in puncture resistant closed containers; overloading is avoided
9. Heavy instrument containers are placed at the bottom of trolleys.
10. Secure contaminated items and cover prior to transportation.
11. Used items and equipment are transported to the cleaning area.
12. Clean and disinfect collection trolleys and bins and store appropriately.
13. Allocated vehicles are used for transport. Regular cleaning is required.
SOP 7- DEALING WITH KNOWN INFECTIOUS CASES

(Soiled instrumentation with labeled infectious)

1. Consider every item collected and received to C.S.S.D is 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. Manual wash is avoided.
4. In our setup, infected instruments are soaked in 1% sodium hypochloride solution for 30 minutes.
5. Dedicated washer disinfector is used with load/ recommendation to use lower shelf.
6. Cycle is run according to temperature recommended.(90°C or 85°C).
7. The specification of the washer includes self-disinfection cycle therefore no
8. Need to run the washer twice.
9. Most viruses are killed in the temperature selected. No need to run the washer twice.
10. Report the instruments with detailed.
11. Report any injury or incident happen.
12. Disinfection of the transport container is done using washer disinfector or trolley washer if available (bottom shelf).
SOP 8 - INSTRUMENT SEGREGATION AND LOADING THE TREYS

1. Handle contaminated devices as little as possible.
2. All equipment is transferred from the boxes to the work surface.
3. The process of cleaning & disinfection is carried out according to CSSD manual and protocols (manual/machinery)
4. Items requiring special attention are identified and handle in accordance with documented manufacturers’ instructions
5. Each instrument is 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 parts of instrument.
   - Handle and process all devices in accordance with the manufacture instructions.
   - The broken or 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.
   - 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.
   - Do not pack too densely; all surfaces must be reached by the spray jets.
   - Use detergents according to washer manufacturers’ instructions.
   - Maintain records of all items received and prepared for processing.
SOP 9 - CLEANING OF MEDICAL DEVICES

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 are available with a dedicated drying surface.

4. Sinks and accessories are cleaned at each water change. The sink is used only for washing instruments, not for hand washing or anything else.

5. When cleaning manually, a pre-rinse, wash, rinse and drying process are followed.

6. Water and detergent is measured according to manufacturers’ instructions to have the correct chemical mixture.

7. If the water, is visibly stained at any stage it is replaced.

8. All devices being manually cleaned must be fully immersed in the washing water while being scrubbed.

9. Special attention is paid to the joints of any jointed instrument and meticulous attention paid to the tips or crevices.

10. A clean soft brush or soft cloth is used to clean the surfaces.

11. After decontamination, all devices are visually inspected for soil, damage and Functioning tested.

12. Items are dried using a lint free cloth or the dryer.
SOP 10 - ASSEMBLING OF TREY

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.
5. Cleanliness & functional test is performed every week.
   (Settle plate examination by microbiology department)
6. Trays are perforated to allow penetration of the sterilizing agent and efficient drying.
7. Instruments are laid out according to the order on the check list.
8. The contents of instrument sets are usually decided by the surgical team.
9. Ideally chemical indicator should be place inside every instrument or dressing set. In our set up we are placing the chemical indicator outside each covered pack and inside the implant pack.
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. A tray liner (where indicated) is placed on the bottom of the tray.
14. Instruments are checked visually for cleanliness and missing parts /functional test (tips, screws, free movement, sharpness and overall condition).
15. Instruments with ratchets or hinges are held in an open and unlocked position.
16. Instruments are 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 are placed in a way that allows easy drainage.
20. Heavy instruments are 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.
SOP 11 - PACKING AND WRAPPING

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. Collect clean and dry articles on clean trolleys and bring them to assembly tables.

3. Examine the instruments for cleanliness. Return dirty instruments for re-cleaning.

4. Check the instruments against the ‘Instruments Tray Master List’ which is kept updated at all times.

5. Inspect the instruments for good condition. Segregate damaged instruments and replace with good instruments from the stock.

6. Arrange the instruments in an orderly manner in the tray. Insert an Internal Chemical Indicator.

7. Wrap all trays with double layer linen.

8. All open trays should be wrapped in double layer linen.

9. Seal the pack with Chemical Indicator Adhesive tape carrying pack information.

10. Access to CSSD sterile packaging area is restricted.

11. All staffs are responsible for keeping the preparation room entry / exit neat and tidy.

12. Everybody entering the preparation area must be correctly dressed and conform to policy.

13. No personal possessions other than locker keys can be taken into the preparation area.

14. No jewelry is allowed other than stud like ear ring, and the must be completely covered with head wear.

15. No food or drinks of any kind may be taken into any area of the department.
SOP 12- STEAM STERILIZER

1. We have automatic stem sterilizer. Out of two steam sterilizer one is of MODI and other is of STERIS Company.
2. The first cycle of a day is always a “warm up “cycle.
3. We are conducting Bowie Dick test twice in week.
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 indicator, according to manufacturers’ instructions
7. Detail records of load are kept for easy tracking and recall if necessary.
8. Label Package according to policy.
9. Process is conducted with full loads – not overloaded- to limit the number of cycles you need to run.
10. Loading of autoclave is conducted 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.
11. Load baskets and carts so hands won’t touch packs when removing the hot trolley.
12. On completion of cycle, cycle complete indicator will appear, visually check of the
13. Graph / printer is done 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 cooling for 10 – 20 minutes before storage or dispensing.
17. Inspect packages to ensure integrity and external chemical indicators have changed.
PROTOCOLS TO BE FOLLOWED AND UNDERSTAND:

I. LOADING STEAM STERILIZER:

- Wear relevant protective clothing.
- Load instruments set flat in single layer.
- Load soft packages on their sides with a hands width between items.
- Load soft packs on top shelf and large instrument trays on lower shelf.
- Load containers according to manufacturer’s instructions some may be stacked.
- Do not allow packs to touch top, bottom or sides of autoclave.
- Do not compress packs.
- Position peel packs on sides.
- Do not overload.

II. UNLOADING STEAM STERILIZER

- On completion of cycle record according to policy
- Allow autoclave and packs to cool before handling
- Do not touch packs until completely cooled
- Do not touch hot racks without heat resistant gloves.
- Once cooled check for wet packs, tears, indicator changes etc.

III. MONITORING STEAM STERILIZER:

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

STERILIZATION QUALITY ASSURANCE

Quality is the consistent delivery of products and services according to established standards. Quality control procedures are laid down to provide a technical, statistical sampling method to measure the quality of production.

Need for process monitoring

The purpose of sterilization is to provide the end user with a sterile product. The only way of ensuring sterility is to test every pack microbiologically, which would require opening the sterile pack. To avoid this alternate method is to employ monitors to assure that the parameters of sterilization have been met. Technical quality control indicators in the form of mechanical, chemical and biological indicators have to be incorporated into the Sterility Assurance Program (SAP).

1 MECHANICAL INDICATOR (MI)

1. Pressure Gauges: In jacketed sterilizers there are two main gauges, to determine pressure in the jacket and chamber.

2. Temperature and pressure graphs and recording charts: These describe temperature and pressure inside the sterilizer and various phases of sterilization can be known from the pattern.

3. Check the gauges and print out for every cycle to match with standard for the machine. Keep a copy of the print out in the register.

4. If any discrepancy is noticed, it should be rectified by machine maintenance team.

5. Keep a logbook of all repairs / maintenance performed on the machine.
II CHEMICAL INDICATORS (CI)

Chemical Indicators are substances which change colour when exposed to specified conditions through chemical reaction with the sterilant. They monitor one or more parameters of the sterilization process. They are internal and external process indicators.

External Indicators (Exposure Control)

1. External process indicators inform the user that the pack has been exposed to the sterilization process and may be used also for sealing and labeling of packs.
2. Every steam pack should be affixed with Autoclave indicator tape or label and every EtO pack should be affixed with ETO indicator tape.

Internal Indicators (Pack Control)

- Internal indicators show proper penetration of the sterilant into the pack.
- Multi parameter indicator strips or integrators should be used inside every steam and ETO pack.

Bowie and Dick test (Equipment Control)

Bowie and Dick test is mandatory for pre-vacuum steam sterilizers. It is used to monitor vacuum level and detect air leak.

- Run the Pre-vacuum sterilizer at 132 - 134°C.
- Run the first cycle with empty chamber (Warm up).
- For the second cycle, keep the Bowie and Dick Test Pack on the shelf above the drain, in empty chamber.
- Run the second cycle for 3 1/2 - 4-minute exposure time (As recommended by manufacturer).
- Check the Bowie-Dick indicator sheet for uniform color change.
- If the Vacuum is perfect the entire indicator sheet changes color uniformly. If there is a lighter or white patch in the sheet the sterilizer needs to be repaired.
Biological Indicators (BI – Load Control)

Standardized and certified biological indicators are used to monitor sterilization process. They contain a challenge number of spores (about 1 million) of a micro-organism most resistant to the specific sterilization process.

Description:

1. Biological indicators consist of a spore strip or disc packed in a vial with a sealed ampoule of growth medium. These are activated by crushing the ampoule, allowing microorganisms to come in contact with the growth media.

2. In a faster method, biological indicators employ a fluorescent light to determine an enzymatic reaction that indicates cell division is occurring. This type is “rapid readout” type and results can be obtained in as short a time as one hour.

3. The spore strips have a population of $10^5$-$10^6$ spores to present a challenge to the sterilization process.

Test organisms used:

1. Steam sterilizers – *Geobacillus stearothermophilus*.

2. ETO and Dry Heat - *Bacillus atrophaeus*.

Method of testing:

1. Use two ampoules per test, the load indicator and the control indicator.

2. The load indicator is packed in a paper packet and placed into the sterilizer at the center of the load and the sterilization cycle is run.

3. After the cycle pull out the ampoule, crush the inner glass ampoule to mix the growth medium with spore strip.

4. Incubate the ampoule at 56°C for steam and at 37°C for ETO.

5. The control indicator is not put in the sterilizer, but incubated after crushing the glass ampoule along with the one that underwent sterilization.

6. The control indicator is expected to grow by showing a color change of the medium over 48 hours but not the load indicator.

7. If the load indicator BI shows a color change this indicates failure of sterilization cycle. Recall all packs processed from the last cycle that showed negative BI test.
Frequency of testing:
1. For steam sterilization, the BI should be used daily.
2. For ETO, it should be used in every cycle.
For dry heat sterilization, it should be used weekly.

Unloading:
1. After the cycle is over, only items that are visibly dry should be taken out once the door is opened.
2. Packs cannot be allowed to dry in the sterilizer after the cycle is over or outside.
3. Wait till the packages are cool before they are unloaded.
4. Do not stack the items which are just taken out of the sterilizer, one on top of the other, or else condensation may occur.
5 Store on wire mesh racks to allow for air circulation.

SHELF LIFE
1. Shelf life of a sterile pack depends on the quality of the wrapper, storage conditions, and conditions during transport and amount of handling.
2. Shelf life is given as follows:
   a. Linen packed trays or sets 4 days
   b. Medical grade paper packing 15 days
   c. Non woven packing material 3 months
   d. Peel pouch packing 6 months
3. Sterile materials should be issued in a closed cabinet trolley to OT and clean-decontaminated trolley to wards to minimize contamination
4. Arrangement of sterile packs should be in sequence of their expiry date.
SOP 13 ETHYLENE OXIDE STERILIZER

Instructions

1. It is important that all staff members are aware of the policy and procedures that relate to ETO sterilization (refer to room specification).
2. Operators must know how to operate the ETO sterilizer safely as well as the importance of adequate aeration.
3. Operators need to understand the environment requirements and safe work practices.
4. Operators must know what the emergency procedures are in case of a leak or accident.
5. The ETO sterilizer must be operated accordance with the manufacturer’s instructions.
6. 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.
7. Single-use cartridge delivers the appropriate volume/concentration of ETO.
8. Check with gas manufacturer/supplier for storage recommendations and MSDS sheet.
9. ETO gas is stored at the prescribed temperature in a well-ventilated area in a cupboard marked with Hazardous materials label.
10. The sterilizer operating temperature is usually preset by the sterilizer manufacturer; there are usually two options: 37°C (cold cycle) 55°C (warm cycle).
11. 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.
12. The ETO cartridge must be discarded in a safe manner according gas manufacturer/supplier and hospital policies.
13. 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.
SOP 14 STORAGE OF STERILE GOODS

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 are 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 tempering or having been removed, exposure to contaminate 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.
SOP 15 DELIVERIES AND DISTRIBUTION OF PROCESSED ITEMS

1. All items are checked for sterility before they are released.
2. The following should be checked when deciding if the pack is still sterile:
   a. Holes or tears
   b. Wetness or stains
   c. Broken seals dust
3. All damage items are returned to the CSSD.
4. All items issued will be recorded so that a tracking will be easily possible.
5. Various methods can be used in the transport of sterile packaged items to their point of use.
6. Sterile supply is 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 spread 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.
8. Items must be placed onto a clean trolley that can be covered.
9. Trolleys must not be overloaded.
10. Soiled items must NOT be loaded onto the same trolley.
SOP 16 EQUIPMENT MAINTENANCE

1. Equipment must be maintained according to manufacturer’s 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.

MAINTENANCE OF STERILIZERS

General

Each manufacturer provides users who purchase their sterilizers with a manual that includes comprehensive care and maintenance instructions.

- Routine maintenance: daily inspections and cleaning of gaskets, chart pens, chamber drain screens and internal/external surfaces.
- Scheduled (preventive) maintenance: This level of maintenance should include lubrication of appropriate parts and replacement of expendable parts, i.e., steam traps.
- Calibration: periodic calibration of items such as pressure and temperature gauges, timers, recording and control devices must be carried out by qualified personnel as specified in the manufacturer's instruction manual.

Daily

- Clean the chamber internally.
- Clean the chamber drain.
- Check the door closing motion.
- Clean the traps.
- Blow the safety valve.
- Maintenance records must be kept.
SOP 17 TRACKING SYSTEMS

1. To ensure the effective tracking system proper labeling of pack and record keeping is very important.
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. A common method involves the use of bar codes that are used to identify packs and device locations by a scanning process.
5. Packaging systems should be labeled with,
   - A description of the package contents
   - Identification of the person receiving, cleaning, checking, assembling, sterilizing, storing, dispatching the package
   - A lot control number
   - Any expiration date/shelf life statement applicable to the facility
   - Dispatch information

6. 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.
SOP 18  RECORD KEEPING

Following documents are maintained in CSSD

1. Sterilizer instruction manuals

2. Records of preventive maintenance, repairs and calibration.

3. Load records. These should be kept for two years.
   - It is a method of documenting the sterilization process.
   - At the beginning of the cycle, the date, time, sterilizer operator and cycle identification should be marked on the record.
   - At the end of the cycle, the response of Chemical Indicator should be recorded.
   - Results of Biological Indicator should be recorded when obtained.
   - The sterilization record should be examined and attested.
   - Load record log should be maintained.

4. Re-call register
SOP 19 RECALL POLICIES FOR STERILIZATION

1. Recall policy describe as sterilization process failure and to enable rapid recall of all items suspected to be non-sterile.

2. The biological indicator is sent to microbiology department for testing the efficacy of sterilization procedures.
   In case of the failure of all cycle (biological or mechanical) the CSSD staff informs to all concerned department to return he sterile material issued from the CSSD for Re-autoclaving. If trays are used, then information are given to Infection control Nurse by sister In charge to monitor the patient condition and and follow up.
   The recall procedures include:
   • Sending a recall notice to the departments
   • Identification of persons or department for which the notice is intented.
   • Includes an area to record products and quantity of products to be returned in recall.
   • Includes the action to be taken by persons receiving notice—e.g. return or hold for collection by CSSD staff.

Report is prepared and completed defining
   • The reason for recall
   • The total number of products recalled
   • The actual number located
   • Number of patients potentially exposed
   • The actions taken regarding patient involved
   • Where applicable, the actions taken to prevent this happening again
   • Sterilizing cycle records includes
     a) Date of cycle
     b) Sterilizer code or number
     c) Cycle or load number
     d) Exposure time, temperature and pressure
     e) Name/ID of loading operator
     f) Name/ID of person authorizing release
     g) Specific content of load and
     h) Read out results of indicators used
• Physical
• Chemical
• Biological enzymatic

Tracking Labels and date of Sterilization
All items must have a date of sterilization label or tracking label. This indicates that the item has been processed by CSSD and is for recall purpose in the event of a process failure. Some labels also have a color indicator which changes from pink to black when in contact with steam.
SOP 20 – SHELF LIFE FOR STERILIZED ITEMS

Use of autoclaved and ETO sterilized items is done according to the shelf life of the tray or pack.

SHELF LIFE

1. Shelf life of a sterile pack depends on the quality of the wrapper, storage conditions and conditions during transport and amount of handling.
2. Shelf life is given as follows:
   - Linen packed trays or sets 4 days
   - Medical grade paper packing 15 days
   - Non woven packing material 3 months
   - Peel pouch packing 6 months
3. Sterile materials should be issued in a closed cabinet trolley to OT and clean-decontaminated trolley to wards to minimize contamination
4. Arrangement of sterile packs should be in sequence of their expiry date.

CSSD technician should check for the expiry date every day in sterile storage room. They should also check for the packs to be intact for the sterility. All those set are then sent back to CSSD for resterilisation if evidence of expiry or breach in package.
SOP 21 ENDOSCOPE REPROCESSING

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, nasopharygoscope) 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 are 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 i.e. endoscope and/or automatic endoscope reprocessor (AER).

C. PPE

• Personal protective equipment PPE (e.g., gloves, gowns not water permeable, mask, eyewear, respiratory protection devices) are readily available and 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

**STEPS OF REPROCESSING OF FLEXIBLE ENDOSCOPES:**

**Step 1: Precleaning**

- Precleaning is performed at the point of use by wiping the exterior of the endoscope with soft cloth/sponge soaked in freshly prepared enzymatic detergent.

- Suction/biopsy and air/water channels are flushed with enzymatic detergent. Other channels are cleaned per manufacturer’s instructions.

- All detachable parts are removed 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 labelled containers should be used for transportation to distant areas.
Step 3: Leak testing

- Pressure/leak test is performed after each use and before reprocessing, according to manufacturer guidelines to verify the integrity of the endoscope.
- If leak detected, send for repair.

Step 4: Manual Washing

- Disassemble removable parts e.g. all buttons/valves/caps. Ultrasonic cleaning of reusable endoscopic accessories is performed to remove soil and organic material from hard-to-clean areas.
- 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

- Washed instruments are dried with forced air and kept in sterile chamber for 24 hrs.
- Before use they are soaked in glutaraldehyde solution at 20 °C for 20 to 30 minutes.
- Instruments are thoroughly washed with sterile water prior use.

Step 6: Drying

- Compressed air is blown into each channel to remove the water inside
- Surface of endoscope is mopped with a soft fabric, and 70% to 90% ethyl alcohol is poured into all its channels before compressed air is blown into them drying.
- All detachable parts such as air/water valves, suction valves, and waterproof cap are kept disassembled in storage.
- Cabinet is mopped with 70% alcohol daily.
Step 7: Storage

- When storing the disinfected endoscope, hang it in a vertical position to facilitate drying with caps, valves and other detachable components removed, as 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.
### SOP 22 BIO-LOGICAL WASTE

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

#### 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
CSSD IMAGES
THE WASHING AREA WITH AIR DRYER
**ULTRASONIC WASHER DISINFECTOR**
AUTOMATIC WASHER DISINFECTOR
ASSEMBLY AND PACKING AREA
MODI STEAM STERILIZER

STERIS STEAM STERILIZER
ETO STERILIZER

STERILE STORAGE ZONE