CRH SIKKIM MANIPAL UNIVERSITY CENTRAL REFERRAL HOSPITAL - SMIMS **Documented Procedure**	TITLE: CSSD Service DOCUMENT NO: SOP/CRH/HIC/CSSD/22 REVISION NO: 00 REVISION DATE: 00 VERSION NO. 01 ISSUE/EFFECTIVE DATE: 20th January 2017 PAGE NO: Page 1 DOCUMENT CONTROL STATUS: MASTER COPY

Standard Operating Procedure

CSSD service

MASTER

Prepared By	Reviewed By	Approved By	DP
		Dr. Gautam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim, 737102	

CRH SIKKIM MANIPAL UNIVERSITY CENTRAL REFERRAL HOSPITAL - SMIMS **Documented Procedure**	TITLE: CSSD Service DOCUMENT NO: SOP/CRH/HIC/CSSD/22 REVISION NO: 00 REVISION DATE: 00 VERSION NO. 01 ISSUE/EFFECTIVE DATE: 20th January 2017 PAGE NO: 2 DOCUMENT CONTROL STATUS: MASTER COPY

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim - 737 102	DP
Prepared By	**Reviewed By**	**Approved By**	

1. ABBREVIATIONS AND DEFINITIONS

1.1 . Abbreviations

CSSD	Central Sterilized Supply Department
PPE	Personal protective equipment
CRH	Central Referral Hospital
OPD	Outpatient Department
OT	Operating Theatre

Prepared By	Reviewed By	Approved By	DP

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
5th Mile, Tadong, Gangtok
Sikkim - 737102

1.2 . Definitions

Sterilization: Sterilization is a process in which kill all types of micro-organism, fungus, bacteria, Viruses and including spore. without killing the spore cannot use the term the Sterilization.

2. SCOPE

- The purpose of the CSSD is to prepare and furnish other departments with sterile equipment and supplies needed in the patient care in CRH.
- To efficiently control hospital infection and improve clinical care outcomes.
- Receive the soiled/contaminated/unsterilized items from user departments.
- Assembling and packing of the linen and other sets.
- All the packed item to be labeled as D/S-D/E on the autoclave indicator.
- Sterilization by autoclave or ETO.
- Sterilized pack items are stored in the sterilization store room and issued to the user departments.
- The Sterile Supply Department within a hospital receives, decontaminates, packs, sterilizes, stores and distributes to all departments including the wards, outpatient department [OPD] and other special units such as operating theatre [OT].
- Major responsibilities of CSSD include processing and sterilization of medical devices such as rubber goods [catheters, tubing], surgical instruments, treatment trays and

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
5th Mile, Tadong, Gangtok
Sikkim - 737102

sets, dressings etc. It is also responsible for economic and effective utilization of equipment and resources of the Hospital under controlled supervision.

3. RESPONSIBILITIES

1. All CSSD personnel that are assigned or engaged in Sterile service operation.
2. Receiving & delivery to monitor receiving of instruments for the process of sterilization and timely delivery of it.
3. Overall monitoring of sterilization, so that demands of the service & supply is met.
4. Quality control of various procedures of sterilization by following standard guidelines.
5. To provide feedback to the hospital infection control committee.
6. To provide training to the nursing, MBBS student.
7. To keep maintaining all documents & register for every autoclaving cycles & performance test.
8. Reporting of vacancies in CSSD to HR Dept. (staff management)

4. PROCEDURE

SOP No 1. Safety Awareness in Sterile Service Department

- ***Expected Outcome***

- Reduced medical hazards.
- Safe working environment.

- **Objective/Purpose**

  To establish an overview of guidelines and safety awareness procedures in the Sterile service department at Central Referral Hospital.

  - **General Guidelines**

    1. All personnel must follow established work and traffic flow patterns.
    2. Employee must be trained in a safe work procedure and be aware of hospital policies.
    3. All employees must be trained in appropriate personnel protective equipment.
    4. Employees must adhere to dress code and policies before entering and when leaving the area.
    5. Employees must follow and practice hand washing guidelines as per WHO guidelines.
    6. Eating and drinking is prohibited in all workspaces including supply storage, processing and decontamination sections.
    7. Work spaces must be free from clutter and have un-obstructed entrances and exits.

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
5th Mile, Tadong, Gangtok
Sikkim - 737102

8. Visitors are prohibited from entering inside CSSD premises without permission.

- **Patient Safety**

1. Ensure that all items are processed according to established guidelines (manufacturer's instructions).
2. All CSSD personnel should be trained in Decontamination and Sterilization Practices.
3. Safe keeping of all items by ensuring that storage areas are kept clean, storage cupboards are locked, equipment is covered and preventive maintenance is performed on all equipment.
4. Assure there is no contamination of patient care areas during collection and transportation of contaminated items.

- **Employee Safety**

1. Prevent burn injuries when loading or unloading steam sterilizers by following procedure and wearing appropriate PPE.
2. Employees must use proper body mechanics when carrying or handling heavy items.
3. Use care and caution when handling sharps.
4. Maintain "line of light "when handling medical devices.
5. In the decontamination area, employees must wear proper personal protective equipment (PPE) to prevent direct exposure from contaminants and injury that could result when handling contaminated and sharp instruments.

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
Sikkim Manipal University
Tadong, Gangtok

6. Appropriate PPE must be worn when handling chemicals used for cleaning and decontamination.
7. Use of electrical extension cords is prohibited in sterile service areas.
8. All employees must be aware of fire and safety regulations.

SOP No 2. Department Cleaning Procedure

- ***Expected Outcome***

Quality controlled safe, clean and functional department.

- **Objective/Purpose**

To ensure an acceptable level of hygiene and cleanliness throughout the CSSD area.

1. PROCESS

1. The CSSD will be cleaned in accordance with the cleaning schedule.
2. Cleaning will take place before work commences or after work is completed.
3. Designated cleaning equipment will be stored in a designated area for that area's use only.
4. Cleaning work will only be undertaken by Staff trained to work in that area.

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
5th Mile, Tadong, Gangtok
Sikkim - 737102

5. CSSD staffs are responsible for making sure that all surfaces are clean.
6. All cleaning procedures and cleaning chemicals used in the department will be in line with Departmental recommendations.
7. The use of brooms is discouraged.

List of Inspection Points

1. Wet mops floors (vacuum first if necessary, do not sweep).
2. Damp wipes all low-level ledges, shelves, and skirting and window ledges.
3. Remove splash stains and finger marks from walls and paintwork using damp cloth.
4. Empty waste bins, replace waste bags, and wash bins if necessary.
5. Clean all internal glass surfaces.
6. Wet wipe walls, wall fittings and ceilings, clean light fittings.
7. Clean all ceiling air vents.
8. Check and clean as necessary around sinks, doors, etc.
9. Empty waste bins and wash inside.
10. Clean and polish all frontages of Autoclaves with Stainless Steel cleaner.
11. Clean sinks taps and surroundings.

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
5th Mile, Tadong, Gangtok
Sikkim - 737102

SOP No 3. Departmental Dress Code

- ***Expected Outcome***

  All CSSD staff are properly attired according to the requirements of their work area.

- **Objective/Purpose**

  To ensure that CSSD staffs are properly dressed according to the requirements of their work.

PROCESS:

1. On entering the Sterile Service Department, all staff will change into departmental uniform provided in the changing area.
2. Prior to entering the preparation area all staff and visitors will wash and dry their hands and put on the relevant PPE.
3. Entry to the CSSD outdoor footwear will be exchanged for inside chapels.
4. Change rooms are allocated for all persons entering the CSSD where they change into scrub suits and cover the head with caps.
5. The used scrub suits are sent to laundry daily.
6. Staff of CSSD will wear aprons, gloves, masks and caps.
7. Visitors will wear footwear according to the areas they are attending.
8. Staff leaving their work stations for toilet and refreshment breaks will also remove masks and aprons.

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Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
5th Mile, Tadong, Gangtok
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9. Staff will also be required to wear a cover all garment when performing duties through the hospital.
10. Caps must cover all hair and staff with facial hair will wear face mask.
11. Minimal jewellery should be worn.
12. Hair and nails must be clean with no nail varnish.
13. Staff with broken or infected skin should report same to the Supervisor and at the same time cover all cuts and abrasions with a water proof dressing.
14. Visitors to the department including maintenance staff shall be required to wear suitable protective clothing gown, overshoe, cap, any protective clothing which become contaminated during the course of the working day should be changed immediately or as directed by CSSD Supervisors or CSSD Technician.

SOP No 4. Control of Packing Area

- ***Expected Outcome***

  Everybody entering the preparation area is correctly dressed and conforms to policy.

- **Objective/Purpose**

  To ensure everybody entering the preparation area of CSSD is correctly dressed.

PROCESS:

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok	DP
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1. All staff visitors and other personnel wishing to enter the preparation room will change into the uniform provided.
2. No personal possessions other than locker keys are allowed to be taken into the preparation area.
3. No facial jewellery is allowed, other than stud type earrings, and these must be covered completely by the headwear.
4. No food or confectionery of any kind may be taken into any area of the department.
5. The instruments are received from the various departments in the receiving area.
6. After receiving, the instrument sets are checked and packed properly.
7. Before entry to the preparation room area, all personnel will put on suitable head covering and a clean room gown. The gowns are to be placed in the wash basket at the end of each shift.
8. Personnel will wash and dry their hands before entering area.
9. Head covering must be worn at all times and only discarded at the end of the shift.
10. All Staff are responsible for keeping the preparation room entry / exit neat and tidy.

SOP No 5. Cleaning of Autoclaves

- ***Expected Outcome***

  Autoclaves maintained in a good condition in accordance with manufacturer's guidelines.

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim - 737 102	DP
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- **Objective/Purpose**

  The CSSD personal maintain the steam sterilizer in a good working order and, to prevent the contamination of items due to deposits from walls of the sterilizer, leaking gasket or plugged drain.

PROCESS:

1. Follow the manufacture's guidelines for the cleaning of all autoclaves.
2. On a daily basis, inspect the door gaskets for cracks and clean with a lint-free cloth, according to manufacturer's recommendations.
3. The autoclave must be turned off and allowed to cool.
4. Wipe outside stainless steel panelling with lint-free cloth.
5. Remove drain plug from bottom of the chamber and remove lint and sediment from strainer.
6. Thoroughly clean the entire inside surface including the walls, rear panel, floor and inside the door, according to manufacturer's recommendation.
7. Be aware that detergents can stain the walls of the autoclave if not thoroughly rinsed off.

Prepared By	Reviewed By	Approved By	DP

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
5th Mile, Tadong, Gangtok
Sikkim

SOP No 6. Steam Sterilization Procedure Steam

- ***Expected Outcome***
  - Consistent sterilisation of items through quality control checks of the autoclave.
  - All packs are sterile and safe to use.
- **Objective/Purpose**
  - To ensure consistent sterilization of items through quality control checks of the autoclave.
  - To ensure that all reprocessed medical devices are sterilized to an acceptable standard and ready for use.

PROCESS:

1. The steam sterilizer must be operated accordance with the manufacturer's instructions.
2. In this process, the steam is introduced into the jacket which ensures preheating of chamber and effective utilization of heat energy. As the pressure inside chamber reaches a set level, almost 100% removal of air is ensured by creating vacuum and pulsing in steam in the chamber.
3. The vacuum is created with the help of water ring type vacuum pump.
4. After fixed number of pulses the steam pressure in the chamber is increased till the sterilization temperature is reached.

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		Dr. Goutam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim - 737102

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5. After the sterilization hold period is completed, vacuum up to a pre-determined level is created in the chamber.
6. After the vacuum drying time is complete, the chamber is brought to atmosphere pressure by injection of sterile air.
7. The sterile charge is then unloaded from the chamber.
8. The person handling the sterile items should never be in contact with the soiled ones.
9. High vacuum steam sterilization cycle consists of following phases:
    a. Vacuum steam pulsing
    b. Heat up
    c. Sterilization Hold
    d. Vacuum drying
    e. Sterile air in
10. The expiry date of an autoclaved item is 7 days from date of sterilization. This should be documented on the pack.

Following are essential pre-requisite that should be observed before attempting to sterilise.

a) All items to be cleaned and dried which will ensure that the minimum number of organisms are present on the item prior to processing.

b) The packaging shall be appropriate for the process and will not obstruct the passage of the sterility while undergoing the sterilisation process.

c) The machinery will be able to perform its task within well-defined parameters.

d) The maintenance and logging of the process and engineering work on the machinery will be strictly monitored.

Time and temperature parameters:

7 minutes at 30 PSI at 134^{o} C

20 minutes at 15 PSI at 121^{o} C

Shelf life- The shelf life of items autoclaved is 7 days. The shelf life of equipment sterilised in ETO machine is 6 months. Items not used within this period will be returned to the CSSD for reprocessing.

Preparation of Supplies for Autoclaving:

- All articles will be washed and dried before autoclaving.
- Instruments and materials to be double wrapped FOR OT.
- Linen should be laundered after each use, and carefully inspected for holes and tears before use.
- Porous metal containers to be used for autoclaving.
- Every item that is packaged to be labelled before sterilization to specify the contents and expiry date.
- Surgical knife blades or suture materials not to be placed inside linen packs or on instrument trays before sterilization.

Daily Preparation of the autoclave:

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim-737102	DP
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1. Record the result according to procedure.
2. Record biological indicator (BI) Test according to procedure.
3. Record contents of load, information must be detailed enough to allow for tracking and recall.
4. Packaging manufacturers must validate that the product contained can be satisfactorily.
5. sterilized within the wrap, pouch, container etc.
6. Ensure that items being loaded are compatible with High Temperatures.
7. Process full loads – not overloaded- to limit the number of cycles you need to run.
8. 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.
9. Load items in a loose fashion to facilitate air removal, and steam penetration of all surfaces.
10. Do not stack items one on top of the other.
11. Packages must not be in contact with walls or ceiling of chamber, package damage from heat or moisture may occur.
12. Load baskets and carts so hands won't touch packs when removing the hot trolley.
13. On completion of cycle, to determine that all parameters have been met.
14. Follow manufacturer's directions for door opening and load transfer.

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim 737102	DP
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15. The person responsible for checking the load should sign their name on the documentation.
16. Before opening the door, thoroughly wash hands according to Hospital Policy.
17. Open the door while standing towards the side to avoid burns.
18. Put on heat resistant gloves and remove carrier from Autoclave.
19. Allow to cool for 10 – 20 minutes before storage or dispensing.
20. Do not touch hot packs.
21. Record results in log book and file for each autoclave according to Procedure no.

SOP No 7. Ethylene Oxide Sterilisation

Expected Outcome

- ETO sterilizers are operated according to manufacturer's instructions.
- The work environment is safe for employees.
- All equipment is sterilized to an acceptable standard.

Objective/ Purpose

- To ensure that all ETO sterilizers are functional and operated according to departmental policy.
- To ensure that all reprocessed medical devices are sterilized to an acceptable standard and ready for use.

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital Sichey, Tadong, Gangtok Sikkim - 737102	DP
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Safety Warning:

- ETO is an odourless gas.
- Skin Contact with liquid EO - immediately wash affected area.
- Eye contact with liquid EO - flush eyes with copious amounts of water for at least 15 minutes.
- Ensure staff have been educated regarding safety precautions when working with ETO.

Process

Daily Preparation of ETO Sterilizer

1. Ensure the work environment is safe for employees.
2. Replace Load Control Slips Daily or computer printout paper.
3. Identifying sterilizer, date and initial on load control slip Check to ensure printer is working where applicable.
4. Complete test and record biological indicator (BI) Test according to manufacturers Instructions.
5. It is important that all staff members are aware of the policy and procedures that relate to ETO sterilization.
6. Operators must know how to operate the ETO sterilizer safely as well as the importance of adequate aeration.

		Dr. Goutam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok 737102	
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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 and air exchanges.
11. Single-use cartridge delivers the appropriate volume/concentration of ETO.
12. ETO gas must be stored at the prescribed temperature in a well ventilated area in a cupboard marked with Hazardous materials label.
13. The cycle must be long enough to allow thorough ETO penetration to kill microorganisms.
14. The sterilizer operating temperature is usually preset by the sterilizer manufacturer; there are usually two options: 37 degree centre grate (cold cycle) 55 degree centre grate (warm cycle).
15. The manufacturer of a device is responsible for providing validated information regarding proper sterilization and aeration of their products, usually between 1 to 6 hours, 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.

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim 737102	DP
Prepared By	**Reviewed By**	**Approved By**	

17. Personnel exposure must be measured as a Time Weighted Average based on environmental exposure. Average personnel exposure concentration should be measured over a specific period of time, usually 8 hours.
18. ETO won't penetrate soil so proper cleaning and decontamination must be done for the items.
19. Aeration Cabinets are required to remove residual ETO before patient contact with the device
20. If plastic instrument containers/trays are used, make sure they can be sterilized with ETO and Aerated.
21. Plastic, rubber or silicone mats must have been validated by the manufacturer for suitability in ETO processing.
22. Verify with the manufacturer if color code tape can be used with ETO.
23. 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.
24. Do not use plastic coated baskets unless designed and validated for ETO sterilization and Aeration.
25. Label Package according to policy.
26. Load items in a loose fashion to facilitate air removal, humidification, ETO circulation and penetration of all surfaces, and ETO removal during aeration.

		Dr. Debdutta Dey Medical Superintendent Central Referral Hospital Tadong, Gangtok Sikkim - 737102	DP
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27. Packages must not contact walls or ceiling of chamber, package damage from heat or moisture may occur.
28. Process full loads to limit the number of cycles you need to run.
29. Load the sterilizer according to manufacturer's instructions, make sure the door to the chamber is locked, and the appropriate cycle is selected based on the types of devices being processed.
30. Load baskets and carts so hands won't touch packs if you need to transfer them to an aeration cabinet.
31. Follow manufacturer's directions for door opening and load transfer.
32. When unloading some sterilizer manufacturers recommend immediate removal if transferring.
33. Opening the door 2 inches for 15 minutes is recommended...obviously you would not remain in the area.
34. Load is transferred to separate aeration unit/area.
35. Rolling carts should be PULLED (NOT pushed) to minimize Operator exposure to off-gassing ETO vapours.
36. Length of aeration depends on Composition/materials, thickness, design and weight of the device and it's wrapping, sterilization and aeration system used, temperature, ETO, concentration, duration of gas exposure, rate of air exchange, and air flow pattern.

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim 737102	DP
Prepared By	**Reviewed By**	**Approved By**	

37. Size and arrangement of packages in the sterilizer/aerator or aeration cabinet and the number of ETO absorbent materials being aerated.
38. Device manufacturer's recommendations must be VALIDATED aeration parameters (time/temperature/pressure).
39. DO NOT remove prematurely, with premature removal, personnel and patients may be adversely affected.
40. Signing a waiver sheet DOES NOT relieve any liability for anyone.
41. "Ambient air" aeration is not recommended as it greatly increases the risk of worker exposure to EO and is not necessarily a reliable means of removing ETO from the items.

SOP No 8. Loading and unloading items from the autoclave

- **Expected Outcome**

  Sterility of packs is not compromised through incorrect loading and unloading.

- **Objective/ Purpose**

  To ensure that items are correctly loaded and unloaded from autoclaves in order to maintain sterility.

Process

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital Sikkim - 737102	DP
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1. Load according to manufacturer's instructions.
2. Wear relevant protective clothing.
3. Load instruments sets flat in single layer.
4. Load soft packages on their sides with a hands width between items.
5. Load soft packs on top shelf and large instrument trays on lower shelf.
6. Load containers according to manufacturer's instructions some may be stacked.
7. Do not allow packs to touch top, bottom or sides of autoclave.
8. Do not compress packs.
9. Position peel packs on sides.
10. Do not overload.
11. On completion of cycle record according to policy.
12. Allow autoclave and packs to cool before handling.
13. Do not touch packs until completely cooled.
14. Do not touch hot racks without heat resistant gloves.
15. Once cooled check for wet packs, tears, indicator changes etc.
16. Store according to policy.

SOP No 9. Sterile Pack Storage

Expected Outcome

Sterility of all packs is maintained whilst in the CSSD.

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital Gangtok	DP
Prepared By	**Reviewed By**	**Approved By**	

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Objective/Purpose

To ensure the safe storage of all sterile packs up to release to other departments.

Procedure

1. This is a clean area and should be kept clean and tidy at all times with limited access.
2. Ensure that stock is rotated and monitor stock levels.
3. Any member of the CSSD staff may issue out packs to customers, provided that ALL the checks have been carried out by the person releasing the goods.
4. Only CSSD staff should be allowed access to the storage area.
5. Doors and windows must be kept closed.
6. Temperature should be controlled.
7. The Sterile Storage area should be arranged to make it easy to identify packs and be well lit and easy to clean.
8. There should be enough shelves and cupboards available to store all sterile good without having to stack them tightly or on top of one another.
9. Products should be stored away from outside walls.
10. There should be space between shelving and floor and ceiling to allow air to circulate and to allow cleaning of the floor area.

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital Gangtok, Tadong, Sikkim - 737102	DP
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11. Surgical and medical supplies should be stored at least 25cms from the floor, 45cms from the ceiling and 5cms from outside walls to allow for air circulation in the room and to prevent contamination during cleaning.
12. Items should not be stored next to or under sinks, on the floor or windowsills where they are likely to get wet or damaged.
13. You need enough space to store all the medical devices your department is using.
14. Do not bend or fold large packs.
15. Storage components should be designed so that you can easily see the number of products in storage.
16. Follow a system of use the First in First out (FIFO) system. Rotate stock so that oldest items are used first.
17. Shelving should be easily cleaned and allow air to circulate around stored products.
18. Products should be stored away from direct sunlight and water.
19. Do not squeeze packs into tight spaces as this can tear the packaging.
20. Cupboards can be used to store small, delicate or expensive items. All cupboards must have doors, preferably with a lock. Open shelves (wire-mesh or bars) allow dust to pass through making them easier to clean than solid shelves.
21. Cardboard boxes should not be used as storage containers because they release fibres, cannot be easily cleaned and sometimes have rough edges which can make holes' in packaging.

22. Shipping cartons should not be brought into the Sterile Storage area because they can collect microorganism during transport, which can increase the risk of infection. Insects and rats, which spread microorganism, should not be allowed to enter either.
23. Surfaces in contact with sterile goods should be as clean as possible to prevent microorganism penetrating the packaging of these items.
24. Trolleys should be cleaned and dried after each use, because even though they are used with sterile items, contamination can be picked up during transport outside the CSSD.
25. The shelf life of a pack is dependent on packaging, handling and storage conditions.
26. The shelf life of a CSSD processed sterile item is based on events rather than time.
27. The date on a sterile package indicates the date the item was sterilized or manufactured.
28. Sterility is maintained as long as the integrity of all barrier properties and seals are maintained.
29. Expiration date is a reminder "Use Before" /" Use First".
30. 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.

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
5th Mile, Tadong, G...

SOP No 10. The Delivery and Distribution of Processed items0

Expected Outcome

Customers receive sterile items safe to use.

Objective/Purpose

To ensure customers receive sterile items in a safe condition and ready to use.

Procedure

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
   - Evidence of crushing
3. All items issued will be recorded so that a tracking system is affected.
4. Sterile supplies should be transported in covered or enclosed trolleys.
5. Trolleys must not be overloaded.
6. Soiled items must NOT be loaded onto the same trolley.
7. Loaded trolleys must not be left to stand.

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
5th Mile, Tadong, Gangtok
Sikkim - 737102

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SOP No 11. Quality control

Objective/ Purpose

To ensure that the CSSD provides a quality service.

Procedure

Area Where Test Is to Be Performed

Packing Area-

1. Check all instrument are present and packed correctly.
2. External chemical indicators are record.
3. Check the functioning of heat sealers daily.

Autoclave Area-

1. Mechanical monitoring of all sterilizers.
2. Perform daily Vacuum Tests on all steam autoclaves (BD).
3. Perform daily Biological Tests on all sterilizers.
4. Check that all packs have external chemical indicators before loading into sterilizer.
5. Check load control test has passed before load is released - ensure a positive colour change – record.

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6. Check that all parameters have been met on autoclave.
7. Complete all log sheets
8. Check that all items removed from the autoclave are intact, dry and undamaged.
9. Check tracking system is in place – record.

Sterile Goods Storage Area

1. Before releasing goods for delivery, check the packaging for damage.
2. Check the external chemical indicator to ensure that the pack has been through.

SOP No 12. Planned Maintenance Schedule of Equipment

Expected Outcome

All equipment is checked and maintained on a regular planned basis.

Objective/Purpose

- To ensure all plant and equipment is checked and maintained in good working order according to manufacturer's guidelines and departmental maintenance schedule Procedure.
- A schedule of planned maintenance of all machinery and equipment used in the Department is documented.

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
Gangtok

process

1. Shutdown of equipment is planned according to schedule.
2. The work to be carried out at each check is documented.
3. All maintenance carried out is recorded.
4. Log Books will be examined at least once in a monthly basis or as appropriate, and signed by the test person, designated for all equipment, for completion and accuracy.
5. Senior staff will carry out daily checks on equipment in all Areas according to policy and as detailed in the Working Instructions Manual.
6. Testing will be carried out at prescribed frequencies (Daily, Weekly, Quarterly and Annually).
7. Results will be recorded on the Daily Test / Check Forms in the respective log books.
8. Service Engineers will carry out inspections under the planned preventative maintenance programme according to the agreed schedule.
9. At the end of the visit the Service Engineer will complete a Preventative Maintenance Plan (PMP) form for the equipment checked.
10. The Service Engineer must sign the report.

SOP No 13. Action for Breakdown of Equipment

Expected Outcome

All breakdowns of machinery are reported and recorded with complete details.

		Dr. Gautam Roy Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim 737102	DP
Prepared By	**Reviewed By**	**Approved By**	

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Objective/Purpose

- To record all breakdowns of machinery.
- To record reasons for breakdowns.
- To record action taken to remedy breakdown.

Procedure

1. All equipment breakdowns will be reported to the Supervisor.
2. The Supervisor will remove the equipment from further use by switching off (if appropriate), implementing the defect reporting procedure and attaching a clear label showing: - "OUT OF ACTION - DO NOT USE"
3. The Supervisor will hand over the equipment to the designated engineer.
4. This must be documented in all cases.
5. All breakdowns or repairs will be phoned into the relevant manufacturer if still under guarantee.
6. If equipment is still under guarantee NO-ONE must attempt to repair the equipment without the manufacturers permission.
7. Equipment on loan or used under service exchange must be returned to the relevant company for repair or replacement.
8. All breakdowns are recorded in the relevant logbook and the engineer will enter the job number and repairs completed and signed before the equipment is put back into use.

Prepared By	Reviewed By	Approved By	
		Dr. Gautam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim 737102	DP

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SOP No 14. Sterile Packaging

Expected Outcome

Pack integrity is maintained through correct use of packaging.

Objective/ Purpose

To ensure that the correct materials are used and that items are correctly packaged in order to maintain sterility.

Procedure

1. Sterile packaging must provide protection against contamination during handling as well as providing an effective barrier against microbial penetration.
2. An ideal packaging should have the ability to allow sterilization agents to penetrate and then provide a barrier, which will maintain the sterility of the wrapped devices.
3. The type of packaging and the way you package the devices will determine if aseptic opening is possible in the operating theatre or the ward.
4. The packaging should allow air that is in the pack to be driven out and the sterilizing agent to reach all surfaces of its content.
5. The packaging should protect the contents against damage during handling and transport.
6. The packaging should be able to withstand the conditions during the sterilization process such as pressure changes, high temperature and humidity.

		Dr. Gautam Dey Medical Superintendent Central Referral Hospital Tadong, Gangtok Sikkim	DP
Prepared By	**Reviewed By**	**Approved By**	

7. It is important that the following points are taken into consideration when choosing a tray/set and packaging method:
   - The type of pack
   - The size and weight of items to be packed
   - The number of times the pack will be handled before use
   - The number and training of personnel who may handle the pack
   - The distances that packs will be transported
   - Whether the storage system is open or closed
   - The condition of the storage area (cleanliness, temperature, humidity)
   - The method of sealing packs.
8. The packaging should bear a clearly visible marking indicating whether or not the product has been through a sterilization process.
9. There are many different types of packaging that can be used for different items.
10. Packaging material used in steam sterilization must be able to withstand high temperatures, allow for adequate air removal, be flexible considering changes in pressure during the process, permit steam penetration to the pack's contents and allow for adequate drying.
11. Packaging materials used with low temperature sterilization processes (e.g., ethylene oxide) must have similar properties, particularly being compatible with the sterilization chemicals, moisture, pressure changes and temperature ranges.

		Dr. Goutam Dey Medical Superintendent Central Referral Hospital 5th Mile, Tadong, Gangtok Sikkim - 737102	DP
Prepared By	**Reviewed By**	**Approved By**	

12. The packaging system chosen should be appropriate for the items being sterilized and compatible with the specific methods of sterilization being used.
13. Choose packaging to suit the dimensions of the instruments/tray and type of sterilization technique to be used.
14. In addition to containers, individual devices and sets can be packaged with sterilization pouches or wraps.
15. The choice of packaging will generally depend on the sterilization method being used.
16. Packaging materials should only be used that have been tested to be compatible and safe for each sterilization purpose.
17. Two sheets of wraps are used providing multiple layers of protection of surgical instruments from contamination. Double wrap = wrap and wrap
18. The use of two layers of wraps reinforces the strength of the packaging.
19. Do not re-use single use packaging.
20. Use a hospital grade masking tape and autoclave tape when using wrap.
21. Do not write on packaging.
22. Paper/Plastic peel-open packaging materials are suitable for steam, steam formaldehyde and low temperature sterilization processes such as ethylene oxide.
23. Disposable peel-open pouches and reels are designed to contain lightweight or small items and are available in various sizes, for single use only.

Prepared By	Reviewed By	Approved By
		Dr. Gautam Dey, Medical Superintendent, Central Referral Hospital, S.T.N.M., Tadong, Gangtok, Sikkim - 737102

DP

24. Peel-open packaging should not be used for heavy or bulky items because the seals can become stressed and rupture.
25. The open end of the pouch is closed with a sealing device. It is essential that the heat sealer is functioning effectively in order to get an adequate seal.
26. Both ready-made pouches and reels are available flat or with side gussets for packing bulkier objects.
27. The user can cut reels to any size needed, in which case both sides of the pack will need to be sealed by the user.
28. Peel-open packaging is useful when visibility of the contents is important.
29. When packaging items, care must be taken to leave a minimum of 1 inch (2.5cm) of space between the end of the item and the seal of the pouch or reel in order to facilitate aseptic opening.
30. When double pouching, the inner pouch should be at least a size smaller than the outer pouch to prevent folding which may entrap air and inhibit the sterilization process.
31. Sterilization containers are a durable sterilization packaging system constructed of a rigid material such as metal, or plastic.
32. Containers must be cleaned in the same way as any other reusable device.

Dr. Gautam Dey
Medical Superintendent
Central Referral Hospital
Sikkim Manipal University, Gangtok
Sikkim - 737102

5 RECORDS

6 REFERENCES

Prepared By	Reviewed By	Approved By	DP
Sd/-		Dr. Gautam Dey, Medical Superintendent, Central Referral Hospital, 6th Mile, Tadong, Gangtok, Sikkim, 737102	