CENTRAL STERILE SUPPLY SERVICES POLICY

MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA
This policy was developed by the Clinical Support Services Unit, Medical Development Services Section of Medical Development Division and the Drafting Committee of Operational Policy of Central Sterile Services Department.

Published in August 2018.

A catalogue record of this document is available from Library and Resource Unit, Institute for Medical Research, Ministry of Health Malaysia

MOH/P/PAK/336.17(BP)e ISBN 978-967-0399-72-0

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ACKNOWLEDGEMENT

Medical Development Division would like to acknowledge the contributions of the following groups and individuals toward the development of this document:

An appreciation to Dato’ Dr Hj. Azman bin Hj. Abu Bakar, Deputy Director General of Health (Medical) for his endless support in developing this policy.

Matron Hjh Mek binti Jusoh and the Drafting Committee on Operational Policy of CSSU for their dedication and continuing support for ensuring that the policy is materialized.

Thanks to others who are directly or indirectly involved in formulating this policy.
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Head of Central Sterile Services unit (CSSU) iii

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Central Sterile Supply Services Policy
PREFACE / FOREWARD
I would like to begin with praise to Allah SWT for blessing us with wisdom and strength in completing the Central Sterile Supply Services Policy.

Central Supply Services Unit (CSSU) is a crucial part of Clinical Support Service. Despite being overshadowed by other clinical services, its presence is indispensable in the Ministry of Health’s visions to combat the rising incidence of hospital acquired infections.

CSSU ensures the standardized method of process for supplying sterile instruments and materials under strict quality control, henceforth enabling the clinicians at the forefront to focus on the care and safety of our patients. This policy is written beyond the process and storage of clinical equipments, but also to armour the CSSU personnel when dealing with hazardous and infectious wastes.

In recent decades, Malaysian healthcare system too is facing the effect of global inflations in healthcare costs. Additionally, new and improved clinical equipment, processes and practices are constantly evolving, and it is our duty as a care provider to be cognizant with the latest medical advancement. This is aligned with ministry’s vision to provide highly efficient, cost-effective, innovative, equitable and technologically-appropriate healthcare system.

This new Central Sterile Unit Standard Operational Policy is produced with endless commitments from the committee members and stakeholders in addressing concerns relating to issues of efficiency and quality of sterilization service. Therefore, I would like to offer the committee the highest commendation for embarking such initiatives. My hope along with the updated guideline is that, CSSU will continue providing the best care to our patients, as well placing the health and safety of our personnel at the foremost importance.

Dato’ Dr Hj Azman bin Hj Abu Bakar
Deputy Director General of Health (Medical)
Ministry of Health
First and foremost, I would like to offer my gratitude to the Medical Development Division for giving the Central Sterile Services Unit an opportunity in developing this policy.

The healthcare professionals responsible for sterilization and disinfection of reusable medical devices are confronted with ever increasing range of challenges.

Clinical sterile items must be delivered in timely and cost-effective manner. Adding on to this challenge, the instrumentations to accomplish sterilization and monitoring standards have become increasingly sophisticated.

The policies must therefore be in place and implemented to ensure the safety of healthcare personnel and environment. This policy is published to guide CSSU operators within the mandated regulations and voluntary guidelines. It is my sincere hope that all healthcare workers involved find this booklet informative, beneficial and invaluable in performing their daily operations effectively.

It is a concise and applicable tool which can be useful for orientation, training and instructional programmes in healthcare facilities as well as educational institutions.

Finally, with much pleasure, I present to you the Ministry of Health’s Central Sterile Supply Services Policy.

Matron Hjh Mek binti Hj Jusoh
Head of Service of CSSU
Ministry of Health
THE ARTICLES
1. **INTRODUCTION**

Central Sterile Services Unit (CSSU) is an integrated service in hospitals that performs sterilization and other actions on medical devices, equipment and consumables. This unit ensures safe management of decontamination services in the healthcare through safe, efficient, effective and reliable systems.

This Policy of CSSU is an introductory text developed to provide guidance and reference for safety of patients and health care workers. It highlights procedures pertaining to the processes of decontamination, cleaning, assembly, packaging, sterilization, storage and distribution of sterile products.

2. **OBJECTIVE**

The purpose of this document is to provide a framework to enable the clinical and non-clinical department to understand the operational and management of CSSU service.

3. **GENERAL POLICY**

   3.1 Traffic Control

   3.1.1 Traffic Control shall be strictly enforced in CSSU.

   3.1.2 All doors opening into the main corridor are to remain closed at all times.
3.1.3 The door at the main entrance is the only door used to enter the CSSU.

3.1.4 Only CSSU personnel are allowed to enter the unit.

3.1.5 Other personnel that require entry into CSSU e.g. engineers, technicians, support service staffs, physicians and administrative personnel must apply Personal Protective Equipment (PPE) before being allowed to enter the Unit.

3.1.6 Limited entry by staff and visitors to the Unit.

3.2 Food and Smoking

3.2.1 Food and beverages are only allowed at the pantry and shall be restricted from all other areas.

3.2.2 Cooking shall not be allowed.

3.2.3 **NO SMOKING** in CSSU.
3.3 Health and Personal Hygiene

3.3.1 Personal hygiene shall be adhered to and communicated to all employees:

i. Hair, body and nails shall be cleaned at all times.

ii. Neither nail polish nor artificial nails shall be worn.

iii. Fingernails shall be kept short and clean.

3.3.2 All personnel working in CSSU shall be free from skin diseases, infectious diseases, mental illness and physical handicaps.

3.3.3 CSSU clinical attire or other garments that become soiled or wet shall be changed immediately.

3.3.4 Hair and goatee/beard except eyebrows and eyelashes shall be completely covered.

3.3.5 Jewellery and wrist watches shall not be worn.
3.4 Dress Code

3.4.1 All personnel working in CSSU shall wear the CSSU Clinical Attire and change upon leaving.

(Refer Figure 1)

Figure 1: CSSU Clinical Attire

3.4.2 Shoes/clogs worn in the Unit shall be cleaned, non-skid soles and sturdy.

3.4.3 Visitors entering CSSU shall adhere to CSSU clinical attire.

3.4.4 Attire shall be changed daily or as needed.
3.4.5 The following dress code applies to all personnel working in the CSSU:

3.4.5.1 Collection (Refer Figure 2)

i. Personnel handling contaminated medical devices during collection shall wear:
   • Head covers / Surgical cap
   • Mask
   • Long sleeved apron/long sleeved water repellent gown
   • Rubber Gloves
   • Shoes

Figure 2: Collection Dress Code
3.4.5.2 Decontamination Zone

(Refer Figure 3)

i. Appropriate PPE should be worn:
   - Long sleeved gowns which shall be impervious and disposable
   - Elbow length latex glove
   - Mask
   - Protective eye covering / visor shield
   - Boots

ii. The attire shall be removed and disposed off in the proper receptacle before leaving.

iii. Head covers / surgical cap and boots to be changed daily and as needed.

iv. Boots shall be removed when leaving the zone.

v. Cover gown shall be backless and non-permeable.
3.4.5.3 Packaging Zone (Refer Figure 1)

i. Personnel working in the packaging zone shall wear CSSU clinical attire.

ii. Personnel working with soft dressing and linen preparation shall wear mask.

3.4.5.4 Sterilization Zone (Refer Figure 4)

i. PPE shall be worn by personnel handling ‘HOT’ medical devices from the autoclave.
ii. Elbow length leather gloves shall be used during loading and unloading.

iii. Sweater / cardigan shall not be used.

Figure 4 : Sterilization dress code

3.4.5.5 Distribution Of Sterile Products

i. Personnel handling sterile products during distribution shall wear CSSU clinical attire (Figure 1).
3.5 **CSSU Space And Environment**

3.5.1 All work surfaces in the CSSU shall be cleaned with approved germicidal disinfectant at the end of each work shift.

3.5.2 Lockers shall be provided for all personnel working in the CSSU.

3.5.3 An area shall be designated for CSSU employees to change their clothing.

3.5.4 Every zone in the CSSU shall be provided with proper dedicated air exchange rate to promote maximum removal of foul air/contaminants from the areas.

3.5.5 The pressure differential scheme shall be strictly designed and employed to ensure the movement of air from clean to less clean areas.

3.5.6 Temperature within CSSU shall not be more than 23°C. Temperature in the sterile store shall be maintained between 20°C – 22°C and the humidity shall be kept at 50% - 60%.

3.5.7 Proper ventilation system at the plant room must be provided and the temperature inside the plant room shall not be more than 35°C to prevent damage to the machine components.
3.5.8 The installation of sterilization equipment shall adhere to the requirement of noise and vibration limits as stipulated by the Occupational Safety and Health Department.

3.5.9 Each sterilizer processing area shall have exhaust ventilation to remove heat, moisture and odor.

3.5.10 The installation of Ethylene Oxide (ETO) machine, sensing device, positive pressure, local exhaust ventilation and chamber ventilation shall be provided.

3.5.11 All sources of contamination shall be properly diluted and discharged.

3.5.12 Exterior shipments cartons shall not be brought into sterile supply storage or processing areas.

3.5.13 Exhaust fan shall be provided in soft dressing and linen preparation area. Use of fans is not allowed.
3.6 Safety

3.6.1 All new equipments / machines for the unit shall be properly tested and commissioned.

3.6.2 CSSU Manager shall be responsible in developing, supervising and maintaining the safety training of the unit.

3.6.3 CSSU Manager is responsible for notifying the Safety Officer of any hazard.

3.6.4 All CSSU employees shall report of any defective equipment, unsafe conditions or hazards to the CSSU Manager.

3.6.5 Keep electrical cords clear of passage ways. Do not use electrical extension cords without consent from the Engineering Department.

3.6.6 All equipment and supplies shall be properly stored. Do not store heavy items on top of the shelves.

3.6.7 All personal electrical appliances shall have suitably star-rated and certified safe to be used by the Energy Commission.

3.6.8 All electrical appliances shall be inspected by the Engineering Department before use.
3.6.9 Scissors, knives, pins, razor blades and other sharp instruments shall be safely stored for use.

3.6.10 All heat producing machineries shall be switched off when not in use.

3.6.11 Immediate notification to the concession company for any ventilation breakdown or illumination sign warning.

3.6.12 Only authorized personnel shall operate autoclaves and other high pressure equipments.

3.6.13 To store all combustible supplies at least 44 cm height from the ceiling.

3.6.14 First Aid Kit shall be readily available and checked at all times.
3.7 **Maintenance**

3.7.1 The installation of all machines shall allow adequate space for the maintenance and repair activities.

3.7.2 The maintenance shall be performed from the unsterilized side of the machine.

3.7.3 Maintenance activities of equipment shall be performed by certified personnel.

3.7.4 Only new original parts shall be used to replace any broken/faulty components. Re-used parts from other machines shall not be permitted at any circumstances.

### 4. POLICY ON DECONTAMINATION

#### 4.1 Objectives

4.1.1 To ensure that all soiled medical devices received in the Decontamination Zone are processed according to Standard Operating Procedure and rendered safe for handling.

4.1.2 To protect staffs and patients from any infection risk of soiled medical devices and equipment.

4.1.3 To eradicate or significantly reduce the number of microorganisms on soiled medical devices and equipment.
4.1.4 To adhere to standard of decontamination for cleaning and disinfecting soiled medical devices and equipment.

4.1.5 To adhere with the standard requirements needed to achieve safe environment.

4.1.6 To ensure staffs perform and adhere to their professional duty of care with regards to providing a safe environment.

4.2 Infrastructure

4.2.1 Decontamination Zone

4.2.1.1 It shall have adequate and designed electrical supply, water supply, lighting and ventilation systems.

4.2.1.2 It shall be supplied with negative pressure air conditioned with a minimum of 10 air exchanges per hour.

4.2.1.3 The loading area shall be adequate for staff and trolley maneuverability.

4.2.1.4 The floor shall be made of heavy duty materials, anti-slippery, anti-dust in nature with no water accumulation at any time.
4.2.1.5 Walls shall be painted with bright color anti-fungal paint.

4.2.1.6 Stainless steel double sinks with hot and cold water supply shall be available.

4.2.1.7 An outlet for air gun shall be available.

4.2.1.8 The drainage system shall be designed with proper sizing to prevent back flow, appropriate material to withstand the water temperature and proper leveling to prevent flooding.

4.2.1.9 There shall be an in-built outlet for reverse osmosis water.

4.2.1.10 Each washer shall have individual pipes with individual socket outlets.

4.2.1.11 An appropriate number of machines shall be connected to an essential power supply. Quality of water supply shall follow the recommended standards.

4.2.1.12 A cart wash area and trolley bay area shall be made available.
4.2.1.13 Detergent store with exhaust fan and dedicated stainless steel shelf shall be available.

4.2.1.14 Separate bathrooms for male and female staff.

4.2.1.15 The main door shall be an automatic sliding door.
4.3 Equipment In Decontamination Zone

4.3.1 Decontamination room shall be equipped with the following:-

i. Washer disinfecter/ decontaminator with accessories

ii. Ultrasonic washer

iii. Dryer

iv. Collection trolley

v. Stainless steel mobile workstation

vi. Magnifying lamp.

4.4 Size and Number of Washer Disinfector

4.4.1 Estimated size and number of washer disinfector varies with the application.

4.4.2 Quantity of washer disinfector required is based on estimated workload divided by actual work load per basket per week.

Example:

Total workload : 1400 basket / week
Total actual output : 1600 basket / week
No of washer required : \( \frac{1400}{1600} = 0.875 = 1 \text{ unit} \)
4.5 Personnel

4.5.1 Team leader in decontamination area shall be headed by a trained nurse with a minimum of 2 years working experience. All staffs involved with decontamination procedure shall be trained.

4.5.2 All personnel entering the Decontamination Zone shall be properly attired. (Refer Figure 2)

4.5.3 All personnel assigned to the Decontamination Zone shall be strictly confined to the designated area. If needed, the personnel shall bathe and change into attire accordingly.

4.6 Receiving and Handling

4.6.1 All medical devices returned to CSSU are considered contaminated and shall be received in decontamination area.

4.6.2 Delicate and precision instruments shall be handled with care to avoid damage.

4.6.3 Returned supplies shall be inspected to ensure all parts of medical instrument are complete.

4.6.4 Notify CSSU Manager for any missing parts or instruments received.
4.6.5 Malfunctioning instruments shall not be used and to be kept in a separate place.

4.6.6 Users are responsible to return all instruments regardless opened or disassembled (if applicable) prior to cleaning and disinfection.

4.6.7 Any single use items received shall be discarded and not to be processed.

4.6.8 Gross soil shall be removed at the point of use where immediate containment, transportation and cleaning may not be feasible.

4.6.9 Personnel shall wear appropriate PPE and follow good work-practice when handling contaminated medical devices.

4.6.10 High Filtration Efficiency (HFE) facemask and eye protection shall be used for any risk of splash or aerosols.

4.7 Inspection, Repair and Ongoing Maintenance

4.7.1 Every medical device shall be inspected upon arrival.

4.7.2 All parts of rigid sterilization container systems shall be cleaned between each use.
4.8 Sorting of Instrument
   4.8.1 Contaminated medical devices shall be sorted and prepared for cleaning.

   4.8.2 Non-interchangeable component assemblies shall be kept together to ensure correct reassembly.

4.9 Method of Cleaning
   4.9.1 Cleaning shall be accomplished manually, mechanically or combination of both methods.

   4.9.2 The cleaning method or methods selected shall be effective, not affecting the functionality of the device and safety.

4.10 Chemical Disinfection
   4.10.1 Select appropriate type of disinfectant and follow manufacturer instructions.

   4.10.2 Protective measures for personnel shall be applied at all times.

4.11 Porter Services
   4.11.1 Used medical devices shall be collected and transported using suitable containers and trolleys.

   4.11.2 The transportation carts / trolleys / containers shall be cleaned and disinfected after used.
4.12 Counter Services

4.12.1 All personnel shall wear CSSU clinical attire (Figure 1) during receiving of soiled medical devices.

4.12.2 Soiled medical devices shall be received in suitable closed containers at the Decontamination Zone.

5. POLICY ON PACKAGING

5.1 Objectives

5.1.1 To provide guidelines for evaluation, selection and use of packaging materials for item to be sterilized.

5.1.2 Packaging material shall ensure sterility of package contents until opened for use.

5.2 Physical Set Up

5.2.1 The room shall be equipped with:
   i. Air conditioning to maintain positive pressure
   ii. Sufficient lighting

5.2.2 The floor and wall must be able to withstand frequent cleaning.

5.2.3 Packing table should be constructed of suitable material (stainless steel material / epoxy coated) with attached magnifying lamp.
5.2.4 Adjustable packing chair with backrest.

### 5.3 General Consideration

5.3.1 All wrappers shall be double layered.

5.3.2 Medical devices shall be wrapped completely and packed to provide aseptic opening.

5.3.3 No package shall be above the maximum size of 30cm x 30cm x 50cm nor should it weight more than 5.5 kilograms.

5.3.4 Chemical Indicators shall be placed for all sets. The Internal Indicator shall be examined before use.

### 6. POLICY ON STERILIZATION

#### 6.1 Objectives

6.1.1 To ensure that all medical devices/surgical instruments which are introduced into the human body site, traumatic or operation wound shall be provided sterile.

6.1.2 Sterilization shall be achieved by means of heat, steam, chemicals and low temperature sterilizers used under carefully controlled conditions.
6.1.3 Each item being processed shall be traceable by a batch coding system.

6.2 Purchasing, Commissioning and Maintenance

6.2.1 Sterilizers and associated equipment purchased shall be in accordance with recognized International Standards and shall meet user requirement.

6.2.2 The number of sterilizers required will depend on the cycle time and the chamber size. The minimum number of sterilizers required to the workload can be calculated as below:

\[
\text{Number of sterilizers required} = \frac{\text{Workload}}{\text{Capacity}}
\]

6.2.3 It is mandatory for all type of sterilizers to be certified under the Occupational Safety and Health Act (OSHA) before use.

6.2.4 Each autoclave shall have a valid design approval and a certificate of fitness for operation from the Department of Safety and Health (DOSH) before it is handed over to the department.

6.2.5 Operating instructions shall be displayed at sterilizer sites.

6.2.6 The manufacturer shall provide written instructions for preventive maintenance of the sterilizer. The
maintenance shall be carried out by a qualified individual. Preventive maintenance and repair records shall be retained for reference.

6.2.7 Every sterilized item shall have a load control identification that indicates the sterilizer use, the cycle or load and the date of sterilization. Its purpose is to readily retrieve items in the event of a sterilization failure or recall.

6.3 Load Monitoring

6.3.1 All sterilizing processes shall be monitored and recorded accordingly.

6.3.2 Notify the Supervisor immediately for any abnormal result.

6.4 Efficiency Tests for Sterilization

6.4.1 Dummy Run shall be done daily for steam sterilization.

6.4.2 Leak Test shall be done daily and after major repair.

6.4.3 Bowie Dick Test shall be tested daily in separate and special cycles.
6.4.4 Chemical Indicator

6.4.4.1 A chemical indicator shall be used in each package to be sterilized.

6.4.4.2 Sterile products shall not be used if the interpretation of the external process monitors suggests inadequate processing.

6.4.5 Biological Monitoring

6.4.5.1 All biological monitors are preassembled by manufacturer.

6.4.5.2 Biological monitoring shall be done once a week, each load for any transplant and after major repair (3 times consecutively daily) on all steam sterilization loads.

6.4.5.3 Biological monitoring shall be done with every ethylene oxide load.

6.5 Malfunction Sterilizer

6.5.1 CSSU Supervisor shall notify the engineering personnel.

6.5.2 A recall system shall be initiated immediately if biological culture is positive.

6.5.3 Stop using the sterilizer until repair is done and tested negative for three (3) consecutive biological cultures.
6.6 Record Keeping Sterilizer

6.6.1 A maintenance record in either hardcopy or electronic format shall be kept for each sterilizer.

6.6.2 The record shall be kept according to the Archive Act.

6.7 Cleaning the Sterilizer

6.7.1 Cleaning and maintenance of the mechanical part of the sterilizer is the responsibility of the appointed maintenance company. The appointed maintenance company shall also responsible for cleaning the sterilizer service area which is the enclosed room located directly behind the sterilizer.

6.7.2 The appointed maintenance company shall shut off the steam supply valve of high vacuum sterilizers at night of the cleaning process.

6.7.3 CSSU staff shall be responsible for direct cleaning of all sterilizers.

6.8 Steam Sterilization Safety

6.8.1 All new equipment shall be tested jointly by the supplier and the representative from the Engineering Department, appointed maintenance company personnel, and department personnel before it is put into use.
6.8.2 Autoclaves shall be operated only by trained and certified personnel.

6.8.3 A preventive maintenance shall be carried out by an appointed maintenance company for all sterilizing equipment. They shall be responsible for all repairs.

6.8.4 Timing cycle shall follow recommendation by manufacturer for a specific product.

6.8.5 Time and temperature settings shall not be changed unless a manufacturer of an item recommends different parameters.

6.9 Ethylene Oxide Sterilization Safety

6.9.1 Operated only by trained staff.

6.9.2 An appointed maintenance company shall be responsible for the activation of the emergency plan in the event of an ethylene oxide spillage or leakage.

6.9.3 Ethylene oxide tanks shall be stored in a controlled ventilated area at a temperature that does not exceed 37.7°C.
7. POLICY ON STORAGE OF STERILE PRODUCTS

7.1 Objectives

To have proper storage and handling of sterile products.

7.2 Storage and Handling

7.2.1 Staff assigned to the sterile store shall be free from upper respiratory tract infection (URTI) and skin diseases.

7.2.2 Staff shall be trained in handling sterile items.

7.2.3 Storage systems

7.2.3.1 Basic systems for storing sterile products shall be opened shelving or closed shelving.

7.2.3.2 Open shelving shall be 25cm from the floor, 5cm from outside walls and 44cm from ceiling.
8. POLICY ON TRANSPORTATION AND DISTRIBUTION OF STERILE PRODUCTS

8.1 Objectives
To maintain sterility and prevent damage of sterile products.

8.2 General Consideration
8.2.1 To have dedicated carts/trolley for delivery of sterile items and shall be kept clean at all times.

8.2.2 Sterile products shall be transported and protected from contamination and damage.

8.2.3 Supply of sterile products shall be transported via dedicated or scheduled route.

9. POLICY ON STERILIZATION OF IMPLANTABLE ITEMS

9.1 Objectives
To control and ensure effective management of instrument and implantable items for quality service.

9.2 General Consideration
9.2.1 Sterile implantable items shall be supplied by the manufacturer.
9.2.2 If the implantable items are not sterile, it should be sterilized according to the manufacturer's recommendation.

9.2.3 An implantable item shall be monitored and quarantined until results of Biological Indicator (BI) reads negative.

9.2.4 Detailed protocols should be available from the manufacturer, regarding handling and sterilization of implant.

10. POLICY ON SHELF LIFE

10.1 The shelf life of a packaged sterile item is EVENT-RELATED.

10.2 Stock shall be rotated according to the principle FIRST IN, FIRST OUT (FIFO).

10.3 The integrity of the pack shall be inspected before being released to the user.

10.4 Sterile products shall be labeled, ‘STERILE UNLESS OPENED, DAMAGED OR WET’.

10.5 Quality Audit of sterile products shall be done by CSSU personnel as scheduled.
11. POLICY ON PRODUCT RECALL

11.1 Objectives
To ensure complete removal from central inventory of all products and equipment that may be unsafe as established by notification/alert or internal surveillance.

11.2 General Consideration

11.2.1 Positive Biological Indicator (BI) results shall be immediately reported to the Supervisor.

11.2.2 The CSSU manager shall determine the cause of sterilization failure and arrange for corrective action.

11.2.3 Retrieve all unused items from affected loads.

11.2.4 Malfunction sterilizers shall not be used until repaired and BI tests are negative.

11.2.5 The CSSU manager shall keep a record of all incidents.
12. POLICY ON SINGLE USE ITEMS

12.1 A device designated for ‘single use’ SHALL NOT be reprocessed.

13. POLICY ON NON-FUNCTIONAL / LOST INSTRUMENTS

13.1 Damaged or spoilt and lost surgical instruments shall be accompanied by Breakages and Lost Form signed by the Supervisor.

13.2 The user shall lodge a police report if an instrument or sets are found lost.

14. POLICY ON INCOMPLETE PROCEDURE SETS

14.1 Sterile product opened and found to be incomplete, SHALL NOT BE USED and returned to CSSU.

15. POLICY ON BIOHAZARD CASES

15.1 All surgical instruments used shall be double bagged and labelled Biohazard.
16. POLICY ON LOANER INSTRUMENTATION

16.1 Arrangements can be made with the vendor or other healthcare facilities. Request for the loaner of instruments shall be directed to the responsible personnel only.

16.2 All items shall be delivered directly to CSSU decontamination area.

16.3 CSSU shall not be responsible for any items not listed on the vendor’s inventory list.

16.4 CSSU shall monitor proper count of the items borrowed and returned.
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REFERENCES


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DRAFTING COMMITTEE FOR CENTRAL STERILE SUPPLY SERVICES POLICY

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