Institution Name: Al Masarra Hospital

Document Title: Policy and Procedure of Cleaning, Disinfecting & Sterilization of Equipment

Approval Process

	Name	Title	Institution	Date	Signature
Written by	Wafa Al Balushi	Infection Control Practitioner	Al Masarra Hospital	20/4/22	
Reviewed by	Noora Al Zadjali	HOD Infection Control	Al Masarra Hospital	29.5.2022	
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Approved by	Dr. Bader Al Habsi	Hospital Director	Al Masarra Hospital	24.5.2022	

Content Table:

Acronyms

AMRH	Al Masarra Hospital
BI	Biological Indicators
CSSD	Central Sterile Supply Department
HCAI	Healthcare-Associated Infection
HOD	Head of Department
IP&C	Infection Prevention & Control
OSHA	Occupational Safety & Health Administration
SUD	Single Use Devices

Policy and Procedure of Cleaning, Disinfecting & Sterilization of Equipment

1. Introduction

The process of sterilization and decontamination are complex, require specific infrastructure and equipment and involved several steps that need to be correct, from devices collection, receipt by the unit, processing, storage and distributing them through the facility. The Central Sterile Supply Department (CSSD) is typically divided into four major areas to accomplish the functions of decontamination, assembly and sterile processing, sterile storage, and distribution.

2. Scope

This document is applicable to all healthcare workersin Al Masarra Hospital (AMRH).

3. Purpose

3.1 To provide a standard procedure on the appropriate use of Central Sterile Supply Department (CSSD) services for the reprocessing of reusable items, proper storage, and event-related shelf life of all sterile items and equipment.

3.2 To reduce effectively and comprehensively the Healthcare-Associated infection (HCAI).

4. Definitions

4.1 **Chemical indicators**: devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment.

4.2 **Containment device:** reusable rigid sterilization container, instrument case, cassette, or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization.

4.3 **Contaminated**: state of having been actually or potentially in contact with microorganisms.

4.4 **Decontamination:** the use of physical or chemical means to remove, inactive, or destroy blood borne pathogens on a surface or items to the point where they are no longer capable of transmitting infections particles and the surface or item is rendered safe for handling, use, or disposal. *(Occupational Safety & Health Administration (OSHA))*

4.5 **Decontamination area**: area of health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

4.6 **Dust cover**: protective plastic bag used to protect sterile items from environmental contamination such as moisture, dust, and lint, also known as a sterility maintenance cover.

4.7 **Labeling**: any legend, work, or mark attached to, included in, belonging to, or accompanying any medical device or product.

4.8 **Shelf life**: the sterilized, medical device and the period of time during which the item is considered safe for use.

4.9 **Sterile storage area**: area of healthcare facility designed to store clean and sterile items and protect them from contamination.

5. Policy

5.1 The CSSD must be responsible to supply sterile equipment according to the policy.

5.2 The CSSD technicians and healthcare workers who are handling CSSD items in Al Masarra Hospital must follow this policy.

6. Procedure

6.1 General Guideline

6.1.1 The delivery of sterile healthcare products for use in patient care depends not only on the efficacy of the sterilization itself but also on the following factors:

6.1.1.1 Efficient facility design in terms of functional, controlled, one-way traffic flow with identified work zone.

6.1.1.2 Efficient trained personnel who is competent to perform the function of CSSD with the knowledge of the department's reporting structure.

6.1.1.3 Effective quality control including process improvement system that encompasses all aspects of device reprocessing from point of use through sterilization to reuse.

6.1.1.4 Effective and monitored infection prevention and control practices.

6.1.2 Observe standard precautions when handling contaminated items and instruments such as Personal Protective Equipment (PPE), hand hygiene, waste management.

6.1.3 Cleaning and decontamination is the first important step of the sterilization process.

6.1.4 CSSD reprocess in accordance with the manufacturer's published operator's manual for equipment in use.

6.1.5 Discard disposable Single Use Devices (SUDs) at the point of use by the end user, since it will not be reprocessed by CSSD.

6.1.6 End users shall spray reusable devices after use with a hospital-approved transport medium immediately at the point of use.

6.1.6.1 Place used devices in a covered receptacle in the soiled utility room.

6.1.7.2 Segregate these devices per set with heavier items on the bottom, and must be transported immediately to CSSD in a covered receptacle.

6.1.7 End user is responsible to transfer to the CSSD any new device delivered to the ward/department.

6.1.8 Sterility is "event-related" based on handling, storage practices, and packaging degradation.

6.2 Packaging

6.2.1 An effective packing material for steam sterilization processing should:

6.2.1.1 Allow for adequate air removal

6.2.1.2 Provide an adequate barrier to microorganisms or their vehicles

6.2.1.3 Resist tearing and can withstand normal handling

6.2.1.4 Allow for a method of sealing that results in a complete seal that is tamper-evident and provides seal integrity

6.2.1.5 Allow for ease of aseptic presentation

6.2.1.6 Be free of toxic ingredients

6.2.1.7 Capable to withstand high temperature

6.2.2 During storage, transport, and prior to use in CSSD, packing materials should be held at room temperature (20° to 23°) and at relative humidity ranging from 30% to 60%.

6.2.3 Examine regularly all packing materials, woven or non-woven, for defects and extraneous matter prior to use

6.2.4 Keep wrappers snug to prevent low spot that could condensate on the exterior of the package.

6.2.5 Package labels (e.g. process indicators, labels for product identification, lot number, and expiration labels) should be capable of remaining securely affixed to packages throughout the course of their handling from sterilization to the point of use.

6.2.5.1 If the marking pen is used to label paper/plastic pouches, the labeling information should be written only on the plastic side of the pouch.

6.2.6 Package closures must allow the steam sterilization process to occur, avoid constriction of the package, and maintain package integrity.

6.3 **Handling and Inspection**

6.3.1 Minimize handling of sterile items.

6.3.2 Inspect all sterile packages for tears, punctures, and abrasions prior to storage and use. If your inspection reveals any of the above, do not use this package.

6.3.3 Notify and return to CSSD any sterile packs found to be wet. CSSD will recall all other packs sterilized in that particular load.

6.3.4 Return to the decontamination area for reprocessing if an item is dropped on the floor or place on a patient's bed but were not use

6.3.5 Return all recalled items to the decontamination area for decontamination prior to re-sterilization.

6.4 **Sterile Storage Area**

6.4.1 Store sterile supplies in a way that sterility will not be compromised. Maintain a clean and dry storage area with low traffic volume.

6.4.2 Covered or closed shelving is preferred in a clean area with limited access, positive air pressure, and effective ventilation.

6.4.3 Storage shelves or cabinets must be 18 inches from the ceiling, 8 to 10 inches from the floor, and 2 inches from the outside wall. They must be away from sprinklers and air vents, and temperature and humidity must be controlled.

6.4.4 Do not store sterile packs under sinks, exposed pipes, floors, or window sills.

6.4.5 Minimize the handling of sterile items to reduce and prevent the risk of packages from being crushed, bent, compressed or punctured. Utilize the First In, First Out Principle.

6.4.6 Inspect all sterile items for package integrity and expiration dates prior to storage.

6.4.7 Use sterility maintenance covers (dust cover) to protect sterilized items that are used less than once a month to maintain sterility.

6.5 **Shelf Life of Devices Sterilized by CSSD**

6.5.1 Event–related sterility is known as the sterility based on the proper handling, storage, and packaging degradation. The items consider sterile if the following point are observed:

6.5.1.1 No barrier tears, compression, abrasion, punctures, moister, dirt, bending, or damage in any way.

6.5.1.2 Each package must not reseal or opened.

6.5.1.3 The package must be properly opened without contaminating the contents.

6.5.2 Consider any package that is not intact (i.e. with compromised integrity) as contaminated and must not be used and should returned in their original packaging to CSSD office for reprocessing.

6.5.3 Inspect the integrity of sterile packs regularly, prior to storage and use.

6.6 **Distribution**

6.6.1. Handling and inspection

6.6.1.1 Handle sterile supplies in such a way as to avoid compromising or contaminating the package.

6.6.1.2 Care should be taken to avoid dragging, sliding, crushing, bending, compressing or puncturing the packaging or otherwise compromising the sterility of the contents.

6.6.1.3 Inspect packaging for integrity and labeling before an item is stored or issued.

6.6.2 Distribution Carts

6.6.2.1 Cover all clean or sterile items being transported in uncontrolled environments.

6.6.2.2 Arrange items that are placed inside plastic or paper bags or boxes for transport within the containers so as to prevent them from being crushed, damaged or contaminated.

6.6.2.3 Decontaminated and dry any transport carts after each use and before they are used for sterile supplies.

6.6.3 Quality Assurance Testing

6.6.3.1 Perform quality assurance testing of reprocessed items on an ongoing basis

6.6.3.2 Before starting any sterilization load CSSD technicians use Bowie-dick test to ensure the effectiveness of the machine.

7. Responsibility

7.1 **CSSD Technician Shall:**

7.1.1 Train to effectively perform the function of CSSD with the knowledge of the department's reporting structure.

7.1.2 Perform relevant and effective documentation and reporting practices.

7.1.3 Clean and decontaminate the equipment before the sterilization process.

7.1.4 Practice standard precautions when handling contaminated items and instruments.

7.1.5 Reprocess or handle all devices whether loaned or owned by the organization in the same manner.

7.1.6 Store sterile supplies in a way that sterility will not be compromised. Maintain a clean and dry storage area with low traffic volume.

7.1.7 Conduct an annual audit and contacts each unit to ensure compliance in sending reusable devices that have not been used within the parameters of their existing packaging degradation.

7.1.8 Inspect packaging for integrity and labeling before an item is stored or issued.

7.1.9 Cover all clean or sterile items being transported in uncontrolled environments.

7.1.10 Arrange items that are placed inside plastic or paper bags or boxes for transport within the containers so as to prevent them from being crushed, damaged or contaminated.

7.1.11 Decontaminate and dry any transport carts after each use and before they are used for sterile supplies.

7.1.22 Perform quality assurance testing before starting any sterilization load CSSD technicians use Bowie-dick test to ensure the effectiveness of the machine.

7.2 **Staff Nurse Shall:**

7.2.1 Place used devices in a covered receptacle in the soiled utility room.

7.2.2 Segregate these devices per set with heavier items on the bottom, and call CSSD technician immediately.

7.2.3 Notify and return to CSSD any sterile packs found to be wet.

7.3 **Infection Prevention & Control Department Shall:**

7.3.1 Monitor the infection control practices and standard precautions in the CSSD department.

7.3.3 Follow and collect the monthly report of the workload in the CSSD.

7.3.4 Conduct audit for CSSD department.

8. Document History and Version Control

Document History and Version Control			
Version	**Description of Amendment**	**Author**	**Review Date**
1	Initial Release	Wafa Al Balushi	September 2019
2	Review and Update	Wafa Al Balushi	April 2025
Written by	**Reviewed by**	**Approved by**	
Wafa Al Balushi	Noora Al Zadjali	Dr. Bader Al Habsi	

9. Related Documents

9.1 Appendix 1. Audit Tool.

10. References

Title of book/journal/articles/ Website	Author	Year of Publication	Page
GCC Infection Control Manual	GCC Centre for infection Control	2018	326-330
Decontamination and Reprocessing of Medical Devices for Health-care Facilities	World Health Organization	2016	10-11

Appendices

Appendix 1. Audit Tool

Department: _____ **Date: _____**

S.N.	Audit Process	Standard/Criteria	Yes	Partial	No	N/A	Comment
		STRUCTURE					
1.	Observation	Is there an availability of traffic flow with identified work zone?					
2.	Observation Interview	Are the hand hygiene sinks and antiseptic soaps and its dispensers available?					
3.	Observation Interview	Is the hand rub available?					
4.	Observation Interview	Are the personnel who are performing the function of CSSD efficient, trained and with the knowledge of departments reporting structure?					
		PACKAGING					
5.	Observation Interview	Is the CSSD technician following the standard precautions when handling contaminated items and instruments?					
6.	Observation	Is an effective packaging material for steam sterilization					

	Interview	processing available and followed? a. Allow for adequate air removal b. Provide an adequate barrier to microorganisms or their vehicles c. Resist tearing and can withstand normal handling d. Allow for a method of sealing that result in a complete seal that is tamper-evident and provides seal integrity e. Allow for ease of aseptic presentation f. Be free of toxic ingredients g. Be non-linting h. Capable to withstand high temperature i.					
7.	Observation Interview	Is the temperature of the room during storage, transport, and prior to use in CSSD, packaging materials between (20^{o}C to 23^{o}C) and at relative humidity ranging from 30% to 60%?					
8.	Observation Interview	Is the wrapper snug and wrapped too tightly for preventing low spots that collected on the exterior?					
9.	Observation Interview	Are the package labels clear and remains securely affixed to packages throughout the course of sterilization?					
10.	Observation Interview	Is the package closure allowing the steam to sterilization process to occur and avoid construction of the package and maintain package integrity?					

11.	Observation Interview	Is the wrapper snug and wrapped too tightly for preventing low spots that are collected on the exterior?					
		HANDLING AND INSPECTION (DISTRIBUTION)					
12.	Observation Interview	Is the handling of all sterile items minimized by staff?					
13.	Observation Interview	Are all the packages free from punctures and abrasions prior to storage?					
14.	Observation Interview	Are all the wet sterile packages returned back to the CSSD for reprocessing?					
15.	Observation Interview	Are any items dropped on floor or placed on the patient bed returned back for reprocessing?					
16.	Observation Interview Document Review	Are all recalled items prior to sterilization returned for decontamination?					
		STERILE STORE AREA					
17.	Observation Interview Document	Is the sterile store maintained clean and dry and with low traffic volume?					

	Review						
18.	Observation Interview	Are the shelves: a. Covered shelving and in positive air pressure and in effective ventilation? b. 18 inches under the ceiling? c. 8 to 10inches from the floor? d. 2 inches from the outside wall? e. Away from sprinklers and vents?					
19.	Observation Interview	Is the temperature and humidity under control in the store?					
20.	Observation Interview	Is the principle of first in, first out utilized?					
21.	Observation Interview	Is the sterile packs store away from sinks, exposed pipes, floor or window sills?					
22.	Observation Interview	Is the sterilization date and sterilization load number fixed to each package prior to issue supplies?					

23.	Observation Interview	Are all sterile packages or items inspected for date of expiry and integrity prior to storage?					
		SHELF LIFE OF DEVICES STERILE IN HOUSE AND COMMERCIALLY					
24.	Observation Interview Document review	Is the CSSD department conducting an annual-based audit to the hospital wards and departments who are using the sterile packages and items?					
		QUALITY ASSURANCE TESTING					
25.	Observation Interview	Is the CSSD technician performing quality assurance testing of reprocessed items on an ongoing basis?					
26.	Observation Interview	Is the Bowie-dick indicator running in every load?					
		OUTCOME					
27.	Observation Interview	The sterile items and packages have the following characteristics: a. No barrier tears, compressions abrasions puncture moisture dirt bending or damage in any way. b. The pack have not been opened or released.					

		c. The pack properly opened without contamination of the contents.					
28.	Observation Interview Document review	Is a documented evidence for annual auditing to wards and departments using sterile packages and items kept and maintained?					

Appendix 2. Document Request Form

Document Request Form

Section A: Completed by Document Requester

1. Requester Details

Name	Wafa Al Balushi	Date of Request	April 2022
Institute	Al Masarra Hospital	Mobile	95821833
Department	Infection Control and Sterilization Service	Email	wafa22oman@gmail.com

The Purpose of Request

☐ Develop New Document	☑ Modification of Document	☐ Cancelling of Document

1. Document Information

Document Title	Policy and Procedure of Cleaning, Disinfecting & Sterilization of Equipment
Document Code	AMRH/IC/P&P/007/Vers.02

Section B: Completed by Document Controller

☑ Approved	☐ Cancelled	☐ Forward To:……..

Comment and Recommendation:

Name	Kunooz Al Balushi	Date	April 2021
Signature	Kunooz	Stamp	

Appendix 3. Document Validation Checklist

Document Validation Checklist

Document Title: Policy and Procedure of Cleaning, Disinfecting & Sterilization of Equipment		**Document Code:** AMRH/IC/P&P/007/Vers.02			
No	Criteria	**Meets the Criteria**			**Comments**
		Yes	**No**	**N/A**	
1.	**Approved format used**				
1.1	Clear title – Clear Applicability	✓			
1.2	Index number stated	✓			
1.3	Header/ Footer complete	✓			
1.4	Accurate page numbering	✓			
1.5	Involved departments contributed	✓			
1.6	Involved personnel signature /approval	✓			
1.7	Clear Stamp	✓			
2.	**Document Content**				
2.1	Clear purpose and scope	✓			
2.2	Clear definitions	✓			
2.3	Clear policy statements (if any)	✓			
3.	**Well defined procedures and steps**				
3.1	Procedures in orderly manner	✓			
3.2	Procedure define personnel to carry out step	✓			
3.3	Procedures define the use of relevant forms			✓	
3.4	Procedures to define flowchart				
3.5	Responsibilities are clearly defined	✓			
3.6	Necessary forms and equipment are listed	✓			
3.7	Forms are numbered	✓			
3.8	References are clearly stated	✓			
4.	**General Criteria**				
4.1	Policy is adherent to MOH rules and regulations	✓			
4.2	Policy within hospital/department scope	✓			
4.3	Relevant policies are reviewed	✓			
4.4	Items numbering is well outlined	✓			
4.5	Used of approved font type and size	✓			
4.6	Language is clear, understood and well structured	✓			

Recommendations ...✓... For implementation ..... More revision..... To be cancelled.....

Reviewed by: Kunooz Al Balushi **Reviewed by: Ruvilee Ramel-Bueno**

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