HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Infection Prevention and Control Department		
Document:	Multidisciplinary Policy and Procedure (MPP)		
Title:	Guidelines for Central Sterile Supply Department (CSSD)		
Applies To:	All MCH Department		
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1. PURPOSE:

1.1 To protect the Central Supplies and Sterilization Department (CSSD) staff from any occupational and environmental risks exposure.

1.2 To provide guidelines 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.

2. DEFINITONS:

2.1 Biological indicators (BIs) - test systems containing viable microorganisms providing a defined resistance to a specified sterilization process.

2.2 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.

2.3 Decontamination – according to OSHA, "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal."

2.4 Instructions for Use (IFU) – manufacturer's written instruction for use.

2.5 Labeling – any legend, work, or mark attached to, included in, belonging to, or accompanying any medical device or product.

2.6 Reusable medical device – device intended for repeated use on different patients, with appropriate decontamination and other processing between uses.

2.7 Shelf life – term is used with respect to a sterilized, medical device and the period of time during which the item is considered safe for use

2.8 Sterile storage area – area of a healthcare facility designed to store clean and sterile items and protect them from contamination.

2.9 Sterilization-Level of reprocessing required when processing critical medical devices. It results in the destruction of all forms of microbial life including bacteria, viruses, spores, and fungi.

3. POLICY:

3.1 Training on work practices that comply with the Hazard Communication Standards should be provided to all employees and yearly competencies on hand hygiene and proper use of PPEs.

3.2 CSSD staff must be well trained on all infection prevention & control protocols including aseptic technique during biohazard transportation, reprocessing techniques, inspection, packaging, sterilization & storage.

3.3 All instrument cleaning, disinfecting, and sterilizing should occur in a designated central processing area in order to control quality and ensure safety.

3.4 Cleaning of instruments should be carried out by trained staff in the central sterilization and supply department.

3.5 CSSD trained staff work activities include but not limited to sorting, disassembling, cleaning, inspecting, disinfecting, packaging, sterilizing, storing and distributing reprocessed items.

3.6 The appropriate use of personal protective barriers during high-risk cleaning and disinfecting processes reduces the risk for blood and body fluid exposure for central services personnel.

3.7 Contaminated instrument securely contained in its rigid containers and transported inside (a closed cart) or

(locked transportation box delivered on trolley) with biohazard tag sign. Transportations carts/ transportations boxes used for contaminated instruments must be dedicated for its use unless disinfected manually or mechanically in the CSSD to transport sterile items.

3.8 Bowie Dick test for steam sterilizers must be performed on daily basis, after maintenance. records are kept for 1 Year.

3.9 Standard Precautions: Implementation of infection prevention protocols for patients undergoing invasive surgical procedures is extremely important in preventing surgical site infections (SSIs).

4. PROCEDURE:

4.1 Hand Hygiene (HH):

4.1.1 Hand washing stations including hand washing sinks with hands-free controls, Soap, hand sanitizer dispensers, and paper towels should be located in or near all work areas including changing rooms and in the entrance of the Decontamination Area and IAP Area etc.

4.1.2 Staff must perform Hand hygiene before entering of the CSSD areas & starting the work shift.In case of gloves tear with accumulation of fluid inside the gloves or visible contamination on hands during the decontamination process, CSSD staff must immediately remove gloves and perform Hand washing with antiseptic soap & water.

4.1.3 CSSD technician and HCWs should keep fingernails short and clean at all time.

4.1.4 For female staff, nail polish or acrylic nails are not allowed during the duty hours.

4.2 PERSONAL PROTECTIVE EQUIPMENT (PPE):

4.2.1 In CSSD department, wearing the PPE should be strictly followed based on infection and prevention control standards which are as following;

4.2.1.1 Sufficient and appropriate PPE are available in adequate amount, types, and sizes with proper qualities & easily accessible to the staff. (Heavy duty gloves, face shields /eye goggles, impermeable gowns/aprons etc).

4.2.1.2 Full PPE should be worn in the Decontamination area.

4.2.1.3 CSSD technician must be trained on the correct Donning and Doffing practices including sequence, technique, safety & disposal.

4.2.1.4 In the Inspection, Assembly, Packaging Area and Sterile storage, Head cover and clean scrub suite are required

4.3 DRESS CODE:

4.3.1 Clean areas dress code is Medical uniform (scrub), hair covering, dedicated shoes, and for dirty area full PPEs.

4.3.2 Attire should be changed daily or as needed if visibly contaminated with blood or other potentially infectious material.

4.3.3 Scrubs should be laundered appropriately after each use in a healthcare-accredited laundry facility.

4.3.4 CSSD Personnel should not wear jewelry (Rings, bracelets, watches etc.) during duty hours.

4.3.5 CSSD staff should must change their surgical attire upon leaving the department.

4.3.6 Staff changing rooms are available, clean, arranged for CSSD staff to change before going inside the working areas

4.4 ENVIRONMENTAL HYGIENE:

4.4.1 Environmental services department should consult IPC department & CSSD to establish policies and procedures for cleaning practices and cleaning frequency.

4.4.2 Environmental cleaning and disinfectant agents must be approved by MOH to be used in the healthcare facilities.

4.4.3 Environmental cleaning is not allowed during sterilization process due to possibility of spread dust to Reusable Medical Devices (**RMD**).

4.4.4 Environmental Cleaning Methods: Floor are swept & wet mopped at least after each decontamination procedure in the decontamination area.

4.4.4.1 Floor are swept and wet mopped at least after each shift in the cleaning area.

4.4.4.2 All areas must be free of dust, and insects etc.

4.4.4.3 The Process of cleaning should be from clean areas to dirty areas, from high areas to low areas (i.e., top of walls to floor) and from least contaminated to most contaminated

4.4.4.4 In case of hazardous chemicals spill etc. disinfection must be performed immediately using the spill kit according to the steps of spill management.

4.4.4.5 High touch horizontal surfaces must be cleaned and disinfected at the beginning and end of each shift & more frequently during the shifts e.g. tabletops, counter tops, light switches, door knobs, rack handles, display screen buttons, etc.

4.4.4.6 Decontamination sink should be cleaned after each shift and more frequently as needed.

4.4.4.7 **Inspection, Assembly & Packaging Area (IAP)**

4.4.4.7.1 Work tables preferably cleaned before starting the sorting process in the decontamination area & Inspection process in the IAP area.

4.4.4.7.2 High level disinfected items must be passed through the hatch window to the IAP area. Backflow only allowed in case of soil after cleaning or moist after sterilizing through the secured hatch window in tray or basket for reprocessing.

4.4.4.7.3 In IAP area, drying procedures are performed by using the appropriate drying tools such as dry cabinet or lint free wipes, prohibited to use lint towels.

4.4.4.7.4 IAP area, Loading and unloading of the surgical instruments into/out of the sterilizers rack is performed accurately.

4.4.4.8 Shelves, cabinets, racks, wall, and ceiling are cleaned based on regular cleaning schedule using a checklist Offices. Changing /locker room etc are cleaned at least daily.

4.4.4.9 Light fixtures, and air vent should be cleaned at least every six months or as necessary (by Environmental Service or Maintenance department)

4.4.4.10 Hand washing station is mandatory in the decontamination area. hand rub dispensers are available in all CSSD areas.

4.4.5 Environmental Cleaning Equipment:

4.4.5.1 Cleaning equipment's are separate and dedicated for each area. (e.g. mops and bucket)

4.4.5.2 Cleaning equipment must be kept clean and dry & are appropriately stored after use.

4.4.5.3 Mop heads must be appropriately laundered after each use or disposed of if single use.

4.4.6 Environmental Cleaning Schedule:

4.4.6.1 All cleaning activities must be performed according to the approved cleaning schedule with specified frequency for each area.

4.4.6.2 Cleaning activities must be documented using a checklist that include cleaning frequency, responsible worker, used agents, methods & environmental surfaces intended to be cleaned.

4.4.6.3 Quality of the cleaning activities should be regularly monitored by CSSD supervisor, Infection control Team & environmental services supervisor.

4.4.6.4 Housekeeping staff use appropriate PPE during their routine cleaning activities. Cleaning equipment are separate and dedicated for each area.(mops and bucket etc). Housekeeping equipment is kept clean and dry after use.

4.5 OCCUPATIONAL HEALTH AND STAFF SAFETY:

4.5.1 Fire Safety:

4.5.1.1 Attention must be paid on the fire safety guide inside the CSSD for the electrical and chemical hazards that may occur during sterilization processes.

4.5.1.2 CSSD technicians should be trained to deal with fire incident plan by knowing the fire alarm, emergency code, and the emergency exits.

4.5.1.3 CSSD technicians should be trained to use the fire disregarder that belong to the CSSD.

4.5.2 CSSD Staff Health:

4.5.2.1 According to the Occupational Safety and Health Administration (OSHA) regulations, all employees who are dealing with potentially contaminated items should receive hepatitis B immunization.

4.5.2.2 Employee Health Care Clinic should offer certain vaccines for HCWs including CSSD technician for the purpose of diseases prevention as per institutional policy (mumps-measles-rubella, varicella, influenza, tetanus-diphtheria, etc.).

4.5.3 Sharp Injury:

4.5.3.1 All sharp injuries from sharp instruments including sharp skin hook, broken metal instruments ETC must be reported.

4.5.3.2 Sharp needles and blades should not be received in CSSD; If incidentally have been sent to CSSD should be reported and disposed in sharps container.

4.5.3.3 Take care when handling glass and other fragile objects.

4.5.3.4 In case of needle stick injuries incidents following procedure must be followed:

4.5.3.4.1 Encourage the wound to gently bleed, ideally holding it under running water.

4.5.3.4.2 Wash the wound using running water and plenty of soap.

4.5.3.4.3 Don't scrub the wound whilst you are washing it, do not squeeze the puncture site.

4.5.3.4.4 Dry the wound and cover it with a waterproof plaster or dressing.

4.5.3.4.5 Seek urgent medical advice from your IPC team.

4.5.3.4.6 Report the injury to your employer.

4.6 Chemical Hazards: Chemicals must be labeled, stored, and handled appropriately under the supervision of the safety department. Use Safety Data Sheets (SDS), and keep it readily available.

4.7 Emergency Eyewash Station:

4.7.1 An eyewash station, separate from other cleaning facilities/sinks, is installed to prevent a potential hazard to the eye due to contact with a biological or chemical agent. Emergency safety station / eyewash bottle is available, functioned, and tested at least weekly in decontamination area, available with unobstructed access for immediate use within a travel time of 10 seconds, or accessible within 30 meters of areas of potential chemical exposure .

4.7.1.1 It should permit hand-free operation and have a stay-open feature to flush both eyes.

4.7.1.2 It should be tepid, not too hot, or too cold to prevent burn to the eyes

4.7.1.3 It must be regularly tested and documented.

4.7.1.4 Technicians must follow the SDS instructions for a chemical reaction. If blood or blood products make contact with eyes, rinse the eyes gently but thoroughly (remove contact lenses), for at least 30 seconds, with water or normal saline.

4.7.1.5 If blood or body fluids are sprayed into the mouth, spit out and then rinse the mouth with water several times

4.8 Waste Management:

4.8.1 Hazard yellow containers, sharp containers, and regular black container should be available in sufficient numbers, and to be located in a place that is easy to reach and access. All materials that have been used in the decontamination area are disposed in the yellow bag All used PPE, Biological Indicator (BI) vail, empty Plasma Cassettes should be disposed inside hazard waste container. Waste should be segregated accurately that no medical waste inside the regular waste container or regular waste inside the yellow medical waste container. Medical waste bags and sharp boxes should not reach over filled (i.e., 3/4 filled).

4.9 DESIGN LAYOUT: CSSD should be divided into 3 areas with complete physical separation between these areas (Receiving and Decontamination area), (Inspection, Assembly, Packaging (IAP), and Sterilization area), (Sterile Storage, and Dispatching areas).

4.9.1 Sterilization services MUST be centralized in one UNIT/ Department and none of the sterilization activities are carried out by individual departments outside CSSD. In general, there must be a centralized area for reprocessing Reusable Medical Devices (RMD)

4.9.2 Adequate space in Sterile processing unit is critical to provide for a good workflow and efficient and effective processes that promote staff safety, standardize procedures, minimize environmental contamination, and maintain the sterility of processed items.

4.9.3 The size of the CSSD should be appropriate for the volume of work being performed, the processes being conducted, the types of services provided, and the amount of equipment required to perform the required tasks.

4.9.4 CSSD must have physical barriers with clear demarcation for clean and dirty areas. There must be complete physical separation between the clean areas (i.e packaging, sterilization & storage areas) and decontamination area with demarcation signs posted for each zone. . (2 or 3 zones)

4.9.6 **Decontamination area:**

4.9.6.1 This area should have a three-section sink for cleaning (one section for cleaning, one for

initial rinsing, and one for final rinsing).

4.9.6.2 The sinks should be approximately 36 inches from the floor and 8 to 10 inches deep. The sink should be large enough to place a tray or container basket of instruments flat in the sink.

4.9.6.3 The area should have a source of critical water for the final rinse. Automated washer disinfector function properly, the strainers and chambers are free of soil.

4.9.6.4 Loading and unloading procedures of the washer disinfector are performed properly in Decontamination Area.

4.9.6.5 Automated washer disinfector function properly, the strainers and chambers are free of soil. Loading and unloading procedures of the washer disinfector are performed properly in Decontamination Area.

4.9.7 Walls should be constructed of non-particulate, non-fiber shedding materials to withstand cleaning & disinfection etc.

4.9.8 The ceiling in the restricted area should be constructed of enclosed fixtures hold all pipes and duct work.

4.9.9 The door should be made of a durable, smooth, and cleanable material. Doors should open easily following the one-way directional workflow

4.9.10 Floors should be level and constructed of non-particulate, non-fiber shedding materials to withstand daily cleaning & disinfection activities. The work surfaces should be covered with a nonporous material that can withstand frequent cleaning with germicides. Lighting fixtures should put into a selected position to facilitate the work.

4.9.11 Cleaning efficiency test files include: ultrasonic tests, protein efficiency tests for washer disinfectors, manual cleaning detergent efficiency tests are kept for one year.

4.10 Traffic Control and Workflow:

4.10.1 CSSD should be away from the main traffic pattern and restricted to the authorized personnel Identified ONLY based on the in the facility's policies and procedures of the department.

4.10.2 Visitors must be accompanied by authorized personnel should be allowed in the restricted areas(e.g., decontamination, preparation, packaging, sterile processing, and sterile storage).

4.10.3 Anyone in these areas should wear surgical attire (scrubs) and dedicated shoes, and their head and facial hair (except eyebrows and eyelashes) should be covered.

4.10.4 Visitors dress code in the clean area are (yellow-gown, head-cover, dedicated shoes or shoes cover) and for dirty area full PPE.

4.10.5 Areas, including locker rooms, break rooms, meeting rooms, offices, and sterilizer service access rooms may be limited based on the facility's policies and procedures.

4.10.6 CSSD areas must be physically separated at least two zones to prevent cross-contamination.

4.10.7 The decontamination, packaging, sterilization, and sterile storage area/rooms should be physically separate to eliminate environmental contamination.

4.10.8 The workflow processes allow items to move progressively from the dirty phase to the high disinfection phase. Then from the safe handling phase to the final phase.

4.10.9 CSSD Technicians should be organized so that activities and objects flow in a unidirectional way i,e from dirty to clean area & sterilization process is never circumvented. See appendices 7.1

4.11 Environmental Control Parameters:

4.11.1

AREAS IN CSSD	TEMPERATURE	PRESSURE	HUMIDITY
Decontamination Area	16°C - 18°C	Negative 10 air changes per hourne	30%-60%
Inspection, Assembly & Packaging Area (IAP)	20°C – 23 °C	Positive 10 air changes per hour	30%-60%
Sterile Storage Areas	20°C – 23 °C	Positive 4 air changes per hour	30%-60%

4.11.2 CSSD environmental monitoring file are available. Temperature, humidity, pressure value must be recorded daily and air. Documentation is kept for 1 year.

4.12 TRANSPORTATION OF CONTAMINATED RMD TO CSSD

4.12.1 All contaminated Items must be transported to the CSSD for reprocessing in a covered container or closed cart with ideal characteristic such as:

4.12.2 Transportation carts should be equipped with a secured lid to prevent spread of infection & instruments from falling over. Carts should be Leak-proof to prevent accidental spillage of

contaminated fluids.

4.12.3 Transportation carts should be easily cleaned, disinfected, and dried to prevent recontamination in the second rotation.

4.12.4 Contaminated instruments should be transported on a rotational basis by direct routes far from public traffic or through dedicated elevators.

4.12.5 Transportation staff must consider the risk associated with hazardous items & wear the proper PPE.

4.12.6 PPEs and biohazards material spill kits should be available in the vehicle, and if only one vehicle is available, it must be decontaminated before using again to transport clean or sterile items.

4.12.7 Keep the cart closed at all times except during loading and unloading.

4.12.8 During transportation, never leave the trolley or transportation cart unattended.

4.12.9 The Transportation Policy and Procedures for transportation of Reusable Medical Devices (RMD) out-Side the Hospital:

4.12.9.1 Transportation of reusable medical device (RMD) from CSSD facility to another CSSD facility out of hospital, need to be monitored and controlled under strict conditions to prevent cross contamination and to assure that items are securely contained without spillage or damage. CSSD worker must consistently follow safe transportation procedures.

4.12.9.2 A Clear MEMO should be announced to all hospitals facility to clarify the situation and notify the frequency of collection and transportation.

4.13 DECONTAMINATION AREA

4.13.1 RECEIVING CONTAMINATED INSTRUMENTS:

Once the CSSD technician receives the instrument following must be ensured:

4.13.1.1 All items/instruments must be clearly identified with a label stating name the of sending department/s.

4.13.1.2 Quantity needs to be documented manually or by the tracking system

4.13.1.3 Manual or electronic system is available for all received items. Information MUST include: Sender / Receiver ID, department's name, RMD sets and packages names, Date, Time & quantities etc

4.13.1.4 Sort disassemble, and segregate the RMD.

4.13.1.5 Report any damage, missing, or defected RMD. Accidental sharp objects must be reported & safely disposed of in sharp containers.

4.13.1.6 Point of use treatment procedure is applied in all hospital departments with the MOH approved spray solution, Received dried soiled instruments are reported by CSSD HCW to the intended department.

4.13.2 **MANUAL CLEANING:**

4.13.2.1 Cleaning Technique: Cleaning must be performed immediately once the instruments are received to reduce the formation of biofilm that adheres to surfaces of the instruments and pre-soaking if applicable.

4.13.2.2 Manual cleaning is necessary when:

4.13.2.2.1 Mechanical cleaning is not available.

4.13.2.2.2 Manual cleaning is mandatory, it is performed before loading in the washer disinfectors, Ultrasonic cleaners or manual disinfection. Brushes in a different sizes\shapes for cleaning soiled instrument, are available.

4.13.2.2.3 Delicate instruments that may be manually cleaned include ophthalmology equipment, microsurgical instruments, lensed instruments, flexible and semi-rigid endoscopes etc

4.13.2.2.4 In some cases, the instrument manufacturer's written IFU may require manually cleaning before instruments are placed in mechanical cleaning equipment.

4.13.2.2.5 The manufacturer's instructions for use (IFU) of complex instruments are available in hard/soft copies for proper disassembling, cleaning, assembling, and sterility option in Decontamination Area.

4.13.2.2.6 Items with narrow lumens cannot fit in the automatic washer.

4.13.2.3 Manual cleaning sinks (minimum 2 deep sinks) are available, dilutions measurement tool is available, cleaning detergent and cleaning efficiency test must be MOH approved product. Decontamination sink are cleaned frequently as needed, Not allowed to observe any blood, dirty objects, scale

4.13.3 Water Quality: Water used in all phases must be purified for high-quality instruments outcome.

4.13.4 CART WASHERS: They are designed to clean carts used for transport of all devices and instruments.

4.14 All reusable devices requiring in-house reprocessing will be reprocessed by CSSD in accordance with the Spaulding Classification system that segregates medical devices and places them in categories based on the risk of infection related to their use. The categories are as follows:

4.14.1 Critical Items

4.14.1.1 This category includes objects and items entering the vascular system and sterile tissue.

4.14.1.2 Examples of critical items are surgical and dental instruments, cardiac and blood catheters, implants and needles, blood compartments of hemodialysis equipment, laparoscopes, arthroscopes, and other scopes that are introduced into sterile tissues.

4.14.1.3 These items present a high risk of infection and require sterilization after each patient use. All reusable items in this category must be processed by the CSSD.

4.14.2 Semi-critical Items

4.14.2.1 This category includes objects and items that come in contact with intact mucous membranes and non-intact skin but do not penetrate body tissues or the vascular system.

4.14.2.2 Examples of semi-critical items are non-invasive medical equipment, flexible and rigid fiber optic endoscopes, respiratory therapy and anesthesia equipment, endotracheal tubes, and cystoscopes.

4.14.2.3 These items require high level disinfection after each patient use.

4.14.2.4 Any reusable items in this category must be processed by CSSD.

4.14.3 Non-critical Items

4.14.3.1 This category includes items and objects that come in contact with intact skin only.

4.14.3.2 Examples of non-critical items are bedpans, blood pressure cuffs, tourniquet cuffs, and crutches

4.14.3.3 These items could potentially contribute to secondary transmission of microorganisms to healthcare workers' hands; therefore, they require cleaning with hospital-approved disinfectant at the point of use.

4.14.3.4 These items do not require CSSD service.

4.15 General Guidelines

4.15.1 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:

4.15.1.1 Efficient facility design in terms of functional, controlled, one way traffic flow with defined work zones. Specific utility requirements per work zone must be in place and function as intended consistently.

4.15.1.2 Efficient trained personnel who are competent to perform the function of CSSD with the knowledge of the Department's reporting structure.

4.15.1.3 Effective and monitored infection prevention and control practices.

4.15.1.4 Effective quality control including process improvement systems that encompass all aspects of device reprocessing from point of use through sterilization to reuse.

4.15.2 Relevant and effective documentation and reporting practices that enable traceability of each facility-sterilized medical device to the patient on whom it was used.

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

4.15.4 Observe standard precautions when handling contaminated items and instruments.

4.15.5 CSSD reprocess in accordance with the manufacturer's published IFU in conjunction with the IFU for the chemicals in use and the operator's manual for equipment in use.

4.15.6 Discard disposable single use devices (SUDs) at the point of use by the end user, since it will not be reprocessed by CSSD

4.15.6.1 Consult Infection Prevention & Control (IP&C) for any unused SUDs which have expired.

4.15.6.2 Segregate these devices per set with the heavier items on the bottom, and must be transported immediately to CSSD in a covered receptacle. Never leave these items unattended.

4.15.7 End user is responsible to transfer to the main CSSD any new devices delivered to the organization with the original packaging, product insert, the most recent IFU, and the "transfer memo" form.

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

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

4.15.10 Provide hand hygiene facilities in convenient locations.

4.16 Packaging

4.16.1 An effective packaging material for steam sterilization processing should:

4.16.1.1 Allow for adequate air removal;

4.16.1.2 Provide an adequate barrier to microorganisms or their vehicles;

4.16.1.3 Resist tearing and can withstand normal handling;

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

4.16.1.5 Allow for ease of aseptic presentation;

4.16.1.6 Be free of toxic ingredients and non-fast dyes;

4.16.1.7 Be non-linting; and

4.16.1.8 Capable to withstand high temperature

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

4.16.2 Examine regularly all packaging materials, woven or non-woven, for defects and extraneous matter prior to use.

4.16.3 Keep wrappers snug to prevent low spots that could collect condensate on the exterior of the package; however, care should be taken not to wrap too tightly, because strike-through could occur.

4.16.4 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.

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

4.16.4.2 All pouches, wrapped packages, sets are labeled before sterilization including: sterilization date, sterilizer number, cycle load number, department / unit name, Item description, technician initials.

4.16.4.3 If a marking pen is used to label any device to be sterilized in the hospital, the ink should be non-toxic, and the labeling information should be written on the indicator tape or affixed labels.

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

4.17 Handling and Inspection

4.17.1 Minimize handling of all sterile items.

4.17.2 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.

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

4.17.4 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.

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

4.18 Sterile Storage Area

4.18.1 Store sterile supplies in a way that sterility will not be compromised. Maintain a clean and dry storage area with low traffic volume. Sterile storage shelves are free from dust & away from the sprinklers and air vents. The lighter items on the top shelves & heavier items on bottom shelves (Not allowed to use the tape indicator on the rigid container)

4.18.2 Sterilization loading logbook for each sterilizer including information of sterilization date, sterilizer number, Cycle load number, Department name, Item Description, items quantity, Technician initials are documented and kept for one year.

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

4.18.4 Storage shelves or cabinets are clearly labelled with approved label material, placed 40 cm from the ceiling, 20 cm from the floor and at least 5 cm away from wall. They must be away from sprinklers and air vents and temperature and humidity must be controlled.

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

4.18.6 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.

4.18.7 Affix sterilization date and sterilization load number to each package prior to issuing supplies sterilized in-house.

4.18.8 Inspect all sterile items for package integrity and/or expiration dates prior to storage.

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

4.18.10 Cover sterile packs with dust covers at the CSSD prior to distribution.

4.18.11 Sterilizers physical parameters printout records hard/soft copy must be kept for one year. These parameters are: leak test cycle, temperature, pressure, sterilization duration, etc.

4.18.12 Consult with IP&C with regards to the use of items beyond the expiration use by date.

4.19 **Shelf Life of Devices Sterilized In-house by CSSD and/or Commercially**

4.19.1 The shelf life for all sterile items is 'event-related'

4.19.1.1 Event-related sterility refers to the sterility based on the proper handling, storage, and packaging degradation. The items or supplies are considered sterile only if the following are met:

4.19.1.1.1 No barrier tears, compressions, abrasions, punctures, moisture, dirt, bending, or damage in any way.

4.19.1.1.2 Each package must have not been opened and/or resealed

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

4.19.1.1 If the packaged item does not have an expiration date and does not contain fluids, antimicrobial agents, special coating or other materials, medication, or movable tips/parts that are subject to deterioration or degradation over time, which reducing the effectiveness or quality of the product, the event-related expiration date applies.

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

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

4.19.1.5 CSSD must conduct an annual hospital-wide 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.

4.20 Distribution

4.20.1 Handling and inspection

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

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

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

4.20.2 Distribution containers and/ or carts

4.20.2.1 Cover all clean or sterile items being transported in uncontrolled environments or use an enclosed cart with a solid bottom shelf

4.20.2.2 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.

4.20.2.3 Reusable carts should have an enclosable opening. Clean reusable covers for carts after each use.

4.20.2.4 Decontaminate and dry transport carts after each use and before they are used for transporting another load of sterile supplies.

4.20.2.5 Follow manufacturer's written IFU on distribution and decontamination procedures for automated cart distribution systems and pneumatic systems.

4.20.3 Receiving and dispatching logbook are available and must include: Sender/Receiver ID, department's name, sets and packages names, Date, Time and quantities.

4.21 Quality Assurance Testing

4.21.1 Perform quality assurance testing of reprocessed items on an ongoing basis.

4.21.2 Provide effective decontamination protocols.

4.21.3 Include **Chemical Indicators (CIs**) in each package and must be sterilant specific. These are read by the end users after opening the sterile pack but before use. Chemical indicators class 6 or 5 must present inside each package.

4.21.3.1 In textile packs wrapped in woven or non-woven materials, the CIs are placed in between the layers of a folded surgical gown within the pack, between multiple layers of draping material or between layers of surgical towels.

4.21.3.2 In an instrument set, the CIs should be placed among the instruments that are placed on stringers.

4.21.4 In containment devices, the CIs should be placed in the areas recommended by the containment device manufacturer.

4.21.5 In multi layered instrument sets in containment devices, the CIs should be placed in the locations determined by the product manufacturer.

4.21.6 Place biological indicators (BI) that are sterilant specific near the drain as per the manufacturer's IFU and run in every load.

4.21.7 Incubate and read BI that has been run/ processed in the sterilizer in accordance with the manufacturer's published instructions.

4.21.8 Biological indicator test file is available. Biological tests for steam sterilizers must be performed minimally weekly preferable daily, with the implants load, and after maintenance. Biological test for plasma sterilizers is performed daily, and after maintenance. All records are kept for 1 year

4.21.9 Planned Preventive Maintenance (PPM) file must be available.

4.21.10 Machine Operation file are available, all machines checked daily, out of service machines have posted sign.

4.22 "**Sterility is Event Related" dependent upon**:

4.22.1 Appropriate & effective handling and storage [end user responsibility] and

4.22.2 Packaging degradation [**CSSD responsibility- every 4 years even if the packaging is intact]** CSSD reprocesses items stored sterile but not utilized in 4 years, based on Event Related Sterility (ERS) guidelines.

4.23 All end users must use the form provided to log your items returned to CSSD this week for reprocessing.re: OR areas only, the tray inventory provided will be utilized for this purpose. Peel items will need to be listed by hand on the form provided.

4.23.1 All items must be returned to the CSSD office in the original packaging.

4.23.1.1 Do NOT open the item at source.

4.23.1.2 Do not return to CSSD via the main CSSD decontamination window.

4.23.2 All items requiring reprocessing will be returned to you within 2- 3 days.

4.23.2.1 Please remember you have not used them in 4 years.

4.23.2.2 Please reconsider the need to have this item sterile on the shelf since it has not been used in 4 years

4.23.3 Should there be any items no longer required to be kept sterile on your units, CSSD will require an e-mail from the Nurse Manager asking CSSD to remove them from circulation.

4.23.4 Should the packaging integrity be compromised in any way it must be returned to CSSD for reprocessing at the time.

4.23.4.1 This would include the item being bent, crushed, torn, stained, wet, having a visible foot print on it, abraded, resealed with scotch tape etc.

4.23.4.2 When in doubt page the CSSD for point of use consultation. Do not open it until we arrive!

4.23.5 When this annual process has been completed, it is the end user responsibility to notify the CSSD via e-mail that the process is complete. This includes units who do not require inventory reprocessing for that year.

4.24 Chemical use

4.24.1 IP&C will evaluate and approve any chemicals being used in CSSD.

4.24.2 Material Safety Data Sheets (MSDS) of chemicals kept in soft and hard copies must be regularly reviewed and updated. Warning labels and easy access to SDS should be in place.

4.24.3 Other ways to avoid workplace hazard are:

4.24.3.1 Provide appropriate personal protective equipment (PPE) such as gloves, goggles, and gown when handling hazardous cleaning detergents and chemicals.

4.24.3.2 Where the eyes or body of any person may be exposed to corrosive materials, medical services and first aid should be readily provided. Suitable facilities for quick drenching or flushing of the eyes and body should be available within the work area for immediate emergency use.

4.24.3.3 Use automatic washing machines that automatically dispense the chemicals used for washing to minimize employee exposure to chemicals. Workers must be cautious and must use appropriate PPE (e.g., goggles, and/or gloves) when changing detergent and other chemical container.

4.25 Burns / Cuts: Establish work practices that will prevent hazards such as:

4.25.1 Do not remove items from sterilizers until cooled.

4.25.2 Avoid handling sharp ends of instruments.

4.25.3 Use forceps or other devices to remove sharp instruments from baskets and autoclaves.

4.25.4 Use appropriate PPE, especially, hand protection gears such as oven mitts to protect the hands when handling hot items, and steel mesh or Kevlar gloves when handling or sorting sharp instruments.

4.26 Slips, Trips, and Falls. CSSD employees are exposed to slippery floors due to steam and washing processes.

4.26.1 Keep floors clean and dry to avoid slips. Wet surfaces enhance the growth of molds, fungi, and bacteria, which can cause infections.

4.26.2 Keep aisles and passageways clear and properly maintained with no unnecessary obstruction that can create hazards. Provide sufficient and accessible floor or ceiling electrical outlets for equipment to avoid trips due to crisscrossing power cords.

4.27 Bloodborne Pathogens

4.27.1 CSSD employees are potentially exposed to bloodborne pathogens and other infectious materials such as bloody, contaminated surgical instruments and sharps. Employees must safely discard disposable sharp items and reprocess reusable instruments /equipment.

4.28 Multi-Disciplinary Environmental Rounds (MDER)

4.28.1 The MDER table indicators for monitoring: See appendices 7.2

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 N/A

5.2 **Materials and Equipment**

5.2.1 N/A

6. RESPONSIBILITIES:

6.1 CSSD STAFF

7. APPENDICES:

7.1 Unidirectional work flow

7.2 The MDER table indicators for monitoring

8. REFERENCES:

8.1 GDIPC. Guidelines for Central Sterile Services Department - Version 1: January 2021
8.2 The GCC Infection Prevention and Control Manual. 3rd edition

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Ms. Marilou C. Magallano	IPC Practitioner		December 12, 2024
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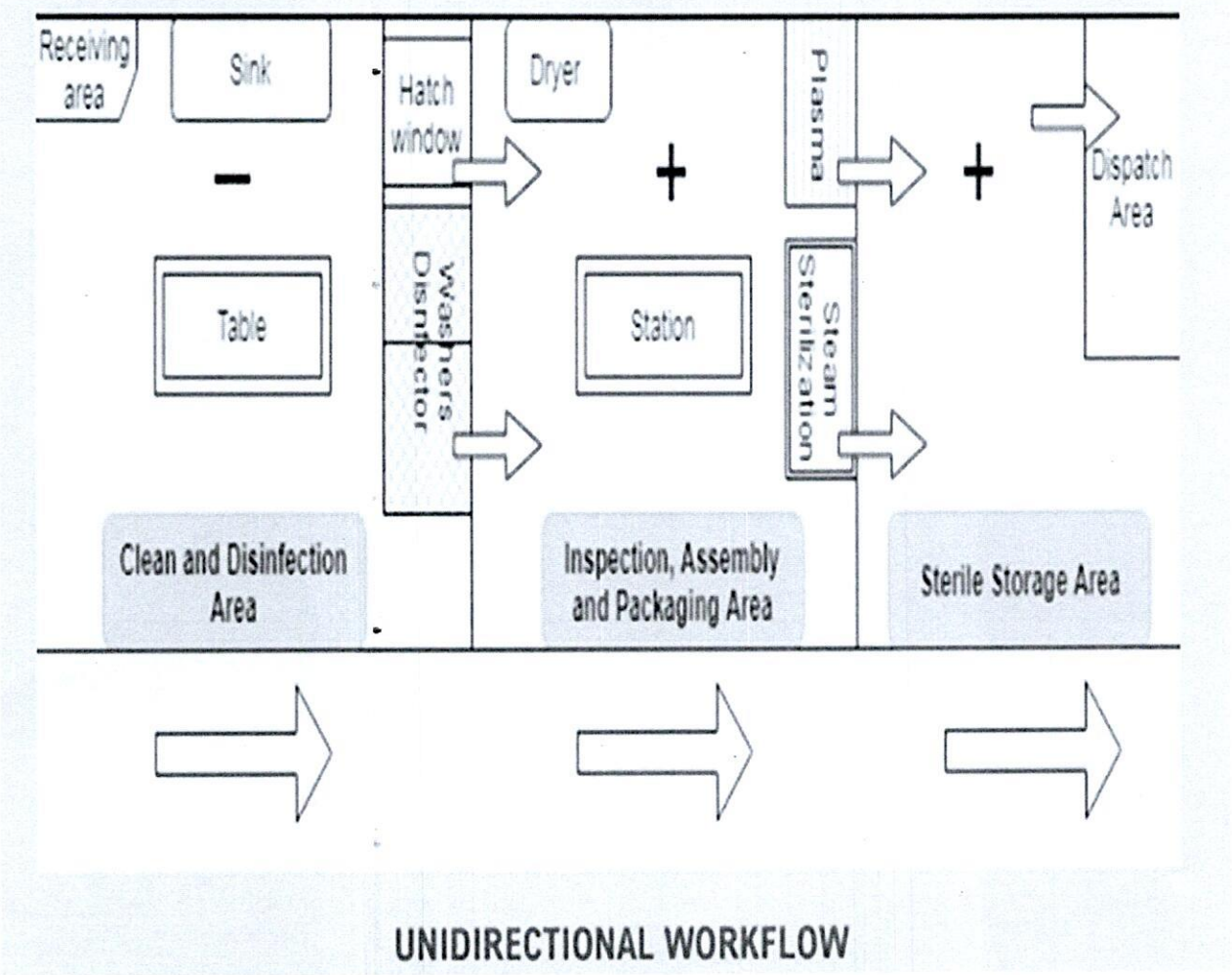
Reviewed by:	Mr. Sabah Turayhib Al Harbi	Nursing Director		December 19, 2024
Reviewed by:	Mr. Abdulellah Ayed Al Mutairi	QM & PS Director		December 22, 2024
Reviewed by:	Dr. Thamer Naguib	Medical Director		December 26, 2024
Approved by:	Mr. Fahad Hazam Al Shammari	Hospital Director & IPC Committee Chairman		December 29, 2024

7.1 Unidirectional work flow



7.2 The MDER table indicators for monitoring

ITEMS	INDICATOR	MDER SCHEDULE	IN-CHARGE
1. Water quality	Hardness	Weekly	Facility Management
2. Air quality	a. Air changes b. Air Pressure c. Toxic gases • Ethylene oxide • Hydrogen peroxide	Monthly or when required Quarterly or when required When alarm is on or when necessary. Quarterly/when necessary	Facility Management Facility Management Infection Prevention & Control (IP&C) IP&C
3. PPE	Use and availability	On regular basis	IP&C
4. Chemical Hygiene		On regular basis	IP&C