Section 9: SUPPORT SERVICES

TITLE/DESCRIPTION:	INDEX NUMBER
STERILE SUPPLIES AND EQUIPMENT MANAGEMENT	ICM - IX - 01

EFFECTIVE DATE:	APPLIES TO:	ISSUING AUTHORITY:
01/01/2009 01/01/2013 01/01/2018	All GCC Countries	GULF COOPERATION COUNCIL – CENTRE FOR INFECTION CONTROL (GCC-CIC)

DEFINITION

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.

REFERENCES

1. Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter 108: Laboratory safety. In APIC Text of infection control and epidemiology (4th ed.).
2. Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter 107: Environmental services. In APIC Text of infection control and epidemiology (4th ed.).
3. Hospital's administrative policy on management of spills of hazardous material.
4. Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities, Amendment 4. ANSI/AAMI ST79:2010/A4:2013.

COMMENTS

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:

A. Critical Items

1. This category includes objects and items entering the vascular system and sterile tissue.
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.
3. These items present a high risk of infection and require sterilization after each patient use.
4. All reusable items in this category must be processed by the CSSD.

B. Semi-critical Items

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.
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.
3. These items require high level disinfection after each patient use.
4. Any reusable items in this category must be processed by CSSD.

C. Non-critical Items

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

2. Examples of non-critical items are bedpans, blood pressure cuffs, tourniquet cuffs, and crutches.
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. These items do not require CSSD service.

TERMINOLOGIES

1. **Biological indicators (BIs)** - test systems containing viable microorganisms providing a defined resistance to a specified sterilization process.
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.
3. **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. **Contaminated** - state of having been actually or potentially in contact with microorganisms.
5. **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."
6. **Decontamination area** – area of health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.
7. **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.
8. **Instructions for Use (IFU)** – manufacturer's written instruction for use..
9. **Labeling** – any legend, work, or mark attached to, included in, belonging to, or accompanying any medical device or product.
10. **Reusable medical device** – device intended for repeated use on different patients, with appropriate decontamination and other processing between uses.
11. **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.
12. **Sterile storage area** – area of a healthcare facility designed to store clean and sterile items and protect them from contamination.

PROCEDURE

A. General Guidelines

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:
   a. 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.
   b. Efficient trained personnel who are competent to perform the function of CSSD with the knowledge of the Department's reporting structure.
   c. Effective and monitored infection prevention and control practices.
   d. Effective quality control including process improvement systems that encompass all

aspects of device reprocessing from point of use through sterilization to reuse. Relevant and effective documentation and reporting practices that enable traceability of each facility-sterilized medical device to the patient on whom it was used.

2. Cleaning and decontamination is the first important step of the sterilization process.
3. Observe standard precautions when handling contaminated items and instruments.
4. 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.
5. Discard disposable single use devices (SUDs) at the point of use by the end user, since it will not be reprocessed by CSSD. Refer to **ICM-IX-03** Single Use Devices.
   a. Consult Infection Prevention & Control (IP&C) for any unused SUDs which have expired.
6. End users spray reusable devices after use with a hospital-approved transport medium immediately at the point of use.
   a. Place used devices in a covered receptacle in the soiled utility room.
   b. 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.
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. Refer to attached document.
8. Reprocess or handle all devices whether loaned or owned by the organization in the same manner.
9. Sterility is "event-related" based on handling, storage practices, and packaging degradation.
10. Provide hand hygiene facilities in convenient locations.

B. Packaging

1. An effective packaging material for steam sterilization processing should:
   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 results 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 and non-fast dyes;
   g. Be non-linting; and
   h. Capable to withstand high temperature.
2. 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%.
3. Examine regularly all packaging materials, woven or non-woven, for defects and extraneous matter prior to use.
4. 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.
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.
   a. 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.

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

C. Handling and Inspection

1. Minimize handling of all sterile items.
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. Notify and return to CSSD any sterile packs found to be wet. CSSD will recall all other packs sterilized in that particular load.
5. 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. Return all recalled items to the decontamination area for decontamination prior to re-sterilization.

D. Sterile Storage Area

1. Store sterile supplies in a way that sterility will not be compromised. Maintain a clean and dry storage area with low traffic volume.
2. Covered or closed shelving is preferred in a clean area with limited access, positive air pressure, and effective ventilation.
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.
4. Do not store sterile packs under sinks, exposed pipes, floors, or window sills.
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. Affix sterilization date and sterilization load number to each package prior to issuing supplies sterilized in-house.
7. Inspect all sterile items for package integrity and/or expiration dates prior to storage.
8. Use sterility maintenance covers (dust covers) to protect sterilized devices/items that are used less than once a month to maintain sterility.
9. Cover sterile packs with dust covers at the CSSD prior to distribution.
10. Consult with IP&C with regards to the use of items beyond the expiration use by date.

E. Shelf Life of Devices Sterilized In-house by CSSD and/or Commercially

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

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:
   a. No barrier tears, compressions, abrasions, punctures, moisture, dirt, bending, or damage in any way.
   b. Each package must have not been opened and/or resealed.
   c. The package must be properly opened without contaminating the contents.
2. 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.

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. Inspect the integrity of sterile packs regularly, prior to storage and use.
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. Refer to CSSD hospital policy.

F. Distribution

1. Handling and inspection
   a. Handle sterile supplies in such a way as to avoid compromising or contaminating the package.
   b. Care should be taken to avoid dragging, sliding, crushing, bending, compressing, or puncturing the packaging, or otherwise compromising the sterility of the contents.
   c. Inspect packaging for integrity and labeling before an item is stored and/or issued.
2. Distribution containers and/ or carts
   a. Cover all clean or sterile items being transported in uncontrolled environments or use an enclosed cart with a solid bottom shelf
   b. 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.
   c. Reusable carts should have an enclosable opening. Clean reusable covers for carts after each use.
   d. Decontaminate and dry transport carts after each use and before they are used for transporting another load of sterile supplies.
   e. Follow manufacturer's written IFU on distribution and decontamination procedures for automated cart distribution systems and pneumatic systems.

G. Quality Assurance Testing

1. Perform quality assurance testing of reprocessed items on an ongoing basis.
2. Provide effective decontamination protocols.
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.
   a. 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.
   b. In an instrument set, the CIs should be placed among the instruments that are placed on stringers.
   c. In containment devices, the CIs should be placed in the areas recommended by the containment device manufacturer.
   d. In multilayered instrument sets in containment devices, the CIs should be placed in the locations determined by the product manufacturer.
4. Place biological indicators (BI) that are sterilant specific near the drain as per the manufacturer's IFU and run in every load.
5. Incubate and read BI that has been run/ processed in the sterilizer in accordance with the manufacturer's published instructions.

Appendix A-IX-01:
Instructions for Use (IFU) Transfer Memo

End User to CSSD "Instructions Transfer" Template

Ref.#:

Date: .....

TO:

Supervisor, KAMC CSSD Nursing Services

FROM: .....

.....

Name of Device : .....

one tray system or scope type(same part # & manufacturer) per memo only!

Manufacturer: .....

☐ **S.U.D.** ☐ **Device** ☐ **Scope** ☐ ***System*** ➔ ***# trays*** ☐

* *all 3 parts- first time received*
* *2nd & 3rd parts-manuf. changes & end user info*
* *3rd part - end user info only*
* *email to CSSD* - use one click e/m button only!.
* *3rd part - end user info only*
* *email to CSSD* - use one click e/m button only!.

I am transferring:

Part 1 ☐ **Information For Use- IFU** *(formerly known as "Manufacturer's Instructions"):*

- ☐ information for use re: care, cleaning & sterilization*(document must relate on paper to the item)*
- ☐ IFU Date: _____
- ☐ relevant catalogue for the above mentioned item(s)
- ☐ original product insert from the original packaging & packaging itself

via: ☑ **CSSD SPT1pgr xxx.** _____ CSSD will pick up *(MOR only),* with vendor still available!

(verifies vendor inventory w/ vendor checklist, reviews IFU provided, identifies issues at the time with end user and vendor- provides status if required)

- ☐ Other: (Palace use only) .....

Part 2 ☐ **Vendor Details:** *(photocopy or attach business card here)*

- Name .....
- Company .....
- E/mail .....
- Cell .....
- Office .....

Part 3 ☐ **End User Info:**

- Contact details : Name: Ext. Pgr.
- Service :
- Owned : ☐
  - ❖ Loaner : ☐ J.I.T. ☐ Long Term
  - ❖ Demo : ☐ for demo only

Current location of item: .....

DATE required: ..... **TIME required:** .....

Thank you ☐ ☐

CSSD office use only

1		Pick up Point	8		Vendor - inservice
a		SPT - verify actual instr. w/vendor list	9		CRN - inservice
b		CRN - review IFU	10		CRN - Instr. to _____ for processing
c		SPT/CRN - initiates feedback end user/vendor.	11		SPT - IFU & Memo. scanned onto computer
d		SPT - trays appropriate?	12		SPT - Computer named & filed
2		AA3 - notified*[Log#]*_____	13		SPT - to link Q.R. to the scanned IFU.
3		CRN - notified	14	*Comments:*	
4		SPT - notified			
5		SPT - completes checklist-*[refer to vendors's initial list]*			
6		CRN - Quick reference complete			
7		CRN - reviews checklist, IFU			

filename://Copy of Appendix A-IX-01 Instructions for Use (IFU) Transfer memo.xls

"Sterility is Event Related" dependent upon:

1. Appropriate & effective handling and storage [end user responsibility] and
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.

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.

1. All items must be returned to the CSSD office in the original packaging.
   * Do NOT open the item at source.
   * Do not return to CSSD via the main CSSD decontamination window.

2. All items requiring reprocessing will be returned to you within 2- 3 days.
   * Please remember you have not used them in 4 years.
   * Please reconsider the need to have this item sterile on the shelf since it has not been used in 4 years

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. Should the packaging integrity be compromised in any way it must be returned to CSSD for reprocessing at the time.
   * This would include the item being bent, crushed, torn, stained, wet, having a visible foot print on it, abraded, resealed with scotch tape etc.
   * When in doubt page the CSSD for point of use consultation. Do not open it until we arrive!

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.

TITLE/DESCRIPTION:	INDEX NUMBER
MANAGEMENT OF INFECTIOUS WASTE	ICM - IX - 02

EFFECTIVE DATE:	APPLIES TO:	ISSUING AUTHORITY:
01/01/2009 01/01/2013 01/01/2018	All GCC Countries	GULF COOPERATION COUNCIL – CENTRE FOR INFECTION CONTROL (GCC-CIC)

DEFINITION

To define themet hods for handling, transporting, and disposing infectious waste to ensure cost reduction and the safety of healthcare workers (HCWs), sanitation workers, and the general public.

REFERENCES

1. Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter 113:Waste Management. In APIC Text of infection control and epidemiology (4th ed.).
2. Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter 107: Environmental services. In APIC Text of infection control and epidemiology (4th ed.).

COMMENTS

1. Infectious waste (also called medical, biomedical, regulated or biohazard waste) is defined as materials generated as a result of the diagnosis or treatment of a patient and that is capable of producing an infectious disease.
2. Infectious waste should always be segregated, collected, transported and stored in a safe manner with consideration of the risk , occupational safety rules and should be in accordance with local regulations.
3. Staff should be knowledgeable about the risks and safety operating procedures of the waste they are handling.
4. The risk of acquiring an infection from medical waste is extremely remote. No waste disposal worker or member of the general public has ever acquired an infection from medical waste.
5. In general, the microbial load of hospital waste is less than that of residential waste.
6. Careless designation and disposal of all hospital waste as “infectious waste” by HCWs leads to unnecessary consumption of hospital resources to manage such waste.
7. Infectious waste has been specifically defined by regulatory authorities such as the Centers for Disease Control (CDC) and the Environmental Protection Agency (EPA). For any infectious waste to be capable of causing infection, a susceptible host must be exposed to a pathogen in the waste and must have a portal of entry, and the pathogen must be of sufficient virulence and quantity.
8. General hospital waste is categorized as items not soaked in blood or body fluids.
9. Infectious waste is categorized as:
   a. Blood and blood products: Bulk blood, blood-tinged suctioned fluids, excretions, secretions are considered infectious waste.
   b. Pathology waste: includes human or animal tissues such as placenta, uteruses, organs, and body parts that are collected at autopsy or during surgery.
   c. Microbiological cultures, stocks and microbiological waste: items containing blood or other potentially infectious materials, as well as, discarded live and attenuated vaccines.

d. Sharps: used or unused sharps (e.g., hypodermic, intravenous or other needles; auto-disposable syringes; syringes with attached needles; infusion sets; scalpels; pipettes; knives; blades; broken glass).
e. Contaminated items: items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling.
f. Animal waste: discarded material originating from animals inoculated with infectious agents during research, production of biological, or pharmaceutical testing should be considered infectious waste.
g. Selected isolation waste: discarded waste materials contaminated with excretions, exudates, and secretions from patients with highly communicable diseases (classification 4 by the CDC in Classification of Etiologic agents on the Basis of Hazards, i.e., Ebola) treated in isolation.

10. Isolation and operating rooms: waste is considered general hospital waste unless it meets the criteria of infectious waste.
11. Waste containers:
    a. Sharps containers
        i. Must be rigid, puncture-proof, leak-proof and closable.
        ii. Equipped with a hermetical seal with an opening aperture which allows insertion of sharp items (e.g., needles and lancets).
        iii. Has a biohazard logo and labeled as "Sharp Items" which must be printed in both Arabic and English.
        iv. Size must be adequate in order to be carried in one hand and be provided with a handle if not wall mounted type.
    b. Plastic bags
        i. Should be tear-resistant and leak proof.
        ii. Must not contain Polyvinyl Chloride (PVC).
        iii. Thickness must not be less than 70 microns thick.
    c. All designated infectious waste containers should have a biohazard symbol or labeled with the word "Infectious" both in Arabic and English or be color-coded (i.e., yellow bags), rendering them identifiable by hospital staff.
12. Storage
    a. There could be 2 types of storages in the hospital:
        i. Temporary storage area: storage in the wards located in the dirty utility which are used to hold infectious waste temporarily to be collected and transported to the central storage area every after end of the shift or as needed.
        ii. Central storage area: used to hold infectious waste for not more than 24 hours to be eventually collected and transported off-site for treatment. The room must have a concrete floor and be well-sealed to protect it from water leakage, rain, spread of odor, from rodents, insects, birds and stray animals.
    b. Dispose infectious waste as soon as possible after generation.
    c. Minimize the storage time to reduce the risk of potential exposure and reduce odor.
    d. Limit access to storage areas and have a biohazard symbol labeled with the word "storage area" in both Arabic and English; and posted where it is readily visible to anyone.

PROCEDURE

A. Four (4) methods of waste segregation must be followed at the point of generation (i.e., by the end user).
   1. **BLACK** bags
      a. Used to dispose of general hospital waste.
      b. Items that would not release (drip) blood or other potentially infectious materials in a liquid or semi-liquid state if squeezed.
      c. Place solid waste not grossly contaminated with potentially infectious blood or body fluids from isolation rooms or operating rooms in black bags.
      d. Laboratory solid waste, not included in the infectious waste category.
   2. YELLOW bags
      a. Used to dispose of infectious waste. Refer to categories of infectious waste.
      b. Containers with blood/body fluids that cannot be emptied.
      c. All microbiological waste (specimens, cultures, and stocks of etiologic agents).
      d. Items moderately or heavily soaked (dripping) in blood or body fluids.
      e. Chemotherapy waste: Trace amounts of cytotoxic liquid waste (e.g. contaminated PPEs and empty IV bags).
      f. Place infectious waste in the appropriate designated container, lined with yellow disposal bags.
      g. One designated infectious waste garbage bin lined with a yellow disposal bag can be kept in the dirty utility room of non-ICU units or areas.
   3. SHARPS containers
      a. Used to dispose all used and unused sharps (e.g., Hypodermic, intravenous or other needles, auto-disable syringes, syringes with attached needles, scalpels, glass pipettes, knives, blades, broken glass).
      b. Do not disassemble blades or needles from equipment.
      c. Discard sharps so that they do not protrude from the opening of the container.
      d. Replace the sharps container promptly when the sharps container is ¾ filled (and reaches the fill line) (Housekeeping Services).
   4. RED bags
      a. Use to transport body parts, organs, or fetuses for burial.

B. Healthcare Workers
   1. Discard all waste generated in your area into the appropriate bin.
   2. Wearing the appropriate protective apparel, carefully pour potentially infectious liquid waste down the drain (if local regulations allow or if there is a waste treatment plant available in the healthcare facility).
   3. Care should be given not to generate splashes that may contaminate yourself and the surrounding environment.
   4. Hand hygiene sinks should not be used to dispose of such fluids.
   5. Place empty bulk blood and blood product containers in black bags.
   6. Perform hand hygiene immediately after body fluid exposure.

C. Environmental Services (Housekeeping Services)
   1. Pick up waste at least once per day and as needed.
   2. Handle bags at the top so that the bags do not come in contact with your body. Do not use your hands to compress (squeeze) waste in containers/bags.

3. Tie bags using a self-lock plastic tie and securely before placing them in a temporary holding area such as a dirty utility room. Do not store waste bags in hallways or corridors.
4. Replace the sharps container promptly when it is ¾ full or reaches the fill line.
5. Fasten the cover of a full sharps container securely before removing.
6. Label the infectious waste bags or sharp containers with the following information:
    a. Generating department
    b. Date collected
    c. Time
    d. Weight
7. Decontaminate disposal bins/containers or frames when visibly soiled. These items should be cleaned weekly or as needed with hospital-approved disinfectant.
8. Decontaminate carts used for transporting waste within the hospital daily using a hospital-approved disinfectant solution.
9. Use leak-proof carts that are readily cleanable to transport infectious waste from the point of generation or storage to the point of disposal and treatment.
10. Place yellow bags in a holding area for incineration.
11. Pick up and discard broken glass using a mechanical device such as forceps or a brush and dust pan. Broken glass should never be handled with gloved or non-gloved hands.
12. Clean blood spills according to a written procedure (see "Blood Spills Cleaning" below).

D. Blood Spills and Spills of Other Potentially Infectious Material (OPIM)

All work locations where employees may come into contact with blood or other potentially infectious material must have blood spill biohazard equipment/kits available to safely and effectively clean up any spills. This kit must include the following:

1. Personal protective equipment (PPE) such as gown, gloves, eyewear, mask.
2. Supplies such as forcep, plastic scoop and scraper, absorbent granules or absorbent pads, hospital-approved disinfectant, yellow plastic bag and sharp container.

Procedure

The steps described below should be taken when cleaning and decontaminating spills of blood or other potentially infectious materials:

1. **Control** access to area:
   Prevent people from walking through affected area and spreading the blood or other potentially infectious material to other areas. Use the signage for wet floor sign

2. **Contain** spill:
   Use other absorbent granules or absorbent pads to contain the spill.
    a. Put on appropriate PPEs
    b. Use plastic scoop or other mechanical means to remove any broken glass or other sharp objects from the spill area, and dispose into the sharp container
    c. Sprinkle absorbent granules over the spill and leave for two minutes or as per the manufacturer's recommended contact time. Allow the spill to solidify before removing.
    d. Remove the solidified waste material using the scoop and scraper and carefully dispose all contaminated materials into the infectious waste bag

e. If there is no available absorbent granules contain the spill by placing absorbent pads (i.e. paper towel) on top of the spill and apply the appropriate disinfectant. To avoid creating aerosols, never spray disinfectant directly onto the spilled material. Instead, gently pour disinfectant on top of paper towels covering the spill or gently flood the affected area, first around the perimeter of the spill, then working slowly toward the spilled material. If sodium hypochlorite solution (5.25% household chlorine bleach) is used, prepare a fresh solution on a daily basis. Leave for the recommended contact time.
f. Pick up all absorbent material and carefully place in the infectious yellow bag for disposal. Remove PPEs and place in a yellow bag for disposal.
g. Seal the yellow bag.
h. Wash hands thoroughly with soap and water.

3. **Contact** housekeeping to clean the affected area with hospital-approved disinfectant.

E. Spills Occurring Within the Biosafety Cabinet

When infectious material is spilled within the biosafety cabinet, it should be cleaned up immediately by the individual performing the work. If the cabinet is certified and working properly and not overfilled with laboratory equipment, which limits the cabinet's air flow, there is little risk of aerosolization of the material into the general laboratory environment.

Additionally, employees working with potentially infectious microorganisms must wear adequate PPE.

When cleaning and decontaminating a spill within a biosafety cabinet, care should be taken not to move hands and arms in and out of the cabinet unnecessarily. This action creates turbulence that reduces the laminar air flow characteristics and the effectiveness of the biosafety cabinet. A suitable disinfectant and laboratory wipes should always be available within the cabinet or on the supply cart or table directly adjacent to the biosafety cabinet.

Procedure

To effectively clean and decontaminate a spill within the biosafety cabinet follow these steps:

1. With cabinet air flow running, cover the affected area immediately with absorbent material.
2. Using hospital-approved disinfectant, gently spray the top of the covered spill.
   a. Leave for the recommended contact time.
   b. Pick up the absorbent material and place in a small autoclave bag inside the biosafety cabinet.
   c. Clean the affected area again with disinfectant. If chlorine bleach is used, the affected area should be cleaned with 70% ethanol afterward to remove residual bleach. Chlorine bleach will pit and corrode the stainless steel work area inside the biosafety cabinet.
   d. Place the sealed bag in a biohazard waste receptacle.

Appendix A–IX-02: Summary of Infectious/Hazardous Waste Management Plan

Waste Category	Examples	Red Bag	Yellow Bag[1] (Incineration	Yellow Container 2	Black Bag (Sanitary Landfill)	Steam Sterilization
Microbiology	Stocks and cultures of infectious		X			X[3]
Anatomical waste	Tissues, organs, other body parts, specimens of body fluids and their containers (stored in lab for burial	X				
Blood/blood products/ body fluids: All clinical areas: • < 20-ml volumes	Blood containers, IV tubing without needles, suction canisters, pleuro-vacs, evacuated containers, hemo-vacs, etc.				X	
• > 20-ml volumes			X			
Items contaminated with blood: • If saturated and/ or dripping	Paper towel, gauze, disposable objects, gloves, etc.		X			
• Not saturated and/or dried					X	
Chemotherapeutic waste	Bulk[4] chemicals and sharps			X		
	Trace[5] chemicals		X			
Sharps	Contaminated needles, syringes, scalpel blades, razors, pasteur pipettes, tubes and broken glass			X		
Contaminated animal carcasses, body parts, and bedding	Contaminated animal carcasses, body parts, and bedding of animals that were intentionally exposed to highly infectious pathogens.		X			X[3]
Other hospital waste	Non-hazardous medical wastes				X	

[1] Yellow bags (70 -micron thickness, leak-proof, labeled Cytotoxic and/or Biohazard as per ICM-IX-02 Management of Infectious Waste).
[2] Yellow containers must be heavy-duty, leak-proof, and puncture-proof. Containers must be labeled as Biohazard or Cytotoxic separately as per ICM.
[3] If steam sterilization is not used, place in yellow bag for incineration.
[4] Waste materials contaminated with any visible liquid are classified as bulk chemical waste, including contaminated sharps. and must be incinerated at ≥1200°C.
[5] Waste materials contaminated with traces of chemotherapy agents (e.g., empty vials, IV tubing, gowns, gloves).

Note: Radioactive wastes should be placed in hermetically sealed containers with an international logo of Radiation Hazard.

TITLE/DESCRIPTION:	INDEX NUMBER
SINGLE USE DEVICES (SUD)	ICM - IX - 03

EFFECTIVE DATE:	APPLIES TO:	ISSUING AUTHORITY:
01/01/2009 01/01/2013 01/01/2018	All GCC Countries	GULF COOPERATION COUNCIL – CENTRE FOR INFECTION CONTROL (GCC-CIC)

DEFINITION

To outline a process for the evaluation, approval, and appropriate decontamination and reprocessing of single use devices (SUDs) when indicated.

REFERENCES

1. Association for the Advancement of Medical Instrumentation. (2006). Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.
2. Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter 30: Aseptic technique. In APIC Text of infection control and epidemiology (4th ed.).
3. Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter 07: Product evaluation. In APIC Text of infection control and epidemiology (4th ed.).
4. Association for Professionals in Infection Control (APIC) and Epidemiology, Inc. (2014). Chapter 32: Reprocessing single-use devices. In APIC Text of infection control and epidemiology (4th ed.).
5. Drug and Health Products. Reprocessing of reusable and single-use medical devices. Health Canada, British Colombia. Available at: www.bc-sc.gc.ca Accessed: March 2009.
6. John Hopkins Hospital. (2006). Reprocessing of single-use patient care items by third part vendors. Interdisciplinary Clinical Practice Manual. Policy No. IFC-004
7. Saudi Food and Drug Authority, Kingdom of Saudi Arabia. Available at: www.sfda.gov.sa. Accessed: March 2009.

COMMENTS

1. The institutional facilities should not reprocess used SUDs for reuse because it is not safe.
2. SUD refers to a patient care item intended to be used once on an individual patient during a single procedure and then discarded. This item is labeled as "single-use" or "disposable."
3. Reuse refers to the use of an item labeled by the original manufacturer as a single-use or disposable patient care item that has been cleaned, disinfected, or sterilized and then tested for functionality after its original use on a patient.
4. Reprocessing refers to the cleaning, disinfecting, repackaging, and sterilizing of an item that was either (a) used on a patient or (b) not used on a patient but has its original packaging compromised. Manufacturer's instructions now known as information for use (IFU) must be adhered to when evaluating reprocessing of SUD.
5. Reprocessing a SUD may affect the function of the device and/or material from which the device is made. Single-use devices may not be designed to allow for thorough decontamination and re-sterilization processes. Unforeseen problems such as inadequate decontamination, material alteration, mechanical failure, and residual chemical agents can render the reprocessed item unsafe. In addition, validation of the SUD's functionality after reprocessing cannot be guaranteed.
6. Critical and semi-critical medical equipment/devices labeled as SUD must not be reprocessed and reused unless the reprocessing is carried out by a licensed re-processor who can validate the functionality of the reprocessed SUD.

PROCEDURE

1. SUDs must be discarded by the end user at the point of use as per hospital waste disposal protocol.
2. Examine used SUDs being considered for reuse on an individual basis and consider potential risk implications as follows:
   a. Describe the item.
   b. Use of the item (i.e., invasive (critical) vs. non-invasive (non-critical)).
   c. Availability of manufacturer's IFU reprocessing instructions.
   d. Risks to the patient (i.e., infection and/or mechanical defects causing injury).
   e. Quantity to be reprocessed.
   f. Cost per item.
   g. Is it a stock item?
   h. Nil stock (none in supply stores).
   i. Next delivery date.
   j. Ethical, moral, and legal implications.
3. Fill out a hospital standard written request for evaluation of the SUD.
   a. If reuse of a SUD is considered, the conclusion must be influenced by unique circumstances pertaining to the individual device. Complete the attached evaluation form and forward it to Infection Prevention and Control (IP&C) Department.
   b. If re-sterilization of unopened expired devices or opened unused devices is considered, the conclusion must be guided by the manufacturer's instructions/recommendations. Obtain and complete the appropriate form from Central Sterile Supply Department (CSSD).
4. Submit the SUDs in its original packaging with all pertinent IFU along with a written request to the CSSD supervisor for review and assessment.
5. The CSSD supervisor assesses the item and discusses the findings with the IP&C to determine the appropriate course of action with the following consideration:
   a. Risks involved with product safety and performance.
   b. Method of re-sterilization.
   c. Frequency of re-sterilization.
   d. Quality control.

Form 1-IX-03:
Evaluation for Reprocessing Single Use Items/Devices

Requestor:			Date:
Name:			Badge #:
Title:			Department:
	Questions	Yes/No	Describe
1.	Describe the item Expiration date		
2.	Use of item (invasive or non-invasive)		
3.	Provide manufacturer's reprocessing instructions		
4.	Risks to the patient?		
5.	Quantity to be reprocessed?		
6.	Cost per item?		
7.	Is it a stock item? Oracle #		
8.	Special Purchase Request (SPR) #		
8.	Nil stock?		
9.	Next delivery date?		
Infection Control Department			
Evaluator:			Date:
Name:			Badge #:
Findings:			
Action:			