DEDER GENERAL HOSPITAL

Standard Operating Procedure (SOP) for Decontamination of Medical Devices and Patient Care Equipment

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1. Purpose

The purpose of this SOP is to establish a systematic **process for cleaning, disinfecting, and sterilizing medical devices and patient care equipment. The goal is to reduce the risk of healthcare-associated infections (HAIs)** by ensuring that reusable medical devices and equipment are properly decontaminated.

2. Scope

This SOP applies to **all healthcare personnel**, including **doctors, nurses, decontamination technicians**, and **support staff,** who are responsible for **handling and maintaining reusable medical devices and patient care equipment**. It is also applicable to any area of the healthcare facility where medical equipment is processed, including **operating rooms, patient wards, and decontamination units.**

3. Definitions

- **Decontamination:** The process of cleaning and disinfecting medical devices and equipment to remove or neutralize harmful microorganisms.
- **Cleaning:** The removal of visible dirt, blood, body fluids, and other contaminants from the surface of medical devices and equipment using water, detergents, or enzymatic products.
- **Disinfection:** The process of using chemical agents or heat to kill most pathogenic microorganisms, excluding bacterial spores, on the surface of medical devices and equipment.
- **Sterilization:** The complete destruction or removal of all microorganisms, including bacterial spores, from medical devices and equipment, usually through methods such as steam, chemical, or gas sterilization.
- **Critical Equipment:** Equipment that comes into contact with sterile tissues or the vascular system, such as surgical instruments. This equipment must be sterilized.

- **Semi-Critical Equipment:** Equipment that comes into contact with mucous membranes or non-intact skin, such as endoscopes. This equipment requires high-level disinfection.
- **Non-Critical Equipment:** Equipment that comes into contact only with intact skin, such as stethoscopes or blood pressure cuffs. This equipment requires low-level disinfection.

Materials Required:

1. **Personal Protective Equipment (PPE):**
   - Gloves, gowns, masks, and face shields to protect staff during decontamination procedures.
2. **Cleaning Agents:**
   - Detergents, enzymatic cleaners, or other solutions appropriate for the removal of organic materials from medical devices and equipment.
3. **Disinfectants:**
   - EPA-registered disinfectants appropriate for the level of disinfection required (low, intermediate, or high).
4. **Sterilization Equipment:**
   - Autoclave (steam sterilization), ethylene oxide gas sterilizer, or other methods depending on the type of equipment.
5. **Cleaning Tools:**
   - Brushes, cloths, and sponges suitable for cleaning various types of medical equipment, including those with lumens or crevices.
6. **Sterile Water/Distilled Water:**
   - For rinsing equipment after disinfection or sterilization.

Procedure:

1. Pre-Decontamination Process:

A. **Inspection of Equipment:** Inspect all medical devices and equipment for visible contamination and damage before cleaning. Remove any damaged equipment from service for repair or disposal.

B. **Follow Manufacturer Instructions:** Always refer to the manufacturer's instructions for cleaning, disinfection, and sterilization of each specific device.

C. **Segregation:** Separate used equipment from clean or sterilized equipment to prevent cross-contamination.

2. Cleaning of Medical Devices:

Cleaning is the first and most crucial step in the decontamination process. All devices must be cleaned before being disinfected or sterilized.

Steps:

1. Don appropriate PPE before handling soiled medical devices.
2. Disassemble equipment if necessary, following the manufacturer's guidelines.
3. Rinse equipment under warm running water to remove visible debris and organic material.
4. Apply a suitable cleaning agent (detergent or enzymatic cleaner) to the device.
5. Use cleaning brushes to scrub all surfaces, including any difficult-to-reach areas, such as lumens and joints.
6. Rinse equipment thoroughly with clean water to remove residual detergent or cleaning solution.
7. Dry the equipment using a clean, disposable towel or air dryer.

3. Disinfection of Medical Devices:

Depending on the classification of the equipment (critical, semi-critical, or non-critical), appropriate disinfection methods should be applied.

A. **Low-Level Disinfection (for Non-Critical Equipment):**

- Used for equipment such as stethoscopes and blood pressure cuffs that come into contact with intact skin. - Wipe the equipment with a low-level disinfectant.
- Allow sufficient contact time (as specified by the disinfectant manufacturer) before wiping dry or allowing to air dry.

B. **High-Level Disinfection (for Semi-Critical Equipment):**

- Used for equipment like endoscopes and respiratory therapy equipment that come into contact with mucous membranes. - Immerse the equipment in a high-level disinfectant (e.g., glutaraldehyde or hydrogen peroxide). - Ensure all parts of the equipment, including lumens, are fully submerged in the disinfectant. - Soak the equipment for the recommended contact time (as per the disinfectant manufacturer). - Rinse with sterile or distilled water and allow the equipment to dry completely before storage or use.

4. Sterilization of Medical Devices:

Critical equipment that enters sterile body tissues or the vascular system must undergo sterilization.

A. **Steam Sterilization (Autoclaving):**

- Place cleaned and dried medical devices in sterile wraps or pouches. - Load the autoclave correctly, ensuring that items are not overcrowded. - Run the autoclave at the manufacturer-recommended settings (typically 121°C at 15 psi for 30 minutes).
- Use sterilization indicators (e.g., chemical or biological indicators) to verify successful sterilization.
- Allow the sterilized items to cool before handling or storing.

B. **Gas Sterilization (Ethylene Oxide):**

- Used for heat-sensitive devices. –
- Place equipment in gas-permeable packaging.
- Run the sterilization cycle as recommended, ensuring proper ventilation afterward to remove residual gas.

C. **Chemical Sterilization:**

- Used for equipment that cannot withstand heat or moisture.
- Immerse the equipment in a chemical sterilant (e.g., peracetic acid) for the recommended time.
- Rinse the equipment thoroughly with sterile water to remove chemical residue.

5. Post-Decontamination Handling and Storage:

- **Storage of Sterilized Equipment:**
  Store sterilized medical devices in a clean, dry, and designated sterile storage area. Ensure that storage conditions maintain the sterility of the equipment.
- **Transporting Clean/Decontaminated Equipment:**
  Use covered trays or containers when transporting decontaminated equipment to avoid cross-contamination.
- **Record-Keeping:**
  Keep records of all sterilization cycles, including equipment processed, dates, times, personnel involved, and sterilization indicator results.

Special Considerations:

1. **Single-Use Devices:**
   Single-use devices should not be reused and must be disposed of following the facility's biohazard waste disposal protocols.

2. **Handling Malfunctioning Equipment:**

   Equipment that is damaged or malfunctioning should not be processed and should be reported to the maintenance department for repair or disposal.

3. **Outbreak Situations:**

   During infection outbreaks, additional precautions may be implemented, such as increased frequency of decontamination or use of more potent disinfectants.

Monitoring and Compliance:

1. **Routine Audits:**

   Monthly audits will be conducted to ensure that all decontamination procedures are being followed correctly. Audits will focus on the proper cleaning, disinfection, sterilization, and storage of medical devices.

2. **Non-Compliance:**

   Staff found to be non-compliant with decontamination protocols will receive retraining, and repeated non-compliance will result in disciplinary action.

3. **Quality Assurance:**

   Supervisors will regularly review and evaluate the effectiveness of the decontamination process by inspecting equipment and reviewing sterilization logs.

Training:

1. **Initial Training:**
   All staff involved in decontamination must receive comprehensive training during onboarding. Training will include the proper use of equipment, cleaning agents, and sterilization techniques.
2. **Refresher Training:**
   Refresher training will be provided annually and as needed following changes in policies, procedures, or equipment.
3. **Training Documentation:**
   Records of all training sessions, including participants and training content, will be maintained by the infection control or human resources department.

References:

1. Centers for Disease Control and Prevention (CDC) guidelines for disinfection and sterilization in healthcare facilities.
2. World Health Organization (WHO) guidelines for infection prevention and control.
3. Manufacturer's guidelines for medical device reprocessing.
4. Local health authority regulations.