Current Status: *Active* **PolicyStat ID:** *6795279*

Origination: *06/2004*
Effective: *08/2019*
Last Approved: *08/2019*
Last Revised: *08/2019*
Next Review: *08/2022*
Owner: *Sherie Goldbach: Project Coordinator*
Policy Area: *Infection Prevention*
Policy Tag Groups:
Applicability: *UNC Medical Center*

Central Processing Department (CPD) and Other Surgical Services Support Areas Using Sterilizers or Storing CPD Sterilized Items

I. Description

Describes the process used by the Central Processing Department and Surgical Services for sterilization of medical instruments and supplies.

II. Rationale

Appropriate sterilization of instruments is essential for the safe delivery of surgical care. The Central Processing Department (CPD) provides a centralized service for instrument processing, decontamination, sterilization, and case cart preparation. Steam, ethylene oxide (EO), and hydrogen peroxide plasma (e.g., Sterrad, V-Pro) are used. This policy shall apply to CPDs in the Ambulatory Surgical Center, the Main Campus, and Hillsborough Hospital. Sterilization will meet parameters outlined by the manufacturer, CDC guidelines or recommendations from professional organizations, (e.g., SHEA, APIC, SGNA). Storage of sterile supplies in Central Distribution is addressed in Appendix A.

III. Policy

A. Adherence to "Cleaning, Disinfection and Sterilization of Patient-Care Items" Policy

Staff responsible for cleaning, disinfecting and/or sterilizing will review and comply with the "Cleaning, Disinfection and Sterilization of Patient-Care Items" Infection Control Policy.

B. Physical Layout

The physical plan of CPD is designed to avoid cross-contamination between soiled and clean supplies, and is divided into *5* areas.

1. The decontamination/clean-up area is for the reception and cleaning of used instruments and materials that will be reused. They are either cleaned by hand in the sink, or in the automated washer-decontaminator, or both.

2. A designated clean/hold area is for the placement of decontaminated materials.
3. The assembly area is for handling and repackaging clean items to be sterilized. Instrument trays are assembled in this area.
4. The sterile storage area is for the storage of sterile items.
5. The sterilizer area is for sterilization.

C. Decontamination of Reusable Items

1. Soiled instruments and small equipment are received and removed from different areas of UNC Hospitals and brought to CPD in a covered container. The covered CPD container is labeled with a BIOHAZARD label. These items are placed in the decontamination/clean-up area where they are thoroughly washed with detergents and appropriately prepared for reissue. Reusable sharps that are contaminated with blood or other potentially infectious materials should be handled with caution and transported in a puncture-resistant container labeled with a biohazard label. Tongs or forceps should be used to remove the contaminated sharps from the CPD biohazard container. The employee must not reach by hand into the container to remove contaminated sharps. Emphasis is placed on efficient and thorough washing of the soiled items. The covered biohazard containers are cleaned with a bleach solution or put through the washer disinfector between each use. The green CPD biohazard containers kept in the dirty utility room in some clinical areas should be cleaned by CPD staff on a routine basis and when visibly soiled.
2. Soiled medical supplies and/or instruments are sent by a designated elevator in a covered cart from Main ORs and Children's OR [COR] to CPD for reprocessing. These items are cleaned in the same manner as other soiled supplies brought to CPD.
3. Reuse of single use medical/surgical devices is prohibited at UNC Health Care, unless the items are reprocessed by approved third party reprocessors. (See Infection Control Policy: Reuse of Single Use Devices.)
4. Decontamination and sterilization of instruments used for patients known or suspected to have Creutzfeldt-Jakob Disease (CJD) require special procedures. Employees should be familiar with and strictly follow the guidelines provided in the CJD Infection Control Policy.

NOTE:	**All chemicals (e.g., detergents, germicides) used in CPD should be examined before opening to ensure the seal has not been broken. If it is unclear if the seal is broken, and the product may have been altered, do not use the chemical and contact Hospital Epidemiology.**

D. Endoscope Reprocessing

Staff responsible for cleaning and disinfection of endoscopic instruments will be familiar with and comply with the Endoscope Infection Control Policy and the section on endoscope reprocessing in the Perioperative Services Infection Control Policy.

E. Handling of Sterile Reusable Materials

1. Reusable items for sterilization are washed with an approved detergent or other method

according to the equipment's instructions for use. They are then either wrapped or placed in peel pouches or containers for sterilization.

2. Validation of Sterilizer Parameters
    a. Each operator should understand the sterilization parameters for each sterilizer used.
    b. These parameters will be in written form and posted in the sterilization record's envelopes.
    c. All sterilizer receipts will be maintained in a specified notebook or electronically. Each receipt will be reviewed after each run and then be signed by the person performing the review. The sterilizer operator will also document the results in Censitrac.
    d. The sterilization parameters in the log books and Censitrac will be verified once a day.
3. Sterilization Control Systems
    a. Each item sterilized is labeled with the date (month, day and year), sterilizer number, and load number.
    b. Chemical integrator strips are placed inside each item. The item is sealed with steam tape, ethylene oxide tape, or Sterrad or VPro tape. Peel pouches are either self-sealing or sealed by a heat sealer.
    c. The Censitrac computer system is used for documenting information for each sterilizer. The sterilizer number, load number, date, contents of the load, daily Bowie-Dick test, biologicals and chemical indicators are documented. Temperature of the load and total time are documented on the 3M Attest® Rapid Readout Steam or EO log sheet.
    d. The Bowie-Dick test is placed in an empty sterilizer the first cycle for each day in the steam sterilizers to evaluate the efficacy of air removal.
    e. The physical receipts or printouts and chemical and physical indicators will be placed in the QA book and maintained with other sterilizer information. Records are retained for five years.
4. Biological monitoring of sterilizers
    a. Steam sterilizers in the main CPD area are tested on the first load of the day with Attest® biological indicators (***Geobacillus stearothermophilus***). Steam sterilizers in Main OR (MOR), Children's OR (COR), and ASC (Ambulatory Surgery Center) are tested on the first load of days Monday – Friday.
    b. Ethylene oxide gas sterilizers in CPD are tested in each load with Attest® biological indicators (***Bacillus atrophaeus***).
    c. The plasma (VPro/Sterrad) sterilizer loads are run with the appropriate self-contained biological test in the first load each day (BI – ***Geobacillus stearothermophilus***).
    d. Every implant load is run with an Attest® rapid readout biological indicator.
5. When a positive biological indicator (Attest® or Verify for VPro) is detected in a Surgical Services Department sterilizer (e.g., OR, CPD, ASC, COR), personnel responsible for that sterilizer will:
    a. Discontinue use of the sterilizer. Fill out and attach a Sterilizer Malfunction form on the sterilizer. The form is located in Appendix "A", of the Central Processing Department Policy: Mechanical Monitoring for Sterilizers.

b. Follow all instructions on the Sterilizer Malfunction Form.

c. Notify Hospital Epidemiology as soon as the positive biological indicator is discovered.

d. Check to see if the chemical indicator on the exterior of the Attest or Verify vial has appropriately changed.

e. Contact Medical Engineering to have the sterilizer evaluated for proper use and function.

f. Recall all items sterilized on all loads since the last negative biological indicator for the sterilizer with the positive biological.

g. After the problem is corrected, and before the sterilizer is returned to service, run one Bowie-Dick test and three consecutive test runs each with a biological and chemical indicator.

h. If the test biological indicators are negative after the appropriate incubation time for the specific BI used, (i.e., 4 hours of incubation for EO, 24 hours of incubation for Sterrad or VPro, or 3 hours of incubation for steam, the sterilizer may be released for normal use.

i. Notify Hospital Epidemiology (984-974-7500) to report updated information.

6. Recall of Equipment

   a. The red and white load number sticker with date, sterilizer number and load number are used to recall sterile items. All items are returned to CPD for reprocessing.

F. Procedures Regarding Shelf Life of Sterilized Items

All items sterilized in the Central Processing Department or other Surgical Services reprocessing areas do not require an expiration date. These items are considered sterile and may be used as long as the integrity of the package is not compromised by becoming torn, wet (or evidence of moisture damage), punctured, opened or have an unsealed or broken seal/lock.

1. A load number sticker will be placed on each hospital-processed item. No expiration date will be present.
2. A load number sticker will be placed on each package for recall purposes only. This is not to be used as an expiration date.
3. All items processed for sterilization will be properly wrapped and processed in such a manner so as to provide an effective barrier to microorganisms and allow aseptic presentation upon opening.
4. All packages must be inspected before use. If the package is torn, wet, punctured or has a broken seal, it is considered contaminated and should not be used.
5. Any package that has fallen or been dropped on the floor must be inspected for damage to the packaging or contents. If the package is heat-sealed in impervious plastic and the seal is still intact, the package should be considered not contaminated. If undamaged, items packaged in plastic need not be reprocessed.
6. Medications or materials within a package that deteriorate over time will be dated.
7. Rotation of supplies is important to ensure previously processed items are used before those more recently processed.

8. The loss of sterility is event-related, not time-related. Storage areas will be routinely cleaned, have the proper pressure differential and air exchanges per hour temperature and humidity conditions (e.g., temperature and relative humidity are not excessive (temperature >90°F, relative humidity >80% for longer than 48 hours) and should not in any way compromise the integrity of the package.
9. Items to be sterilized will be wrapped with a one-time use disposable wrap.
10. When commercially prepared sterile items have an expiration date furnished by the manufacturer, packages are considered sterile until damaged or opened. When the manufacturer has an expiration date on the item, it must be used before the expiration date is achieved. Any package that is not used before the expiration date should either be discarded or reprocessed as appropriate by an approved third party reprocessor.

G. Transport of Sterilized Items

1. Sterilized items are moved from CPD to the ORs inside a case cart, hand carried, or sent via the clean elevator.
2. If the clean elevator is out of service, sterilized items may be transported via the dirty elevator if covered with a clean sheet.

H. Cleaning Sterilizers

1. Steam sterilizer drains are to be cleaned daily in CPD, Monday-Friday in the ASC, and weekly in the ORs.
2. The EO sterilizer is cleaned according to the sterilizer manufacturer's instructions.
3. VPro/Sterrad sterilizers in CPD, ASC, and HBH are cleaned according to the sterilizer manufacturer's instructions.

I. Storage of Sterile Supplies

1. Sterile supplies shall be stored at least 8 inches from the floor, 2 inches from an outside wall, and 24" inches from ceilings. Items stored on perimeter shelving may be stored to the ceiling. They are stored in the Sterile Storage Area on carts. The bottom shelf of storage carts or shelving should be solid in CPD sterile storage adjacent to the sterilization rooms. These carts are cleaned one time per month and when visibly soiled with an EPA-registered germicidal solution. Cleaning of shelving in clean storage must be documented.
2. Items received throughout the hospital and clinical areas from CPD will be stored at least 8 inches from the floor, 2 inches from an outside wall, and 24" inches from ceilings but do not require solid bottom shelving.
3. Sterile supplies are rotated with the most recently sterilized items used last. Any opened or damaged packages are removed from the shelves and reprocessed.
4. Corrugated cardboard boxes and fans are not permitted in CPD.
5. Traffic in the Sterile Storage Area is kept at a minimum.

J. Housekeeping

1. Within Central Processing Department, cleaning will be performed according to the frequency and responsibilities detailed in the Cleaning Central Processing Department Policy.

K. Personnel

Personnel shall adhere to guidelines established by Occupational Health Services (OHS). (Refer to the "Infection Control and Screening Program – OHS.")

1. A clean, hospital laundered scrub suit from the Pyxis machine is acquired and worn daily by all personnel. At end of shift, scrubs shall be redeposited back into the Pyxis.
2. Outer/undergarments: Cover gowns (e.g., white coats) are not required as a cover when entering areas outside of CPD. Undershirts under hospital-provided scrubs may be either crew or v-neck (but must be short sleeved and not have a high neck; i.e., no turtle or mock neck shirts).
3. Warm-up Jackets: Hospital-provided, hospital-laundered warm-up jackets can be worn over the teal, hospital-provided scrubs within CPD. In the clean side, the warm-up jackets should be closed to prevent possible contamination to sterile items in the room. Personal, home laundered warmup jackets cannot be used in CPD as a cover
4. A clean, disposable bouffant cap is used to cover hair in the Decontamination area. In all other areas, a non-disposable cloth hat may be worn, but it must be laundered daily and when visibly soiled.
5. Personnel working in the decontamination area should wear gloves, scrubs, water-repellent gown, and face mask with shield to protect eyes and shoe covers.
6. Exiting CPD: When leaving CPD areas for public areas, personnel will change scrubs if soiled. Mask, disposable bouffant cap, gloves, and shoe covers will be removed before exiting CPD.
7. Outside the Clinical Area (Exiting)
    a. When leaving restricted zones (operating rooms, procedural areas) for public areas, personnel will change scrubs if soiled.
    b. Mask, disposable bouffant cap, and shoe covers will be removed before entering the public area.
    c. Gloves will be removed/discarded upon leaving the area and hand hygiene performed.
    d. When returning to the restricted zone, hospital-provided scrubs and warm-up jackets ideally should be changed.
8. Signs will be posted at exits from restricted areas stating attire requirements.
9. Access to the department is restricted to departmental personnel unless permission to enter the Central Processing department is granted by a supervisor. Decontamination area may only be accessed by approved badges. Visitors will be instructed regarding dress requirements to enter the area (e.g., disposable coveralls, disposable cap). The decontamination area door is kept locked at all times.
10. Frequent hand hygiene with an antimicrobial agent (e.g., 2% chlorhexidine gluconate) or

waterless alcohol based agent (e.g. Purell) is encouraged. Good personal hygiene is stressed. The Hand Hygiene and Use of Antiseptics for Skin Preparation Policy should be strictly followed.

11. OSHA regulations state eating, drinking, applying cosmetics or lip balm and handling contact lenses are prohibited except in the break room in contaminated areas. The approved area for these activities is the staff break room.
12. All percutaneous, mucous membrane, and nonintact skin exposure to blood and other potentially infectious materials must be reported by calling the **Needlestick Hotline at 984-974-4480**. This service is available 24 hours a day.
13. Standard Precautions will be followed when handling equipment contaminated with blood or other potentially infectious materials.
14. The Tuberculosis Control Plan and the Exposure Control Plan for Bloodborne Pathogens will be followed. These policies are located on the Infection Control website.
15. Infection control education is provided annually, including the OSHA mandatory education for bloodborne pathogens and tuberculosis, through the Learning Made Simple (LMS).

IV. Implementation

The Manager(s) of Central Processing or his/her designee is responsible for the enforcement of the procedures in CPD.

Attachments:

01: Central Distribution Storage of Sterile Supplies
02: Procedure for Handling Stained Medical Records

Approval Signatures

Step Description	Approver	Date
Policy Stat Administrator	Patricia Ness: Clin Nurse Education Spec	08/2019
	Thomas Ivester: CMO/VP Medical Affairs [DW]	08/2019
	Emily Vavalle: Director, Epidemiology	08/2019
	Sherie Goldbach: Infection Prevention Registrar	08/2019

Applicability

UNC Medical Center