**PURPOSE:**

Effective procedures for cleaning, high-level disinfection and sterilization procedures in health care settings are vital to the prevention of hospital-acquired infections. Most high-level disinfection and sterilization takes place in the hospital central Sterile Processing Department. The purpose of this policy and is to describe the qualifications and procedure for staff performing high level disinfection at Children’s Hospital Los Angeles outside of the hospital central Sterile Processing Department.

**DEFINITIONS:**

1. **High Level Disinfection (HLD):** a process that results in the complete elimination of all microbial life with the exception of bacterial spores.
2. **Non-Critical item:** a patient care item that comes into contact with intact skin only
3. **Semi-Critical item**: a patient care item that comes into contact with non-intact skin or intact mucous membranes
4. **Critical item:** a patient care item that comes into contact with non-intact mucous membranes or normally sterile spaces in the body
5. **Single use item/ device:** an item that is intended by the manufacturer for one use or on a single patient during a single procedure.
6. **Reusable patient care item:** an item that is intended by the manufacturer to be reused on different patients.

**PROCEDURES:**

1. Sterilization of critical equipment should not be performed in any outpatient clinics or care centers; all critical equipment should be sent back to central hospital Sterile Processing Department (SPD) for reprocessing.
2. High Level Disinfection should be performed at the central hospital Sterile Processing Department when feasible. However, HLD may be performed outside of SPD if the following conditions are met:
   * Approval for performing HLD outside of the Sterile Processing Department is granted by the Medical Director of Infection Prevention and Control and the Infection Control Committee (ICC).
   * Infection Prevention and Control staff will inspect the facilities and equipment set up for performing high level disinfection outside of Sterile Processing Department to ensure all necessary equipment is present and the environment of care is acceptable per regulatory standards.
   * Staff performing high level disinfection, both on and offsite, shall undergo annual training in High-Level Disinfection.
   * Staff performing high level disinfection outside of Sterile Processing Department must complete an observed competency conducted by SPD and Infection Prevention and Control staff. This competency is maintained by the unit manager in the employee personnel file.

**High-Level Disinfection Steps:**

1. **Pre-Cleaning**

* Any instrument or item that will be High-Level Disinfected or Sterilized must be pre-cleaned with a hospital-approved enzymatic cleaner immediately after use to facilitate removal of bioburden.
* Items should be transferred from the patient room to the designated disinfection area in a covered biohazard bin.
* For items that are transferred from outpatient clinics or care centers to SPD, they should be pre-cleaned prior to transportation.
* Staff should don the following PPE prior to pre-cleaning: gown, face shield/eye protection, and mask.

1. **Manual Cleaning (not applicable for items disinfected in the Trophon automated probe disinfection system)**

* The employee who is performing manual cleaning with a chemical disinfection must wear personal protection that will include:

a. impervious gown

b. fluid-proof face mask

c. eye protection (i.e. splash proof goggles)

d. extended cuff gloves

* All surfaces and lumens of the equipment must be thoroughly and manually cleaned with an enzymatic cleaner and dried before disinfection.
* All blood, mucus, and other body fluids must be completely removed to ensure effective disinfection.

1. **High-Level Disinfection**
   1. Disinfection procedures will conform to the manufacturer Instructions for Use, as well as national standards disinfection (i.e. CDC, APIC, AORN, SGNA, ISHCSMM, TJC, and OSHA.)
   2. Guidelines specific to channeled endoscopes can be found in policy PER - 130.0 Reprocessing of Channeled Flexible Endoscopes.
   3. HLD will be performed only on reusable medical devices that are listed in the semi-critical category, which include those items that come in contact with unbroken skin or mucous membrane. These items include but are not limited to the following: respiratory equipment, anesthesia equipment, ENT equipment, TEE probes for Cardiology, vaginal/rectal ultrasound probes.
   4. Only chemical agents registered with the EPA as disinfectants are appropriate for high-level disinfection. Manufacturer Instructions for Use should be followed and only hospital-approved HLD solution should be used.
   5. The employee who is performing the disinfection must wear personal protection that will include:

* impervious gown.
* fluid-proof face mask.
* eye protection (i.e.: splash proof goggles).
* extended cuff gloves
  1. The disinfectant solution will be tested before use with hospital approved test strips and/or chemical indicator to ensure a consistent concentration. Results of testing shall be documented.
  2. The container storing the disinfectant will be labeled with the chemical being used and the expiration date if applicable. The disinfectant will be stored in a container that can be covered with a well fitting lid when not in use to prevent the escape of fumes into the general area.
  3. The instrument or item being High-Level Disinfectant must be allowed to remain fully immersed in the disinfectant for the length of time recommended by the manufacturer.
  4. All surfaces and lumens of the item should be thoroughly rinsed with sterile water following disinfection and dried before storage.
  5. Ultrasound probes reprocessed in the automated Trophon system should be cleaned and dried before being placed into the Trophon system. After the system has completed its disinfection, the probe should only be wiped with a clean cloth after disinfection (no rinsing with sterile water).

**Storage**

Devices must be stored in a way that prevents recontamination or damage between uses.

**Disposal**

The solution must be neutralized with an approved agent before the used solution may be discarded in standard sewer system. Alternately, if the pH of the neutralized solution has not been tested, the used solution will be hauled as toxic waste by an approved waste hauler.

**Employee Monitoring**

Employees involved in high-level disinfection should report to Employee Health immediately any symptoms suggesting overexposure to high level disinfection solution (i.e.: nausea, vomiting, respiratory, eye or skin problems).

**Transport**

Any instrument or item being transported for reprocessing must be transported by a hospital-approved courier service. Soiled items should be pre-cleaned prior to transport to help facilitate removal of bioburden. Items should be transported in a leak-proof, puncture-proof, covered biohazard bin.

**ATTACHMENTS**

1. [IC – 204.1 Appendix A Overview of Protocol for Enhanced Cleaning, Disinfection and Quality Control](https://secure.compliance360.com/ext/IiPMUmTeHZl_m2lC9JK9Ew==)

**RELATED POLICIES:**

1. [PER - 130.0 Reprocessing of Channeled Flexible Endoscope](https://secure.compliance360.com/ext/o_7eKyCQ24GJBsHWt17Z1Q==)
2. [PER – 113.0 Instrument Decontamination Process](https://secure.compliance360.com/ext/s_NnufjSI2m1yHygdsz0oQ==)
3. [IC – 219.0 Reprocessing of Single Use Devices](https://secure.compliance360.com/ext/Hl5rTK5thpfp9wpFNYomvQ==)

**REFERENCES:**

1. Rutala WA, ed. Cleaning, Disinfection and Sterilization. 2010
2. LA City Regulations on Management and Disposal of Toxic Wastes
3. APIC text of Infection Control and Epidemiology 4th Edition, 2014. Chapter 31 -Cleaning Disinfection and Sterilization.

**POLICY OWNER:**

*Executive Director, Accreditation & Licensing, Infection Prevention, and Emergency Management*