

Best Practices for High Level Disinfection – Part I

Nancy Chobin, RN, AAS, ACSP, CSPM, CFER

This material may not be published, broadcast, rewritten, or redistributed.
©2017 Sterile Processing University, LLC.

**This in-service has been Approved by the CBSPD for 1.5 CEUs.

The “Bible” for Chemicals is ANSI/AAMI - ST58:2013, “Chemical sterilization and high-level disinfection in health care facilities”. This document is a national standard that provides Guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the Food and Drug Administration for use in hospitals and other health care facilities. This in-service will only address high level disinfection.

The LCS/HLD products that have been cleared for market by the FDA are listed on the FDA website (www.fda.gov). The list is updated when new high level disinfectants are cleared for market. The information on the site includes:

- the concentration of active ingredients
- the sterilization or high-level disinfection contact time and temperatures, and the maximum reuse time period for each product.

This website also identifies the LCSs/HLDs cleared by the FDA in a 510(k) with claims for processing reusable medical and dental devices.

The HLD Environment – It is strongly recommended that there is a designated area for high-level disinfection. High-level disinfection should occur in a clean environment to prevent recontamination of the medical device as it is removed from the process. The space used for cleaning/decontamination should be separate from the space used for high-level disinfection of medical devices, and these spaces should be separate from patient procedure areas and personnel support areas. Material should flow in a one-way direction from the cleaning area to the high-level disinfection area and then on to storage or distribution. Where possible, solid walls should separate the cleaning area from the high-level disinfection area.

In GI/Endo a separate room for HLD is strongly recommended. In SPD, HLD should be performed in a clean area (e.g. the Prep/Packaging area), not in the Decontamination area. The floors, walls, and ceiling surfaces should be constructed of nonporous material and need to withstand frequent cleaning and wet conditions.

Policies and procedures should be standardized throughout the health care facility or area, with emphasis on necessary engineering controls, appropriate personal protective equipment (PPE), hygiene, and safe work practices.

Sufficient space is needed for the preparation, quality monitors, chemicals, record-keeping supplies, and hand hygiene facilities. The high-level disinfection process should be located in a restricted-access area and should not be performed in

- high-traffic areas,
- near any potential sources of contamination, such as scrub sinks, hoppers, wash sinks, or containers for the disposal of linen and trash.

Sinks of adequate size are needed for the disposal of the liquid chemical disinfectants.

Proper ventilation is needed to ensure an irritation-free, safe, and comfortable work environment. If you detect chemical odors it could mean that the ventilation might not be adequate. Sometimes the odors of chemical high-level disinfectants are masked (e.g. perfume scent is included in the formulation). That does not mean the chemical may be safe. The ventilation system should be designed to control potential airborne concentrations of HLD. Make sure that the ventilation system is operational at all times. High-level disinfectants should always be used in an area that is properly ventilated. The room/location where the HLD is being used should have a minimum air exchange rate of 10 air exchanges per hour (check local regulations – could be higher). Local exhaust ventilation should be located at the level of the point of discharge of the vapors and pull vapors away from the work area, not toward personnel in the room. Fans and open windows should not be permitted (will interfere with the proper function of the ventilation system).

Ventilation - Glutaraldehyde vapors are a respiratory irritant. In addition, the liquid can cause skin irritation. Always use glutaraldehyde products in a limited traffic area. The odors can be detected at 0.4ppm. Vents should be located at the point of discharge of the vapors (or at floor level) since glutaraldehyde fumes are heavier than air. If you cannot control the fumes with ventilation, you can use a need local exhaust hood.

Local Exhaust Ventilation - These units capture chemical vapors during processing. The hoods should be connected to non-re-circulating exhaust system to the outside of the building. If this is not possible, there are self contained systems.



One type of fume hood used to contain glutaraldehyde fumes

The system should be designed to maintain adequate air movement to capture vapor from the top of the container and thereby minimize personnel exposure. Follow the manufacturer's instructions for use (IFUs) for operation and maintenance of the unit.

Storage and Disposal of HLDs - Before using the HLD, consult with the IFU, the Safety Data Sheet (SDS) and the high-level disinfectant product label for the specific product regarding for storage instructions. Generally, unused chemical solutions should be stored in tightly closed containers; in a cool, secure and properly marked, well-ventilated area. They should not be stored under sinks which is an uncontrolled environment for temperature and humidity.

Topping Off - It is unacceptable to top off a basin or automated endoscope reprocessor (AER) with a HLD solution unless the HLD disinfectant manufacturer has provided IFUs on this process. Understand that some volume of loss occurs with each processing cycle. Topping off does not extend the use life days of the solution even if the Minimum Effective Concentration (MEC) testing is still met.

Training and Competencies - Competency should be assessed for all employees performing these activities upon orientation, whenever products or processes are changed, and at least annually thereafter. Only those personnel trained in the use of the specific high level disinfectant(s) in use are authorized to be in the areas where high level disinfection is performed. A copy of the Safety Data Sheet for the high level disinfectant(s) in use must be available and reviewed by staff members.

PPE - When processing instruments with chemical solutions, personnel should wear appropriate PPE designed to protect their skin, eyes, mucous membranes, and clothing from splashes. There should be a written policy and procedure for the PPE, including its correct use. Gloves, impervious to the chemical should always be worn if there is any possibility of contact with a chemical solution. Protect the forearms by wearing elbow-length gloves or by protective sleeves made of a material impervious to the chemical. Impervious or fluid resistant gowns provide additional protection to skin and clothing. Check with the manufacturer's SDS and written IFU for specific glove usage and protective clothing recommendations. Protect the eyes against contact with chemical solutions. Vapor levels must be kept below any applicable OSHA permissible exposure limit (PEL). Check the SDS and product literature for specific eye protection and first-aid guidance.

Emergency Eyewash Stations - Suitable eyewash units must be available for immediate emergency use in all places where chemicals are used. The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units (ANSI Z358). Employees who may be exposed to hazardous materials must be instructed in the location and proper use of emergency eyewashes.

Emergency eyewash units are available as a plumbed (connected to plumbing) or free-standing units. Eyewash units provide a minimum of 0.4 gallons per minute continuously for at least 15 minutes, that they be designed to flush both eyes simultaneously, and that they have a "hands-free, stay open" feature once activated. Under the ANSI standard, drench hoses or eyewash bottles are not acceptable emergency eyewash units. If installed on a sink, it must be a clean sink, not the Decontamination sink.



Above meets ANSI eyewash unit Requirements - Plumbed unit



Does not meet ANSI Requirements



Self-Contained Eyewash

Emergency eyewash units should be located within 10 seconds of travel time or 55 feet of travel distance of all chemical use locations. For a strong acid or strong caustic, the eyewash unit should be immediately next to the hazard. A door is considered to be an obstruction. "Where the hazard is not corrosive, one intervening door can be present so long as it opens in the same direction of travel as the person attempting to reach the emergency eyewash and shower equipment and the door is equipped with a closing mechanism that cannot be locked to impede access to the equipment."

In addition:

- Nozzles and flushing fluid units shall be protected from airborne contaminants (caps). The caps should remain on the unit to prevent contamination of the eyewash.
- The caps should automatically “pop” off when the unit is activated; - should not require a separate motion by the operator when activating the unit.



- Be located in an area identified with a highly visible sign positioned so the sign shall be visible within the area served by the eyewash.



- Plumbed eyewashes should be activated (tested) weekly for a period long enough to verify operation and ensure that the flushing solution is available (15 minutes).
- When activating plumbed eyewashes verify that the unit is providing lukewarm, tepid water (between 15°C and 43°C [60°F and 100°F]). (ANSI Z358.1).
- Routine testing and water temperature should be documented.

Definitions -

- **Low level disinfection** – A process that kills most vegetative bacteria, some viruses, and some fungi, but not mycobacteria or bacterial spores.

- **Intermediate level disinfection** - A process that kills viruses, mycobacteria, fungi, and vegetative bacteria, but not necessarily bacterial spores.

NOTE: The above disinfectants are used for environmental disinfection only. This means they should only be used on non-living surfaces such as floors, walls, counters, etc.

- **High Level Disinfection** - A process that kills all microbial organisms but not necessarily large numbers of bacterial spores.
- **High Level Disinfectant** - A chemical capable of killing bacterial spores when used in sufficient concentration under suitable conditions.

NOTE: High Level Disinfectants should only be used on patient care devices which will be used directly on/in the patient (i.e. flexible endoscopes).

- **Sterilization** - Is a validated process used to render a product free from viable microorganisms.
- **Tuberculocidal** – is a disinfectant that kills TB (tuberculosis) microorganisms.
- **Bacteriostatic** – is an agent that inhibits bacterial growth.
- **Bactericidal** – any substance capable of killing bacteria.

***Spaulding’s Classifications** - The Spaulding classification of a device will determine the level of disinfection required. Items are categorized into three groups:

- **Critical** items – enter sterile tissue; the device must be sterile when used.
- **Semi critical** items – come in contact with intact mucous membranes or non-intact skin. These require at least high level disinfection.
- **Non-critical items** – come in contact with intact skin. These only need sanitization.

(*Spaulding, 1972)

Cleaning - Cleaning is an essential step in any high-level disinfection process. The HLD process has been tested against a known number of microorganisms. Therefore, its success depends on the cleanliness of the items to be processed. Organic matter can dilute or inactivate the active ingredients in the high level disinfectant which can interfere with its contact to the device surfaces. Processing personnel should visually inspect each item carefully to detect any visible soil. Inspection using magnification (e.g. lighted magnifying lamp) might identify residues more readily than the unaided eye. Visual inspection alone may not be sufficient for assessing the effectiveness of the cleaning process (e.g. cleaning effectiveness testing). The introduction of detergents (e.g. if the device is inadequately rinsed after cleaning) can alter the pH of the HLD solution making the HLD process ineffective.

General Disinfection Guidelines

- Items must be thoroughly cleaned.
- Follow the disinfectant manufacturer's instructions for use, concentration, contact time, rinsing, etc.
- Understand that the temperature of the solution may affect the effectiveness of the disinfectant.
- All surfaces of the device must make direct contact with the disinfectant.
- Use a syringe to draw the HLD into lumened devices.
- All items processed with HLDs should be thoroughly rinsed.
- Follow the manufacturer's written IFU regarding the quantity and quality of the rinsing solution needed to reduce chemical residues.
- You need to know how many rinses are recommended.
- The rinse water should NOT be reused.
- Rinsing should take place in a separate, clean container or other clean sink.
- The contact time, temperature and concentration of the chemical vary with different disinfectant products.
- Water quality can interfere with the action of the chemicals.
 - If air is entrapped within a device the disinfectant cannot reach the device. This is especially true of lumened devices.
- Read the product label for use and rinse water recommendations (e.g. sterile water).
- Read all safety information.
- Your chemical probably requires a spill plan; first aid steps. You need to know these.
- Never use environmental disinfectants for medical devices being used in patients.
- Use a timer as the "gatekeeper" to ensure the recommended soak time is achieved.

Shelf Life and Use Life - HLDs have a shelf life and use life. The **shelf life** is the date that is printed on the jug. This date is the date the bottle must be opened and used by. **Use life** is how long the HLD can be used once activated or opened. This can be 7, 14, 28 days, depending on the product and formulation. You must read the label for the use life. Understand that the use life can be affected by soils, temperature and in-use dilution (not completely drying an item so the residual water dilutes the concentration of the HLD making it ineffective). This is why the solution is tested before each use.

Solution Effectiveness – It is important to remove all excess moisture from items being processed. High level disinfectants can be diluted by water remaining on the surfaces and in the lumens of items.

The concentration of the HLD active ingredient can be reduced to a level that is too low to be effective in killing certain microorganisms within the recommended exposure time. Therefore, the effectiveness of the solution (called Minimum Effectiveness Testing (MEC) - also called Minimum Recommended Concentration testing or MRC) should be routinely tested. This testing verifies the minimum concentration of a high-level disinfectant that achieves the claimed microbicidal activity. AAMI recommends testing the HLD solution before EACH use.

It is recommended to use the test strips from the HLD manufacturer to test the solution since these tend to be more accurate. Only use the appropriate solution test strip or chemical monitoring device to test the HLD solution. The solution test strip or chemical monitoring device should be read before the HLD solution is used. If the interpretation of the solution test strip suggests that the concentration of the active ingredient is inadequate, the solution should be discarded even if it is within its use life. Always refer to the visual color interpretation reference charts.

All MEC/MRC testing should be documented. You must follow the test strip manufacturer's instructions for storage, use and interpretation.

REFERENCES:

AAMI, ANSI/AAMI - ST58:2013: Chemical sterilization and high-level disinfection in health care facilities.

The Basics of Sterile Processing textbook, 6th edition, Sterile Processing University, LLC.

QUIZ: HIGH LEVEL DISINFECTION - PART I

Please click on the link below to take the quiz.

https://www.spdceus.com/ceus/2017/hld1_quiz.html

Good Luck!