Best Practices for High Level Disinfection

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Objectives

- To define disinfection
- To review general disinfection guidelines
- To discuss the commonly used high level disinfectants in healthcare; glutaraldehyde, ortho-phthaldehyde, Trophon
The “Bible” for Chemicals

- ANSI/AAMI
- ST58:2013
- Chemical sterilization and high-level disinfection in health care facilities
This recommended practice 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 U.S. Food and Drug Administration for use in hospitals and other health care facilities.
What is Available?

- Products containing the following active ingredients are marketed under various brand names and in various concentrations:
  - glutaraldehyde
  - glutaraldehyde with phenol-phenate
  - hydrogen peroxide
  - sodium hypochlorite–hypochlorous acid
  - ortho-phthalaldehyde
  - combinations of peracetic acid and hydrogen peroxide
The LCS/HLD products that have been cleared for market by the FDA are listed at:


This list is updated as new products are cleared and includes the concentration of active ingredients, the sterilization high-level disinfection contact time and temperatures, and the maximum reuse time period for each product.
This website identifies the LCSs/HLDs cleared by the FDA in a 510(k) with claims for processing reusable medical and dental devices.
Selecting a HLD

- Has the liquid chemical sterilant/high-level disinfectant or gaseous chemical sterilization system been cleared by the FDA?
- When should chemical sterilization/high-level disinfection be selected?
- What types of medical devices are suitable for sterilization or high-level disinfection by this product or process?
Selecting a HLD

- What criteria were used to determine the suitability of a device for chemical sterilization or high level disinfection?
- How is sterilization or high-level disinfection accomplished? (What is the process, and how is it used?)
- Is a dedicated container or other equipment needed in order to use the LCS/HLD? If so, does the LCS/HLD manufacturer have material requirements for the container?
Selecting a HLD

- How can the efficacy of the product be measured? How can the user determine whether the product is effective, initially and after several uses? (For example, is there a test to determine the concentration or strength of the active chemical?)
- How can the efficacy of the process be measured? Can the process be monitored with physical, chemical, and biological indicators? What kind of qualification, routine, and product testing is required for the process?
Selecting a HLD

- How is the device handled after processing to prevent recontamination?
- What are the limitations of the product or process?
- Before exposing a device to the product or process, how should it be cleaned?
- How much time is required for the sterilization or high-level disinfection process?
Selecting a HLD

- Is the system user friendly? For example, how many steps are involved in the process?
- Has the medical device to be sterilized or high-level disinfected been validated for efficacy and verified for compatibility with the process? Is any special preparation needed for the device before processing (e.g., disassembly)?
Selecting a HLD

- Is control of water quality critical to the process? If so, what water quality is necessary? What water control steps are necessary?
- What are the requirements for record-keeping?
- If lumened instruments are a consideration, will the lumen achieve adequate contact?
- What type of quality control monitor will be used?
Safety

- Health care personnel should take into account some health and safety considerations when selecting a chemical sterilant/high-level disinfectant, including:
- To what extent has toxicity testing been performed?
- Has a copy of the SDS (formerly known as MSDS) been provided?
Safety

- What are the potential short- and long-term adverse health effects of overexposure to the chemical sterilant/high-level disinfectant?
- Is the chemical sterilant/high-level disinfectant potentially toxic to personnel? In what way? Are there toxic vapors or toxic byproducts? Does the chemical sterilant/high-level disinfectant react with certain materials (e.g., cleaning agents, adhesives) to form toxic products?
Safety

- At what level of exposure is the chemical sterilant/high-level disinfectant toxic to humans? By what route of exposure is it toxic (skin contact, inhalation)? Is there an applicable OSHA regulation for occupational exposure? If so, what is the PEL established by OSHA for the active ingredient?
- How would the user be able to detect toxicity problems? What are the symptoms of adverse health effects?
Safety

- What PPE is required? Do the chemical sterilant/high-level disinfectant manufacturer’s written IFU indicate that special types of gloves are required when working with the product?
Safety

- Is environmental or personnel monitoring required by OSHA, recommended by ACGIH®, or necessitated by the potentially hazardous nature of the sterilant? If so, which methods are appropriate?

- Are there specific IFU that explain how toxic conditions or reactions can be avoided during use? (i.e. must time, temperature, or humidity be controlled?)
Safety

- Should a local exhaust hood be used?
- Are special storage conditions necessary for the chemical?
- Does the chemical sterilant/high-level disinfectant leave residues on processed items that could be toxic to patients or health care personnel? Is there a method of reducing residues on processed items to nontoxic levels?
Safety

- What level of in-service instruction or other personnel training in the safe use of the chemical sterilization system does the manufacturer provide?
- What level of testing has been done to determine that processed devices remain safe for patient use after repeated processing?
Safety

• Is it necessary to retain employee health records? If so, for how long?
• Where will the eyewash station be located? Are existing eyewash stations placed appropriately, and are they adequate for the chemical sterilant/high-level disinfectant?
HLD Environment

- Designated area for high-level disinfection is strongly encouraged.
- 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 chemical sterilization or high-level disinfection of medical devices, and these spaces should be separate from patient procedure areas and personnel support areas.
HLD Environment

- 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 chemical sterilization/high-level disinfection area.
HLD Environment

- The floors, walls, and ceiling surfaces should be constructed of nonporous material that will withstand frequent cleaning and wet conditions.
- Policies and procedures should be standardized throughout the health care facility, with emphasis on necessary engineering controls, appropriate personal protective equipment (PPE), hygiene, and safe work practices.
HLD Environment

- Adequate space should be provided for preparation, quality monitors, chemicals, record-keeping supplies, and hand hygiene facilities.
- The high-level disinfection process should be located in a restricted-access area.
- High-level disinfection should not be performed in high-traffic areas or 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 for the disposal of the liquid chemical disinfectants are recommended.
Ventilation

- Proper ventilation will help ensure an irritation-free, safe, and comfortable work environment.
- Chemical odors could be the first indication that the ventilation might not be adequate.
- The sharp, pungent odors of chemical high-level disinfectants could be masked if a perfume scent is included in the formulation.
- The ventilation system should be designed to control potential airborne concentrations of chemical sterilants, and measures should be taken to ensure that it is operational at all times.
General Ventilation

- Chemical sterilants/high-level disinfectants should be used in an area that is properly ventilated.
- Rooms in which chemical disinfection is performed should be large enough to ensure adequate dilution of vapor and should have a minimum air exchange rate of 10 air exchanges per hour (local regulations might require a higher minimum exchange rate).
- Ideally, 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.
- CAUTION—Fans and open windows will interfere with the proper function of the ventilation system and should not be permitted.
Local Exhaust ventilation

- When general room ventilation is not adequate a self-contained, freestanding system or a local exhaust hood should be installed to capture chemical vapor during processing.
- The local exhaust system should be designed to maintain adequate air movement to capture vapor from the top of the container and thereby minimize personnel exposure.
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.
PPE

- When processing instruments with chemical solutions, personnel should wear appropriate PPE designed to protect their skin, eyes, mucous membranes, and clothing from splashes.
- The health care facility should develop a written policy and procedure for the PPE, including its correct use.
Eye Protection

- Eyes must be protected against contact with chemical solutions.
- To prevent eye irritation, vapor levels must be kept below any applicable OSHA permissible exposure limit (PEL).
- The manufacturer’s SDS (formerly known as MSDS) and product literature should be consulted 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 Z358.1).
ANSI Requirements Eyewash

- 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.
ANSI Requirements Eyewash

- Emergency eyewash units should be located within 10 seconds of travel time or 100 feet of travel distance of all chemical use locations; for a strong acid or strong caustic, the eyewash unit should be immediately adjacent to the hazard.

- The eyewash facilities should be identified with a highly visible sign and should be maintained in accordance with the manufacturer's written IFU.
Before attempting to implement the ANSI standard, health care personnel should consult the standard to familiarize themselves with all its provisions.
ANSI Requirements Eyewash

- Plumbed eyewashes/facewashes and showers should be activated weekly for a period long enough to verify operation and ensure that the flushing solution is available.
- When activating plumbed eyewashes, eye/facewashes, and showers, personnel should also verify that they are providing lukewarm, tepid water (between 15°C and 43°C [60°F and 100°F]). (ANSI Z358.1).
- Routine testing should be documented.
Emergency Eyewash

- Controlled, low velocity flow rinses both eyes and is not injurious to user. (Section 5.1.1)
- Water flow is sufficiently high to allow user to hold eyes open while rinsing. (Section 5.1.2)
- Unit must deliver at least 0.4 gallons (1.5 liters) of water per minute for 15 minutes. (Section 5.1.3)
- Outlet heads shall be positioned between 33" (83.8 cm) and 45" (114.3 cm) from the floor and at least 6" (15.2 cm) from the wall or nearest obstruction. (Section 5.4.4)
- Protect spray heads from airborne contaminants. Covers shall be removed by water flow. (Section 5.1.3)
- Valve actuator shall be easy to locate and readily accessible to user. (Section 5.2)
- "Hands-free" stay-open valve activates in one second or less. (Section 5.1.4, 5.2)
- Unit washes both eyes simultaneously. Water flow covers area indicated on Guardian test gauge. (Section 5.1.8)

**LOCATION**
Install eyewash unit within 10 seconds (approximately 50 feet) of hazard, on the same level as hazard and with unobstructed travel path. Where strong acids or caustics are being handled, the eye/face wash shall be located immediately adjacent to the hazard. (Section 5.2.1.8)

**IDENTIFICATION**
Identify eyewash with highly visible sign. Area around eyewash shall be well lighted. (Section 5.4.3)

**WATER TEMPERATURE**
Water delivered by eyewash shall be tepid (60-100°F). (Section 5.4.5)

**TRAINING**
Instruct all employees in the location and proper use of eyewashes. (Section 5.4.4)

**MAINTENANCE/INSPECTION**
Activate eyewash at least weekly. (Section 5.5.2) Inspect annually for compliance with standard. (Section 5.5.3)
Definitions

- **Disinfection** - process of killing most pathogenic m/o but not necessarily spores
- **Disinfectants** - chemicals used on inanimate objects/surfaces
- **Antiseptics** - chemicals used to reduce m/o on body surfaces
Definitions

- **Sterilization** - destruction of all microbes including spores
- **Tuberculocidal** - kills TB microorganisms
- **Bacteriostatic** - inhibits bacterial growth and leaves a residual film
- **Bactericidal** - kills bacteria
Levels of disinfection

- low level – usually environmental
- intermediate level - environmental
- high level – patient care device (e.g. flexible endoscope)
Spaulding’s Classifications*

- **Critical** – enters sterile tissue; must be sterile when used
- **Semi critical** – comes in contact with intact mucous membranes – needs to be HLD
- **Non-critical** – comes in contact with intact skin – needs sanitization
General Disinfection Guidelines

- Items must be thoroughly cleaned
- Follow disinfectant manufacturer’s instructions for use, concentration, contact time, rinsing, etc.
- Temperature may affect efficacy of the disinfectant
- All surfaces of the device must make direct contact with the disinfectant
- Use syringe to suction into lumened devices
General Disinfection Guidelines

- Contact time, temperature and concentration of the chemical vary with products
- Water quality can interfere with the action of the chemicals
- If air is entrapped within a device the disinfectant cannot reach the device
  - Especially true of lumened devices
General Disinfection Guidelines

- Read the product label for use and rinse water recommendations (e.g. sterile water)
- Read all safety information
- Use in well ventilated area
- May require spill plan; first aid steps
- Never use environmental disinfectants for medical devices being used in patients
- Need emergency eyewash wherever being used
Shelf Life and Use Life

- HLDs have a shelf life and use life
  - **Shelf life** – printed on jug – gives the date the bottle must be opened and used
  - **Use life** is how long the HLD can be used once activated or opened
    - Can be 7, 14, 28 days
    - Must read the label
  - Use life affected by soils, temperature and in-use dilution
Hierarchy of Microorganisms

- **PRIONS** → Sterilization extended
- **SPORES** → Sterilization
- **Mycobacteria (TB)** → High level disinfection
- **Non-lipid/sm viruses** → Int. level disinfection
- **Fungi** → Int. level disinfection
- **Vegetative bacteria** → Low level disinfection
- **Lipid/med. Size viruses (HBV,HIV)** → Low level disinfection
Glutaraldehydes

- High level disinfectant for immersible items
- Acid and alkaline preparations
  - Rapicide, Cidex, Aldahol, etc.
- Solution must make contact with all surfaces of the device
- Thorough pre-cleaning required!
Glutaraldehydes

- Mainly used for flexible and rigid scopes
  - Can also be used for laryngoscope blades; require HLD
- Non corrosive to plastic, metal and lensed instruments
Glutaraldehydes

- Requires activation with a buffered agent
- Gets added to solution in jug.
- Once activated, product good for 14-28 days depending on formulation used
- **Minimum Effective Concentration (MEC)**
  - Check before each use
  - Use test strips provided by mfr
- Soak time 10-45 min (usually)
- Use life affected by soils, temperature and in-use dilution
Cidex with Activator
Glutaraldehyde Solutions

- In 2% solution effective against all vegetative bacteria, viruses, TB and fungi
- Can be toxic, requires thorough rinsing to remove all residues
  - can cause sloughing of tissue
- Quality of rinse water issue-can re-contaminate device
- Mix according to manufacturer’s instructions, date solution made, when expires (different formulations)
Glutaraldehyde Solutions

- After soaking, thorough rinsing (x 3) with **sterile water** recommended to prevent re-contamination (if need to present sterile otherwise potable water)
- Containment of device from solution to use needs to be addressed
- Use in well-ventilated, restricted area
- Monitoring devices and neutralization pads available
Neutralization Pads

- Specifically designed to both absorb and neutralize small spills.
- Plastic backing for extra protection.
- Large size, approximately 170 square inches.
- Place under and around soaking baths.
- Avoids use of towels which can expose personnel to fumes.
Minimum Effective Concentration

- Called MEC testing (also called Minimum Recommended Concentration MRC)
- Verifies the minimum concentration of a liquid chemical sterilant/high-level disinfectant that achieves the claimed microbicidal activity
- AAMI recommends testing the HLD solution before EACH use
- Best accuracy is with the strip provided by the HLD manufacturer
MEC/MRC Testing

- Testing should be documented
- Must follow the test strip manufacturer’s instructions for storage, use and interpretation
Glutaraldehyde

- QA testing of strips (if recommended)
  - Test each bottle when opened-date bottle
  - 2 solutions; one full strength; one half strength
  - Use 3 strips per solution; verify full strength passes; half strength fails
  - Must be documented separately from MEC testing
Cidex Generic Test Strips
MEC Testing for HLDs
Glutaraldehydes

- **Proper ventilation**
  - vapors respiratory irritant; liquid skin irritant
- **Use in limited traffic area**
- **Odors can be detected at 0.4ppm**
- **Vent location - point of discharge of the vapors (or at floor level)**
Glutaraldehydes

- May need local exhaust hood
  - captures vapors during processing
  - should be connected to non-re-circulating exhaust system to the outside
  - self contained systems

- Monitor fume hoods for efficacy
Fume Hood
Glutaraldehydes

- **Personal protective equipment**
  - eye shields, fluid resistant mask (for liquid not fumes), butyl rubber gloves (no vinyl or neoprene), polyethylene gown with long sleeves
- **Store solution covered**
Glutaraldehydes

- OSHA Ceiling limit for exposure 0.2ppm
- ACIGH recommends 0.05 ppm (American Congress of Industrial and Governmental Hygienists)
- In the absence of an PSHA standard, OSHA defers to the ACIGH
- Levels therefore should be below 0.05 ppm
Glutaraldehydes

- Spill Plan needed (ammonia)
- Disposal - check local or state restrictions
- Requires dilution with copious amounts of running water
- Dispose of containers per label instructions
Glutaraldehyde:

- Many formulations of glutaraldehyde in use today such as:
  - Cidex®
  - Aldahol®
  - Rapicide™
  - Banicide Advanced®
  - Sporicidin®
  - Cetylcide-G®
  - Procide-D®

- Omnicide™
- Metricide®
- Wavicide-01®

NOTE Some of these formulations are only validated for use in AERs.

NOTE 2: There are additional formulations; all are listed in FDA (2009).
Ortho-phthalaldehyde (0.55%) Cidex OPA

- Non-Glutaraldehyde
- Non-toxic
- 12 minute soak time for manual high level disinfection at MINIMUM of 68 deg.F.
- No employee monitoring
- Stains proteins
- Non-forgiving - must use as directed
- Bladder cancer patient sensitivity
Thermometer
Rinsing

- Must rinse 3 times – do not reuse rinse water
- Use copious amounts of water
- Needs to be rinsed in clean container not a handwash or other sink
Cidex OPA

- Has 14 day use life
- Unused portion can remain in original bottle for 75 days
- Use in well ventilated area
- PPE needed
- May have to double glove (protein)
- Must verify temperature of solution is 68°F before use
- Spill kit recommended
Cidex OPA

- Company has guidance on how to heat up solution if minimum temperature cannot be achieved.
- Requires a thermometer to monitor temperature before and during immersion.
Heat-Up Pad for Cidex OPA
Cidex OPA

- Has a 5 minute HLD claim - **only when used in an automated scope re-processor that can elevate the temperature of the solution**

- 5 minute claim **DOES NOT** apply to OPA when used without an AER
Trophon

- For high level disinfection of ultrasound probes ONLY
- Achieves HLD of ultrasound probes (including shaft and handle) in 7 minutes
- Probe must be pre-cleaned first
- Sterilant - NanoNebulant Concentration 35%; Sonex-HL (USA/CAN)† Volume – 80 ml
- Shelf Life – 2 years
Trophon

- At the beginning of the cycle, the Trophon EPR creates an aerosol of concentrated hydrogen peroxide.
- Hydrogen peroxide is distributed over the surface of the probe, including very small crevices.
- Provides high level disinfection of the shaft and the handle of the probe.
Trophone Unit - Inside
**Trophon**

- Requires a chemical indicator in each cycle
- Small quantities of oxygen and water are the by-products
- Place the pre-cleaned and dried probe into the disinfection chamber,
- Insert a chemical indicator disk and close the door
- Press the start button.
At the end of the cycle, open the Trophon EPR door; remove the probe.

Wipe the probe with a lint free cloth.

Confirm successful high-level disinfection by comparing the chemical indicator disk to the color assessment chart.

Print a disinfection label using the optional Trophon Printer.
The Trophon EPR is **NOT** intended to reprocess single use devices

The Trophon EPR is **NOT** intended to pre-clean ultrasound probes

Cartridges will last for approximately one month from date of installing

The device will automatically prompt to run a purge cycle if it detects that the disinfectant cartridge has been in the device for too long and has expired.
Trophon Unit

- Only validated probes should be placed in the Trophon® EPR.
- All probes referred to on the Validated Probe List have been tested and validated according to the manufacturer’s specifications.
Requirements

- The probe must be pre-cleaned and dried BEFORE the High Level Disinfection process can commence.
- Failure to clean and dry the probe may result in:
  - high level disinfection not being achieved during the Trophon® EPR disinfection cycle
  - the contribution of additional residue on the probe
Requirements

- Must wear gloves when inserting probe
- Must be loaded correctly to prevent damage to the tip of the probe
- Incorrect positioning of the probe may result in:
  - High level disinfection will not be achieved during the Trophon EPR disinfection cycle
  - Excessive disinfectant residuals remaining on the probe surface
  - Damage to the probe
Requirements

- At the end of the cycle, don clean gloves
- Remove probe
- Wipe with single use lint free cloth
- Check the color change of the chemical indicator
- Empty used cartridges should be disposed of in the nearest waste receptacle or according to the facility disposal guidelines.
2. Insert Chemical Indicator as shown. Pre-clean and insert probe as shown. Commence disinfection cycle. CI red when unprocessed.
CI turns Yellow after Processing
Laryngoscope Handles and Blades

- Must be cleaned, HLD or sterilized according to the IFUs
- If HLD can be placed in a zip lock bag with a CLEAN NOT STERILE label affixed over the top
- All items that are HLD must be protected from re-contamination and identified as having been HLD
Monitoring the Process

- Document/record all items processed (including serial# for scopes), patient
- Include documentation of cleaning
- Record all monitoring (CI, MEC)
Monitoring the Process

- Retain with other sterilization records
- Record retention time based upon your facility’s attorney
- Verify competencies for personnel using chemicals
Summary

Effective chemical disinfection requires:

- thorough pre-cleaning of the device
- proper mixing of the chemical
- proper concentration/temperature
- proper documentation of the process
- proper PPE
- proper ventilation/location
Questions?