Best Practices for High Level Disinfection - Revisited

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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
- To review recommendations from ANSI/AAMI Chemical Sterilization and High Level Disinfection in HCF, 2013 (ST-58).

The "Bible" for Chemicals

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

ST-58

- National standard - 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 program will only address HLD

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

FDA

- The LCS/HLD products that have been cleared for market by the FDA are listed at the fda website
- The list is updated when new products are cleared
- Includes
  - the concentration of active ingredients
  - the sterilization high-level disinfection contact time and temperatures, and the maximum reuse time period for each product.

Selecting a HLD

- Is the system user friendly? (How many steps are involved in the process)?
- Has the medical device to be high-level disinfected been validated for efficacy and verified for compatibility with the process?
  - **NOTE: The device manufacturer must provide recommendations regarding which HLD processes have ben validated for their device**
- Is any special preparation needed for the device before processing (e.g. disassembly)?

Safety

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

Safety

- What PPE is required?
- Do the high-level disinfectant manufacturer's written IFU indicate that special types of gloves are required when working with the product? (can be a cost factor)
- Do you have to purchase "special" PPE?

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

- What level of in-service instruction or other personnel training in the safe use of the chemical 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 high-level disinfectant?

HLD Environment

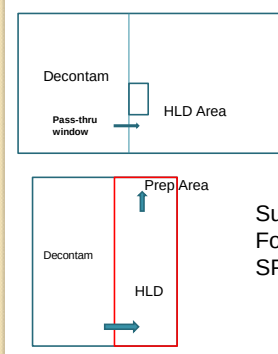
- Designated area for high-level disinfection is strongly encouraged.
- High-level disinfection should occur in a clean environment to prevent recontamination of the medical device as it is removed from the process.
- The space used for cleaning/decontamination should be separate from the space used for 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 high-level disinfection area.

HLD Room

- In GI/Endo a separate room for HLD is strongly recommended
- In SPD, HLD should be performed in the Prep/Packaging area – not Decontam



Suggested Layouts For HLD areas in SPD

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

- You need sufficient space 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.
- If you detect chemical odors it could mean that the ventilation might not be adequate.
- Sometimes the sharp, pungent odors of chemical high-level disinfectants are masked (e.g. perfume scent is included in the formulation).
- The ventilation system should be designed to control potential airborne concentrations of HLD.
- Ensure that the ventilation system is operational at all times.

General Ventilation

- High-level disinfectants should always be used in an area that is properly ventilated.
- The room/location where the HLD is being used 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.
- Follow the manufacturer's IFUs for operation and maintenance of the unit

Storage and Disposal of HLDs

- Before using the HLD, consult with the IFU, the 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, properly marked, well-ventilated area
  - should not be stored under sinks.

Storage and Disposal of HLDs

- Outdated chemicals should be disposed of in accordance with accordance with the manufacturer's written IFU and with federal, state, and local ordinances.
- Empty containers should be disposed of in accordance with the disposal instructions given on the product label.

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.

Training and Competencies

- Ensure that only those personnel trained in the use of the specific high level disinfectants(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.
- The health care facility should develop a written policy and procedure for the PPE, including its correct use.

PPE

- Skin should be protected against contact with chemical solutions.
- Gloves impervious to the chemical should always be worn if there is any possibility of contact with a chemical solution, including the handling of the HLD solution containers, bottles, or cassettes.
- The forearms should be protected by elbow-length gloves or by protective sleeves made of a material impervious to the chemical.

PPE

- Isolation gowns or aprons plus sleeve protectors that are made of appropriate protective materials provide additional protection to skin and clothing.
- The manufacturer's SDS and written IFU should be consulted for specific glove usage and protective clothing recommendations.

PPE

- Protective clothing should be removed quickly if it becomes saturated, and it should be laundered before reuse.
- If any skin contact with a chemical solution should inadvertently occur, the skin should be washed thoroughly with soap and water and should be flushed with water for at least 15 minutes.

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).
- Refer to the manufacturer's SDS and product literature should 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).

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

Correct and Incorrect Emergency Eyewashes

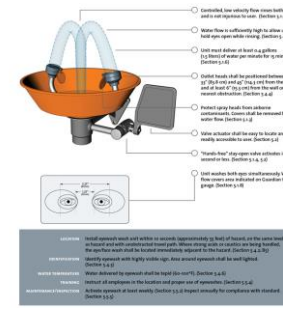
ANSI Requirements Eyewash

- 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 person who has experienced a chemical splash to the eyes or face may be visually impaired, in discomfort or pain, and in a state of panic. For this reason, it is prudent to consider the physical and emotional state of the person as well as the availability of assistive personnel in the immediate area when determining the location of eyewash stations (ANSI Z358).
- The eyewash facilities should be identified with a highly visible sign and should be maintained in accordance with the manufacturer's written IFU.

ANSI Requirements Eyewash

- Before attempting to implement the ANSI standard, health care personnel should consult the standard to familiarize themselves with all its provisions.

Emergency Eyewash



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.

Definitions

- **Low level -** Process that kills most vegetative bacteria, some viruses, and some fungi, but not mycobacteria or bacterial spores
- **Intermediate level -** Process that kills viruses, mycobacteria, fungi, and vegetative bacteria, but not necessarily bacterial spores.

Definitions

- **High Level Disinfection** - 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.
- (According to the FDA, HLD is a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass the AOAC sporicidal activity test as a sterilant.)

Definitions

- **Sterilization** – Validated process used to render a product free from viable microorganisms.
- **Tuberculocidal** - kills TB microorganisms
- **Bacteriostatic** – 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
- **Critical** – enters sterile tissue; must be sterile when used
- **Semi critical** – comes in contact with intact mucous membranes or non-intact skin – requires HLD
- **Non-critical** – comes in contact with intact skin – only needs sanitization

(*Spaulding, 1972)

Cleaning

- Thorough cleaning of items is an important initial step in any high-level disinfection process.
- The process has been tested against a known number of microorganisms, and 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 and can interfere with its contact to the device surfaces.

Cleaning

- Processing personnel should visually inspect each item carefully to detect any visible soil.
- Inspection using magnification might identify residues more readily than the unaided eye.
- Visual inspection alone may not be sufficient for assessing the effectiveness of the cleaning process.

Cleaning

- Substances such as soap, detergent, cork, cotton, lint, cotton wool, cellulose sponges, and the minerals found in hard water also might affect the efficacy of the HLD disinfectant.
- The introduction of detergents (for example, as could occur if the device is inadequately rinsed after cleaning) can alter the pH of the HLD solution.

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
- May require spill plan; first aid steps
- Never use environmental disinfectants for medical devices being used in patients

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 that have been validated for 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

Excess Moisture

- For most HLD processes, it is necessary to remove excess moisture from items being processed.
- The HLD manufacturer's written IFU should be consulted for guidance regarding whether moisture removal is essential.
- HLDs can be diluted by water remaining on the surfaces and in the lumens of items, and 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.

Minimum Effective Concentration

- Called MEC testing (also called Minimum Recommended Concentration MRC)
- Verifies the minimum concentration of a high-level disinfectant that achieves the claimed microbicidal activity
- AAMI recommends testing the HLD solution before EACH use

Test Strips

- Health care personnel should use the appropriate solution test strip or chemical monitoring device to test the HLD solution. The solution should be tested before each use.
- The solution test strip or chemical monitoring device should be read before the HLD solution is used.

Test Strips

- If the interpretation of the solution test strip or chemical monitoring device, performed in accordance with the manufacturer's written IFU, suggests that the concentration of the active ingredient is inadequate, the solution should be discarded even if it is within its use life.
- Refer to the visual color interpretation reference charts.

MEC Testing for HLDs

MEC/MRC Testing

- Testing should be documented
- Must follow the test strip manufacturer's instructions for storage, use and interpretation
- New information on shelf life of test strips

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

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-phthaldehyde (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

Water Quality

- When preparing use solutions (i.e., activated, diluted, or ready-to-use), the user should follow the HLD manufacturer's written IFU concerning the quality of the water to be used in the formulation.
- For some LCSs/HLDs, it might be acceptable to use potable water; for other solutions, softened water or other treated water may be needed. If a water treatment process is used, it should be monitored to ensure that the appropriate water quality is achieved.

Water Quality

- All items processed with HLDs should be thoroughly rinsed, with strict adherence to the manufacturer's written IFU regarding the quantity of rinsing solution needed to reduce chemical residues.
- 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.

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 (glycine)

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.

Trophon 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.

Trophon

- 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.

Trophon

- 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

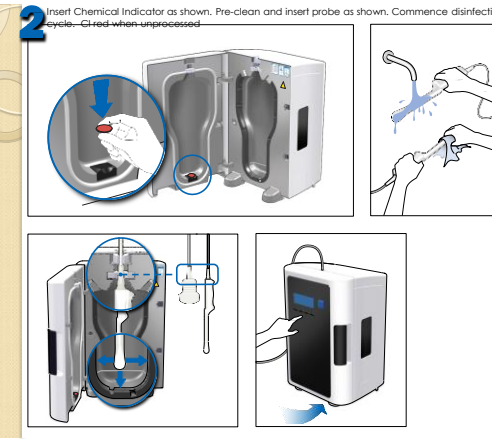
- The probe must be pre-cleaned and dried BEFORE the High Level Disinfection process can commence.
- Failure to clean and dry the probe may result in:
- high level disinfection not being achieved during the Trophon® EPR disinfection cycle
- the contribution of additional residue on the probe

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.



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

TEE Probes

- **Effective December 31, 2015, the Intersocietal Accreditation Commission (IAC) will require that you perform electrical leak tests on all transesophageal (TEE) ultrasound transducers between each use.**
- **In addition, you will need to document whether the test passes or fails in a log, with appropriate action taken if the probe fails.**

TEE Probes

- An electrical leak test checks for damage to the shaft of the TEE probe that could result in electrical discharge to a patient during a procedure.
- Contact your TEE probe manufacturer for the process and equipment they recommend
- Schedule inservices for staff
- Develop a documentation form

Documentation of the Process

- For each HLD cycle, the following information should be recorded and maintained:
  - the assigned lot number, AER, or soaking container identification and cycle number;
  - the specific contents of the load, including quantity, department, and a description of the items;
  - the patient's name and medical record number, if available

Documentation of the Process

- the procedure, physician, and—if applicable - serial number or other identification of the item (required for all flexible scopes)
- the shelf-life date, if applicable, the lot number, and the date that the original container of HLD was opened
- the use-life of the open container
- the date that the product was activated or diluted

Documentation of the Process

- the date that the activated, diluted, or ready-to-use solution was poured into a secondary container; and the reuse-life of the solution
- the exposure time and temperature, if not provided on the physical monitors
- the date and time of cycle
- the time, temperature, and—if applicable—chemical concentration of the exposure phase of the high-level disinfection cycle

Documentation of the Process

- the name or initials of the operator
- the results of MRC or MEC testing, if applicable
- any reports of low MRC or MEC testing results

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?