

## MEMORANDUM

**TO:** Infection Prevention and Control Committee Members

**FROM:** Fred Onger, MD; Chair                      Richard Winn, MD, ID; Co-Chair

**DATE:** July 7, 2014

**SUBJECT:** Agenda for July 14, 2014 Quarterly Infection Prevention and Control Meeting

The next **Quarterly Infection Prevention and Control Committee Meeting** is scheduled for **October 13, 2014** at **12:00 noon** in **HSC 1B212**

The following is the **Infection Control** agenda:

- I. Call to Order (Fred Onger, MD)
- II. Review of the April Infection Control Committee Minutes (Fred Onger, MD)
- III. Reports
  - A. UMC Report (Alanna Emrick)
  - B. City Health Department Update/Infectious Disease (Mary McConnell)
  - C. Ambulatory Clinic Surveillance Report (Diane Baker, RN, BSN)
  - D. Bloodborne Pathogen Exposure Report
  - E. Respiratory Exposure Report
  - F. Notifiable Condition Report
- IV. Old Business  
Nothing to report
- V. New Business
  - A. Evaluation of Storz Cystoscope Procedure (Renee Witherspoon/Safety Services)
  - B. Measles (Diane Baker, RN, BSN)
  - C. Hand Sanitizer Usage (Johnny Castellno)
- VI. Committee Forum (Fred Onger, MD)
- VII. Adjournment (Fred Onger, MD)

Persons with disabilities who may need auxiliary aids or services are requested to contact at least 24 hours prior to this meeting so that appropriate arrangements can be made. Please bring your binders to the meeting.

**IF YOU CANNOT ATTEND THIS MEETING, PLEASE NOTIFY ALEX, 743-4287 AT YOUR EARLIEST CONVENIENCE. \*\*Please review your minutes and attachments prior to the meeting\*\***  
***Lunch will be provided***



# Evaluation of the Storz Cystoscope HLD Procedure and Glutaraldehyde Exposure to Urology Personnel

## Project Overview

4/9/14 - Request from Ahnna Parker, RN,C,MSN,CIC, Director of Nursing Services and Infection Control to Safety Services for assistance on a project to include:

1. Perform **Water Quality Testing** to determine if there are alternatives to use of sterile water for the final rinsing.
2. Conduct **Air Quality Testing** to determine if employees performing the procedure are over-exposed to Glutaraldehyde, and determine if additional air changes/hour are needed in "dirty room."
3. Determine if the MetriCide (containing **2.6% Glutaraldehyde**) can be **discarded to the drain** upon completion of use (every 14 days).
4. **Review the High Level Disinfection (HLD) procedure** for the Karl Storz Flexible Video-Urethro Cystoscope.



**Flexible Video-Urethro Cystoscope**



## Recommendations

1. Develop written procedures and update at least annually to assure that they are current.
2. Provide formalize training to employees performing any HLD instead of only OJT.
3. Increase the HLD time from 20 minutes to the manufacturers recommended contact time of 45 minutes.
4. Add Pressure Testing by submerging the unit.
5. Use a 2.4% Glutaraldehyde solution, i.e. CIDEX.
6. Increase dosage of MetriZyme to 2.5 oz. or 5 tablespoons.
7. Change Sterile/DI water following each HLD rinse.
8. Use lint-free cloths, brushes for cleaning the valves and compressed air to dry channels.
9. Cystoscopes stored overnight should be recleanned prior to reuse.
10. Provide a temperature/humidity indicator

A special thanks to: Martha Escamilla; Greg Lovett, PE, Bowie McGinnis, MBA; Melinda McKinnon, RN and, for their assistance in completing this evaluation. For additional information contact: Renee Witherspoon, MS, CSP, CIH, CHMM, Safety Services [renee.witherspoon@ttuhsc.edu](mailto:renee.witherspoon@ttuhsc.edu); 806.743.2597

## About Glutaraldehyde

In the health care industry, glutaraldehyde is most often used to disinfect equipment that **cannot be heat sterilized** such as dialysis instruments, surgical instruments, suction bottles, bronchoscopes, endoscopes, and ear, nose, and throat instruments.

The chemical is most often used in a diluted form with solutions ranging from 0.1% to 50% glutaraldehyde in water. Trade names for glutaraldehyde-containing formulations include Cidex®, Sonacide®, Sporidicin®, Hospex®, Omnicide®, Metricide®, Rapicide® and Wavicide®.

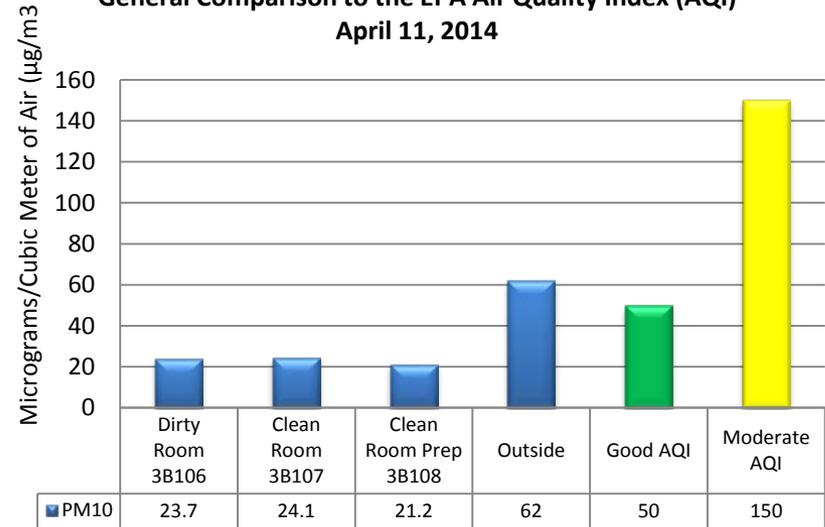
Workers can be exposed to glutaraldehyde through inhalation or skin contact. Health effects that may occur as a result of exposure to glutaraldehyde include but are not limited to the following:

- Throat and lung irritation
- Asthma and difficulty breathing
- Contact and/or allergic dermatitis
- Nasal irritation
- Sneezing
- Wheezing
- Burning eyes and conjunctivitis

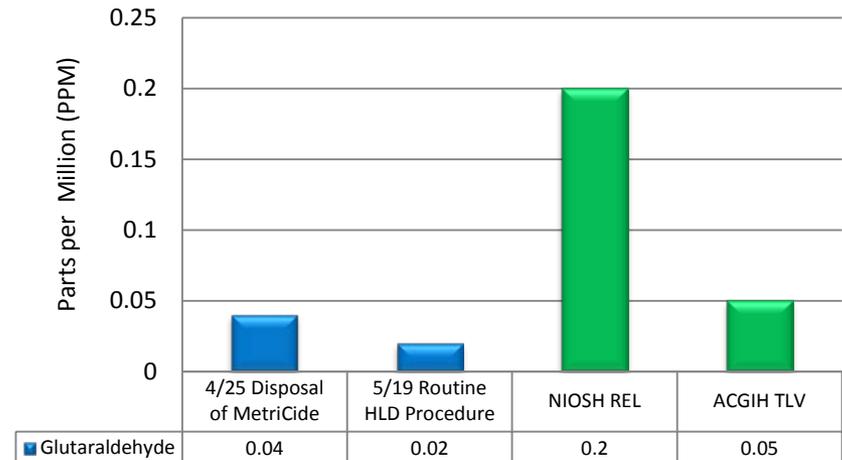
Reference: <http://www.cdc.gov/niosh/topics/glutaraldehyde/>

Exposure Limits	Limit Values	Health Factors & Target Organs
<b>OSHA Permissible Exposure Limit (PEL)</b>	Not established	
<b>NIOSH Recommended Exposure Limit (REL)</b>	0.2 ppm, Ceiling	Eye, nose, and throat irritation
<b>ACGIH Threshold Limit Value (TLV)</b>	0.05 ppm, Ceiling	Nose, throat, eye, and skin irritation; skin sensitization and contact dermatitis

**Graph 1: Urology - HLD Cleaning Rooms  
Particulate Matter 10 micron (PM10) Results  
General Comparison to the EPA Air Quality Index (AQI)  
April 11, 2014**



**Graph 2: Glutaraldehyde Exposure Results  
Job Task Comparison to the NIOSH Recommended Exposure Limit (REL) and the ACGIH Threshold Limit Value (TLV)  
April 25 & May 19, 2014**



- Thank you for the opportunity to present my findings on the Evaluation of the Storz Cystoscope HLD Procedure and Glutaraldehyde Exposure to Urology Personnel.
- **First some background**
  - Cystoscopy is one of the most commonly performed procedures in the urology office and important in the diagnosis of lower urinary tract pathology.
  - Now the development of flexible fiber optic technology, such as the Karl Storz brand Flexible Cystoscopes that we currently utilize in our Urology Department, it significantly reduces patient discomfort during the procedure.
  - But with these complex instruments and contact with intact mucous membranes, considered a Semi-critical device (Earle Spaulding classification system) these instruments must be reprocessed using HLD or high-level disinfection.
  - HLD has the ability to kill all micro-organism, except large number of bacterial spores. The HLD have the ability to sterilize given enough contact time, so having the correct contact time is critical for any HLD process.
  - A common chemical used for HLD is Glutaraldehyde.
    - On the back of the page there is a summary of the hazards.
    - **(Review Hazards)**
- **About the project (see the left side of your handout)**
  - 4/9/14 - Request from Ahnna requested assistance on a project to include:
    - Perform **Water Quality Testing** to determine if there are alternatives to use of sterile water for the final rinsing.
    - Conduct **Air Quality Testing** to determine if employees performing the procedure are over-exposed to Glutaraldehyde, and determine if additional air changes/hour are needed in “dirty room.”
    - Determine if the MetriCide (containing **2.6% Glutaraldehyde**) can be **discarded to the drain** upon completion of use (every 14 days).
    - **Review the HDL procedure** for this Cystoscope.
- Here is a basic overview of my evaluation.
  - **Defined project objectives, and completed some background research.**
    - Ahnna provided me with a 4” 3-ring binder full of information. This information included an excellent White Paper on Reprocessing of Flexible Cystoscopes.
    - I had 4 primary objectives, just discussed.
  - **Determined methods for the evaluation.**
    - I reviewed each objective and determine the best method to evaluate it.
      - For water quality testing, I could use available information from the City of Lubbock and from Plant Operations. (We did receive this approval, so I’ll complete objective here.)
      - For Air Quality Testing, I could use personal monitoring badges to determine the personnel exposure to Glutaraldehyde, and can evaluate Indoor Air Quality by using the Lighthouse brand Particle Counter.
      - To determine if MetriCide can go to the drain after 14 days of use, I would contact the city of Lubbock Wastewater Treatment Plant and obtain authorization.
      - To review the HLD procedure and perform a “Gap analysis”.

- Essentially to determine what steps need to be taken in update the procedure from its current version to its desired version.
- **Observe HLD Procedure with Martha Escamilla, Nursing Assistant with the Dept. of Urology.**
  - She performed the HLD procedure according to how she was trained. I observed and sampled using the badge shown in the handout, also completed the air sampling using the Particle Counter.
    - The results of the sampling are shown on the 2<sup>nd</sup> page, Chart 1, and Chart 2.
    - Observations: Excellent use of PPE & Documentation of the HLD Process. Also good was the posting of the procedure in the room where the procedure is being conducted.
- **Perform the “Gap Analysis” for the procedure**
  - Obtained a copy of the current procedure and compare it to the procedure from the manufacturer.
  - Obtained a copy of the ISO recommendations on Basic Requirements for Medical Endoscopes of Water-Resistant Type
    - The procedure was updated by the manufacturer in February 2014, but only a previous version was available.
  - Reviewed the White Paper on Reprocessing to determine if there were any additional “best practices” to include in the recommendations, not included in the Storz HLD Procedure.
  - Reviewed employee training records. Only OJT is completed – no written documentation.
- **Communicated Results & Recommendations** first to the Department so that they could comment and not be surprised by the results and then to Ahnna. Followed up with emails and finally a written report on June 3<sup>rd</sup>.
  - **Review Recommendations from Handout.**
- **Follow-up if further evaluation is needed.**
  - Currently Urology is working with Gregg Lovett our engineer regarding use of their DI water. The DI water exceeds the USP monograph for “Sterile water for irrigation”. Urology will be collecting the water from a water closet that procedures this DI water, and we will perform microbiological testing on the water to assure that we don’t have bacterial growth.
  - If this water is adequate for use as the final rinse water, the department will determine if they would like to have the DI water plumbed to this location.
- **3 Take away’s from this evaluation:**
  - **1. Follow the procedure recommended by the manufacturer.** Including any recommendations for chemical concentration or specific chemical use. Watch out for chemical use that is incompatible with the instrument manufacturer, such as isopropyl alcohol or saline usage.
    - If you deviate from the procedure, **document your findings** in that it meets or exceeds the standards.
  - **2. In an effort to always improve patient safety, assure that your procedures are up to date.** Manufacturers can update their procedures and not let their customers know of the change.
    - Procedures can contain photos of the process.
    - Continue to post the procedures in the area where it is being performed.
  - **3. Documentation is important** not only for the HLD procedure itself, but **also for training purposes.**
    - Although OJT is good, we need to have more formalized training programs.

Evaluation of the Storz Cystoscope HLD Procedure and Glutaraldehyde Exposure to Urology Personnel  
R. Witherspoon Presentation to the Infection Control Committee on 7/14/14

1. **Develop written procedures.** Procedures have not been updated since 2010.
  - a. Adjust timings at each step to match manufacturer's recommendations. **See attached example procedure developed.** Cut, paste and modify as needed.
    - i. According to the manufacturer, any deviation of the recommended procedures must be validated by the user.
  - b. Periodically evaluate and update written procedures **at least annually** to assure that they are current.
2. **Provide more formalize training** to employees performing any HLD instead of only OJT.
  - a. Develop a checklist so that additional training to new technicians can be performed easily. This to include signatures at the bottom of the page that this training was completed. Once completed, training can be placed in the employee's training file.
  - b. Post a copy of the finalized procedures on the clean side and dirty side.
  - c. Provide periodic refresher training, i.e. annually or whenever changes are made in the procedure.
3. **Increase the HLD time** from 20 minutes to the manufacturers recommended contact time of **45 minutes**.
  - a. In 2008, the CDC released its "Guideline of Disinfection & Sterilization in Healthcare Facilities." This document supports a 20 minute exposure, if the device is properly precleaned. Using the manufacturers recommended contact time continues to be recommended.
4. **Add Pressure Testing by submerging** the unit.
  - a. The updated (Feb. 2014 edition, see attached) instruction manual and ISO recommendations say that submerging the unit to check for leaks is best practice (see page 24 of instruction manual).
5. **Use a 2.4% Glutaraldehyde solution**, i.e. CIDEX.
  - a. Although solutions with >2.4% Glutaraldehyde should be "avoided" according to the Instruction Manual, when contacting the manufacturer directly they do not believe that this is a significant to cause damage to the instrument. **Manufacturers recommendations are preferred.**
  - b. OPA (0.55% ortho-Phthalaldehyde) is not being used as an HDL by the department since some studies show that it may cause anaphylactic reaction in patients with bladder cancer who underwent repeated procedures. OPA is also contraindicated in patients with a history of bladder cancer.
6. **Increase dosage of MetriZyme** to 2.5 oz. or 5 tablespoons.
  - a. According to the manufacturer of MetriZyme, the concentration of this enzymatic cleaner should be 1 oz. (2 tablespoons)/gallon of water. Current usage is 2 oz./2.5 gallons of water (previously to this investigation was 1 oz./2.5 gallons)
    - i. Recalculate volume of containers to confirm.
7. **Change Sterile/DI water following each HLD rinse.**
  - a. Currently 7 liters of sterile water are being used to rinse the scope following HLD, this water is only changed once/week. Since the water becomes contaminated after each use, it is no longer provides a "sterile" rinse prior to reuse.
  - b. Since there is a concern about cost of Sterile Water, there is option to use DI water available from Plant Operations that can be plumbed to your location.
    - i. According to the Instruction Manual "demineralized" water can be used. Demineralized is synonymous with dionized water or DI water. According to our engineers, DI water exceeds the standard for "Sterile Water." Additional documentation is available for this upon request.
    - ii. If you choose to use this DI water instead of the purchased "sterile water", we do side by side testing similar to what was performed by the UMC Clinical Lab. If the test is successful, we can get a cost to plumb it to your location.
8. Begin using lint-free cloths, brushes for cleaning the valves and compressed air to dry the channels.
  - a. The manufacturer recommends use of these items, and periodic lubrication for metal to metal contact. There was no mention of periodic lubrication in any employee interviews regarding the procedure.
  - b. As an option, compressed air tank can be used and refilled as necessary for drying.
9. Cystoscopes stored overnight should be recleaned prior to reuse.
  - a. This is a recommendation from the "white paper" provided to me by Melinda on 4/9.
10. Provide a temperature/humidity indicator for the room since these are parameters mentioned in the instruction manual.