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**Circular Letter DHCQ 10-11-539**

**TO:** Acute Care Hospital CEO  
Chief Medical Officer  
Chief of Infectious Disease  
Chief Nursing Officer  
Director of Infection Control  
QA/Risk Manager(s)

**FROM:** Alice Bonner, PhD, RN, Director

**DATE:** November 10, 2010

**RE:** High Level Disinfection

The Department has been conducting unannounced, focused infection prevention surveys at acute care hospitals. The purpose of this letter is to advise you of deficient practices involving high level disinfection (HLD)<sup>1</sup> that have come to our attention during these surveys. Specifically, some of the steps in the disinfection process for reusable, semi-critical items<sup>2</sup>, such as vaginal probes, laryngoscopes, and transesophageal echocardiography probes, were not consistently implemented at some hospitals. The deficient practices observed during survey were primarily associated with the manual HLD process. Based on these findings, the Department advises each hospital to conduct a detailed review of HLD policies, procedures, and practices.

General information about HLD

HLD is often used to reprocess reusable, heat-sensitive medical devices that cannot undergo traditional sterilization procedures (e.g., saturated steam under pressure, ethylene oxide). A number of high level disinfectant products (e.g., glutaraldehyde, ortho-phthalaldehyde, and peracetic acid) are available to disinfect semi-critical devices. The type of high level disinfectant selected must be compatible with the recommendations of the device manufacturer. Additionally, strict adherence to the disinfectant manufacturer's instructions must be maintained for the HLD processes to be effective. The hospital should also ensure that policies and procedures for HLD are consistent with current recommended national guidelines.

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<sup>1</sup> A process that uses a high level disinfectant to eliminate all microorganisms in or on an instrument, except for small numbers of bacterial spores.

<sup>2</sup> The category of medical devices or instruments that come in contact with mucous membranes and do not ordinarily penetrate sterile tissue.

The manual HLD process requires multiple steps to be effective. Depending on the device, these steps may include the following:

1. **Thoroughly clean** contaminated devices prior to disinfection, since residual organic matter will reduce the effectiveness of the high level disinfectant.
2. **Test** the disinfectant solution for physical (i.e., temperature) and chemical (i.e., minimum effective concentration [MEC])<sup>3</sup> properties needed to ensure efficacy of HLD (temperature varies with solution used).
  - a. use a thermometer to measure temperature and document findings
  - b. use product specific testing mechanisms (e.g., test strips or liquid chemical monitors) to measure the MEC and document findings
3. **Disinfect** the device by immersion in a high level disinfectant solution for the recommended amount of time and at the recommended minimum temperature (time and temperature vary with solution used).
4. **Rinse** (immerse) the device for the recommended amount of time to prevent adverse effects associated with high level disinfectant residue (i.e., clear water rinses).
5. Use **drying techniques** that create an environment unfavorable for bacterial growth.<sup>4</sup>
6. **Store** the device in accordance with manufacturer's instructions to prevent recontamination.

In addition, some test strip manufacturers (see 2b above) recommend that the test strips used for HLD undergo quality-control procedures, which are typically performed when the test strips are opened and on a regular basis as established by the hospital's quality control program. These procedures are conducted to ensure the test strips are valid to measure the MEC of the HLD solution.

The quality control program is established to minimize errors that can occur between different users, minimize the possibility that outdated materials are used, and/or minimize the chance of using a product that has been improperly stored or handled (e.g., in accordance with manufacturer's guidelines, some products must be discarded within 90 days of the date the bottle was opened, or discarded immediately if the product was left open to air and moisture for more than 30 minutes). **Please be aware that test strips are often packed separately from the chemical disinfectant and contain specific manufacturer's instructions for test strip use.**

An evaluation of manual HLD protocols should include a focused review to ensure:

- Staff are trained and demonstrate competency in the high level disinfection process. Hospital protocols and training should incorporate device and disinfectant specific manufacturer's guidelines.
- The temperature of the high level disinfectant solution is manually monitored in accordance with the manufacturer's guidelines (some manufacturers require a minimum temperature, e.g., 77° F).
- The device is immersed in the high level disinfectant solution in accordance with the manufacturer's guidelines for the minimum time period (e.g., 12 minutes).
- A timing mechanism and thermometer are available for use to monitor the HLD process and appropriate documentation is maintained (e.g., date, name of the individual performing the tests, verification of time/temperature).
- The device is thoroughly rinsed to remove chemical residue; during the process of rinsing, some manufacturers require immersion of the device in a large volume of fresh water for a specified duration, and repeated immersion in fresh water.
- Quality control checks on the test strips are performed in accordance with manufacturer's instructions (e.g., at the time the test strip bottle is opened, and on a regular basis as established by the hospital's quality control program) and documented (e.g., date, test results, name of the individual performing the test).
- The expiration date of the test strips is documented (e.g., within 90 days of the date the bottle is opened).

Additional information is available on the Centers for Disease Control and Prevention's (CDC) website at: [http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection\\_Nov\\_2008.pdf](http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf)

<sup>3</sup> MEC may be affected by the frequency of use, e.g., if the solution is used daily or more often, the solution should be tested at least daily; if used once a week, test before use; if used 30 times per day, test each 10<sup>th</sup> use.

<sup>4</sup> Examples include forced air drying or an alcohol rinse. An alcohol rinse is recommended by the CDC for semi-critical devices that have contact with mucous membranes of the upper respiratory tract (e.g., nose, pharynx, esophagus).