How are you doing on high-level disinfection?

Recognizing how seriously reprocessing flaws can affect patients, the Joint Commission elevated its high-level disinfection standards in 2009, placing them at the same level as the sterilization standards.

Under the changes, high-level disinfection is scored as Category A, the same as sterilization, and not as Category C as it was previously. This revision is in the current 2011 infection control standards (IC.02.02.01) for hospitals, critical access hospitals, ambulatory care, and office-based surgery, as well as laboratories and long-term care.

The Joint Commission states that to control the high-level disinfection process, organizations should pay attention to:
- orientation, training, and competency
- levels of staffing and supervision
- standardization of the process
- reinforcing the process
- ongoing quality monitoring.

This article focuses on quality monitoring and documentation for high-level disinfection. Check these areas to be sure you have a safe process and are in compliance with the standards. For complete details, review recommendations from the Association for the Advancement of Medical Instrumentation (AAMI) and AORN.

Choosing a high-level disinfectant

Check the list of high-level disinfectants (HLDs) cleared for processing of semi-critical devices on the Food and Drug Administration (FDA) website. Ensure that the HLD chosen is recommended in the medical device manufacturer’s written instructions for use (IFU) so the medical device is not damaged because of material incompatibility issues.

Quality monitoring

The following factors can alter the effectiveness of a high-level disinfection process. Train your personnel on the importance of monitoring these factors and following the IFU from the manufacturers of the medical device, HLD, and automated processing equipment to ensure the process is effective. This information applies for both manual or automated processing using HLDs. Personnel need to be competent for the process to be improved.

Storage or shelf life

Check each HLD bottle before use to ensure the product is still within the storage or shelf life listed on the label. Do not use the bottle if the solution has expired because it is no longer considered effective even if testing shows its minimum effective concentration (MEC) is correct. The Joint Commission has cited facilities for using expired HLDs.
Testing chemical indicator strips

If you have had a recent Joint Commission survey, the surveyor may have asked you to add a section to your quality assurance policy for testing the chemical indicator strip to ensure it continues to monitor the correct minimum effective concentration (MEC). Check to see if the strip manufacturer’s instructions for use (IFU) describe the process for testing the strips when the bottle is first opened to determine that the strip is effective. If so, those instructions need to be followed.

The process involves preparing a positive solution (full-strength high-level disinfectant, or HLD, solution within the expiration date) and a negative control solution (dilute one part full-strength solution with one part water). The IFU may suggest repeating the same testing regularly to minimize errors between different users and detect storage or handling problems that could reduce the shelf life of the strips.

If the strip is good for 90 days after the bottle is open, possibly test when the bottle is open and at 30, 60, and 90 days. If at any time, the strip is no longer working, discard that bottle of strips and retest the solution. If the new bottle of strips also shows the same result, the solution may no longer be effective. Replace the solution.

Another approach
Another approach is to do a risk analysis to determine if additional QA testing of the strips is needed and if so at what interval, suggests Edwin Ross, CEO of Applied Healthcare Research, Inc, Santa Clarita, California, who consults on Joint Commission readiness, regulatory compliance, and quality improvement. During the risk assessment, determine the likelihood that a high-level disinfection process will fail as a result of the strips not being used, stored, or handled properly. Decide what actions should be implemented to ensure the process is effective. This will determine how often additional testing of the strips should occur or if that step is even needed.

Use pattern
Reuse only products labeled as reusable. The manufacturer has to document that a product is still effective at killing the microorganisms of the type shown on the label after a specified time. The use pattern is event related more than time related. (See the information on MEC monitoring.) Do not use the solution if the MEC is below that required for effective high-level disinfection.

Reuse life
Reuse life is the period of time for which the disinfectant solution can be used. This is the time after the solution is activated or after it is opened if activation is not required. This is provided that the solution still has its active ingredients above the MEC. The reuse life could be 1 day, 14 days, 28 days, or whatever time is on the label. Do not use a solution after its reuse life, even if the MEC is above that required for effective high-level disinfection.

Bioburden, water, and extraneous materials
Instruments must be clean to ensure the effectiveness of the solution. Solutions are developed to be effective only against a known number of microorganisms. Organic matter, soaps, detergents, lint, cotton sponges, and the minerals found in water can inactivate the HLD. Check the HLD IFU for the appropriate water, soaps, and detergent to use.

Dilution and MEC monitoring
In practice, the reuse life is shorter than stated on the label because the solution is diluted by water from the surface or lumens of instrumentation that are not completely...
dried. To avoid this, remove excess moisture from the instruments after cleaning. Discard a solution that is below the labeled MEC no matter how many days it has been in use.

**How to test**

AAMI recommends testing the HLD upon activation and before each use through the reuse period with a chemical monitoring device or strip to detect when the active ingredient falls below the MEC. Specifics on MEC testing:

- Choose a strip that is FDA cleared for use with the HLD and matches the MEC. For example, if the MEC is 2.1, you would not use a monitor labeled for a product with a MEC of 1.5 because it would say the product meets its MEC when it does not.
- Follow the strip manufacturer’s IFU on how to test, store, interpret results, and expiration dates.
- Check the expiration date of the strip before each use. The IFU will tell you how long the strips can be used after the bottle is open (eg, 90 days) so document the bottle opening on the space provided on the bottle. Do not use the strips after this time because they will not be effective at detecting an inadequate MEC concentration. (See the sidebar about testing the chemical indicator strips.)

**Exposure conditions**

Follow the HLD manufacturer’s time and temperature requirements. If the temperature falls below the recommended level indicated on the product for the prescribed time, the process will not be effective. The temperature and time of the solution should be monitored. For a manual process, use a thermometer and a timer. Check with the manufacturer of the automated reprocessing equipment to ensure the solution temperature and time are also being monitored and how you access those results. Reprocess the device if the time at temperature is not as recommended by the medical device manufacturer.

**Evaporation, light, and pH**

Evaporation, especially with chlorine products, can affect the HLD’s concentration, as does exposure to light. For manual processing, keeping a cover on the container minimizes this problem. Detergents that enter the HLD solution can alter the solution’s pH and reduce its effectiveness. Ensure that devices are rinsed adequately after cleaning to remove this detergent.

**Device characteristics**

The HLD solution is only effective if it can contact all surfaces of a medical device. Infections have resulted because devices were not correctly connected in automatic processing equipment, and the HLD did not contact all surfaces of the lumens. Ensure that instruments are totally immersed, and lumens are filled with the HLD.

**Rinsing**

Using the wrong kind of water can recontaminate a medical device. For high-level disinfection, sterile water, filtered water, or potable tap water can be used if the potable tap water is followed with a 70% alcohol rinse followed by forced air drying.

**Documentation**

For each manual process, the results of physical monitoring, which include the time at temperature, should be documented. For automated processing equipment, the displays, digital printouts, and gauges should be checked at the beginning of the cycle to verify the
cycle identification number has been recorded, and the printer is functioning properly. At the end of the cycle, the printout should be examined, interpreted, and initialed. Do not use processing equipment that does not have a physical monitoring device. If the physical monitoring for either the manual or automated processing equipment indicates a malfunction, the medical device should not be used but be reprocessed.

For manual processing, the solution should be visually inspected before each use and discarded if precipitates are observed, even if the solution is within its use life. Visual inspection should ensure the solution is covered to protect it from evaporation and light. Document these visual observations.

**AORN recommendations**

AORN recommends documenting the patient, procedure, physician, load contents, personnel performing the process, method of cleaning and identifier for automated equipment, date and time of disinfection, type of disinfectant and lot number, MEC test results, temperature of disinfectant and submersion time, verification of rinsing, testing results of insulated electrical instruments, and disposition of defective equipment.

High-level disinfection requires as much diligence and attention to detail as sterilization. A well planned and managed quality monitoring program is a major part of ensuring the process is safe for patients.

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