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Learning Objectives

1. Understand the value of the 2008 CDC Guideline for Disinfection and Sterilization to the Sterile Processing Department.
2. Describe the method used by the CDC to categorize recommendations.
3. Discuss some of the recommendations provided in the guideline.

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**A new CDC guideline –
Bookmark it now!**

by Susan Flynn, BESC, CSPDT

When developing departmental policies and procedures, sterile processing professionals turn to recommended practices developed by consensus organizations such as the Association for the Advancement of Medical Instrumentation (AAMI) and professional groups such as the Association for periOperative Registered Nurses (AORN). Another key resource is the Centers for Disease Control and Prevention (CDC). Late in 2008, the CDC published a *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*, which presents evidence-based recommendations on the preferred methods for cleaning, disinfection and sterilization of patient-care medical devices and for cleaning and disinfecting the healthcare environment. While a self-study article of this length cannot begin to summarize the information provided in the guideline, it will highlight the categories of information included in the guideline and examples of specific information that may be of use to the Sterile Processing Department. Whether developing departmental policies and procedures; answering a new employee's questions; evaluating disinfectants or sterilants; searching for a reference to support practice; or looking for a common language when working with the facility Infection Preventionist, the CDC guideline is another "go to" resource tool.

Let's begin by reviewing some key definitions provided in the guideline (below).

The Spaulding classification system, used to determine the appropriate method of re-processing contaminated medical devices according to the risk of infection associated with its intended use, is discussed in the

guideline. To summarize, devices are classified into three categories: critical devices – which enter sterile tissue or the vascular system and should be sterilized between patients; semicritical devices – which contact mucosal membranes and may be high-level disinfected; and noncritical devices – which come in contact only with intact skin and for which low-level disinfection is therefore appropriate. Unlike high-level disinfectants, low-level disinfectants do not kill bacterial spores.

The guideline includes a discussion about the factors affecting the efficacy of disinfection and sterilization processes. An understanding of these factors may help sterile processing personnel make better decisions in their daily work life. The factors include:

- Number and location of microorganisms
- Resistance of microorganisms
- Concentration and potency of disinfectants
- Physical and chemical factors
- Presence of organic and inorganic matter
- Duration of exposure and
- Biofilms.

Why are these factors relevant to your daily work? Understanding that meticulous cleaning can help reduce the number of microorganisms, and that a reduced population can be inactivated in a shorter amount of time is an important concept.

A new employee may be concerned about the resistance of a virus such as HIV to a disinfection or sterilization process. The guideline provides a reference figure comparing the resistance of microorganisms that could be used to teach that, in fact, HIV and other viruses are relatively easy to in-

| | |
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| Cleaning | "Removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms, and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the item for safe handling and/or further decontamination" ¹ |
| Disinfection | "Thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g. bacterial spores)." ¹ |
| Sterilization | "Validated process used to render a product free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero." ¹ |

activate using disinfectants while bacterial spores and prions, which cause Creutzfeldt-Jakob Disease (CJD), are the most difficult.

When using disinfectants and sterilants, it's important to consider the effect of physical and chemical factors. For example, is the efficacy of a particular disinfectant sensitive to pH? Is your ethylene oxide sterilizer designed to provide adequate in-chamber relative humidity (RH), as RH is a critical factor influencing the activity of ethylene oxide.

The guideline reinforces the importance of meticulous cleaning prior to sterilization by discussing the negative impact both organic and inorganic matter have on the process, whether by reacting with the active agent or acting as a physical barrier to shield microorganisms.

Sterilization methods and sterilizing practices

Have you ever wondered how steam kills microorganisms or how many microorganisms typically contaminate a reusable surgical instrument when it arrives in decontam? The guideline provides an overview of methods of sterilization (steam, flash, ethylene oxide, hydrogen peroxide and peracetic acid), including a discussion of the microbicidal activity, mode of action, and uses of each method.

The guideline states that steam sterilization is the preferred method for heat resistant items "because it has the largest margin of safety due to its reliability, consistency, and lethality."¹ Microorganisms are destroyed during exposure to moist heat "by the irreversible coagulation and denaturation of enzymes and structural proteins."¹

A detailed discussion of low-temperature sterilization methods is included in the guideline and a table summarizing the advantages and disadvantages of sterilization methods is a helpful reference. The discussion about ethylene oxide (EO), used to "sterilize critical items (and sometimes semicritical items) that are moisture or heat sensitive and cannot be sterilized by steam sterilization"¹ includes a review of both 100% EO and the various EO gas mixtures,

along with reminders about the toxicity of EO and the need for aeration to remove residual EO from sterilized items. A description of the hydrogen peroxide gas plasma sterilization process concludes with its use as a sterilant for "materials and devices that cannot tolerate high temperatures and humidity, such as some plastics, electrical devices, and corrosion-susceptible metal alloys."¹ Disadvantages of this process are the tendency of the cycle to abort because of failure to achieve vacuum if any moisture is present, and the concern about hydrogen peroxide penetration into long or narrow lumens. Peracetic acid is described as "a highly biocidal oxidizer that maintains its efficacy in the presence of organic soil."¹ The guideline reminds the reader that the appropriate channel connector must be connected to lumened endoscopes processed in the automated processor to ensure that peracetic acid has direct contact with the lumen.

One of the features of the guideline is the extensive bibliography. For example, the reader learns that studies investigating the microbial load present on used instruments have found a relatively low level of organisms. A variety of studies are referenced to facilitate further research on this topic. While bioburden may be relatively low, other studies have determined that contaminating salts and serum can negatively impact the efficacy of sterilization, reinforcing the need for meticulous cleaning before sterilization. A theme stressed throughout the guideline is that healthcare facilities should develop protocols for adequate cleaning of contaminated devices, including narrow-lumened devices, to ensure the sterilization process is not compromised.

As would be expected, the guideline comments on sterilization monitoring. Consistent with AAMI and AORN recommended practices, the guideline states that sterilization processes "should be monitored routinely by using a combination of mechanical, chemical, and biological indicators to evaluate the sterilization conditions and indirectly the microbiologic status of the processed items."¹ Providing rationale to support the use of biological indicators, the

guideline goes on to state: "Biological indicators are the only process indicators that directly monitor the lethality of a given sterilization process. Spores used to monitor a sterilization process have demonstrated resistance to the sterilizing agent and are more resistant than the bioburden found on medical devices."¹

The actual recommendations for disinfection and sterilization can be found toward the end of the guideline. To help the reader appreciate the strength of the recommendations, they are categorized according to the availability of supporting science, theoretical rationale, or relevant government regulation as explained in the table below. The comprehensive recommendations are divided into sections. Some of the sections of particular interest to Sterile Processing Departments are:

- Occupational Health and Exposure
- Cleaning of Patient-Care Devices
- Indications for Sterilization, High-Level Disinfection, and Low-Level Disinfection
- High-Level Disinfection of Endoscopes
- Flash Sterilization
- Methods of Sterilization
- Packaging
- Monitoring of Sterilizers
- Quality Control
- Reuse of Single-Use Medical Devices

Let's look at a short sampling from some of these categories to get a flavor for the type and specificity of the recommendations. The *Occupational Health and Exposure* section includes a recommendation, rated as Category IC and Category II, to "educate health-care workers in the selection and proper use of personal protective equipment (PPE)." The *High-Level Disinfection of Endoscopes* section includes a Category 1A recommendation that the endoscope be meticulously cleaned with a compatible enzymatic cleaner immediately after use. A Category 1B recommendation in the *Flash Sterilization* section states "Do not flash sterilize implanted surgical devices unless doing so is unavoidable."¹

In the *Methods of Sterilization* section, there are recommendations reminding the reader that "steam is the preferred method for sterilizing critical medical and surgical instru-

Recommendations - CDC system for categorizing recommendations¹

See **SELF-STUDY** on page 28

| Category IA | Category IB | Category IC | Category II |
|---|---|---|---|
| Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies. | Strongly recommended for implementation and strongly supported by some experimental, clinical, or epidemiologic studies, and by a strong theoretical rationale. | Required by state or federal regulations. | Suggested for implementation and supported by suggestive clinical or epidemiologic studies or by a theoretical rationale. |
| No recommendation | | | |
| Unresolved issue. These include practices for which insufficient evidence or no consensus exists regarding efficacy. | | | |

Self-Test Answers: 1. A, 2. A, 3. B, 4. A, 5. A, 6. A, 7. B, 8. A, 9. A, 10. A

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1. Sterilization is a process used to render a product free of all forms of viable microorganisms.
A. True B. False
2. The importance of cleaning prior to sterilization is a theme of the CDC guideline.
A. True B. False
3. According to the Spaulding classification system, non-critical patient care items must be sterilized between patients.
A. True B. False
4. The resistance of microorganisms and the presence of organic and inorganic matter are among the factors affecting the efficacy of disinfection and sterilization processes.
A. True B. False
5. The guideline recognizes biological indicators as the only process indicators that directly monitor the lethality of a given sterilization process.
A. True B. False
6. The guideline features evidence-based recommendations for healthcare facilities.
A. True B. False
7. A Category IA ranking signifies that a recommendation is required by state or federal regulations.
A. True B. False
8. The guideline recommends quarantining implantable devices until the BI result is negative.
A. True B. False
9. The guideline recommends that endoscopes be meticulously cleaned immediately after use.
A. True B. False
10. The guideline states that steam sterilization is the preferred method for instrumentation that is not damaged by heat, steam pressure, or moisture.
A. True B. False

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ments that are not damaged by heat, steam pressure, or moisture” (Category IA), to completely aerate items that have been ethylene oxide sterilized (Category IB), and to use items that have been sterilized by the peracetic acid immersion process immediately (Category II).

In the *Monitoring of Sterilizers* section, the use of BIs in every load containing implantable items, and the quarantining of those items until the BI is negative is a Category 1B recommendation.

How often do you see your facility Infection Preventionist (IP)? In the *Quality Control* section, it is a category IB recommendation that infection control rounds be conducted periodically in Central Processing. Use this recommendation as a premise to invite your IP to the department if it’s been awhile since you’ve met.

Has your department ever been asked to reprocess a single-use device? The Category II and Category IC recommendation in the section on this topic reminds the reader that the “FDA considers the hospital that reprocesses a single-use device as the manufacturer of the device and regulates the hospital using the same standards by which it regulates the original equipment manufacturer.” While this discussion has largely faded away, the guideline would be a great reference should pressures from the current economic crisis revive the issue in your facility.

Product evaluation

Perhaps your department is evaluating high-level disinfectants or low-temperature sterilants? When researching new products or technologies, it’s useful to refer to impartial sources of information, such as the CDC guideline, in addition to vendor literature. Augmenting the discussion about sterilants, several tables at the end of the guideline provide useful comparisons of commercially available products and technologies. For example, the table summarizing the characteristics of an ideal low-temperature sterilization process could be adapted to create a matrix to rank the attributes of the sterilants you wish to evaluate. Similarly, the attributes (such as need for activation, disposal restrictions, materials compatibility, safety, etc.) in the table comparing high-level disinfectants and chemical sterilants could be used to objectively compare various chemistries.

Conclusion

The 2008 CDC guideline provides an excellent reference for the Sterile Processing Department. It reviews the role that adequate cleaning, disinfection and sterilization can have in reducing the risk of healthcare-associated infections linked to the use of reusable surgical instrumentation; discusses the modes of action and uses of commercially available disinfectants and sterilants; and provides evidence-based recommendations for healthcare facilities. An electronic (i.e. easily searchable) copy of the guideline is available free of charge online at (http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf). Take the time to bookmark the guideline now for future reference! **HPN**

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Reference

1. Rutala, William A., Weber, David J., and the Healthcare Infection Control Practices Advisory Committee (HICPAC), *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*. CDC.

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