Medical Equipment, Devices, and Supplies

Standard PCI.03.00

The hospital reduces the risk of infections associated with medical/surgical equipment, devices, and supplies by proper cleaning, disinfection, sterilization, and storage.

Intent of PCI.03.00

Failure to properly clean, disinfect, sterilize, and store equipment, devices, and supplies poses high risks to patients, staff, and others in the hospital by exposure to potential pathogens, including MDROs, bloodborne pathogens, endotoxins, chemicals such as preservatives, and other organic or inorganic materials. The US Centers for Disease Control and Prevention (CDC) defines *cleaning* as: "the removal of foreign material (e.g., soil, and organic material) from objects." CDC goes on to say that "[cleaning] is normally accomplished using water with detergents or enzymatic products. Thorough cleaning is required before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes."

In 2008 the CDC Healthcare Infection Control Practices Advisory Committee's *Guideline for Disinfection and Sterilization in Healthcare Facilities* recognized Earle H. Spaulding's approach to disinfection and sterilization of patient-care items and equipment using a three-level method. The Spaulding Classification of Surfaces includes the following:

- Level 1—Critical: Objects which enter normally sterile tissue or the vascular system and require sterilization
- Level 2—Semicritical: Objects that contact mucous membranes or non-intact skin and require high-level disinfection, which kills all but a small number of bacterial spores
- Level 3—Noncritical: Objects that contact intact skin but not mucous membranes, and require low-level disinfection

Manufacturer's instructions for use for instruments and equipment, as well as the equipment or agents used to clean, disinfect, or sterilize them, must be explicitly followed, along with applicable laws and regulations. Evidence-based guidelines and professional practice standards must also be consulted to determine the level of disinfection or sterilization required for items. However, laws and regulations, and manufacturer's instructions for use, take precedence over evidence-based guidelines or professional practice standards when these conflict. When medical device manufacturers' instructions conflict with manufacturers' instructions for automated high-level disinfection or sterilization equipment, the hospital must have a process to resolve this conflict. This may include contacting manufacturers directly for guidance. In situations in which none of these offer guidance, then a decision for how to proceed must be based on expert consensus using an evidence-based process. In all cases, the stricter standard must be followed if laws and regulations or manufacturer's instructions for use conflict.

Cleaning, disinfection, and sterilization of medical equipment, devices, and supplies involves low-, intermediate-, or high-level disinfection (HLD), or sterilizing agents and processes, based on the manufacturer's instructions for use (IFUs); guidelines from established organizations such as the Association for the Advancement of Medical Instrumentation (AAMI) and International Standards Organization (ISO), and others; the item's intended use; and standards such as the Spaulding Classification. Some equipment or instruments may fall under more than one classification depending on how they are used.

Storage of these items is also determined by the Spaulding Classification, along with manufacturer's IFUs, laws and regulations, national health care industry standards, professional practice standards, and evidence-based guidelines. As previously stated, the hospital must discern how to proceed when the guidance from these sources is in conflict. In all cases, equipment must be stored in a way that prevents contamination or loss of

sterility before use. It is critical that these high-risk processes are integrated into the infection prevention and control program, as well as the quality and patient safety program, with oversight by hospital leaders.

Measurable Elements of PCI.03.00

1. The hospital implements proper infection prevention and control practices when cleaning and performing low-level and intermediate-level disinfection of noncritical medical equipment, devices, and supplies that address the following:
   - Use of approved disinfectants in accordance with the product label directions, including the indication, specified-use dilution when applicable, contact time, and method of application
   - Use of disinfectant agents and methods approved by the equipment or device manufacturers
2. Ⓓ The hospital implements proper infection prevention and control practices when performing high-level disinfection and sterilization of critical medical equipment, devices, and supplies that address the following:
   - Use of approved chemical sterilants and high-level disinfectants in accordance with the product label and the device manufacturer's instructions
   - Required documentation for device reprocessing cycles, including but not limited to sterilizer cycle logs, the frequency of chemical or biological testing, and the results of testing for appropriate concentration for chemicals used in high-level disinfection
   - Resolution of conflicts or discrepancies between medical device manufacturers' instructions and manufacturers' instructions for automated high-level disinfection or sterilization equipment
   - Criteria and the process for the use of immediate-use steam sterilization
   - Actions to take in the event of a reprocessing error or failure identified either prior to the release of the reprocessed item(s) or after the reprocessed item(s) was used or stored for later use
3. Ⓓ Staff who reprocess medical/surgical equipment, devices, and supplies receive initial and ongoing training and demonstrate competency in cleaning and disinfection protocols; the training and staff competency are documented.
4. A qualified individual(s) oversees the cleaning, disinfection, sterilization, and storage processes for equipment, devices, and supplies.
5. Methods for cleaning, disinfection, sterilization, and storage of equipment and devices are coordinated and uniformly applied throughout the hospital.
6. Cleaned, disinfected, and sterilized equipment, devices, and supplies are properly stored in designated storage areas that prevent contamination prior to use.
7. The hospital implements a process to track high-level disinfected and sterilized instruments used for patient procedures to specific disinfection and sterilization cycles, equipment, and individual patients.
8. Ⓓ The hospital has a written procedure to identify and recall instruments for individual sterilization cycles and equipment.

Standard PCI.03.01

The hospital implements a process for managing the reuse of single-use devices in accordance with manufacturer's requirements and any applicable laws and regulations.

Intent of PCI.03.01

The reuse of reprocessed single-use devices and supplies has the risk of inadequate or unsafe performance. Some single-use devices may be reused under specific circumstances only when permitted by local and national laws and regulations. This standard addresses types of single-use critical and semicritical [medical] devices listed in the Spaulding Classification; it is not meant to include noncritical devices.

Medical devices manufactured to be single-use devices may be either marked with a symbol such as ②, or words such as "single-use only," "not to be reused," or "disposable."