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."

There are risks associated with the reuse of reprocessed single-use devices, including an increased risk of infection and a risk of inadequate or unacceptable performance following reprocessing.

When the reprocessing and reuse of single-use devices is allowed, reprocessing must meet the same criteria as the original manufacturer to ensure that the device is safe for reuse, in both function and cleanliness.

Many devices are complex in design and are therefore difficult to clean, disinfect, or sterilize. Reprocessing may impact the effectiveness or function of the device, leading to a risk of the device breaking or failing during use. Chemicals used for reprocessing may corrode the device, and the reprocessing may damage the device. Most single-use devices are not designed for reprocessing, leading to increased risk of cross-infection. If the hospital permits the reuse of reprocessed single-use devices, there is a hospital policy to guide reprocessing and reuse. The policy is consistent with national laws and regulations and professional standards.

There is oversight of the process for the reuse of reprocessed single-use devices based on data, hospital needs, and alternatives to reusing devices. The list of single-use devices approved for reuse is routinely reviewed to ensure that it is accurate and current.

If the hospital permits the reuse and reprocessing of single-use devices, hospital policy includes the following:

- Alignment with local laws and regulations and standards from a recognized agency
- List of single-use devices and materials that may be reused
- Process for identifying when a single-use device is no longer safe or suitable for reuse
- Cleaning process for each device that starts immediately after use and follows a clear protocol
- Process to identify patients on whom reusable medical devices have been used
- Proactive evaluation of the safety of reusing single-use items, including but not limited to adverse events associated with surgery such as surgical site infections or an outbreak of infections or disease
- Collection and analysis of data on adverse events related to reused devices to identify risks, and implementation of actions to reduce these risks

Measurable Elements of PCI.03.01

1. Ⓓ The hospital identifies, in writing, single-use devices and materials that may be reused in accordance with local and national laws and regulations. (*See also* GHI.04.00, ME 4)
2. The hospital has a process for identifying when a single-use device is no longer safe or suitable for reuse.
3. The hospital has a process for cleaning, disinfection, or sterilization for each reusable, single-use device, in accordance with laws and regulations, manufacturer's requirements, or other applicable requirements.
4. Ⓓ The hospital has a written process to track the reuse of single-use devices to individual patients.
5. Ⓓ The hospital collects and analyzes data for any adverse events, and implements improvements related to the reuse process.

Standard PCI.03.02

The hospital implements a process for managing expired and damaged devices and supplies.

Intent of PCI.03.02

The use of expired or damaged supplies presents a risk to patients related to infection, or loss of integrity and function. The hospital must implement a process to manage inventory of devices and supplies, including expiration dates, and remove those items from service when outdated. This includes a process to identify damaged supplies, such as loss of package integrity, or damage that impairs the intended use of the supplies, and remove those from service. Most medical supplies are imprinted with an expiration date. The manufacturer does not guarantee the sterility, safety, or stability of the item after the expiration date. A policy defines the process for ensuring proper management of expired supplies. Damaged supplies pose risks to patients, as the