The Joint Commission

The Joint Commission Guide to Reprocessing Reusable Medical Devices

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Introduction

Note: At the time of publication, the "Infection Prevention and Control" (IC) chapter of The Joint Commission's *Comprehensive Accreditation Manuals* and corresponding E-dition is being revised to better align with the language of Centers for Medicare and Medicaid Services (CMS) requirements. Updates and revisions to the IC chapter are scheduled to become effective July 1, 2024, for several accreditation programs. Although requirement numbers may change, the overarching concepts will remain. As always, readers are encouraged to refer to the most current version of IC standards available for their program setting.

Proper *reprocessing* (a term for device cleaning, disinfection, and sterilization) of reusable medical devices is essential to prevent and control infection among patients and to mitigate exposure of patients and staff to chemicals used. The cleaning, disinfection, and sterilization processes described in this book are complex, though they have a simple common denominator: A reusable medical device must be cleaned first and then disinfected (at the required level of intensity) or sterilized.

Joint Commission compliance data, published investigations of outbreaks related to medical devices and equipment, and numerous government agency and media reports have illustrated that the processes involved in medical device reprocessing pose a serious, widespread challenge for many health care organizations (HCOs). The challenge arises when staff vary from or miss steps in manufacturers' instructions for use.[1] Broad in scope, this problem affects inpatient settings such as acute care and long-term care facilities and outpatient settings such as ambulatory surgical centers, endoscopy centers, outpatient clinics, hemodialysis centers, and dental and physician offices.[2,3]

Consequently, it is critical for Joint Commission–accredited HCOs to understand the regulations, standards, protocols, procedures, and best practices related to medical device cleaning, disinfection, and sterilization. Not following manufacturers' instructions for cleaning and inspecting medical devices between patients can result in blood, tissue, and other debris being retained in or on medical devices. Moreover, not following manufacturers' validated parameters for sterilization can result in the release of a nonsterile device back into use, putting patients at risk. Ineffective reprocessing of medical devices has led to multiple outbreaks of infection, causing morbidity and mortality among care recipients.[4–13]

Related Joint Commission and JCI Standards

The Joint Commission addresses medical device cleaning, disinfection, and sterilization under two key standards—one in the "Infection Prevention and Control" chapter and the other in the "Environment of Care" chapter of your organization's *Comprehensive Accreditation Manual* or its E-dition® counterpart:

- **Infection Prevention and Control (IC) Standard IC.02.02.01—**The [organization] reduces the risk of infection associated with medical equipment, devices, and supplies.
- **Environment of Care (EC) Standard EC.02.04.03—** The [organization] inspects, tests, and maintains medical equipment.

These standards apply to all Joint Commission accreditation programs. This book aims to help HCOs understand proper cleaning, high-level disinfection, and sterilization as well as maintenance of supplies, equipment, and accessories.

Joint Commission International (JCI) covers cleaning, disinfecting, and sterilizing medical devices under two Prevention and Control of Infections (PCI) standards[14]:

- **Standard PCI.6—**The [organization] reduces the risk of infections associated with medical/surgical equipment, devices, and supplies by ensuring adequate cleaning, disinfection, sterilization, and storage.
- **Standard PCI.6.1—**The [organization] identifies and implements a process for managing the reuse of single-use devices consistent with regional and local laws and regulations and implements a process for managing expired supplies.

For the past 10 years, Joint Commission standards and elements of performance (EPs) related to cleaning, disinfection, and sterilization have been consistently among the top 5–cited standards for noncompliance. Compliance with PCI standards also remains a significant, higher-hazard challenge. (This book does not address PCI compliance in detail, but the principles and procedures discussed throughout would apply to international health care settings.)

Compliance Obstacles

Joint Commission surveyors in the United States frequently cite organizations for reprocessing deficiencies under IC.02.02.01 and EC.02.04.03. In fact, for accredited ambulatory care, critical access hospital, hospital, and office-based surgery organizations, Joint Commission standards and elements of performance (EPs) related to cleaning, disinfection, and sterilization are among the most cited for noncompliance each year.

Indeed, during the past five years, findings related to cleaning, disinfection, and sterilization have been among the top five drivers of Joint Commission Immediate Threat to Health or Safety (ITHS) declarations. In other words, not only are deficiencies pertaining to medical device reprocessing among the most frequently cited, but they also are among the most immediately hazardous.

Implications of an ITHS finding

When surveyors suspect a finding at the ITHS level, they are required to call The Joint Commission's Central Office, where a team reviews the finding and, if warranted, informs an officer of The Joint Commission.

Only an officer can declare an ITHS—after meeting with the organization's leaders and reviewing the findings.

Once an ITHS declaration is made, the HCO's accreditation status is changed to Preliminary Denial of Accreditation (PDA). The PDA status will remain until a surveyor can return and confirm that the ITHS has been fully abated. In addition to notifying the Centers for Medicare & Medicaid Services (CMS) for deemed organizations, state agencies may also need to be notified of findings related to an ITHS.

Full-year 2022 compliance data

In 2022, the top-cited higher-risk EP for hospitals, critical access hospitals, ambulatory care organizations, and office-based surgery practices was **IC.02.02.01, EP 2:** The [organization] implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. (*See* Tool I-1, "Most Frequently Cited Higher-Risk EPs for Four Joint Commission Accreditation Programs," for a visual depiction of the following data.)

Ambulatory care organizations with noncompliant reprocessing: Of the 782 ambulatory care organizations surveyed in 2022, 39% were not compliant with IC.02.02.01, EP 2. As shown in Tool I-1, eight of the citations under IC.02.02.01, EP 2, were declared ITHS (dark red) and 133 fell in the "high likelihood to harm" (bright red) zone of the aggregate *Survey Analysis for Evaluating Risk*® (*SAFER*®) Matrix, The Joint Commission's system of classifying deficiencies based on likelihood, severity, and scope of potential harm. Surveyors classified 85 findings under this EP as moderate risk (orange zone). This means that 29% of all findings under IC.02.02.01, EP 2, were of moderate or higher risk.

Also ranking among the top 10 for noncompliance was **EC.02.04.03, EP 4:** The [organization] conducts performance testing of and maintains all sterilizers. These activities are documented. (*See also* IC.02.02.01, EP 2.)

In 2022, 12.21% of surveyed ambulatory care organizations did not comply with EC.02.04.03, EP 4.

Surveyors classified 26 of the findings as high risk and 13 of them as moderate risk.

Hospitals with noncompliant reprocessing: For accredited hospitals, the results were even worse. Of the 1,511 hospitals surveyed in 2022, 53.64% were noncompliant with IC.02.02.01, EP 2. As Tool I-1 indicates, the findings included 18 ITHS declarations, 477 citations classified as high risk, and 115 citations classified as moderate risk. This means that approximately 40% of the findings under this EP were of moderate or higher risk.

Critical access hospitals with noncompliant reprocessing: Critical access hospitals fared almost as poorly. Of the 131 critical access hospitals surveyed in 2022, 51.91% were noncompliant with IC.02.02.01, EP 2. The findings included one ITHS declaration, 34 citations classified as high risk, and nine classified as moderate risk. Approximately 34% of the citations under this EP were of moderate or higher risk.

Office-based surgery practices with noncompliant reprocessing: Of the 182 office-based surgery practices surveyed in 2022, 45.83% were not compliant with IC.02.02.01, EP 2. These findings included four ITHS declarations, 25 high-risk citations, and 12 moderate-risk citations. Nearly 23% of the findings under this EP were of moderate or higher risk.

Reprocessing Challenges

Failure to properly clean and disinfect or sterilize medical devices is not only hazardous for patients undergoing procedures, but it also increases the risk of person-to-person spread of infection in health care facilities. Common problems include the following (details are provided later in this book)[8–13, 15–21]:

- Reprocessing in a manner inconsistent with the intended use of the medical device or reprocessing equipment
- Failure to follow manufacturers' instructions for use (IFUs)
- Not seeking clarification when manufacturers' IFUs are unclear, inadequate, or suspected to be outdated due to conflicting or updated information on a manufacturer's website or a recent report for the US Food & Drug Administration (FDA), for example
- Lack of adequate education, training, and competency assessment for staff responsible for using or reprocessing medical devices or supervising the use and reprocessing of medical devices
- Continued use of devices despite integrity, maintenance, and/or mechanical issues
- Design flaws in the device or piece of equipment that negate the ability to effectively reprocess it
- Reprocessing of medical devices that have been FDA–approved for only a single use (Note: Some of these items may be reprocessed by FDA–approved reprocessors.)

As this book will explain, risk can be reduced when facilities do the following[8–21]:

- Ensure that reprocessing instructions supplied by each item's manufacturer match the required level of reprocessing based on how the organization is using the device.
- Make sure that staff have access to current IFUs that provide information relevant to their job duties, whether involving use or reprocessing of the device. (Note: Organizations must have a process for ensuring that they have the most up-to-date version of instructions.)
- Provide the appropriate physical environment as well as compatible supplies and equipment to support use, reprocessing, and storage.
- Ensure that staff are educated, trained, and competent to reprocess each reusable medical device and to use each reprocessing accessory correctly.
- Implement stringent inspection and, as applicable, quality controls for devices, accessories, and reprocessing.

Why This Book?

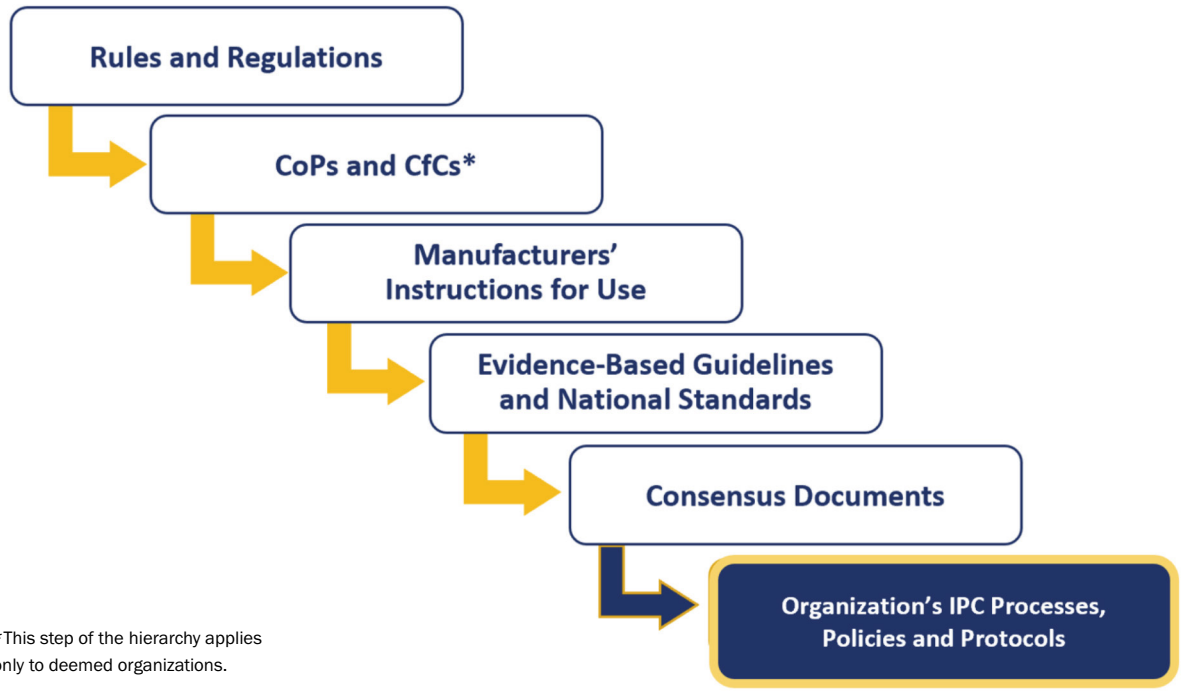
Clearly, when it comes to cleaning, disinfecting, and sterilizing medical devices, errors can occur; therefore, HCOs need to be proactive, organized, and vigilant to prevent them. Accordingly, the primary purposes of this book are to support effective, safe cleaning, disinfection, and sterilization and to help Joint Commission–accredited and JCI–accredited organizations comply with the standards. *The Joint Commission Guide to Reprocessing Reusable Medical Devices* explains the *why* behind required and

recommended practices and clarifies the complexity associated with device reprocessing. Notably, using Joint Commission standards to check for defects in device reprocessing may significantly reduce the frequency of adverse events associated with reusable devices.[22]

Hierarchical approach to developing reprocessing policies and procedures

Every organization uses different combinations of medical devices, equipment, supplies, and accessories. The Joint Commission is not prescriptive about products. Instead, the standards focus on processes that increase reliability of achieving the best outcome. Therefore, The Joint Commission's and JCI's requirements in this realm are not highly specific because of the need to allow organizations some flexibility in developing their own policies and protocols while following some common principles and processes. As this book emphasizes, The Joint Commission expects organizations to observe a hierarchical approach (*see* Figure I-1) when developing their cleaning, disinfection, and sterilization policies and procedures. Organizations must start by adhering to applicable (federal, state, and local) laws and regulations; followed by CMS Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) for organizations in the United States that use their accreditation for deemed status purposes; manufacturers' instructions for use; and, finally, national standards such as The Joint Commission's evidence-based guidelines, consensus documents, and position papers. Organizations must use care when choosing any evidence-based guidelines, consensus documents, and position papers to ensure that they do not conflict with a

Figure I-1.
Hierarchical Approach to Cleaning, Disinfection, and Sterilization



*This step of the hierarchy applies only to deemed organizations.

Source: *Joint Commission Perspectives*®, April 2019. *See also* the Hierarchical Guide to Comply with Infection Prevention and Control Requirements on JointCommission.org. This hierarchy does not necessarily apply to JCI because CMS does not have international authority. Accessed May 20, 2023. https://www.jointcommission.org/resources/patient-safety-topics/infection-prevention-and-control/infection-prevention-and-control-hierarchy

requirement in the preceding portions of the hierarchy. Though listed at the bottom of the hierarchy, an organization's own policies, processes, and protocols must be followed. Indeed, Joint Commission surveyors frequently cite organizations for not following their own written policies and procedures.

Despite the variation in policy and protocol development based on an organization's unique attributes and choices related to cleaning, disinfection, and sterilization, organizations must follow rigorous approaches, validate their choices, and adhere to their own rules. It bears repeating that if an organization's policies and procedures go beyond what The Joint Commission and CMS require, surveyors can still cite the organization for not observing its own policy. The Joint Commission does not endorse or disparage any medical devices or accessories. Specific manufacturers, brands, and models are not named in this book. The Joint Commission's overriding goal is to help HCOs implement processes that contribute to safe and effective care of the highest quality and value.

Audiences for This Book

This book is a resource for infection preventionists and anyone responsible for selecting, using, or reprocessing medical devices and equipment, including those with oversight of these processes. In particular, staff involved in the following activities or their oversight will benefit from this book:

- Cleaning, disinfecting, and sterilizing medical devices
- Maintaining the equipment used in disinfection and sterilization
- Handling, storing, and disposing of disinfectants and sterilants
- Educating, training, and evaluating the competency of staff involved in the above processes
- Developing policies and procedures governing reprocessing

This book presumes some general knowledge of infection prevention and control as well as medical devices and how they are used. This book is helpful for those new to the topic as well as intermediate-level and seasoned professionals.

Note that this book is not a general overview of all aspects of cleaning, disinfection, and sterilization in health care settings. This book does not address environmental disinfection. Although low-level disinfection of noncritical equipment is mentioned in the discussion of the Spaulding classification system in Chapter 1, this topic is not the book's focus. The intent of this book is to highlight specific problem areas related to high-level disinfection or sterilization.

Intended primarily for a US audience, *The Joint Commission Guide to Reprocessing Reusable Medical Devices* refers to US government agencies and does not address international laws and regulations. However, this book does describe the pertinent JCI standards. More importantly, the principles and practices discussed throughout this book are applicable anywhere in the world. International audiences should find value in the subsequent chapters.

How This Book Is Organized

This book is organized into three chapters:

- **Chapter 1. Reprocessing Basics: The Spaulding Classification System, Single-Use Devices, and Manufacturer Instructions**
  Chapter 1 explains that the level of reprocessing required for a reusable medical device is based primarily on its *intended use*—that is, critical, semi-critical, or non-critical. *Critical use* means a device will be used in the vascular system or sterile tissue. *Semi-critical use* means a device will come into contact with mucous membranes or non-intact skin. *Non-critical use* means a device will contact intact skin only. In a nutshell, critical devices require sterilization; semi-critical devices require at least high-level disinfection (HLD); and non-critical devices require low-level disinfection or intermediate-level disinfection (if contaminated with blood). All medical devices must be cleaned before being disinfected or sterilized.

- **Chapter 2. High-Level Disinfection of Semi-Critical Devices: An Ongoing Challenge**
  Chapter 2 emphasizes that more health care–associated infections (HAIs) have been linked to

flexible endoscopes than to any other medical device. This chapter, which focuses on the high-level disinfection of flexible endoscopes and ultrasound transducers used in semi-critical applications, explains each step in the HLD process for these semi-critical devices: treatment at the point of use, containment (when applicable) and transportation to the decontamination area, inspection for surface integrity and leak testing, cleaning, rinsing and drying, visual inspection, high-level disinfection (manual or automated), rinsing after high-level disinfection, drying after rinsing, and storing the device.

- **Chapter 3. Sterilization**
  Chapter 3 explains each step in the sterilization cycle for critical devices: point-of-use treatment, preparing for transport, transport to the decontamination area, cleaning and decontamination, inspection, packaging, sterilization, release, storage, and verification of process integrity. Various process controls are discussed in detail.

Each chapter includes customizable, downloadable tools to help organizations comply with Joint Commission requirements and establish their own robust policies and procedures. (For readers of the print version of this book, the URL to access all tools is provided on page vi and can be typed into your browser.

At the end of the book is a glossary of key terms, which are indicated in bold teal text when introduced in the chapters.

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Tool to Try

Tool I-1. Most Frequently Cited Higher-Risk EPs for Four Joint Commission Accreditation Programs

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