



An advisory on safety & quality issues

Issue Two

May 2014

Improperly sterilized or high-level disinfected equipment

Issue:

While on survey, Joint Commission surveyors are increasingly finding noncompliance with standard IC.02.02.01, which requires organizations to reduce the risk of infections associated with medical equipment, devices, and supplies. In 2013, standard IC.02.02.01 was one of the [top five non-compliant Joint Commission requirements](#) for hospitals, critical access hospitals, ambulatory and office-based surgery facilities. The 2013 noncompliance rate by program was: hospital (46 percent); critical access hospital (47 percent); ambulatory care (38 percent); and office-based surgery (29 percent). Even more disturbing is the fact that of 13 immediate threat to life (ITL) discoveries from surveys conducted in 2013, seven were directly related to improperly sterilized or high-level disinfected equipment. The Joint Commission takes ITLs seriously; if discovered on survey, the organization immediately receives a preliminary denial of accreditation (PDA) and, within 72 hours, must either entirely eliminate the ITL or implement emergency interventions to abate the risk to patients (with a maximum of 23 days to totally eliminate the ITL). Corrective actions may include: reprocessing of all equipment or instruments involved in the infection control breach; evaluating staff competency and conducting training; and implementing an equipment tracking process that traces items used back to the patient, in the event of an infection control breach or recall.

Breaches in equipment sterilization and high-level disinfection processes can result in outbreaks of HIV, and hepatitis B and C, as well as the transmission of bacterial infecting agents, such as *Pseudomonas aeruginosa*, *E.coli*, MRSA (methicillin resistant *Staphylococcus aureus*), salmonella, and *Clostridium sordellii*. In many instances, the problem is long-standing, and the true scope of the problem isn't known until there is an outbreak or the CDC is called in because the contamination is out of control. Facilities that undergo an outbreak or shut-down also have repercussions from bad publicity and loss of business, not to mention damage to the organization's reputation. A typical case scenario (aggregated from the reports to The Joint Commission's Office of Quality Monitoring) follows: *A process failure occurred in the processing of endoscopes. Specifically, the soaking cycle required a soaking cycle of 20 minutes; the programmed cycle was 5 minutes. A number of patients were at risk for infection, including lung transplant, HIV, oncology and cystic fibrosis patients. The organization had no mechanism in place to track equipment use by patient.*

According to reports to The Joint Commission's Office of Quality Monitoring, findings from non-complying organizations include:

- The mistaken belief that the risk of passing bloodborne pathogens or bacterial agents to patients is low
- Staff lack the knowledge or training required to properly sterilize or high-level disinfect equipment
- Staff don't have access to or lack knowledge of evidence-based guidelines
- Lack of leadership support
- Frequent leadership and staff turnover makes sterilization or high-level disinfection of equipment a low priority
- Lack of a culture of safety that supports the reporting of safety risks
- Processes for sterilization or high-level disinfection are not followed (i.e., staff take short-cuts)
- The time frames for proper sterilization or high-level disinfection of equipment are not followed
- There is no dedicated staff person to oversee the proper sterilization or high-level disinfection of equipment

(Cont.)



Legal disclaimer: This material is meant as an information piece only; it is not a standard or a *Sentinel Event Alert*.

The intent of *Quick Safety* is to raise awareness and to be helpful to Joint Commission-accredited organizations.

The information in this publication is derived from actual events that occur in health care.

- Facility design or space issues prevent proper sterilization or high-level disinfection of equipment (e.g., processing takes place in a small room that is also used for storage)
- Lack of monitoring or documentation of sterilization or high-level disinfection of equipment, which makes it difficult to track the use of equipment on a specific patient, complicating the patient notification process when an outbreak occurs
- Equipment is spread throughout the facility and may be processed or stored in numerous locations, making it difficult to track the equipment for documentation purposes.

Safety Actions to Consider:

- Make sure staff are competent and trained in sterilization or high-level disinfection of equipment
- Make manufacturer's instructions available to staff and ensure that the instructions are followed
- Use and follow evidence-based guidelines when sterilizing or high-level disinfecting equipment
- Ensure oversight of sterilization or high-level disinfection of equipment
- Follow your organization's policies and procedures for sterilizing or high-level disinfecting of equipment
- Use a central location to sterilize or high-level disinfect equipment within the facility, when feasible

Resources:

- American National Standards Institute (ANSI) and Association for the Advancement of Medical Instrumentation (AAMI): *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012
- American National Standards Institute (ANSI) and Association for the Advancement of Medical Instrumentation (AAMI): *Chemical sterilization and high-level disinfection in health care facilities*, ANSI/AAMI ST58:2013
- Centers for Disease Control and Prevention: *CDC Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008
- Association of periOperative Registered Nurses: *AORN 2013 Perioperative Standards and Recommended Practices for Sterilization*

Note: This is not an all-inclusive list.