American Journal of Infection Control 44 (2016) e35-e39

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

Taking the chaos out of accreditation surveys in sterile processing: High-level disinfection, sterilization, and antisepsis

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Key Words:
Health care-associated infections
Surgical site infections

Health care accreditation processes are conducted with a focus on safety and quality of patient care. Accreditation, or lack of it, can affect the organization's ability to be reimbursed for services provided. Sterile processing in health care facilities has become an increasingly larger focus of the accreditation survey process. Health care organizations that reprocess medical devices must be prepared to demonstrate compliance with standards when they are surveyed. Understanding and following current guidelines and recommendations can help ensure the health care facility is ready for unannounced accreditation surveys.

The main goal of any health care accreditation survey process is to help organizations take a systems approach in evaluating their patient care and improving facility-wide processes for safer patient care.

Certification and accreditation can also have an influence on a health care organization's bottom line. Facilities must comply with the government's Conditions of Participation (CoPs) to qualify for federal funding for patients in Centers for Medicare and Medicaid (CMS) programs.[1] To receive payment from CMS, a health care provider must be accredited by an approved national accreditation organization (AO) to determine compliance with Medicare conditions.

CMS may grant authority to an AO only if the organization applies and demonstrates its ability to meet or exceed the Medicare conditions of participation/coverage as cited in the *Code of Federal Regulations*. AOs that have CMS authority include:

- Accreditation Association for Ambulatory Healthcare,
- Accreditation Commission for Healthcare,
- American Association for Accreditation of Ambulatory Surgery Facilities,
- American Osteopathic Association/Healthcare Facilities Accreditation Program,
- Center for Improvement of Healthcare Quality,
- Community Health Accreditation Program,
- DNV Healthcare, and
- The Joint Commission.[2]

Health care accreditation is universally recognized as a means of improving the safety and quality of patient care. Accreditation surveys can be performed by a variety of agencies and professional organizations with the main emphasis on a facility's risk reduction and process improvement activities. Due to current outbreaks caused by questionably reprocessed medical devices, and the national emphasis on decreasing health care-associated infections such as surgical site infections, surveyors are placing an emphases on activities around reprocessing reusable medical devices.[3] During the accreditation process health care facilities should expect and be prepared for surveyors to thoroughly review sterile processing procedures and any areas where reprocessing takes place. Surveyors will more than likely also want to focus on flexible endoscope reprocessing.

CMS WORKSHEETS

CMS has 3 surveyor worksheets for assessing facility compliance with the CoPs and that focus on patient safety. The worksheets include:

- Quality Assessment and Performance Improvement,
- Infection Control, and
- Discharge Planning.[4]

Health care organizations can use the worksheets to help evaluate their own compliance and performance by doing a self-assessment.

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Publication of this article was supported by an educational grant from Clorox Healthcare, Sealed Air, and Tru-D. Content of this article was initiated and written by the author with no input or financial support to the author from Clorox Healthcare, Sealed Air, or Tru-D.
Conflicts of Interest: None to report.

0196-6553/
http://dx.doi.org/10.1016/j.ajic.2016.03.002

The Infection Control worksheet consists of 5 modules, and each module is subdivided into multiple sections. Each section describes the essential items to be assessed during the onsite survey. Sterilization and high-level disinfection (HLD) are found in Module 3 of the Infection Control worksheet. Section 1.A.3 of Module 3 states: "The Infection Control Officer(s) can provide evidence that the hospital has developed general infection control policies and procedures that are based on nationally recognized guidelines and applicable state and federal law."[4]

Surveyors will want to see that the organizational policies on sterilization and HLD are based on current published standards, guidelines, and recommendations by professional organizations such as the Association of periOPerative Registered Nurses (AORN), the Association for the Advancement of Medical Instrumentation (AAMI), and the Centers for Disease Control and Prevention.

CURRENT REPROCESSING GUIDELINES

Some of the most currently updated resources for sterilization and HLD standards, guidelines, and recommendations include:

- AORN *Guidelines for Perioperative Practices, 2015*,[5]
- AORN *Guidelines and Tools for the Sterile Processing Team Derived from AORN Guidelines for Perioperative Practice, 2016*,[5]
- AAMI *ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* (ANSI/AAMI ST79: 2010, A1:2010, A2:2011, A3:2012, and A4:2013),[6]
- AAMI ST58:2013 *Chemical Sterilization and High-Level Disinfection in Health Care Facilities*,[7]
- AAMI ST41:2008 (R2012) *Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness*,[8]
- AAMI ST91:2015 *Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities*,[9] and
- Centers for Disease Control and Prevention's *Guideline for Decontamination and Sterilization in Healthcare Facilities, 2008*.[10]

When developing polices, it is a good idea to reference which specific recommendations or guidelines the policy will follow (eg, the decision to store flexible endoscopes and endoscope accessories in a manner that minimizes contamination and protects the device or item from damage can be attributed to AORN *Guideline for Processing Flexible Endoscopes* recommendation IX). Citing the published standards or guideline used as the resource for each specific policy ensures the most currently updated resources are being used. Delineating the specific section of a guideline will be a great reference point when it is time to update the policy.

CMS ADDRESSES USE OF IMMEDIATE USE STEAM STERILIZATION

On August 29, 2014, CMS sent a memo to State Survey Agency Directors titled "Change in Terminology and Update of Survey and Certification Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings." The letter stated that IUSS is not an appropriate substitute for maintaining a sufficient inventory of instruments and that IUSS will be part of the survey procedure. If surveyors find IUSS used in a manner that places patients at risk for infections, they should issue an appropriate infection control citation.[11] Health care facilities should anticipate and be prepared for IUSS to be among the top priorities during their next accreditation survey.

The CMS letter stated that IUSS should only be used in an emergency and that the facility should have processes in place to ensure:

- IUSS is not used for implants;
- The manufacturer's instructions for use (IFU) are followed;
- The sterilizers are well maintained;
- Correct monitors are used, evaluated, and documented by trained personnel;
- Items are aseptically transported and cooled before use; and
- Personnel are monitored for strict adherence to policy.[11]

JOINT COMMISSION RESOURCES

The Joint Commission publishes the official handbooks used in the survey process. Examples include the *Comprehensive Accreditation Manual for Hospitals*, the *Comprehensive Accreditation Manual for Ambulatory Care*, and the *Comprehensive Accreditation Manual for Office-Based Surgery*. The accreditation manuals are crucial to understanding Joint Commission standards and preparing for a survey. These 3 official handbooks are organized in the same way; however, there are some slight modifications that take into account the different practice settings.[12-14]

To provide guidance on what to expect from a survey process, the Joint Commission uses standards, rationale statements, and elements of performance. The standards are considered the performance objectives. The rationales describe the importance of those standard objectives. Each individual standard has at least 1 but more often several elements of performance. The elements of performance specify how the standard or objective should be met. The elements of performance are where the rubber meets the road because the elements of performance individual scores determine overall compliance with the standard. Facilities must receive a minimum of score of 90% on every element of the survey.[12-14] The standards most significant to those areas that reprocess reusable medical devices can be found in the following categories:

- Environment of care,
- Human resources,
- Infection prevention and control (IPC),
- Leadership, and
- Performance improvement.[3]

One of the top-5 overall noncompliance citings from Joint Commission surveyors relates to infection control standard IC.02.02.01. This standard requires facilities to reduce the risk of infections associated with medical equipment, devices, and supplies. Approximately 25%-50% of hospitals, critical access hospitals, and ambulatory and office-based surgery facilities surveyed in 2013 were found to be noncompliant with IC.02.02.01.[15]

Some of the Joint Commission citings for noncompliance include:

- Lack of knowledge or training required to properly sterilize or apply HLD to equipment,
- No access or lack of knowledge of evidence-based guidelines,
- Lack of leadership support,
- Sterilization or HLD of equipment a low priority,
- Lack the culture of safety,
- Short-cuts taken relating to sterilization or HLD,
- No dedicated staff person to oversee proper sterilization or HLD,
- Facility design and space issues,
- Lack of monitoring or documentation makes it difficult to track instrument and equipment use to individual patients, and
- Reprocessing and storage of equipment in several locations within the facility.[15]

The Joint Commission recommends the following safety actions to consider: