HEALTHCARE PURCHASING NEWS

SELF-STUDY SERIES

Accreditation preparation for sterile processing

by Rose E. Seavey MBA, BS, RN, CNOR, CRCST, CSPDT

October 2019

The self-study lesson on this central service topic was developed by 3M Health Care. The lessons are administered by Endeavor Healthcare Media

Earn CEUs

After careful study of the lesson, complete the examination at the end of this section. Mail the completed test and scoring fee to *Healthcare Purchasing News* for grading. We will notify you if you have a passing score of 70 percent or higher, and you will receive a certificate of completion within 30 days. Previous lessons are available at www.hpnonline.com.

Certification

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this in-service for one (1) contact hour for a period of five (5) years from the date of original publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individual until re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD. For additional information regarding certification contact CBSPD - 148 Main Street, Suite C-1, Lebanon, NJ 08833 • www.sterileprocessing.org.

IAHCSMM (International Association of Healthcare Central Service Materiel Management) has pre-approved this in-service for 1.0 Continuing Education Credits for a period of three years, until September 9, 2022. The approval number for this lesson is **3M-HPN 190909**.

For more information, direct any questions to *Healthcare Purchasing News* (941) 927-9345, ext. 202.

LEARNING OBJECTIVES

1. *Discuss the motivation and focus of a healthcare accreditation survey process.*
2. *Describe the importance of following current published standards, guidelines and recommended practices.*
3. *Illustrate the Joint Commission's updated High-Level Disinfection and Sterilization scoring guidelines.*

Sponsored by:

3M Health Care

Risk reduction and process improvements are the heart and soul of any accreditation survey. Healthcare accreditation surveys are designed to help organizations take a well-thought-out approach to evaluating patient care processes and improving those processes for the betterment of patient care and safety. Accreditation surveys are performed by various organizations and are widely recognized as a means of improving the quality of healthcare. Surveyors are healthcare professionals (nurses, physicians, medical directors, engineers and administrators) who perform surveys whose main focus is on the safety of patients.

The foremost emphasis on healthcare accreditation surveys is to measure the safety and performance of organizations in order to assess compliance with current nationally published standards, guidelines and recommended practices. Surveyors will be seeking processes aimed at improving the quality and safety and that policies are written according to currently published, evidenced-based best practices. Surveyors will want to see policies that are consistent throughout the organization and that those policies are routinely followed. Each accreditation organization (AO) has specific standards and available documents that healthcare facilities can review before a survey.[1]

Many insurance companies require accreditation in order to be reimbursed for payment for services rendered. Healthcare facilities must demonstrate they comply with the government's Conditions of Participation (CoP) to qualify for federal funding for patients on the Center for Medicare and Medicaid Services (CMS) programs. Therefore, accreditation has a definite financial impact on a healthcare organization's budget based on reimbursements.[1]

CMS compliance

Payment from CMS depends on a healthcare's accreditation status. Facilities must be certified and accredited by a CMS approved AO in order to establish compliance with Medicare conditions. AOs are granted deeming authority as an accreditation provider by applying and demonstrating their ability to meet or exceed the Medicare conditions of payment (CoP) as cited in the Code of Federal Regulations.[1]

There are many AOs that have received deeming authority by CMS such as:

- Accreditation Association for Ambulatory Health Care (AAAHC)
- Accreditation Commission for Health Care (ACHC)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- Healthcare Facilities Accreditation Program (HFAP)
- Center for Improvement in Healthcare Quality (CIHQ)
- Community Health Accreditation Partner (CHAP)
- DNV GL - Healthcare (DNV GL)
- Institute for Medical Quality (IMQ)
- National Dialysis Accreditation Commission (NDAC)
- The Compliance Team (TCT)
- The Joint Commission (TJC)[2]

No matter which AO the organization engages, the intent of the survey is to ensure the organization complies with the government's rulings. In order to evaluate compliance with healthcare organizations CoP, the CMS provides surveyor worksheets that focus on patient safety by evaluating efforts intended at decreasing healthcare-acquired conditions such as surgical site infections (SSI).

The CMS surveyor worksheet for infection control is broken down into the following modules including:

- Module 1: Infection Control/Prevention Program
- Module 2: General Infection Control Elements
- Module 3: Equipment Reprocessing
- Module 4: Patient Tracers
- Module 5: Special Care Environments

Each module is broken down into several sections, which describe the elements to be assessed during a survey.[1]

High-level disinfection (HLD) and sterilization fall under the CMS Infection Control Worksheet under Module 3, Equipment Reprocessing. The surveyor will most likely want to see that the policies are developed and written according to current published standards, guidelines and recommendations by professional organizations. Referencing the precise recommendations in policies is a great way to let surveyors know that you follow current published standards and guidelines.[3]

The Joint Commission

TJC offers accreditation for many types of health care organizations, including hospitals, doctors' offices, nursing homes, office-based surgeries, behavioral health treatment facilities, and providers of home care services. Having TJC accreditation and certification is a symbol of quality and commitment to standards of performance.[4]

TJC standards and elements of performance

TJC standards offers direction on what to expect from a survey process. Standards have rationale statements and elements of performance (EP). The standards are the performance objectives, while the rationales demonstrate the importance of those objectives. Each standard has elements of performance (EPs) which make clear how the standard is met. The conformity with the standard is determined by each EP score. The standards that have the most influence on Sterile Processing are:

- Environment of Care,
- Human Resources,
- Infection Prevention and Control,
- Process Improvements, and
- Leadership.[1]

Specific concerns with processing

One of the most noncompliant TJC standards relating to sterilization HLD is the infection control standard IC.02.02.01. This standard requires healthcare organizations to reduce the risk of infections associated with medical equipment, devices and supplies. After a reviewing high-level disinfection (HLD) and sterilization, TJC updated its scoring around process steps that pose the highest risk to patients if they are not followed.[5] Recently TJC announced their 4-1-1 Survey Enhancements which is meant to take an in-depth review at four high-risk areas which are:

- Sterile medication compounding,
- HLD and sterilization,
- Suicide prevention, and
- Hemodialysis.[5]

These refined standards went into effect September 1, 2018. Surveyors will be looking closely at scoring revisions for all the high-risk processing steps. Standard IC.02.02.01 will be scored as noncompliant if the manufacture instructions for use (IFU) are not followed.[5] This includes IFUs for instruments, equipment (e.g. sterilizers, ultrasonic, washers, etc.) containers, wrap, solutions, chemical and biological monitors, etc.

Surveyors will want to see that the organization has adopted evidence-based guidelines (EBG) and standards such as those published by:

- Association of periOperative Registered Nurses (AORN),
- Association for the Advancement of Medical Instrumentation (AAMI), and
- Centers for Disease Control and Prevention (CDC),

when developing infection prevention (IP) processes.[6,7]

In addition to following the EBG, surveyors will closely monitor processes to make sure the IFUs are being followed, according to Sylvia Garcia-Houchins, TJC's Director of Infection Prevention and Control. Some sticking points will be ensuring items are prepared for sterilization according to the IFU and therefore items are unlatched and disassembled.[7] The manufacturer's IFUs for storage must be followed, unless directions are not provided. In that case, compliance with the organization's policy or risk assessment will be evaluated.

During the survey, facilities may be cited if a "ready to use" instrument is visibly soiled and staff may be asked about their wipe and flush process at the point of use policy.[7]

Surveyors may:

- watch as a surgical case is opened
- inquire what the staff looks for when an instrument tray is opened
- ask what the staff does if visible bioburden is found on a sterile product[7]

Organizations must have a process in place that maintains moisture on soiled instruments. The process and or product used is up to the organization, though it should comply with AAMI and AORN standards.[7]

TJC's updated scoring guidelines echoes the Occupational Safety and Health Administration's (OSHA) requirement that sharps must be placed in a puncture-resistant red container or one marked as "biohazard".[7] In addition, all soiled instruments must be safely transported in a way that would not lead to contamination or injury. Appropriate transport containers/carts should be used. They should be covered, prevent items from falling off and have solid sides and bottoms. If open carts are used for transport, they need to be covered and marked as biohazard.[7]

Surveyors will want to "observe the instruments coming through the cleaning process to ensure they have been disassembled and are packaged in accordance with the item manufacturer instructions", says Garcia-Houchins .[7] Items in assembled peel packs, not yet sterilized, will be assessed for items being in an unlatched position.[7]

In the past, surveyors have cited facilities if processed hinged or ringed instruments were not "wide open". However, current AORN and AAMI guidelines state items should be sterilized in the unratcheted position and disassembled in accordance with manufacturer instructions.

In her blog, Garcia-Houchins stated: "We recognize that some instruments, such as scissors, are likely to close after sterilization when they are being transported or stored. Therefore, surveyors will review the process for ensuring the item is prepared in a manner that will ensure exposure to the sterilant. Surveyors will observe the instruments coming through the cleaning process to ensure that they have been disassembled and are packaged in accordance with manufacturer instructions. They will also review peel packs to see if items that are awaiting sterilization or have just been sterilized are in the unratcheted position. In order to ensure accurate scoring, surveyors may ask for manufacturer instructions for use to confirm whether an item should be taken apart."[7]

Staff may be asked to assemble a tray so the surveyor can observe that instruments are opened and inspected for cleanliness. Another option for surveyors is to ask to open a packaged tray not yet sterilized in order to inspect for opened and disassembled instruments according to the IFUs. [7] Surveyors will be reviewing sterilization monitor processes to ensure internal and external chemical indicators are used according to their specific IFU and that the physical cycle monitors are observed prior to releasing a sterilizer load. [7]

Sterilization of implant loads should be conducted according to AAMI and AORN

Self-Study Test Answers: 1. B, 2. B, 3. B, 4. A, 5. B, 6. B, 7. C, 8. D, 9. B, 10. A

Page 50

guidelines. So, prior to releasing the load, surveyors may review if staff asses the physical monitors, use of biological indicators (BI), and use of a type 5 integrating indicator. A noncompliant score will be given if an implant is used and the BI results are not recorded, unless the facility has an emergent release policy stating they can be released prior to reading the BI results.[7]

Storage of HLD items will be reviewed for compliance with the manufacturers' storage IFUs and/or organization policies and risk assessments. Noncompliant scoring will be given if the guidelines are not followed or if surveyors observe staff contaminating other items such as those that have undergone HLD.[7]

Careful endoscope drying prior to storage is extremely important and will be monitored during a survey process. "Surveyors will check for compliance with manufacturers' instructions for drying scopes but will no longer score any finding related to hang time unless a reprocessing frequency has been specified by the endoscope manufacturer and is not followed," commented Garcia-Houchins.

Accreditation preparation

Accreditation surveys are unannounced, therefore healthcare organizations should be continuously prepared for a survey. Creating a multidisciplinary sterilization and HLD accreditation preparation committee, which includes representatives from all stakeholders, can be very helpful to ensure the organization is improving processes and therefore reducing risks to their patients.

When writing organization policies and procedures (P&P), a multidisciplinary approach should be used to ensure standardization throughout the organization. The P&P should be written according to current published guidelines. Facilities can follow which organizational guidelines they choose (e.g. AORN, AAMI, CDC, etc.) however, those resources should be referenced in the P&P. Surveyors will want to know which guidelines the organization follows and that it matches the written P&P. Referencing the exact guideline or standard will also be very helpful when it is time to update the P&P.

The committee should include representatives from all stakeholders, have readily available the current accreditation standards the facility uses, and ensure P&P are written and referenced to current guidelines or standards. Mock surveys conducted by this committee can be extremely helpful to ensure P&P are continuously followed. Multidisciplinary risk assessments should be routinely conducted (at least annually) to look for opportunities for process improvements that can reduce risks to their patients and employees.

As former U.S. Deputy Attorney General Paul McNulty said, "If you think compliance is expensive — try non-compliance!" No facility wants to be in the media headlines or be on trial for putting their patients at risk for transmission of infections. HPN

References

1. Seavey, R. Association for the Advancement of Medical Instrumentation. *Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys.* ANSI/AAMI Third ed. 2017.

2. Centers for Medicare & Medicaid Services. CMS-Approved Accrediting Organizations—Contacts for Prospective Clients. Available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf. Accessed August 19, 2019.

3. CMS Hospital Infection Control Worksheet. Available at: https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf. Accessed August 19, 2019.

4. About The Joint Commission. Available at: https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx. Accessed August 19, 2019.

5. 4-1-1 on Survey Enhancements: New scoring revisions for IC.02.02.01 now in effect. Available at: https://www.jointcommission.org/issues/article.aspx?Article=TxyLLkKRMlk3fa49bol37ifaNk%2FVnXTyOEFelZ4nD%2B4%3D. Accessed August 19, 2019.

6. Garcia-Houchins, S. Disinfection and Sterilization: Dispelling the Myths. Available at:_https://www.jointcommission.org/disinfection_and_sterilization_dispelling_myths/. Accessed August 19, 2019.

7. Garcia-Houchins, S. High Level Disinfection and Sterilization Scoring Re-Evaluated. The Joint Commission Blog Detail Page. Available at: https://www.jointcommission.org/on_infection_prevention_control/high_level_disinfection_and_sterilization_scoring_re-evaluated/?fbclid=IwAR3liWA7YzhKFFNh4Gw3UfjUBX8VNu8RPQ5-3CHs2QtLUjlwCbirxRg0TJI. Accessed August 19, 2019.

Rose Seavey MBA, BS, RN, CNOR, CRCST, CSPDT, is an Educational Consultant to 3M Health Care. Ms. Seavey is President/CEO of Seavey Healthcare Consulting. Ms. Seavey is the 2019 recipient of the AAMI Standards Developer Award. Ms. Seavey is the author of the book tilted Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys, *published by AAMI, now in its third edition.*

CONTINUING EDUCATION TEST • OCTOBER 2019

Accreditation preparation for sterile processing

Circle the one correct answer:

1. **The heart and soul of any accreditation surveys is:**
   A. Practicing good procedures during a survey
   B. Reducing risks and improving processes throughout the facility
   C. Ensuring all departments stay within their budget
   D. Making sure the halls are clear of equipment during a survey
2. **Accreditation has no financial impact on a healthcare facility.**
   A. True
   B. False
3. **The only accreditation organization with deeming authority from the CMS is the Joint Commission.**
   A. True
   B. False
4. **The Joint Commission surveyors are focusing on sterilization and high-level disinfection because recent breaches have resulted in high risks to patients.**
   A. True
   B. False
5. **The Joint Commission standard that requires healthcare organizations to reduce the risk of infections associated with medical equipment, devices and supplies is:**
   A. IC.01.01.02
   B. IC.02.02.01
   C. IC.03.03.01
   D. IC.04.04.04
6. **When developing policies and procedures each department must write their own individual policy.**
   A. True
   B. False
7. **The Joint Commission enhanced their surveys in order to:**
   A. promote patient safety and quality of care
   B. align the accreditations requirements with current recommendations from scientific professional and governmental organizations
   C. All of the above
   D. None of the above
8. **The Joint Commission surveyors want to observe the following:**
   A. Wiping/flushing soiled instruments in the operating room or procedure room where it is clinically appropriate
   B. A process for keeping soiled instruments moist
   C. The facility's policy for keeping instruments moist is followed
   D. All of the above
9. **Under the new 4-1-1 survey enhancements the Joint Commission surveyors will expect that all used instruments will be sprayed with an enzymatic detergent no matter what your policy states.**
   A. True
   B. False
10. **The Joint Commission will score or cite a facility if sharps are being transported in a manner that violates OSHA requirements (e.g., sharps not placed in puncture-resistant container that is red or labeled biohazardous).**
    A. True
    B. False

CONTINUING EDUCATION TEST SCORING

HEALTHCARE PURCHASING NEWS EDUCATION HUB

HPN is thrilled to now offer all CEU quizzes online by scanning the QR code on the right or visiting: https://educationhub.hpnonline.com.
The cost to take the quiz online remains at $10.

Due to rising costs if you would like to mail in your completed quiz using the method below the price is now $50 for each test taken.

Request for Scoring

❑ I have enclosed the scoring fee of **$50 for EACH test taken** — payable to **Endeavor Business Media**. We regret that no refunds can be given. (It is not neccessary to submit multiple tests separately.)

Detach exam and return to:
Continuing Education Division
Healthcare Purchasing News
2477 Stickney Point Road, Suite 221B
Sarasota, FL 34231

HSPA HEALTHCARE STERILE PROCESSING ASSOCIATION

CBSPD

The approval number for this lesson is **3M-HPN 190909.**

FLOWCODE PRIVACY.FLOWCODE.COM