Sterilization and High-Level Disinfection: What Centers for Medicare and Medicaid Services (CMS) Will Be Looking For

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Objectives

After completion of this self-study activity, the learner will be able to:
1. Explain advantages of an accreditation survey process and the Centers for the Medicare and Medicaid Services (CMS) deeming authority.
2. Identify the CMS infection prevention and control expectations relating to reprocessing of critical and semi-critical devices.
3. Identify helpful resources for survey preparation.

Test Questions

1. Accreditation or lack of accreditation can affect a healthcare organization's reimbursement.
   A. True B. False

2. The Joint Commission is not a CMS-approved accreditation organization.
   A. True B. False

3. CMS feels that if the manufacturers’ sterilization instructions are not followed the sterilization outcome is guesswork and the facility should be cited as a violation of standards.
   A. True B. False

4. The survey worksheets currently being used by CMS surveyors are in a pilot phase and the CMS welcome any feedback as they begin to test and refine the tools.
   A. True B. False

5. The elements to be assessed relating to reprocessing of critical and semi-critical equipment are covered in the infection control draft worksheet.
   A. True B. False

6. High-level disinfection (HLD) will not be a big focus during a facility's next CMS survey.
   A. True B. False

7. Pre-cleaning includes all device channels and lumens with cleaning brushes appropriate for the size of the channels or ports.
   A. True B. False

8. Sterile medical devices and instruments should be stored in a way that does not compromise the package integrity.
   A. True B. False

9. Single-use devices can be used for more than one patient before being discarded.
   A. True B. False

10. If activities are likely to generate splashes or sprays of blood or body fluids, a fluid-resistant face mask and eye protection should be worn.
    A. True B. False
Introduction

Accreditation is a universally acknowledged means of improving the quality of healthcare. Survey accreditation processes for healthcare facilities are peer reviewed by professionals, and the survey process is conducted with a focus on safety and quality of patient care. Many private insurance companies require accreditation as a condition of payment. To qualify for federal funding for patients in Medicare and Medicaid programs, healthcare facilities must demonstrate that they comply with the government’s Conditions of Participation (CoPs). Accreditation or lack of accreditation can affect a healthcare organization’s reimbursement, and that could make or break healthcare facilities that function with tight budgets.

A key advantage of accreditation is the structure and emphasis placed on improvement of performance and safety. Having an accrediting organization measure the performance and safety of healthcare facilities helps to ensure compliance with published standards and recommended practices. Best practices are built on sound principles, scientific data backed up by research and the opinions of experts in the field. Following these best practices helps to improve the quality and safety of patient care.

The accreditation process is designed to help healthcare facilities take a systems approach to evaluating their care processes and improving those processes for the betterment of patient care and safety. Each accreditation organization has accreditation standards and supporting documents that healthcare facilities can review before a survey. In general, the resources provided by accreditation organizations include all standards related to the healthcare facility as a whole.

Both The Joint Commission (TJC) and the Centers for Medicare and Medicaid Services (CMS) have recently spelled out their expectations regarding reprocessing of reusable medical devices in healthcare facilities. With the emphasis on infection prevention, healthcare professionals must increase their efforts to reduce healthcare-associated infections (HAIs) and in particular surgical site infections (SSIs).

In the March 2012 3M™ Sterile U inservice, titled “Preparing for Joint Commission Survey”, Martha Young discussed TJC’s emphasis relating to cleaning, disinfection and sterilization and how an organization can ensure a positive TJC accreditation survey. This Sterile U inservice will cover the CMS infection prevention and control expectations relating to reprocessing of medical devices and the relating requirements of the governments CoPs.

CMS gives deeming authority

The mission of CMS is to ensure healthcare security for beneficiaries. On July 30, 1965, President Johnson signed the Medicare and Medicaid programs into law. “Section 1865(b)(1) of the Social Security Act (the Act) permits providers and suppliers “accredited” by an approved national accreditation organization (AO) to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions.” In order to receive deemed status as an accredited provider, the CMS will evaluate the organization seeking the deeming authority for:

- Requirements for accreditation;
- Survey procedures;
- Ability to provide adequate resources for conducting required surveys;
- Ability to supply information for use in enforcement activities;
- Monitoring procedures for provider entities found out of compliance with the conditions or requirements; and
- Ability to provide CMS with the necessary data for validation. In order to be granted deeming authority for Medicare, an AO must apply and demonstrate its ability to meet or exceed the Medicare conditions of participation/coverage as cited in the Code of Federal Regulations:
  - Ambulatory Surgical Centers (ASCs) in accordance with 42 CFR 416
  - Critical Access Hospitals (CAHs) in accordance with 42 CFR 485 Subpart F
  - Home Health Agencies (HHAs) in accordance with 42 CFR 484
  - Hospice in accordance with 42 CFR 418
  - Hospitals in accordance with 42 CFR 482.5

The CMS-approved AOs are:

- Accreditation Association for Ambulatory Healthcare (AAAHCA)
- Accreditation Commission for Healthcare (ACHC)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)
- Community Health Accreditation Program (CHAP)
- DNV Healthcare (DNV)
- The Joint Commission 1,5
CMS sterilization clarification for ASCs

A CMS memo was sent to all state survey agency directors on September 4, 2009. The subject of the memo was “Flash Sterilization Clarification – FY 2010 Ambulatory Surgery Centers (ASC) Surveys.” This message illuminated CMS’s position on flash sterilization for ASCs which frequently and sometimes routinely use this sterilization process. Since that memo, the term “flash” sterilization has been replaced with Immediate-Use Steam Sterilization (IUSS). CMS implemented the following set of questions for surveyors to use when assessing the appropriateness of the ASC sterilization practices relating to IUSS:

1. Is the sterilizer labeled for this cycle by the manufacturer?
2. What is the sterilizer manufacturer-recommended load for that cycle?
3. Is the containment device used labeled by its manufacturer for use in that cycle?
4. For what load is the containment device recommended by its manufacturer?
5. Is the chemical indicator used labeled for use in this cycle by its manufacturer?
6. If a biological indicator is used, is it labeled for use for this cycle by its manufacturer?
7. If the cycle is used frequently, is it checked regularly with a biological indicator?

CMS went on further to say “If manufacturers’ instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the ASC’s practices should be cited as a violation of 42 CFR 416.51(a).”

CMS survey & certification focus on patient safety and quality

“The U.S. Department of Health & Human Services (HHS) is placing a high priority on improving patient safety and quality of care in our nation’s healthcare system. For example, in April 2011, HHS announced a new initiative, the Partnership for Patients: Better Care, Lower Costs (PfP), which aims to keep hospital patients from getting injured or sicker, and to help them to heal without complication.”

The HHS PfP is striving to reduce hospital readmissions by 20% and HACs by 40% by 2013.

The CMS Director of Survey & Certification Group sent a memo on October 14, 2011 to State Survey Agency Directors on the subject of Survey & Certification Focus on Patient Safety. The memorandum discussed the focused survey initiatives as a means to reduce healthcare-acquired conditions (HACs). The memo said CMS will be trying three new surveyor worksheets in order to assess compliance with hospitals CoPs for Quality Assessment and Performance Improvement, Infection Control, and Discharge Planning.

Revised CMS draft surveyor worksheets

The three draft worksheets were updated and included in another CMS memo dated May 12, 2012. The CMS memo clarified that the three worksheets are in draft form and they welcome feedback as they begin to test and refine these survey assessment tools. The pilot test phase will end sometime in 2013. Until that time there may be additional revisions based on information gathered during the pilot.

The CMS survey worksheet instructions cover items to be assessed by a combination of observation, interviews with hospital staff, patients, medical records and a review of necessary infection control program documentation. The three Draft Predecisional Surveyor Worksheets are attached to the memo. The Assessing Hospital Compliance with the Condition of Participation for Infection Control begins on page 21.

Policies and procedures

Specific facility policies and procedures may be reviewed during the survey, depending on concerns or observations. The governing body of the healthcare organization must approve the facilities policies and procedures. CMS would like to see that your infection control policies are developed and written according to current published standards and recommendations by professional organization. It is a good idea to identify and document which professional recommendations the facility used to create the policy.

The Association for the Advancement of Medical InstrumentANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities is the reference document used by TJC surveyors are now using to survey facilities. It only makes sense the CMS surveyors would also use this reference as well. Other highly referenced recommended practices on HLD and sterilization are the Association of periOperative Registered Nurses (AORN) and the Centers for Disease and Control (CDC) Guideline for Decontamination and Sterilization in Healthcare Facilities.
CMS surveyor worksheets on high-level disinfection and sterilization

The infection control draft worksheet is made up of the following five modules:

Module 1: Infection Control/Prevention Program
Module 2: General Infection Control Elements – to be applied to all locations (e.g., general wards, critical care units, labor and delivery, emergency departments, endoscopy suites, and radiology)

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. High-level disinfection (HLD) and sterilization is covered under Module 3 Equipment Reprocessing.

Module 3: Equipment reprocessing

CMS will be holding facilities accountable for accomplishing HLD and sterilization of reusable instruments and devices in a consistent manner with the infection control policies and procedures (P&P). The P&P should discuss what to do when there are discrepancies between manufacturer’s instructions for use (IFU) of a device and manufacturer’s IFU for the device reprocessor.(CoP for Infection Control Section 3.A and 3.B)

Section 3.A. Reprocessing of semi-critical equipment

HLD will be a large focus for CMS surveyors. According to the Spalding Classification any items that come in contact with nonintact skin or mucous membranes are considered semi-critical and should receive a minimum of high-level disinfection. Some of the specific elements to be addressed during the survey include 3.A.1 All reusable semi-critical items receive at least high-level disinfection.

Other elements considered in section 3.A.3 through 3.A.15 are:

- Flexible endoscopes are inspected for damage and leak tested.
- Items are pre-cleaned according to manufacturers’ IFU and prior to HLD.
- Pre-cleaning includes all device channels and lumens with cleaning brushes appropriate for size of instrument channel or port.
- Enzymatic and detergent solutions are used and discarded according to the IFU.
- Cleaning Brushes are disposable or cleaned and HLD or sterilized after each use.
- Manufacturers’ IFU for HLD chemicals are followed for preparation and testing for appropriate concentration.
- Proper connectors are used for automated reprocessing equipment.
- Devices are disinfected for the appropriate length of time and temperature according to the IFU.
- After HLD, devices are rinsed with sterile water, filtered water, or tap water followed by a rinse with 70-90% ethyl or isopropyl alcohol and then dried thoroughly.
- Devices are stored in a manner to protect from damage or contamination. Endoscopes are hung in a vertical position.
- HLD equipment has routine maintenance completed and records are available.
- Each instrument or endoscope used can be tracked to the patient via a log.

For manual disinfection, the CMS surveyor may pick up a disinfection solution container and quiz the staff on the label. For instance, they may ask what is the kill time for that particular product or how long is the solution good for. In addition CMS will want to know how the items were cleaned prior to placing in the soaking solution. The written manufacturer’s IFU including cleaning and disinfection for each device should be readily available for review.

The CMS survey process leaves very little “wiggle room” relating to compliance with the CoP. The CMS survey worksheet makes it clear that if any of the above elements to be assessed (3.A.1 and/or 3.A.3 through 3.A.15) are not met, then the surveyor should cite the healthcare facility at 42 CFR 482.42(a)(1).
Section 3. B Reprocessing of critical equipment sterilization of reusable instruments and devices

CMS surveyors will want to see that facilities are sterilizing according to the CMS standards. Items that enter sterile tissue or the vascular system are categorized as critical and should be sterile when used.16

The specific elements regarding reprocessing of critical equipment to be checked include:

- Items are thoroughly pre-cleaned according to manufacturers’ IFU and visually inspected for residual soil prior to sterilization.
- Pre-cleaning includes all device channels and lumens with cleaning brushes appropriate for size of instrument channel or port.
- Enzymatic cleaner or detergent is used and discarded according to the manufacturers’ IFU (typically after each use).
- Cleaning brushes are disposable or cleaned and HLD or sterilized (per manufacturers’ instructions) after each use.
- Instruments are appropriately wrapped/packaged for sterilization, after pre-cleaning.
- Package systems selected is compatible with the specific sterilization process.
- Hinged instruments are open.
- Instruments are disassembled if indicated by the manufacturer’s IFU.
- Each package has a correctly placed chemical indicator (package process indicator).
- Each sterilizer load has a chemical indicator (load process indicator).
- A biological indicator is used at least weekly for each sterilizer and with every load containing implantable items.
- For dynamic air removal sterilizers, a Bowie-Dick test is run each day the sterilizer is used to confirm sufficient air removal.
- Sterile packs are labeled to identify the sterilizer used, the specific cycle or load number, and date the item was sterilized.
- Sterilizer documentation logs for each sterilizer are current and include results from each load.
- Sterilizer maintenance is routinely performed according to the manufacturer’s IFU.
- Sterilizer maintenance records are readily available.
- Sterile medical devices and instruments are stored in a way that does not compromise the package.
- The integrity of sterile packages is inspected prior to use.
- Compromised sterile packages are not used and are reprocessed.
- If immediate-use steam sterilization (IUS) is used, the following criteria must be met:
  - The device is thoroughly cleaned prior to sterilization.
  - Device is placed in a FDA cleared sterilizer container or tray for that sterilizer cycle.
  - The sterilizer cycle used is approved by both the instrument and sterilizer manufacturer.
  - Sterilizer monitors include physical, chemical and biological monitors which are approved for the specific cycle being used.
  - The facility maintains a sufficient quantity of instruments to meet the expected surgical volume.
  - Adequate time is permitted to complete all critical steps of reprocessing according to the manufacturer’s IFU.
- Instruments subjected to IUSS are used immediately and handled in a manner to prevent contamination during transport from the sterilizer to the point of use.
- The facility has a policy and procedure (e.g. recall of device and risk assessment) to address reprocessing error/failure that could result in infectious disease transmission.
- The recall/risk assessment policy is followed for any sterilization process failure.8

The CMS survey worksheet makes it clear that if any of the above elements in section 3.B.1 and/or 3.B.3 through 3.B.16 are not met, the healthcare facility should receive a 42 CFR 482.42(a)(1) citing.8

Section 3. C Single-use devices (SUDs)

Single use devices should be used in a manner consistent with the healthcare organization’s infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:

- All Single-Use Devices (SUDs) are discarded after use and not used for more than one patient.
- If the facility elects to reuse SUDs, an entity or a third party reprocessor that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific item in question, reprocesses these items.
- The organization must maintain documentation from the third party reprocessor that verifies the FDA clearance of reprocessing for each specific device.8

The CMS survey worksheet states if the answer is “no” to any of the assessed elements in Section 3.C on Single-Use Devices they should cite 42 CFR 482.42(a).8
Module 1: Infection control/prevention program

The CMS survey worksheet covers many elements relating to infection control/prevention program and resources. Some of the items on the surveyor worksheet that are relevant to sterilization and HLD include but are not limited to:

• **Section 1.A. Infection control/prevention program and resources**
  
  – 1.A.3 The infection preventionist (IP) is able to provide evidence that the organization has infection control policies and procedures based on nationally recognized guidelines and applicable state and federal law. For sterilization and HLD nationally recognized guidelines include the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), the Centers for Disease Control and Prevention (CDC) and the Society of Gastroenterology Nurses and Associates, Inc. (SGNA).

• **Section 1.D Personnel education system/infection control training**
  
  – 1.D.2 Healthcare personnel in contact with bloodborne pathogens are trained on bloodborne pathogen standards upon hire and when problems are identified.
  
  – 1.D.10 Job-specific competency and compliance on infection prevention policies and procedures are ensured through routine training and whenever infection prevention problems are identified.
  
  + ANSI/AAMI ST79 has specific recommendations related to personnel performing reprocessing duties in ST79 under Section 4.3.

• **Section 2.C Personal protective equipment/standard precautions**
  
  – 2.C.1 Standard Transmission-based precaution supplies (e.g. gloves, gowns, mouth, eye, nose, and face protection) are available and conveniently located to the point of use.
  
  + For personnel working in the decontamination area Personal Protective Equipment (PPE) should include heavy duty utility gloves and a liquid-resistant covering with sleeves (for example, a backless gown, jumpsuit, or surgical gown). (ANSI/AAMI ST79 Section 4.5.2)
  
  – 2.C.2 Healthcare workers wear gloves when performing procedures or activities may involve contact with blood, body fluids, mucous membranes, or non-intact skin.
  
  – 2.C.4 When performing procedures or activities that may involve contact with blood, body fluids, secretions, or excretions, healthcare workers wear gowns for protection.
  
  – 2.C.5 Hand hygiene is performed immediately after removing gowns and gloves.
  
  – 2.C.6 Proper eye, mouth and nose protection is worn when performing procedures or activities that are likely to generate splashes or sprays of blood or body fluids.
  
  + PPE should include a fluid-resistant face mask and eye protection. PPE used to protect the eyes from splash could include goggles, full-length face shields, or other devices that prevent exposure to splash from all angles. (ANSI/AAMI ST79 Section 4.5.2)
Summary

The CMS surveyors want to see complete compliance with the CoP and they are black and white when it comes to making sure that healthcare organizations are conforming to all of the elements to be assessed during the survey. Responsibilities for sterilization and high-level disinfection (HLD) goes beyond the sterile processing department and the operating room. Cleaning, disinfection, packaging, sterilization, and sterile storage happens in many areas and will also be on the CMS radar screen. Following the recommended practices from AAMI, AORN, and CDC and being aware of what CMS is looking for in a survey will help you prepare for an accreditation survey and more importantly improve patient care.
References


Answers

1. A
2. B
3. A
4. A
5. A
6. B
7. A
8. A
9. B
10. A

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Rose Seavey, MBA, BS, RN, CNOR, CRCST, CSPDT is the President/CEO of Seavey Healthcare Consulting, LLC, and formerly the Director of the Sterile Processing Department at The Children’s Hospital of Denver. She served on the Association of periOperative Registered Nurses (AORN) Board of Directors from 2008–2010 and was honored in 2012 with AORN’s award for Outstanding Achievement in Mentorship and in 2001 with the Outstanding Achievement in Clinical Nurse Education. In 2003, Ms. Seavey served as President of the American Society of Healthcare Central Service Professionals (ASHCSP) and was awarded the National Educator of the Year award in 2002. Ms. Seavey was selected as one of the Who’s Who in Infection Prevention in 2006 by Infection Control Today. In 2012, she received the 2012 Industry Leadership Award from the Massachusetts Chapter of Central Service Professionals in recognition of outstanding education and leadership to the Sterile Processing Profession. Ms. Seavey is the author of the book titled Sterile Processing In Healthcare Facilities: Preparing for Accreditations Surveys, published by AAMI. She is a member of the AAMI National Nominating Committee for 2011-2014 and co-chairs the AAMI Working Group for Hospital Steam Sterilizers. She is a member of several AAMI working group committees developing recommended practices. In addition, Ms. Seavey has lectured and authored many articles on various topics relating to perioperative services and sterile processing, locally, nationally and internationally.

Ms. Seavey is a consultant for 3M HealthCare, Infection Prevention Division.
Sterile Process and Distribution CE Information

CE Applicant Name: ___________________________  City: ___________________________

Address: __________________________________  State: ___________________________  Zip Code: ___________________________

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 1.5 contact hours for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding Certification contact: CBSPD, Inc. 148 Main St., Lebanon, NJ, 08833 or call 908-236-0530 or 1-800-555-9765 or visit the website at www.sterileprocessing.org.

IAHCSMM has awarded 1.5 approved contact hours for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CE Application Form

This inservice is approved by the California Board of Registered Nurses, CEP 5770 for 1 contact hour. This form is valid up to five (5) years from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions. Keep a copy for your records.

6. Submit this form and the answer sheet to:
   3M Infection Prevention
   Attn: HC4160
   RR Donnelly Fulfillment Services
   585 Hale Avenue North
   Oakdale, MN 55128-9935

7. For questions please call the 3M Healthcare helpline: 1-800-228-3957.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of RR Donnelly's receipt of the application.

Application  Please print clearly or type.

Name: ____________________________________  Daytime phone: (___________)

Mailing Address: ____________________________  Position/Title: ________________________

City: ______________________________________  Social Security or Nursing License Number:

State: ___________________________  Zip Code: ___________________________

Date application submitted: ____________________  Signature: _________________________

Offer expires September, 2017