Surviving an Accreditation Survey in Sterile Processing

Objectives

- Identify accreditation standards that pertain to high-level disinfection and sterilization.
- Describe current published standards and guidelines for healthcare facilities that perform sterilization and/or high level disinfection.
- Develop a plan for “how to be prepared” for your next accreditation survey.

Risk Reduction and Process Improvement are the Heart and Soul of Accreditation Surveys

Accreditation Survey

- Improving the quality of health care
  - Peer review
  - Focus on safety, quality, and process improvement
- Condition of payment
  - Private insurance companies
  - Federal funding
- Measures compliance
  - Published recommended practices
  - Accreditation standards and supporting documents

Centers for Medicare & Medicaid Services (CMS)
Compliance with Medicare Conditions

Accrediting organization with deeming authority by CMS
- Accreditation Association for Ambulatory Healthcare (AAAHC)
- Accreditation Commission for Healthcare (ACHC)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAASF)
- American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFPA)
- Center for Improvement of Healthcare Quality (CIHQ) - new 8/9/2013
- Community Health Accreditation Program (CHAP)
- DNV Healthcare (DNV)
- The Joint Commission (TJC)

Policy and Requirements for an Application for Deeming Authority. Accessed 7/12/2012 at:

TJC Survey Process

- Submit an application
- Pay a fee
- Resurveyed within three years
- 2006 unannounced survey process
  - Between 18 and 39 months after previous survey
  - Morning of survey
  - Biographies and pictures of surveyors assigned

Eiland, John E. Surveyor, The Joint Commission. Joint Commission presentation at IAHCSMM annual meeting in May 2013. Presentation available on flash drive provided to attendees.

The Joint Commission

- Independent, nonprofit
- Accredits and certifies over 18,000 health care organizations and programs including:
  - Hospitals,
  - Doctor’s offices,
  - Nursing Homes,
  - Office-based surgeries,
  - Behavioral health treatment facilities, and
  - Providers of home care services.
- Nationally recognized as symbol of quality

Joint Commission Resources

Nonprofit affiliate of TJC, publishes the official handbooks used in the TJC survey process
- Comprehensive Accreditation Manual for Hospitals: The Official Handbook (CAMH)
- Comprehensive Accreditation Manual for Ambulatory Care (CAMAC)
- 2013 Comprehensive Accreditation Manual for Office-Based Surgery Practices (CAMOBS)
Accreditation Standards

- **Standards** = performance objectives
- **Rationales** = describe importance
- **Elements of Performance (EPs)** = meet goals
- Scores determine the compliance
  - **Minimum score of 90% on every EP**


TJC Focus on Reprocessing

“…beginning in 2010, surveyors have spent additional time during survey evaluating the cleaning, disinfection, and sterilization (CDS) processes”

- Surveyors received in-depth training on sterilization processes through AAMI
  - Survey to ANSI/AAMI ST79
  - ST79 Available to staff

http://www.jointcommission.org/assets/1/18/jconline_July_20_11.pdf
Eiland, John E, Surveyor, The Joint Commission. Joint Commission presentation at IAHCSMM annual meeting in May 2013. Presentation available on flash drive provided to attendees.

TJC Second Generation Tracer – 2013

- “The organization reduces the risk of infections associated with medical equipment, devices, and supplies”
- **Deficiencies:**
  - 47% Hospitals
  - 43% Critical access hospitals
  - 37% Ambulatory care organizations
  - 26% Office based-surgery practices
  - Leadership, IPC, OR, Sterile Processing, ES, and Engineering – all play a CRITICAL ROLE in reprocessing.
  - Standardizing the use of HLD and sterilization practices


TJC Facilities Out of Compliance

1. Not using current evidence-based guidelines (EBG) (**IC.01.05.01 EP 1**)
2. Orientation, training, and competency not conducted by personnel trained on recent EBG (**IC.02.02.01**)
3. Lack of quality control and manufacturers’ instructions for use (IFU) - using nonvalidated conditions (concentration, exposure times, and temperatures)
4. Lack of participation and collaboration with IPC (**IC.0202.01**)
5. Recordkeeping - “incomprehensible” or non-standardized logs (**IC.0202.01 EP 2**)

- Traceable path to the patient and product identification in the event of a recall

## Most Frequently Scored Standards 2014

<table>
<thead>
<tr>
<th>Score</th>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
</table>
| 56%   | EC.02.06.01 | Safe and Functional Environment EP 13 Temp. and Humidity  
- Staff know required **temperature and humidity** parameters  
- Log each day (paper or automation)  
- Must have mandatory feedback |
| 53%   | EC.02.05.01 | Risks with Utility Systems  
- Positive vs. Negative airflow  
- Staff know what it is and what they can do to maintain appropriate pressure |
| 52%   | IC.02.02.01 | Reduce Risk of Infection  
- Cite any deviation from perfect compliance  
- More places performing sterilization or HLD the more risks you have  
- AAMI ST58 2013 |
| 36%   | EC.02.02.01 | Manage Risks Related to Hazardous Materials  
- Eyewash in Immediate Area  
- Plumbed  
- Inspection and documentation weekly  
- Evaluate new products |

Patton Healthcare Consulting Newsletter, April 2015

## CMS – Infections and ERCP Scopes April 3, 2015

- Looking for compliance with CDC and FDA advice
- Opening conference ask if duodenoscopes are used
  - Ask for copy of MFG IFU
  - Surveyor must observe endoscope being processed
    - Any identified noncompliance must be cited
    - Risk for immediate jeopardy
      - Strictly and meticulously follow MFG IFU cleaning and reprocessing
      - Adhere to nationally recognized guidelines
  - **ADVICE** – Rewrite polices and redo competency validation

## TJC Personnel Considerations

- **HR.01.06.01:** Staff are competent to perform their responsibilities
  - EP 1. The facility defines the competencies it requires of its staff…
  - EP 2. The facility uses assessment methods to determine the individual’s competence…
    - Test taking, return demonstration, or the use of simulation.
  - EP 3. An individual with the educational background, experience, or knowledge …assesses competence.

## Leadership Standards and EPs

- **LD.04.01.11:** The facility makes space and equipment available as needed for the provision of care, treatment, and services.
  - EP 2. The arrangement and allocation of space supports safe, efficient, and effective care, treatment, and services.
    - Need for sufficient space to adequately reprocess
  - EP 5. The leaders provide for equipment, supplies, and other resources.
CMS Surveyor Worksheets

- Focus on patient safety and reducing Healthcare Acquired Infections (HAI)
  - Infection Control Worksheet
    - 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


CMS Pre-Decisional Surveyor Worksheet

- Module 1: Infection Control/Prevention Program
  “1. A.3 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.”


Standards & Guidelines

- AORN Guidelines for Perioperative Practices, 2015
- AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities
- AAMI ST41:2008 (R2012) Ethylene Oxide Sterilization In Health Care Facilities: Safety And Effectiveness
- AAMI ST91:2015 Flexible and semi-rigid endoscope processing in health care facilities

Newly Released Sterile Processing Collection

All the tools and resources needed for the Sterile Processing Team, all in one product!

AORN Guidelines and Tools for Sterile Processing Team includes:
- 8 AORN Guidelines
- 22 Policy and Procedure Templates
- 24 Competency Verification Tools
- 2 Sterile Processing Job Descriptions
- 4 Crosswalks from the AORN Guidelines to the AAMI standards
Memo Aug. 2014
Change in IUSS Terminology

- IUSS not an appropriate substitute for maintaining a sufficient inventory of instruments.
- IUSS survey procedure
  - Using IUSS in a manner that places patients at risk
  - No to any survey question
  - Infection Control Citation

IUSS Position statement


CMS – Change in IUSS Terminology

- IUSS not an appropriate substitute for maintaining a sufficient inventory of instruments.
- IUSS Survey Procedure
  - “If there is evidence to establish that the answer to any of the following questions is “no” or the provider or supplier is using IUSS in a manner that places its patients at risk for infection, a citation under the appropriate infection control CoP/CfC is warranted.”


CMS – Change in IUSS Terminology

- IUSS not an appropriate substitute for maintaining a sufficient inventory of instruments.
- IUSS survey procedure
  - Using IUSS in a manner that places patients at risk
  - No to any survey questions
  - Infection Control Citation

Centers for Medicare and Medicaid Services

September 4, 2009 - CMS released a memo to state survey agency directors regarding sterilization practices.

“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 416.44(b)(5).” (CMS, 2009)


CMS – IUSS Survey Procedure

• Used only emergently
• Process in place to ensure:
  • IUSS is not used for implants
  • IFUs are followed (instrument, sterilizer, container cleaning supplies)
  • Sterilizers are maintained
  • Correct monitors are used, evaluated by trained personnel and documented
  • Aseptically transported and cooled prior to use
  • Personnel are monitored for adherence to policy


CMS Letter Endnotes


“Short cycle” confusion

• American Society of Ophthalmic Administrators (ASOA) released a public statement 2/15 titled, CMS Clarifies Policy to Permit Use of Short Cycle Steam Sterilization on Ophthalmic ASCs.

• Outpatient Surgery E-Weekly 2/10/15 states that based on the CMS clarification ACSs “can now breathe a sigh of relief” and that short cycle sterilization, as widely practiced in ambulatory ophthalmic centers, is now acceptable.

• 12 February 2015 Letter from AAMI to CMS - clarification – “short cycle” not defined.

CMS 2/26/2015
Sterilization of Ophthalmological Surgical Instruments

- “Short cycle” – form of **terminal** sterilization
  - Wrapped/contained load
  - Pre-cleaning performed according to manufacturer's IFU
  - Load meets device manufacturer's IFU – including complete dry time
  - Packaged in a wrap or rigid container validated for later use.


Calculating IUSS Rates?

- No national benchmark
  - Divide IUSS by number of procedures *

- Identify trends to determine:
  - Service
  - Types of instruments
  - Type of procedures
  - Specific surgeons
  - Time of day
  - Reason for IUSS


CDC Guide to Infection Prevention for Outpatient Settings

- Updated in 2014 to include the companion checklist
- Checklist useful to self-audit
  - IP regularly available?
  - Are appropriate P&P in place?
  - Do personnel follow correct Infection Prevention practices?


Unacceptable Excuses

- Not Following Standards and Guidelines
  - Didn’t know about the standards/guidelines
  - Standards/guidelines not available to staff
  - Available but not current/up-to-date
  - No one designed as subject matter expert
  - Personnel are not trained on standards/guidelines etc.
  - Not enough personnel and/or time
  - Necessary equipment and tools not available
Processing Policies & Procedures

- Facility design and housekeeping,
- Personnel – qualifications, training, and continuing education,
- Dress code - PPE,
- Sterilization monitoring,
- Receiving purchased or borrowed items,
- Loaner instrumentation (minimum 24 hour lead time)
- Handling, collection, and transport of contaminated items,
- Assembly, package configurations, and sterilization monitoring,
- Processing endoscopes
- Following manufacturer’s written IFU,
- Maintenance and repair of medical devices, etc.

Reference to current published standards
- Not because it is a TJC or CMS standard!

Preparing for a Processing Audit

- Accreditation Documents
  - Accreditation Preparation Committee

- Relevant Professional Standards and Recommended Practices
  - Sterile Processing,
  - Operating room,
  - Infection prevention and control,
  - Clinical/biomedical engineering,
  - Endoscopy,
  - Risk management,
  - Quality,
  - Safety,
  - Education,
  - Administration, and
  - Materials management, etc.

Surveys Preparation

- Self assessment
  - Subject Matter Experts
    - Verify that each element of performance (EP) in each standard is addressed

- Front line staff involvement
  - Cite the EP (not just the standard)
  - Describe how that expectation is met

Accreditation Preparation Resource

Sterile Processing In Healthcare Facilities: Preparing for Accreditation Surveys 2nd Ed.
- Hospitals
- Ambulatory Care
- Office-Based Surgery Practice
- Current professional guidelines
  - AORN, AAMI, SGNA, CDC
- Current Accreditation standards
  - CMS, TJC, AAAASF

http://www.aami.org/publications/books/sphc.html
Seavey, R. Association for the Advancement of Medical Instrumentation. Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys. 2014
Crosswalk
TJC Standards Linked to Current AAMI ST79

http://www.aami.org/publications/books/sphc.html
Seavey, R. Association for the Advancement of Medical Instrumentation. Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys. 2014

ST 79 Relative to TJC Design Considerations

- Functional workflow patterns (3.2.3)
- Traffic control (3.2.4)
- Electrical systems (3.3.3)
- Steam for sterile processing (3.3.4)
  - Steam quality (3.3.4.2)
  - Steam purity (3.3.4.3)
- Utility monitoring and alarm systems (3.3.5)
- General area requirements (3.3.6)
  - Ventilation (3.3.6.4)
  - Temperature (3.3.6.5)
  - Humidity (3.3.6.6)
- Special area requirements and restrictions (3.3.7)
  - Decontamination area (3.3.7.1)
  - Preparation area (3.3.7.2)
  - Sterile storage (3.3.7.4)
  - Break-out area (3.3.7.8)
  - Emergency eyewash/shower equipment (3.3.8)
- Housekeeping (3.4)

TJC – Design Considerations

- EC.01.01.01: The hospital plans activities to minimize risks in the environment of care.
- EC.02.02.01: The hospital manages risks related to hazardous materials and waste.
- EC.02.04.01: The hospital manages medical equipment risks.
- IC.02.02.01: The organization reduces the risk of infections associated with medical equipment, devices, and supplies.
- LD.03.01.01: Leaders create and maintain a culture of safety and quality throughout the organization.
- LD.03.03.01: Leaders use hospital-wide planning to establish structures and processes that focus on safety and quality.
- LD.04.01.07: The organization has policies and procedures that guide and support patient care, treatment, or services.
- LD.04.01.11: The hospital makes space and equipment available as needed for the provision of care, treatment, and services.
- LD.04.04.07: The hospital considers clinical practice guidelines when designing or improving processes

Seavey, R. Association for the Advancement of Medical Instrumentation. Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys. AAMI 2014. ANNEX G

The Joint Commission (TJC)

Standard IC.01.03.01

- The facility identifies risks for acquiring and transmitting infections.

Element of Performance # 4

- The facility reviews and identifies its risks at least annually and whenever significant changes occur with input from, at a minimum, infection control personnel, medical staff, nursing, and leadership.
Quality Process Improvement

• Addressing and reducing risks
  • Objective is to **proactively identify** the risks to **reduce the likelihood** of a process failure.

• Risk Reduction Tools
  • Root Cause Analysis
  • Failure Modes and Effects Analysis (FMEA)
  • Tracers

• Risk Assessment can be your best friend in survey


Common High-Risk Areas

• IUSS
• P&Ps not standardized
• Loaner instrumentation
• Torn wrappers
• No IFUs
• Sets weighing more than 25 pounds
• Sterilization process failures
• Inefficient staff orientation
• No standardization
• Lack of competency documentation

Risk Analysis of the Sterilization Process Resources

Reference Articles

• *Risky business: Risk analysis in CSSD*, written by Sue Klacik
  Published in Healthcare Purchasing News in August 2010

• *Are You Taking Risks When Cleaning Reusable Medical Devices?*, written by Martha Young, BS, MS, CSPDT
  January, 2013 In-service article archived at [http://www.3m.com/sterileu](http://www.3m.com/sterileu)

Instruments Held Completely Open?

• Three facilities issued Immediate Jeopardy (IJ) by CMS
  ✓ “All instruments must be held completely open with no tips touching.”
  ✓ “Stringers are not adequate to hold completely open.”

[Image of a person holding a question mark]
Surveyor “Opinions” Cost Hospital

• One faculty issued “IJ”
  • 10 days to fix the problem
  • Purchased approximately 230 clamps at $30 each ($6,900)
    • Vendor questioned if the order was a mistake (8 to 10 is normal)
  • Reprocessed every peel pack and instruments set
    • Cost: packaging, sterilization costs, labor etc.?
    • Impact on surgery schedule...

What does AORN Say - Assembly?

IV.h. Items to be sterilized should be placed in the package or tray in an open or unlocked position.
[3: Limited Evidence]
  • The open or unlocked position facilitates sterilant contact of all surfaces of the item.

  • IV.h.1. Racks or stringers designed and intended for sterilization can be used to maintain instruments in their open position.

What does AAMI ST79 say?

8.4 Preparation and assembly of surgical instrumentation

8.4.1 General considerations

...Instruments sets should be sterilized in perforated or wire-mesh-bottom trays, or in containment devices... with all instruments held open and unlocked.
AAMI Current vs. Proposed Wording

Current edition ST79
8.4.4 Instrument placement
c) All jointed instruments should be in the open or unlocked position with ratchets not engaged. Racks, pins, stringers, or other specifically designed devices can be used to hold the instruments in the open position...

Proposed wording:
- Ratcheted instruments should be unlatched. Racks, pins, stringers, or other specifically designed devices can be used to hold the instruments in the unlatched position.

Does not state “jointed”, “open” or “unlocked” – just ratcheted” and “unlatched”

Unsubstantial or Personal Opinions?
- What reference is the surveyor basing their finding on?
- Unlocked ratchet is what is meant by the statements in AORN and AAMI.
- Decontamination is where clamps need to be held wide open.

Personal Opinions

- Surveys vary by state and surveyor
  - Do not be argumentative
  - Be assertive, not aggressive
  - Educate the surveyors on wording and interpretation
  - Have documents available that support your case and how you meet the EPs.
- Policies
- Standards
- Recommend Practices
- IFU

Another interpretation?
- CMS surveyor – CA
  - Peel packs for single item only!

Figure 8—Example of single- and double-packaging with paper–plastic pouches — Reprinted from ANSI/AAMI/ISO 14971:2007/(R)2010 with permission of Association for the Advancement of Medical Instrumentation, Inc. (C) 2007 AAMI. www.aami.org. All rights reserved. Further reproduction or distribution prohibited.
Documentation a Hot Button

- Air flow documentation
- Daily temp and humidity logs
- Logs for LMA reprocessing
- Logs for phaco coaxial I/A tips limited usage
- Instrument set weight logs
- IUSS – how facility is decreasing (PI standards)
- Premature release forms for implants, etc.
- Loaners
- Documentation standardized in all areas
- Documentation of failed loads
- Documenting the disinfection of brushes
- Documentation of cleaning (AORN RP XIV)

Improper Air Handling Self Assessment
EC.02.05.01 EP 6 (Risk Element) 47%

- Identify all positive and negative locations
- When was your last assessment?
- What mechanism do staff have to routinely monitor?
  - Tissue test
  - Electronic monitor with alarm
  - Ping pong ball in the wall
- Know when to notify facilities
- Helps with compliance
  - Pass through kept closed, etc.

Air Distribution/Flow

Is This Proper Storage?
Is this proper storage?

Is this proper wrapping?

Is This Proper Storage?
More storage issues…

Lack of Traffic Control in Restricted Areas

Keep Doors and Windows Closed
Deep cleaning…
No Separation of Clean and Dirty

- Tell a surveyor they are wrong
  - Tell them you don’t remember seeing that in the standard
  - You had been following the community standard
  - You will need to take that to your committee to make that policy change
  - Ask which specific standard they are using

Never Ever

- Be rude or disrespectful
- Interrupt
- Ask why they are asking something
- Belittle a standard or regulation
- Contradict something in your minutes
- Suggest you have known of an issue for a prolonged time and done nothing or stopped trying
Strange Idea and No Evidence or Standard

- Don’t volunteer to change practice (if they have no standard or evidence)

- Tell surveyor you see their point but politely and gently suggest you won’t be able to get it through the committee without more evidence

Never claim perfection!

- Surveyors will cite you if you claim 100% sterilization documentation compliance and they see violations
  - More willing to ignore if you say you are working on it

Other Survey Hints

- Know every document you give them
- Know everyone they spoke with and what they said
- Know what questions are being asked
  - Share this with staff
- Know where your deficiencies are and fix if possible before they leave (more apt to change a citing)

Summary of Suggestions

- Be proud of your facility
  - Make a good first impression
  - Treat surveyor as if they are there to help you
  - Be assertive but have your “ducks in a row”

- Write policies referenced to standards/guidelines
Document and Display Your Success Stories

- Story boards for process improvement (PI) initiatives
  - IUSS: Show process improvements (benchmark against self)
  - Standardization
  - Loaned instruments
  - IFUs readily available
  - Certification “…demonstrated knowledge” framed photos

- Constant and consistent preparation for an accreditation!

References

- Eiland, John E, Surveyor, The Joint Commission. Joint Commission presentation at IAHCSMM annual meeting in May 2013. Presentation available on flash drive provided to attendees.

The Final Word…

Risk reduction and process improvement are the heart and soul of surveys.

Thank you

References

Questions?