SESSION TITLE: Sterile Processing: Preparing for Accreditation Surveys

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SESSION NUMBER: 9015 & 9106R

DATE/TIME: Monday, March 4, 2013, 8-9am & 9:30-10:30am

CONTACT HOURS: 1.0 CH

OVERVIEW:
Health care accreditation processes are conducted with a focus on safety and quality of patient care. Sterile processing in health care facilities has become an increasingly larger focus of the accreditation survey process. This presentation is intended to help health care professionals prepare for a Joint Commission (TJC), Centers for Medicare and Medicaid Services (CMS), or other accrediting and/or regulatory agency survey as it relates to sterile processing of surgical instruments and other medical devices in health care settings.

OBJECTIVES:
1. Discuss the latest requirements from accrediting organizations specifically relating to reprocessing of medical devices.
2. Describe key published standards and recommended practices for safe and effective reprocessing of reusable patient care items.
3. Identify current resources available to help health care facilities prepare for a successful accreditation survey.

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COMMERCIAL SUPPORT:
Rose Seavey Seavey Healthcare Consulting, Inc. (travel expenses)
TODAY Investigates: Dirty surgical instruments a growing problem in the OR 2/22/2012

- *Filthy surgical instruments: The hidden threat in America’s operating rooms*
  - 2009 rotator cuff repair and 7 other joint surgery patients
    - Arthroscopic shaver & inflow/outflow cannula
    - MFR updated cleaning IFU 10 steps
      - Final step - use a digital scope to visually inspect the insides of handpieces!

http://www.iwatchnews.org/2012/02/22/8207/filthy-surgical-instruments-hidden-threat-americas-operating-rooms
http://todayhealth.today.msnbc.msn.com/_news/2012/02/22/10471434-today-investigates-dirty-surgical-instruments-a-problem-in-the-or

Sterilization is a Complex Process

- Requires:
  - Environmental controls
  - Appropriate equipment and supplies
  - Adequate space
  - Qualified, competent personnel - ongoing training
  - Monitoring for quality assurance

- TJC engineer on site
  - Review of the environment

Eiland, John E, Surveyor, The Joint Commission. Joint Commission presentation at IAHCMM annual meeting in May 2012. Presentation available on flash drive provided to attendees
Accreditation Survey

• Improving the quality of healthcare
  - Peer review
  - Focus on safety and quality
• Condition of payment
  - Private insurance companies
  - Federal funding
• Measures compliance
  - Published standards and recommended practices
  - Accreditation standards and supporting documents


CMS Compliance with Medicare Conditions

• HC facilities must be accredited by an accrediting organizations 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)
  - Community Health Accreditation Program (CHAP)
  - DNV Healthcare (DNV)
  - The Joint Commission (TJC)

The Joint Commission

• Independent, nonprofit

• Accredits and certifies over 18,000 HC 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

TJC Survey Process

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

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)

TJC Accreditation Standards

• Standards = performance objectives
• Rationales = describe importance
• Elements of performance (EPs) = scores determine compliance
  - Minimum score of 90% on every EP
• Standards relating to reprocessing
  - Environment of Care,
  - Human Resources,
  - Infection Prevention, and control and
  - Leadership

TJC Increase Focus on Sterilization/HLD

“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
- Survey to ANSI/AAMI ST79 (Available to staff)
- After training – more than tripled citing related to noncompliance for Sterilization/ HLD* From 10% to 40% *
- One non-compliance in Sterilization/HLD = citing (others up to 3)*

http://www.jointcommission.org/assets/1/18/jconline_July_20_11.pdf

CMS Pilot test on Hospital Infection Control Surveyor Worksheet 5-18-2012

- CMS Memo to State Survey Agency Directors
  - CMS testing three revised surveyor worksheets for assessing compliance with three hospital Conditions of Participation (CoPs):
    1. Quality Assessment and Performance Improvement (QAPI),
    2. Infection Control, and
    3. Discharge Planning.

CMS Memo Summary

- Draft Worksheets Made Public:
  - Focusing on compliance as a means to reduce hospital-acquired conditions (HACs)
  - Infection Control/Prevention Program
    » Module 1: Section 3.A. Reprocessing of Semi-Critical Equipment
    » Module 1: Section 3.B. Reprocessing of Critical Items – Sterilization of Reusable Instruments and Devices
  - May be additional revisions based on information gathered during the pilot test phase, which will end sometime in FY 2013.


TJC Personnel Considerations Standards and EPs

- HR.01.06.01:
  Staff are competent to perform their responsibilities
  - EP 1. The hospital defines the competencies it requires of its staff who provide patient care, treatment, or services.
  - EP 2. The hospital uses assessment methods to determine the individual’s competence in the skills being assessed.
    » Note: Methods may include test taking, return demonstration, or the use of simulation.
  - EP 3. An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence.

The Joint Commission. 2012 Hospital Accreditation Standards (HAS)
Leadership Standards and EPs

- LD.04.01.11: The hospital 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 adequate reprocess

  - EP 5. The leaders provide for equipment, supplies, and other resources.

The Joint Commission. 2012 Hospital Accreditation Standards (HAS)

The Joint Commission Revision to IC.02.02.01

TJC will survey:

» Orientation, training and competency of staff reprocessing medical devices
» Levels of staffing and supervision
» Standardization of process regardless of whether it is centralized or decentralized
» Reinforcing the process (adherence of organization’s procedures to manufacturer’s guidelines)
» Ongoing quality monitoring

The Joint Commission Perspectives®, October 2009, Volume 29, Number 10
http://www.jcrinc.com/common/PDFs/fpdfs/pubs/pdfs/JCReq/JC-P-02-02-01.pdf
The Joint Commission (TJC)

Standard IC.01.03.01

• “The hospital identifies risks for acquiring and transmitting infections.”

Element of Performance # 4

• “The hospital 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.”

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)
TJC National Patient Safety Goals
Goal 7: Reduce Risk of HAIs

NPSG.07.05.01

- Implement evidence-based practices for preventing surgical site infections.
  - “Implements policies and practices aimed at reducing the risk of HAIs. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Centers for Disease Control and Prevention [CDC] and/or professional organization guidelines).”

- Includes all areas where reprocessing takes place
  - Multiple reprocessing sites

The Joint Commission. 2012 Hospital Accreditation Standards (HAS)

Common High-Risk Areas

- IUSS (flash sterilization),
- P&P not standardized,
- Loaner instrumentation,
- Torn wrappers,
- No IFUs,
- Sets weighing more than 25 pounds,
- Sterilization process failures, and
- Inefficient staff orientation
Addressing and Reducing Risks

Common high risk areas
- IUSS (flash sterilization),
- P&P not standardized,
- Loaner instrumentation,
- Torn wrappers,
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- Sets weighing more than 25 pounds,
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Risk Reduction Tools
- Root Cause Analysis
- Failure Modes and Effects Analysis
- Tracers


The Joint Commission

• Joint Commission EC 02.04.01 - requires accredited hospitals to maintain medical equipment inventory

• EC 02.04.01, EP 3 “The hospital identifies the activities, in writing, for maintaining, inspecting, and testing for all medical equipment on the inventory”
  - Mechanical cleaning equipment and sterilizers
  - Endoscopes (flexible and rigid) now included

Survey Hot Buttons
October 24, 2011

- Laryngoscope blades are semicritical items
  - Sterilized
    » Steam, or
    » Low temperature sterilization
  - High-level disinfection
  - Packaged and Stored to prevent recontamination
    » NOT unwrapped blades:
      - Anesthesia drawers, or
      - Top of core cart
- Laryngoscope handles processed between patients

http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQChapterId=69&StandardsFAQId=386

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.”

The Joint Commission (TJC)

Standard IC.01.03.01

• “The hospital identifies risks for acquiring and transmitting infections.”

Element of Performance # 4

• “The hospital 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.”

Disinfection and Sterilization Standards, Recommendations and Evidence-Based Guidelines

• AORN Perioperative Standards and Recommended Practices, 2013


• CDC Guideline for Decontamination and Sterilization in Healthcare Facilities, 2008
AORN RPs Sterilization and Disinfection

- Anesthesia Equipment – Cleaning and Disinfection
- Disinfection – High Levels
- Flexible Endoscopes – Cleaning and Processing
- Instruments and Powered Equipment – Cleaning and Care of
- Packaging Systems – Selection and Use
- Sterilization in the Perioperative Practice Setting

Customizable Policy and Procedure Template available

ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities


2010 & A1:2010

ST79:2010/A2:2011
ANSI/AAMI ST79

2008-2009 amendments:
- TASS,
- Peel pouches,
- Steam quality,
- Devices with lumens,
- Chemical indicators,
- Product families,
- Evaluation of containers,
- Risk analysis,
- Verification of cleaning and sterilization process failures.

2010 -2nd edition changes:
- Steam quality requirements,
- Paper-plastic pouches,
- Mechanical cleaning equipment,
- Product quality assurance testing
- Risk analysis,
- Additional info on Class 6 CIs,
- New section on New Product Evaluation.

2011 amendments
- Manufacturer’s written instructions for use = IFU, and
- Hand washing = hand hygiene

AAMI ST79 Amendment 3:2012 Examples

- The term “SPD” revised to "sterile processing area".
- The design considerations = stronger loaner recommendations
- Anti-fatigue mats are recommended
- Describer how instruments come to SP
  » Delicate instruments on top and heavy on bottom
  » Orderly fashion and
  » Sharps segregated
  » Instruments requiring repair identified at the point of use
- Decontam staff have ready access to the device manufacturer’s IFU
- Workstations should be ergonomic, preferably height adjustable
- Pre-vac sterilization cycles should be used, unless IFU requires gravity
- Dietary service items should never be processed in SP area
## ANSI/AAMI ST79 Recommended Practice

<table>
<thead>
<tr>
<th>If You Have This AAMI Document</th>
<th>What To Purchase</th>
<th>What To Download Free</th>
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CDC Guideline for Decontamination and Sterilization

Nationally recognized and are referenced by accreditation and professional organizations


CDC - Guide to Infection Prevention for Outpatient Settings

- The CDC declared “Inadequate sterilization of surgical instruments has resulted in SSI outbreaks…"
- Evidence-based guidelines produced by the CDC and HICPAC
  - Minimum infection prevention expectations
- Infection prevention a priority
- IP gatekeeper to safe patient care

CDC - Guide to Infection Prevention for Outpatient Settings

• Beyond OSHA bloodborne pathogen
• At least one individual trained in IP
  - Policies and Procedures based on evidence-based guidelines
  - Tailored to the facility
  - Reassessed on a regular basis
  - Based on risk assessment
    » Focus extra attention on areas that pose greater risk (e.g. onsite sterilization of surgical equipment)


Other Key Standards and Guidelines

• APIC
  - Guideline for Disinfection and Sterilization of Prion-Contaminated Instruments
  - SHEA/APIC Guideline: Infection Prevention and Control in the Long-Term Care Facility

• ASGE and SHEA
  - Multisociety guideline on reprocessing of flexible gastrointestinal endoscopes: 2011

• SGNA
  - Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes, 2007
  - Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes, 2009
Sterile Processing: Preparing for Accreditation Surveys

- Help facilities prepare for an accrediting agency survey relating to sterile processing

- Includes:
  - Accreditation standards,
  - Evidence-based guidelines and recommend practices,
  - Crosswalk between AAMI ST79 and TJC
  - Risk reduction tools, and
  - Sample audit tool

Preparation for an Accreditation Survey

Accreditation Preparation Committee

Accreditation Documents

Relevant Professional Standards and Recommended Practices

Representatives should include:
- Sterile Processing,
- Operating room,
- Infection prevention and control,
- Clinical/biomedical engineering,
- Endoscopy,
- Risk management,
- Quality,
- Safety,
- Education, Administration, and
- Materials management etc.

Preparation for and Accreditation Survey

• Polices and Procedures
  - Facility design and housekeeping,
  - Personnel – qualifications, training and continuing education,
  - Dress code -PPE,
  - Sterilization monitoring,
  - Receiving purchased or loaned items,
  - Handling, collection, and transport of contaminated items,
  - Assembly, package configurations and sterilization monitoring,
  - Following manufacturer’s written IFU,
  - Maintenance and repair of medical devices.

• Staff involvement
References:


• Eiland, John E, Surveyor, The Joint Commission. Joint Commission presentation at IAHCSMM annual meeting in May 2012. Presentation available on flash drive provided to attendees.


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