Learning Objectives

1. Identify accreditation standards that pertain to sterile processing.

2. Describe current published standards and recommended practices that constitute best practices in sterile processing.

3. Develop a plan for “how to be prepared” for your next accreditation survey.
New to the 2nd Edition

• Up-to-date information:
  ✓ Current accreditation standards (e.g. CMS, TJC, AAAASF)
    • CMS Pre-Decisional Survey Worksheet
    • 2014 National Patient Safety Goals
      • Hospitals
      • Ambulatory Care
      • Office-Based Surgery Practice

  ✓ Current professional guidelines
    (e.g. AAMI, AORN, SGNA, CDC)

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

Multiple Preparation Tools

• Self audit tools,
  ✓ Sterile Processing,
  ✓ IUSS, and
  ✓ High-level-disinfection

• Risk reduction tools
  ✓ Root cause analysis,
  ✓ Failure modes and effects analysis,
  ✓ Tracer methodology
Annex F - Key Provisions of AAMI ST79 in Relation to Accreditation Standards

2014 TJC Standards Linked to Current AAMI ST79

Crosswalk

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.
ST 79 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)

Objective 1

Identify accreditation standards that pertain to sterile processing.
Accreditation Survey

- Improving the quality of healthcare
  - Peer review
  - Focus on safety and quality

- Condition of payment
  - Federal funding (CMS)
  - Private insurance companies

- Measures compliance
  - Accreditation standards and supporting documents
  - Published standards and recommended practices

CMS Compliance with Medicare Conditions

- Accredited by 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 (AAAAASF)
  - 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:
Risk Reduction and Process Improvement are the Heart and Soul of Accreditation Surveys

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)

Preparing for a Sterile Processing Accreditation Survey

CMS Draft Surveyor Worksheets
(2012-2013)

• Focus on patient safety and reducing healthcare-acquired conditions
  1. Quality Assessment and Performance Improvement,
  2. INFECTION CONTROL, and
  3. Discharge Planning

• 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


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
Preparing for a Sterile Processing Accreditation Survey

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**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

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**Joint Commission Resources**

- Nonprofit affiliate of TJC,
- Publish official handbooks used in the TJC survey process
  - *Comprehensive Accreditation Manuals:*
    - Hospitals: (CAMH)
    - Ambulatory Care (CAMAC)
    - Office-Based Surgery Facilities (CAOBS)
ISOBS
10 Million Office-Based Surgeries per Year
http://isobsurgery.org/?page_id=330

Safety Checklist for Office-Based Surgery
from the Institute for Safety in Office-Based Surgery (ISOBS)

Introduction
Preoperative encounter with practitioner and patient
- Patient medically optimized for the procedure?
  - Yes
- Are all prophylactic steps in plan for the operation made?
- Yes
- Does patient have DVT risk factors?
  - Yes, and prophylaxis arranged
- No

Procedure
- Procedure complexity and sedation/anesthesia reviewed?
  - Yes
- APS instructions given?
  - Yes
- Intra- and post-procedure plans reviewed?
  - Yes

Operation
- Emergency equipment check complete (e.g. wiring, AV, code cart, MRI safe?)
  - Yes
- LMS suitability confirmed?
  - Yes
- Oxygen source and suction checked?
  - Yes
- Anticipated duration of surgery
  - Yes
- Are, if personnel, monitoring and equipment available?

Before discharge
- On arrival to recovery area, with practitioner and personnel?
  - Yes
- Patient identity, procedure, and consent confirmed?
  - Yes
- Are the sites marked and side identified?
  - Yes
- Are DVT prophylaxis provided?
  - Yes
- Are antimicrobial prophylaxis administered within 60 minutes prior to procedure?
  - Yes
- Are all, essential imaging displayed?
  - Yes
- Is the practice confirmed verbally?
  - Yes
- Local anesthetic toxicity precautions
  - Yes
- Patient monitoring per institutional protocol
  - Yes
- Anticipated critical events addressed with team.
  - Yes
- Each member of the team has been addressed by name and is ready to proceed.

Satisfaction
- Prior to discharge, meet personnel and patient?
  - Yes
- Discharge criteria achieved?
  - Yes
- Patient education and instructions provided?
  - Yes
- Plan for post-discharge follow-up?
  - Yes
- Escalated?
  - Yes
- Patient satisfaction assessed?
  - Yes

This checklist is not intended to be comprehensive. Additional modifications to fit local practice are encouraged. *Adapted from the World Health Organization's surgical safety checklist.
© 2013 Institute for Safety in Office-Based Surgery (ISOBS), Inc. All rights reserved. www.isoobs.org

TJC Accreditation Standards

- **STANDARDS** = performance objectives
- **RATIONALES** = describe importance of objectives
- **ELEMENTS OF PERFORMANCE (EP)** = how you meet goals
  - Scores determine the compliance
  - Minimum score of 90% on every EP

- **STANDARDS relating to reprocessing**
  - Environment of Care
  - Human Resources
  - Infection Prevention and Control
  - Leadership
  - Performance Improvement

Seavey, R. Association for the Advancement of Medical Instrumentation. Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys 2014
Increased Focus on Sterilization

- TJC June, 2009
- Centers for Medicare and Medicaid Services (CMS) survey Sept. 2009
- AAMI April/2010 Summit on “Flash” sterilization
  - Produced a multi-society position statement
  - Agreed on terminology transition from “Flash” Sterilization to the term: Immediate-Use Steam Sterilization (IUSS)

http://www.jointcommission.org/joint_commission_online_july_20_2011/

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.
Preparing for a Sterile Processing Accreditation Survey

TJC Focus on Reprocessing

- After TJC surveyor training – citing related to for Sterilization/ HLD more than tripled
  - From 10% to 40% *

- One non-compliance in Sterilization/HLD = citing
  - Others may be up to 3 non-compliance issues


TJC High-level Disinfection and Sterilization: Know Your Practice.

- “The organization reduces the risk of infections associated with medical equipment, devices and supplies”

- Deficiencies:
  - 46% Hospitals
  - 47% 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

Preparing for a Sterile Processing Accreditation Survey

TJC Top 5 Most Challenging Requirements in 2013

Hospital

• 52% LS.02.01.20 The hospital maintains the integrity of the means of egress.
• 52% RC.01.01.01 The hospital maintains complete and accurate medical records for each individual patient.
• 48% LS.02.01.10 Building and fire protection features are designed and maintained to minimize the effects of fire, smoke, and heat.
• 47% EC.02.05.01 The hospital manages risks associated with its utility systems.
• 46% IC.02.02.01 The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.

Critical Access Hospital

• 60% EC.02.03.05 The critical access hospital maintains fire safety equipment and fire safety building features.
• 54% EC.02.05.01 The critical access hospital manages risks associated with its utility systems.
• 49% LS.02.01.20 The critical access hospital maintains the integrity of the means of egress.
• 47% IC.02.02.01 The critical access hospital reduces the risk of infections associated with medical equipment, devices, and supplies.
• 44% LS.02.01.30 The critical access hospital provides and maintains building features to protect individuals from the hazards of fire and smoke.

Preparing for a Sterile Processing Accreditation Survey

TJC Top 5 Most Challenging Requirements in 2013

Ambulatory Care

- 49% HR.02.01.03 The organization grants initial, renewed, or revised clinical privileges to individuals who are permitted by law and the organization to practice independently.
- 38% IC.02.02.01 The organization reduces the risk of infections associated with medical equipment, devices, and supplies.
- 37% MM.03.01.01 The organization safely stores medications.
- 26% IC.01.03.01 The organization identifies risks for acquiring and transmitting infections.
- 25% MM.01.01.03 The organization safely manages high-alert and hazardous medications.

Office-Based Surgery

- 64% HR.02.01.03 The practice grants initial, renewed, or revised clinical privileges to individuals who are permitted by law and the organization to practice independently.
- 29% IC.02.02.01 The practice reduces the risk of infections associated with medical equipment, devices, and supplies.
- 28% MM.01.01.03 The practice safely manages high-alert and hazardous medications.
- 27% MM.03.01.01 The practice safely stores medications.
- 24% NPSG.03.04.01 Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings.

Facilities Out of Compliance

1. Not having or using CURRENT evidence based guidelines (EBG) (IC.01.05.01 EP 1)

2. Orientation, Training and Competency (IC.02.02.01)
   - Initial and ongoing
   - Complete and current documentation
   - Conducted by personnel COMPLETELY trained on RECENT EBG and instructions for use (IFU).

3. Lack of quality control
   - Using nonvalidated conditions (concentration, exposure times and temps)


Facilities Out of Compliance (con’t)

4. Lack of participation and collaboration (IC.0202.01)
   - Supervisory or managerial oversight should have CURRENT education, training and experience
   - Work closely with IPC staff

5. Lapses in record keeping and “incomprehensible” or non-standardized logs (IC.0202.01 EP 2)
   - TRACEABLE path to the PATIENT and product identification in the event of a recall

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 adequately reprocess
  
  – EP 5. The leaders provide for EQUIPMENT, SUPPLIES, and other RESOURCES.

Sterilization 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 IAHCSMM annual meeting in May 2013. Presentation available on flash drive provided to attendees
Survey Hot Buttons

• Laryngoscope blades are semicritical items
  ✓ Sterilization (steam or low temperature)
  ✓ High-level disinfection (minimum)
  ✓ Packaged and stored to prevent recontamination (not touched with bare hands)
    • No unwrapped blades
• Laryngoscope handles processed between patients
• Consistent practice throughout facility

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

John Rosing. Lessons Learned from a Recent TJC Survey. OR Manager Webinar
6/28/2012

Incorrect Storage
CMS Endotracheal Stylets

1. Determine if REUSABLE stylets used with Glidescope (and the like)
   - Guided intubations are processed using HLD or higher
   - Stored in a covered bag

2. If ET tube stylets are DISPOSABLE, the stylets are TOSSED after each use

3. Also consider airway tubes

National Patient Safety Goals

Goal 7: Reduce Risk of HAIs

NPSG.07.05.01

• Implement evidence-based practices for preventing SSIs
  ✓ “Implements policies and practices… meet regulatory requirements and are aligned WITH EVIDENCE-BASED GUIDELINES (for example, CDC and/or professional organization guidelines).

• Includes ALL AREAS where reprocessing takes place
  ✓ Multiple reprocessing sites
Monitoring

- Trust but verify…
  - “I would like you to do a BI every day, preferably every load.”
  - “Put a load sticker on sterilizer tape and label everything.”
    John Eiland

- Quality control for all types of HLD (Cidex, OPA)
  - Quality control strips - every time you open a new bottle
  - 6 strips
    - 3 - full strength
    - 3 - 1/2 strength
  - Document it!

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

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Traceability of Instruments and Implants to the Patient

“Sterilization quality control relies heavily on historical data, especially when quality assurance measures yield conflicting evidence. Record-keeping is needed for both epidemiological tracking and ongoing assessment of the reliability of the sterilization process. Accountability to the patient and surgeon for the sterility of a reprocessed device requires documentation that can be directly traced to the patient.”

“Traceability of implants is especially important because the consequences of implant-related infections are particularly severe and result in increased morbidity and mortality.”

Know Packaging Symbols

- Can be found
  - On the device itself,
  - On the package, or
  - In the associated documentation (IFU)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>🆕</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>☑</td>
<td>Date of expiry</td>
</tr>
<tr>
<td>STERILIZED</td>
<td>Sterilized by ethylene oxides</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch number</td>
</tr>
<tr>
<td>☑</td>
<td>CE logo</td>
</tr>
<tr>
<td>☑</td>
<td>Registered</td>
</tr>
<tr>
<td>☑</td>
<td>EU REPRESENTATIVE</td>
</tr>
</tbody>
</table>

New Symbol

So Many Symbols

- Applicable to a broad spectrum of devices
- Can be found
  - On the device itself,
  - On the package, or
  - In the associated documentation (IFU)
What’s That Sign?

Preparing for a Sterile Processing Accreditation Survey
ANSI/AAMI/ISO 15223-1:2012

Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied –

Part 1: General requirements

CMS Pre-decisional Surveyor Worksheet

• Module 1: Infection Control/Prevention Program
  1. A.3 The Infection Control Officer(s) can provide evidence … infection control policies and procedures that are BASED ON NATIONALLY RECOGNIZED GUIDELINES and applicable state and federal law.

Objective 2

Describe current published standards and recommended practices that constitute best practices in sterile processing.

Nationally Recognized Guidelines

AAMI, ANSII, APIC, AORN, CDC, FDA, OSHA, SGNA, ISO
Disinfection and Sterilization

- AORN Perioperative Standards and Recommended Practices, 2014
- AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities

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

✓ Evidence rated
✓ Customizable Policy and Procedure Template available
Preparing for a Sterile Processing Accreditation Survey

ST 79 Editions

2010 & A1:2010

AAMI ST79 Amendment 3:2012 Examples

- The term “SPD” revised to “sterile processing area”.
- The design considerations = loaner recommendations
- Describes 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
- Anti-fatigue mats are recommended
- Pre-vac sterilization cycles should be used, unless IFU requires gravity (8.6.2.1)
- Dietary service items should never be processed in SP area
Preparing for a Sterile Processing Accreditation Survey

Current ST79 Amendment 4:2013

• New wrap drawings
  ✓ Updated pictures
  ✓ Descriptive instructions

Figure 4—Sequential double-wrapping: envelope fold

Current ST79 Amendment 4:2013

Moisture assessment
• Updates to 8.8.6
  ✓ Handling and inspection
  ✓ Checking for moisture

• New Annex P Tools to Use
  ✓ Check list – wet packs/loads
  ✓ Flow chart
### ANSI/AAMI ST79

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

Nationally recognized and referenced by accreditation and professional organizations


William A. Rutala, Ph.D., M.P.H.,1,2 David J. Weber, M.D., M.P.H.,2 and the Healthcare Infection Control Practices Advisory Committee (HICPAC)

1Hospital Epidemiology
University of North Carolina Health Care System
Chapel Hill, NC 27514

2Division of Infection Disease
University of North Carolina School of Medicine
Chapel Hill, NC 27599-7025


CDC Guideline and Checklist


Preparing for a Sterile Processing Accreditation Survey
Preparing for a Sterile Processing Accreditation Survey

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 high risk areas (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
Preparing for a Sterile Processing Accreditation Survey

IUSS Position Statement

"Immediate Use Sterilization" has traditionally been used to describe steam sterilization cycles where unwrapped medical instruments are subjected to an accelerated steam exposure time and then used immediately after cycle completion without being rested. This is in contrast to traditional "stereotest" cycles where wounds are first wrapped in a single perfusion, in primary packaging designed to ensure the container seals securely and allow the device to be used for immediate. This time "real" time means the accelerated time of exposure of unwrapped devices.

Object 3: Develop a plan for “how to be prepared” for your next accreditation survey.
Preparing for a Sterile Processing Accreditation Survey

TJC Personnel Considerations

• 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. 2014 Hospital Accreditation Standards (HAS)

Personnel Considerations

• Reprocessing responsibilities only assigned to:
  ◦ Qualified individuals
  ◦ Demonstrated and documented competencies in all areas (cleaning, decontamination, packaging, monitoring, sterilizing etc.)

• All staff should be certified within 2 years
  ◦ Certification helps develop
    • Basic level of understanding and knowledge
    • Consistencies and standardization
    • Professional element to the department
    • Self-esteem, confidence and authority

Personnel Considerations

• **Supervisors**
  ◦ Certified - SP Supervisory or Management level
  ◦ Demonstrate comprehensive understanding of:
    • Relevant state and federal regulations
    • OSHA blood borne pathogens exposure control plan
    • Engineering and work-practice controls
  ◦ Actively participate in committees such as:
    • Infection prevention and control
    • Quality improvement
    • Safety, and
    • Product evaluation and standardization

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Staff Competencies

- TJC surveyors will be looking for staff competencies:
  - Demonstration,
  - Certification, and
  - Involvement with professional associations

- They will want to see:
  - Job descriptions which match responsibilities,
  - Documented skills check lists, and
  - Training-based annual evaluations forms

Competency Verification Tools and Job Descriptions

- Competencies
  - Role-specific and JD
    - RN Manager
    - Technician
  - Practice-specific
    - HLD
    - Endoscopes
    - Instruments
    - Packaging
    - Sterilization

- Sterilization competencies
  - Dry Heat
  - Ethylene Oxide
  - Hydrogen Peroxide Gas
  - Plasma
  - Hydrogen Peroxide Vapor
  - Ozone
  - Peracetic Acid

http://www.aorn.org/Competency/Tools
Preparing for a Sterile Processing Accreditation Survey

Accreditation Documents

Accreditation Preparation Committee

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 Accreditation Surveys

Self assessment
- Subject Matter Experts
  - Verify that each element of performance (EP) in each standard is addressed
- Front line staff involvement
  - Cite the Element of Performance
  - Briefly describe how that expectation is met

Preparation for a Sterile Processing Accreditation Survey
Preparing for a Sterile Processing Accreditation Survey

**Processing P&P**

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

- Document published REFERENCES
  - NOT because it is a TJC or CMS standard!

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**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.”

The Joint Commission: 2014 Hospital Accreditation Standards (HAS)
Preparing for a Sterile Processing Accreditation Survey

High-Level Disinfection Self Assessment
IC.02.02.01

• Inventory all locations performing HLD
• Collect documentation that each location maintains
  ✔ Ensure it meets DAILY performance testing PERIODIC testing
    • New disinfection solution or test strips are open
• Competency validation for each employee
  ✔ Ensure it is current and similar throughout the facility
• Review policy & procedures in each area
• Subject matter expert OBSERVE practice

Excuses for Not Following Standards – NOT ACCEPTABLE

• Didn’t know about standards
• They were not available to staff
• Available but not kept up-to-date
• No one designed as expert in RPs (subject matter expert)
• Not enough personnel and time
• Personnel are not trained on RPs, etc.
• Necessary equipment and tools not available
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
- No subject matter expert (SME)

Addressing and Reducing Risks

- Not following recommended practices and standards
- Not following manufacturer’s instructions for use (IFU)
- Risk Reduction Tools
  - Root Cause Analysis
  - Failure Modes and Effects Analysis (FMEA)
  - Tracers
Quality Process Improvement

Risk analysis =
• Risk assessment +
• Risk management +
• Risk communication

Objective is to proactively identify the risks and take action to help ensure that it won’t happen.

Risk Analysis (11.2.2)

• Risk Assessment
  • Since sterility assurance is a probability function, it must be assumed that at some time A FAILURE will occur:
    • Identify possible SOURCES of sterilization failure
    • Estimate LIKELIHOOD that such a failure will occur
    • Assess the CONSEQUENCES if that failure does occur
    • Assess how to prepare the facility to MANAGE THE FAILURE
Risk Analysis of the Sterilization Process Resources


Surveyors Have Asked

- How often you run a Bowie-Dick test
- How often you run a BI
- BI and control lot numbers match and are recorded
- Documentation for the last recall
- Amount of cleaning agent - contact time?
- Shelf life of disinfectant
- Quality checks on HLD solutions
- Hydrogen Peroxide vapor plates – changed and documented?

Personal communications with facilities that have been surveyed by TJC
Surveys Have Asked

- Weight limit on trays (documented)

- Loaner instruments
  - Received 24 hours prior
  - Following MFR IFUs

- Reusable rigid containers
  - How maintained/reprocessed

- IUSS
  - Tracked to the patient
  - Using containment devices for IUSS

Follow Manufacturer's IFU
Devices, Packaging and Sterilizer
TJC Surveyors Have Asked

- Fire extinguishers not blocked
- Fire alarm pull station location
- Sufficient work space
- Adjustable workstations
- Door and pass-through window kept closed
- Equipment maintenance logs
- Traffic patterns separate clean & dirty
- Sterile storage shelves 18” from sprinkler
- Bottom shelves solid and 8-10” from floor
- No cardboard shipping boxes

Personal communications with facilities that have been surveyed by TJC
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No Separation of Clean and Dirty

Separating Clean and Dirty
Lack of Traffic Control in Restricted Areas
TJC Surveyors Have Asked

- Staff competencies documented
- Belong to professional associations
- Certified staff
- Standardized processes
- Dress code enforcement
- PPE readily available and properly used

Surveyors Have Asked

- Solid cleanable surfaces
- Solid ceiling tiles
  - No fiberboard and no stains
- Temperature, humidity and ventilation
- Air flow in all processing areas
- Water quality
- Eye wash stations
  - 10 seconds travel time
  - Rinse for 15 minutes.
  - Temperature 60-100°F
- Deep cleaning to include sterilizer access rooms

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.
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Preparing for a Sterile Processing Accreditation Survey
Deep cleaning…

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

Self Assessment

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

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With a Surveyor
NEVER EVER

• Defend a violation of your policy or an unsafe practice
  ✓ ADMIT to the issue and commit to FIXING it and NOT HAVING IT RECUR.
• Lie (hiding is not lying)
• Volunteer an answer you don’t know
  ✓ Tell them you will find out soon
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Never EVER

• Tell a surveyor they are wrong
  ✔ INSTEAD:
  • Tell them you don’t remember seeing that in the standard and you’ll need TO TAKE THAT REGULATION TO YOUR COMMITTEE to make that policy change so may you PLEASE HAVE IT.
  • You weren’t aware of that and were just following the COMMUNITY STANDARD and will NEED THE REGULATION to share with your peers at the other facilities.
  • You didn’t interpret the standard to mean that but thought it meant this (especially effective if you think the surveyor is testing your knowledge).

Never EVER

• Be rude or disrespectful
• Ask them why they are asking something
• Contradict something in your minutes
• Suggest you have known of an issue for a prolonged time and done nothing or stopped trying
• Interrupt
• Belittle a standard or regulation
  ✔ Sometimes they know its stupid and are only following orders
When the idea is principally foolish and they have NO EVIDENCE or standard…

• Don’t volunteer to change practice (if they HAVE NO STANDARD or evidence, obviously if they do, you will)

• Tell them you see their point but politely and gently suggest you won’t don’t think you will be able to get it through the committee without more evidence

• Tell them that is an amazing insight and you’ll take it to committee to discuss

“Administration Just Won’t Listen”


• Offer several solutions, not just one solution to administration.

• Your authority statement for especially dangerous situations (unsafe sterilization or disinfection practices).

• Make sure administration is there at the meeting with the surveyors.
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Administration Budgets and Patient Safety

• Tell administration it is a PATIENT SAFETY and SURVEY ISSUE in writing and ask for a response back.
  ✓ If the response back to you is verbal EMAIL A SYNOPSIS of your understanding of the conversation back to them

• Keep good documentation of everyone you shared the issue with and all your interventions

Survey Survival Hints

• Give them a yes answer (if you can), but maybe not to the question they asked.
  ✓ e.g. “Have you eliminated vendor trays from getting dropped off within two hours of surgery forcing you to flash sterilize”

  ✓ FACTS: You made a lot of strides on this a few years back but for the last two years have been stuck at 87% of trays getting to the facility 24 hours or greater in advance.

  ✓ Statement: “We have made it so the VENDORS KNOW BETTER than to do that. We have WRITTEN IN OUR CONTRACTS that they don’t get paid for the tray if we don’t have it 24 hours in advance (true). So you know the VENDORS ARE AS MOTIVATED as us to have those trays to us 24 hours ahead of time.”
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If a Surveyor Request is Insane

- Document the event discuss with administration BEFORE THE SURVEYOR LEAVES (Once a surveyor leaves regulatory bodies will not usually reverse an issue)
  - Accrediting bodies frequently reverse decisions of surveyors when more evidence is supplied
- Apologize for escalating if you did
- Keep difficult people away from surveyors if possible and appropriate or ask them if they’ll be Ok with the surveyor

Never Claim Perfection!

- TJC 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 Survival Hints

• Know every document you give them
• Know everyone they spoke with and what they said
  ✓ Share this with other staff
• Know what questions are being asked
  ✓ Share this with staff
• Know where your deficiencies are and fix if possible before they leave (more effective with accrediting bodies)

Summary

• Be proud of your department
  ✓ 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 and recommendations
• 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
  ✓ Goal chart
• Constant and consistent preparation for an accreditation!
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Best Practice Consulting Recommendations

• Processing areas should have:
  ✓ Automatic barcode system,
  ✓ Online subscription to the manufacturers’ instructions for use and
  ✓ Subscription to sterile processing benchmarking tool

• Best practices tools of the trade

Conclusion

• Be in a constant state of readiness, and
  – Aware of CURRENT accreditation standards

• Standardized processes throughout the organization
  – Subject matter experts – sterilization and HLD
  – Comply with current published recommended practices
  – Find the barriers and break them down (it’s usually a systems issue)

• Be proud of what you do and share your quality improvement processes
Objectives Covered

✓ Identify accreditation standards that pertain to sterile processing in health care facilities.

✓ Describe accepted standards and recommended practices that constitute best practices in sterile processing.

✓ Develop a plan for “how to prepare” for an accreditation survey relating to sterile processing.

References

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


References


- Young, M. Preparing for a Joint Commission Survey, March 2012
  ✓ Both articles available at: http://solutions.3m.com/wps/portal/3M/en_US/sterilization/3MSterileU/Home/InServiceArticles/?WT.sl=5

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.


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References


• FileManager/Advocacy-PDFs/CMS_revised_hospital_surveyors_worksheets_5-18-12.pdf


New AAMI Documents Being Developed

• New Technical Information Reports (TIR) being developed
  ✓ AAMI TIR54 Human Factors for Medical Device Reprocessing
  ✓ AAMI TIR55 Flexible Endoscope Reprocessing
  ✓ AAMI TIR Standardized Instructions for Use

• TIR is not a recommended practice
  ✓ Review of an important technical issue or healthcare practice
  ✓ Statement of expert opinion released by a technical committee
Other New AAMI Resources

- Sterile Processing Benchmarks (SPB)
  - Web-based tool
  - Partner with IAHCSMM

- Building for the Future: Construction and Renovation of Sterile Processing Facilities (Cynthia Hubbard)

- Leading Practice Integrated Process Flow and Automation in the Modern Central Sterile Supply Department (Mark Duro)

Remember…

Risk reduction and process improvement is the heart and soul of surveys

Thank you
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Questions?

Type your question in the Q&A box on the left side of your screen and press Enter

Or press *1 on your telephone keypad

Closing Reminders

• Please be sure to fill out the evaluation form at:
  http://aami.confedge.com/ap/survey/s.cfm?s=Preparing

• **CBSPD and IAHCSMM** are offering 1.5 contact hours for this webinar. Please contact Kia L. Reid at k Reid@aami.org to obtain a letter of attendance needed to receive the contact hours from CBSPD and IAHCSMM.

• AAMI is planning the following webinar that may be of interest to you:
  • July 8: Immediate-Use Steam Sterilization (IUSS)
Closing Reminders

• Announcing AAMI University - a better way to manage your professional development
  ✓ Online and live comprehensive education resources for medical technology professionals
  ✓ Access to AAMI’s industry-leading curriculum and instructors
  ✓ Please visit AAMI U at http://university.aami.org/

Learn. Think. Implement.