Updates on AAMI ST79 & SPD Accreditation Surveys

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Objectives

- Identify accreditation standards that pertain to sterilization and High-level Disinfection in health care facilities.
- Describe updates to nationally accepted standards and recommended practices for best practices in sterile processing.
- Develop a template for “how to prepare” for an accreditation survey.

Risk Reduction & Process Improvement
The Heart and Soul of Accreditation Surveys

Infection Prevention: A Shared Responsibility
Collaborative coordinated process

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)
- Center for Improvement of Healthcare Quality (CIHQ)
- Community Health Accreditation Program (CHAP)
- DNV Healthcare (DNV)
- Healthcare Facilities Accreditation Program (AOA/AFPA)
- The Compliance Team (TCT)
- The Joint Commission (TJC)


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:
  - Hospitals (CAMH)
  - Critical Access Hospitals (CAHs)
  - Ambulatory Care (CAMAC)
  - Office-Based Surgery Practices (CAMOBS)

Accreditation Standards

- Standards
  - Performance objectives

- Rationales
  - Describe the importance

- Elements of Performance (EPs)
  - How you meet goals
  - Scores determine the compliance
  - 100% performance expectation—single observation leads to requirement for improvement (RFI)


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.”


AORN Guidelines and Tools for Sterile Processing

- Guidelines
  1. Environmental Cleaning,
  2. Hand Hygiene,
  3. Surgical Attire,
  4. Cleaning and Processing Flexible Endoscopes
  5. High-Level Disinfection,
  6. Cleaning and Care of Surgical Instruments,
  7. Selection and Use of Packaging Systems for Sterilization, and
  8. Sterilization

- Customizable templates:
  1. Policy and Procedure
  2. Competency Verification, and
  3. Job Descriptions

ANSI/AAMI Standards

- ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ST58:2013 Chemical sterilization and high-level disinfection in health care facilities
- ST41:2008 (R2012) Ethylene Oxide Sterilization in health care facilities: Safety And Effectiveness
- ST91:2015 Flexible and semi-rigid endoscope processing in health care facilities
- ST90:2017 Processing of health care products—Quality management systems for processing in healthcare facilities

AAMI Resources for SPD

- AAMI TIR34:2014 Water for the reprocessing of medical devices
- AAMI TIR55:2014 Human Factors engineering for processing medical devices
- AAMI TIR53:2014 Management of loaned critical and semi-critical medical devices that require sterilization or HLD

- Videos
  - Investigation of Sterilization Process Failures
  - Personnel Safety in Sterile Processing Departments
**ST79:2017**

**New and Improved**

- Last revision 2013 – disjointed
- Difficult to find information
- Directives mixed with rationales
- Lots of redundancies
- Major review - format, presentation and content
  - ST79 Advisory Committee
  - Reorganize format – easier to locate directives
  - Stem sentences followed by bullets for the “should”

**ST79:2017 Reformatting Example**

10.4 *Handling and inspection after unloading the sterilizer*

As sterile packages are removed from the sterilizer cart or carriage … they *should* be inspected for the following:

a) damage (e.g., holes, staining, tears, non-intact seals, missing security locks);

b) package identification;

c) external indicator visual change; and

d) moisture.

**Modified User-Friendly Chapters**

- Easier to narrow down subject matter
- Previous - Chapter 8 had four processes (packaging, preparation, sterilization and transport)
  - Now stand alone chapters
    - 8 - Preparation and assembly of instruments
    - 9 - Packaging
    - 10 - Sterilization
    - 11 - Storage and Transportation

**Major Update - Removal Environmental Recommendations**

- AAMI, AORN, IAHCSMM worked with American Society of Heating, Refrigeration and Air-Conditioning Engineers (ASHREA)
- Attainable environmental controls that promote:
  - personnel comfort, and
  - make it clinically safe to process medical devices

**ST79:2017 Updates – HVAC guidance**

- Harmonize with ASHRAE Standard 170
  - sterile processing - a critical area.
- Section 3.3.5.5 *Heating, ventilation, air conditioning HVAC operating parameters*
  - Facilities should identify which version of ASHRAE 170 will be used based on when the HVAC system was initially installed or last upgraded.
  - Decrease citations from TJC/CMS
- New annex Q: *Alternatives for keeping cool*

**AAMI ST79 - Annex Q**

- Alternatives for keeping cool in Sterile Processing:
  - Shorter periods of exposure to heat
  - Be well hydrated before donning PPE
  - Frequent brakes
  - Cooling devices
    - Bandana
    - Skull cap or
    - Scarf or towel
    - Cooling vest
ST79:2017 Updates
Section 5 Receiving

- 5.2.3 Loaned or borrowed instrumentation
  - Formalized program
  - Loaned instrumentation policy
    - Recommendations for what to include in your policy:
      - Applicable IFU
      - Loaned set weights not to exceed 25 pounds
      - Sufficient time to terminally process
      - Records of loaner transactions
  - Avoid the need for IUSS
  - Decontamination of loaned instruments

Chapter 7 - Cleaning, Disinfection and Other Decontamination Steps

- Additional information:
  - Preparation and loading automatic cleaning equipment
  - Ultrasonic cleaners and washer-disinfectors
  - Cleaning verification and documentation:
    - Cleaning equipment performance
    - Process verification and testing automatic cleaning equipment each day
  - Annex D – cleaning verification
    - Revised to accommodate the latest cleaning verification methods

User Verification of Cleaning Processes

- Manual cleaning
  - Visual inspection
  - Protein detection
  - ATP
- Mechanical cleaning equipment
  - Tested for proper functioning:
    - Before initial use,
    - Daily,
    - After major repairs

Inspect for Cleanliness and Damage

- Visual inspection alone might not be sufficient
  - Lighted magnification to inspect cleanliness or damage
- Inspect internal channels with a borescope
Decontamination
- Appropriate cleaning and decontamination solutions
  - Proper dilution
    - water lines in the sink and med cup, or
    - automatic dosing system

ST79:2017 Updates – Cleaning agents
When using an automated chemical delivery system/device the automated dosers should be routinely verified or calibrated.

ST79:2017
Instrument air vs. Compressed air
- 3.3.6.1.1 Design considerations
  - The decontamination area/room should have instrument air
- 7.6.4.2 Manual Cleaning
  h) thoroughly rinse and dry a nonlinting cloth or instrument air
- 2.56 instrument air: Medical gas that falls under the general requirements for medical gases as defined by NFPA 99, is not respired, is compliant with the ANSI/ISA 7.0.01, and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40°C (-40°F).

Rinse Water - Critical Water
- 3.3.6.1.1 Design considerations
  g) have a source of critical water for final rinsing (see AAMI TIR34)
- 7.6.1 Cleaning - General considerations
  c) Devices should be thoroughly rinsed. If a basin is used, the rinse water should be changed after each use.
  - The final rinse (mechanical or manual) should be with purified water (e.g., distilled, or RO water). See TIR34 for recommendations on the use of critical water.

AAMI TIR34:2014
Water for the reprocessing of medical devices
- Utility Water (tap water)
- Critical Water
  - A multistep process may include:
    - carbon bed,
    - softening,
    - deionization (DI),
    - reverse osmosis (RO), and/or
    - distillation
- Final Rinse (mechanical & manual)
- Steam Generation

Annex G
Typical presentation of water quality issues during the reprocessing of medical devices
Troubleshooting potential problems
- Observed problem
- Examples of causes
- Recommendations
Clearer Guidance on Instrument Assembly

- OLD - "All jointed instruments should be in the open or unlocked position when ratchets not engaged"
  - Surveyors cited because of the word “open”

- NEW - 8.2 Instruments
d) Ratcheted instruments should be unlatched. Racks, pins, stringers, or other specifically designed devices can be used to hold the instruments in the unlatched position.

Sterilization Tables Removed

- Typical gravity-displacement & dynamic-air-removal sterilization cycles deleted
- Encourage following IFU
- Discourage unwrapped cycles
- Section 10.2 Sterilization parameters
  - Follow validated IFU for:
    - Device,
    - Sterile barrier system (packaging), and
    - Sterilizer manufactures
  - Use sterilization monitors (Cl, Bi, PCD) cleared for cycle

CDC – Guideline for Disinfection and Sterilization 2008

- “Flash Sterilization is considered acceptable for processing cleaned patient-care items that cannot be packaged, sterilized, and stored before use.”
  - Ref: AAMI. Flash sterilization: Steam sterilization of patient care items for immediate use. AAMI. Arlington, VA, 1996. (22 years ago)

ANSI/AAMI

ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

- IUSS
  - Removed from introduction to recommendations
  - New definition and clearer guidance

AAMI ST79: 2017

Definition: 2.50 Immediate-use steam sterilization (IUSS):

- Sterilization method that involves the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field.
- Immediacy implies item:
  - used during the procedure for which it was sterilized and,
  - in a manner that minimizes exposure to air and other environmental contaminants
- Not stored for future use nor held from one case to another.
- Immediacy is not defined by a specific time frame, but established through the critical analysis and expert collaboration of the health care team.

ST79:2017 10.2.2 Sterilization cycles

The sterilizer manufacturer’s written IFU should be followed for operation of the sterilizer and indications for use.

b) If a rigid sterilization container system designed for IUSS is used,
- container manufacturer’s written IFU regarding exposure time should be consulted, and
- reconciled with that of the sterilizer manufacturer.
AAMI ST79: 2017

10.2.3 Immediate-use Steam Sterilization

- IUSS should not be used for convenience or as a substitute for sufficient instrumentation to:
  - Meet anticipated surgical volume, and
  - Ensure enough time to complete all critical elements

Monitoring IUSS cycles

- 13.7.2 Routine biological monitoring of sterilizers larger than 2 cubic ft (includes IUSS)
  - Dynamic-air removal IUSS monitored with a commercially available disposable BI PCD

- 13.7.4 Routine biological sterilizer efficacy monitoring of gravity cycles
  - Monitored with a user assembled representative BI PCD (same type of tray)

Annex P General Considerations for Cleaning and Disinfection

- Cleaning is a multistep process
  - Includes a discussion on thermal disinfection
    - Safe to handle without PPE
  - Basic types of mechanical cleaners and how they are used
    - Ultrasonic with/without irrigators
    - Washer-pasteurizers
    - Washer-disinfections, single/multi chamber
    - Cart washers

- Section 13 Quality Control
  - Automatic washer - printers on clean side

Internal Chemical Indicators - 13.5.2.2.2

- One or more CIs placed within each package, tray, or rigid container.
  - Preferably a Type 5 or Type 6 - provide more information on the critical steam sterilization parameters.

- Internal CIs should be placed:
  a) so that one CI is visible to the person opening the package;
  b) in the area or areas considered least accessible to steam penetration; and
  c) in accordance with all applicable written IFU.

TJC Focus on Reprocessing

“...beginning in 2009, 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.
<table>
<thead>
<tr>
<th>Non-compliance</th>
<th>Standard</th>
<th>Program – Hospital Accreditation</th>
</tr>
</thead>
<tbody>
<tr>
<td>86%</td>
<td>LS.02.01.03</td>
<td>Provides and maintains systems for extinguishing fires.</td>
</tr>
<tr>
<td>75%</td>
<td>LS.02.01.30</td>
<td>Provides and maintains building features to protect individuals from hazards of fire and smoke.</td>
</tr>
<tr>
<td>73%</td>
<td>EC.02.05.01</td>
<td>Manages risks associated with its utility systems.</td>
</tr>
<tr>
<td>70%</td>
<td>IC.02.02.01</td>
<td>Reduces the risk of infections associated with medical equipment, devices, and supplies.</td>
</tr>
<tr>
<td>68%</td>
<td>EC.02.06.01</td>
<td>Establishes and maintains a safe, functional environment.</td>
</tr>
</tbody>
</table>

Joint Commission Online, September 20, 2017

**TJC High-Level Disinfection (HLD) and Sterilization BoosterPak™**

- **Highlights:**
  - Requirements, and
  - Potential flaws
- **Provides:**
  - Reference, and
  - Links to training
- **Important Takeaways**
- **Important Things to Know**


**TJC Second Generation Tracer**

- “The organization reduces the risk of infections associated with medical equipment, devices, and supplies”
- Leadership, IPC, OR, Sterile Processing, ES, and Engineering – all play a CRITICAL ROLE in reprocessing.

*We are all in this together!*


**TJC Facilities Out of Compliance**

1. Not using current evidence-based guidelines
2. Orientation, training, and competency not conducted by personnel trained on recent EBG
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
5. Recordkeeping: “incomprehensible” or non-standardized logs

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


**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 3. An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence.
  - **Subject Matter Expert (SME)**
  - EP 15. The organization takes action when a staff member’s competence does not meet expectations.

[The Joint Commission. 2017 Accreditation Standards](http://www.jointcommission.org/standards_booster_paks/)

**HR.01.06.01: EP 3**

- Note: “When a suitable individual cannot be found to assess staff competence, the hospital can utilize an outside individual for this task. Alternatively, the hospital may consult the competency guidelines from an appropriate professional organization to make its assessment.”
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 3. The interior and exterior space provided for care, treatment, and services meets the needs
  - EP 5. The leaders provide for equipment, supplies, and other resources.

High-Level Disinfection Noncompliance Reported by TJC

- Failure to measure chemical solution dilution
- Noncompliance with IFU, cleaning, or HLD
- Failure to transport in a covered, rigid container
- Missing biohazard labeling
- Failure to ID your clinical practice guideline for HLD
- No oversight of HLD by IPC
- Mixing clean and dirty

Sterilization Noncompliance Reported by TJC

- Failure to pre-clean instruments at the point-of-use
- Leaving hinged items in the closed/latched position during sterilization
- No documentation of washer and sterilizer maintenance and cleaning per IFU
- Failure to document biological indicator and control results
- Use of double peel packs where inner pack is folded over
- Premature release of IUSS
- Failure to document staff competency

Point-of-use Care and Handling

- **6.3.1 Handling of instruments during surgical procedure**
  - Throughout the surgical or invasive procedure,
    a) instruments should be wiped, as needed, with sterile moistened surgical sponges to remove gross soil; and
    b) cannulated instruments or instruments with lumens should be irrigated with sterile water, as needed, without creating aerosols.

- **6.3.3 Instruments opened but not used**
  - All instruments opened in the operating or procedure room should be considered contaminated whether or not they have been used.
  - Rationale: Scrubbed persons might touch instruments without being aware of it. Used instruments also might come in contact with other instruments.

- **6.3.5 Prevention of Instrument Damage**
  - After precleaning at the point of use, staff should
    a) place instruments into respective containers,
    b) identify instruments in need of repair (for example, a tag);
    c) protect delicate instruments from damage (e.g., microsurgical)
    d) segregate reusable sharp instruments; and
    e) place heavy instrumentation on the bottom
  - Rationale: Proper preparation at the point of use reduces instrument damage. Instruments can shift during transport. Keeping the instrumentation in an orderly fashion will help prevent instrument damage.
OSHA Fines Hospital for Unsafe Practices

$28,000 fine – Bloodborne Pathogen Standard violation

- Disposable blades are included with instruments sent to decontamination area
- Scrub person did not disassemble and wipe down used instruments
- Transporting in open or loosely covered basins
- Biohazard liquids and contaminated instruments transported in loosely covered basins that leaked


TJC New Accreditation Process

Project REFRESH:

- Process improvement activity
- Connection between the established standards and patient safety.
- Guided by four core principles:
  - Simplification,
  - Relevance,
  - Innovation and
  - Transparency.

https://www.intermedix.com/blog/project-refresh-the-joint-commissions-new-accreditation-process

SAFER™ matrix

The Survey Analysis For Evaluating Risk

- Visual approach for risk levels associated with deficiencies
- Surveyors assign levels of risk based on:
  1. Likelihood of harm to patients, staff, or visitors, and
  2. Scope of the issue – how widespread the issue is in the organization.
- Color coded which are most critical

https://www.intermedix.com/blog/project-refresh-the-joint-commissions-new-accreditation-process

Likelihood of Harm

- **High**: Could directly lead to harm without need for other significant circumstances or failures.
  - Likely
- **Moderate**: Could cause harm directly, but more likely as a contributing factor or additional failures.
  - Possible
- **Low**: Undermines safety/quality or contributes to an unsafe environment, but very unlikely to directly contribute to harm.
  - Rare

http://www.jointcommission.org/assets/1/23/jconline_May_4,_20161.PDF

Scope

- **Widespread**: "pervasive at the organization"
  - Process failure/systemic failure
  - Majority of patients are/could be impacted
- **Pattern**: potential to "impact more than a limited number of patients"
  - Process variation
- **Limited**: a “unique occurrence”
  - Outlier
  - Not representative of regular practice
Contaminated items should be kept moist by adding a towel moistened with water (not saline) or a pretreatment product specifically intended for this use, or by placing items inside a package that can maintain moist conditions.

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,
  - front-line staff
  - medical staff,
  - nursing, and
  - leadership.
Quality Process Improvement

- Addressing and reducing risks
  - **Proactively identify** risks to **reduce the likelihood** of a process failure.

- Risk Reduction Tools
  - Root Cause Analysis (reactive analysis)
  - Failure Modes and Effects Analysis (proactive process)
  - Tracers (real-time process)

- **Risk Assessment** 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 subject matter expert
- No standardization throughout the organization
- Lack of competency documentation

Adopting New Technology or Processes using a Multidisciplinary Risk Assessment

<table>
<thead>
<tr>
<th>Title</th>
<th>Publication</th>
<th>Published</th>
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<tr>
<td>A Systematic Approach to Adopting New Technologies for the Sterile Processing Department (SPD) and Operating Room (OR)</td>
<td>OR TODAY</td>
<td>July/Aug 2017</td>
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<tr>
<td>A Systematic Approach to Adopting New Technologies for the SPD and OR</td>
<td>HEALTHCARE TODAY</td>
<td>August 2017</td>
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<tr>
<td>Adopting New Technologies in CS Using a Multidisciplinary Risk Assessment. IAHCSSM Communiqué – CHL Lesson Plan</td>
<td>IAHCSSM</td>
<td>Jan/Feb 2018</td>
</tr>
</tbody>
</table>

Preventive Risk Analysis

- Focus on identifying and addressing **underlying reasons** caused the issue – not a band aid approach

- Efforts also focused on **preventing future occurrences** of the high risk issue


TJC BoosterPak™ Environment of Care - **Takeaways**

- EC.02.04.03, EP4: The hospital conducts performance testing of and **maintains all sterilizers**. These activities are documented.
  - Includes de-centralized (off-site or table-top sterilizers)
  - Adhere to IFUs

http://www.jointcommission.org/standards_booster_paks/
Beginning Jan. 1, 2017, HTM departments must have documentation on-hand for specific devices at the time of a survey. Starting January, if they ask for it and you don’t have it— you don’t have it. They will write you a finding. [http://www.aami.org/TJC_Checklist]

Monitor temperature and humidity in all critical environments, Air pressure relationships
- Staff have a tool to assess pressure relationships
- Alarm locally so staff can react and trouble shoot

Air Flow Detection Tools
- Staff needs tools to monitor positive and negative air
- Surveyor notices air balance off
  - “Oh, I have to call engineering to correct it” = cite
  - Want to see consistent feedback – alarm locally

Location of all scopes, probes, and devices requiring HLD
- Initial and on-going competencies
- Location and accessibility of:
  - IFU (equipment, devices, and supplies)
  - Current HLD evidence-based guidelines available to front-line staff use
- HLD policies are current
  - Include key stakeholders in HLD process
  - IP, EVS, Eng, leadership, front-line staff, management

Dirty scope transportation to decontamination area
- Leak proof
- Puncture resistant container/device, and labeled as biohazardous

Always change cleaning solution after each scope.
- Always measure chemicals accurately, don’t approximate (solution dilution)

http://www.jointcommission.org/standards_booster_paks/
**TJC BoosterPak™ HR-Competency and Training - Takeaways**

- HLD and sterilization require competency:
  - front-line staff, and
  - those responsible for its oversight
- Documented records of training and competency:
  - trained initially and on ongoing basis
- Ensure sterilization and HLD follow:
  - device manufacturer IFU, and
  - evidence-based guidelines


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**CDC -Flexible Endoscopes Free Tool Kit Forms**

HICPAC (Healthcare Infection Control Practices Advisory Committee), Federal advisory committee to CDC

- Essential Elements of Reprocessing for Endoscopes.
  - Extensive tool kit and forms:
    - Policy template
    - Audit tool
    - Competency verification tool
    - Inventory and maintenance log
    - Gap analysis tool, and
    - Root cause analysis template - errors in scope processing


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**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

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**Objective #3**

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

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**Preparing for a Processing Audit**

- Accreditation Documents
- Relevant Professional Standards and Guidelines
- Accreditation Preparation Committee

**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

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*It Takes a Village!*
Preparing for a SAFER Survey

1. Ensure full understanding of requirements
2. Continue conducting self-assessments of compliance
3. “Practice” placing findings (perhaps findings from previous surveys) on the SAFER matrix

Questions? safer@jointcommission.org

https://www.jointcommission.org/webinar_replay_slides_safer_matrix_11-15-16/

Crosswalk
TJC Standards Linked to Current AAMI ST79

http://www.aami.org/publications/bookshop.html


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)

http://www.aami.org/publications/bookshop.html


Sterile Processing In Healthcare Facilities: Preparing for Accreditation Surveys 3rd Ed.

- Current accreditation standards:
  - CMS, TJC, AAAAAF
  - Hospitals,
  - Critical Access Hospitals
  - Ambulatory Care
  - Office-Based Surgery Practice
- Current professional guidelines
  - AORN,
  - AAMI,
  - SGNA,
  - CDC

http://www.aami.org/publications/bookshop.html


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, or services.
- LD.04.04.07: The hospital considers clinical practice guidelines when designing or improving processes

http://www.aami.org/publications/bookshop.html


Standards & Guidelines Crosswalks

Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys

- TJC
- AAMI


The Joint Commission E-dition Accreditation Manual

- TJC
- CMS


AORN to AAMI Crosswalk:

- AORN
- AAMI

Never Ever

- Defend a violation of your policy or an unsafe practice
  - Build credibility
  - Admit to the issue and commit to fixing it and not having it reoccur.
- Volunteer an answer you don’t know
  - Tell them you will find out soon

Never

- 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

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

Compliance is coming – Be prepared!

“If you think compliance is expensive – try non-compliance.”

Former U.S. Deputy Attorney General Paul McNulty

The Final Word...

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

Thank you
References

- ST79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79:2017


Updates on AAMI ST79 & SPD Accreditation Surveys

Questions?