Under the Spotlight: Is Your Facility Prepared for a Sterile Processing Accreditation Survey?

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Under the Spotlight!

Is Your Facility Prepared for a Sterile Processing Accreditation Survey?

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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 healthcare facilities prepare for a successful accreditation survey.

New AAMI Book

- Help facilities prepare for an accrediting agency survey relating to sterile processing in all health care settings.

- Includes:
  - Recommend practices, standards and tools such as:
    • Survey preparation suggestions
    • Risk reduction tools
    • SP best practices audit tool
Accreditation

- Peer review by professionals
- Enhances the quality of health care
- Reprocessing larger focus of survey processes

Sterile Processing Surveys

- Reprocessing of medical supplies in any area
- Accreditation organizations’ requirement related to SP
  - The Joint Commission (TJC)
  - Centers for Medicare and Medicaid Services (CMS), and
  - Other accrediting organizations’ requirements related to SP in any setting
- Standards and evidence-based guidelines
- Survey Preparation,
- Risk reduction tools, and
- “Sterile Processing Best Practices Audit Tool”
The Joint Commission

- Accredits and certifies 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.
- Symbol of quality

TJC Survey Process

- Submit an application
- Pay a fee
- Resurveyed within three years
- Unannounced survey process
Joint Commission Resources

- 2011 Comprehensive Accreditation Manual for Ambulatory Care (CAMAC)

Accreditation Standards

- Standards: performance objectives
- Rationales: describe importance
- Elements of performance (EPs): specifics
  - Scores determine the compliance
  - Minimum score of 90% on every EP
- Standards relating to reprocessing
  - Environment of Care,
  - Human Resources,
  - Infection Prevention, and control and
  - Leadership
Examples of 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.

Examples of 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.
  – EP 5. The leaders provide for equipment, supplies, and other resources.
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).”

TJC Standards and Element of Performance

Annexes

A  TJC Standards and Elements of Performance Related to Sterile Processing in Hospitals

B  TJC Standards and Elements of Performance Related to Sterile Processing in Ambulatory Care Facilities
Tracers

- Program-specific tracers
- System tracers
- Individual tracers

SP tracers – Chapter 8 - Sterile Processing In HC Facilities: Preparing for Accreditation Surveys

Tracer Method

Use in surgery
- wipe, moisten, irrigate during procedure

Transport to OR room
- Storage
- Transport to OR
- Sterilize
- Loading sterilizer
- Assemble and package

Transport to decontamination
- Disassemble
- Soak
- Clean manual and/or automatic

Inspection for cleanliness
- Test for function
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The Joint Commission

- Joint Commission Online July 2011
  - Focus on sterilization and high-level disinfection
  - “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
    - Before training cited 10% noncompliance for HLD/sterilization*
    - After training cited 40% noncompliance for HLD/sterilization*
  - Survey to ANSI/AAMI ST79

http://www.jointcommission.org/assets/1/18/jconline_July_20_11.pdf
*Louise Kuhny, TJC, FPIC Orlando Seminar, 9/22/2011

Centers for Medicare and Medicaid Services (CMS)

- Participation in Medicare
  - Code of Federal Regulations
  - Accreditation Organizations
    - Accreditation Association for Ambulatory Health Care (AAAHC)
    - Accreditation Commission for Health Care (ACHC)
    - American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
    - American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)
    - Community Health Accreditation Program (CHAP)
    - DNV Healthcare (DNV)
    - The Joint Commission

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CMS Memo on Sterilization

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

CMS Surveyor Worksheet

• Infection Control Condition of Coverage for ASCs
  – List of addressed items
  – Interviews and observations
  – 16 pages
  – Annex C
Other accrediting organizations

- DNV Healthcare
- American Association for Accreditation of Ambulatory Surgery Facilities (www.aaaasf.org)
- Accreditation Association for Ambulatory Health (www.aaahc.org)
- Accreditation Commission for Health (www.achc.org)
- American Osteopathic Association/Healthcare Facilities Accreditation Program (www.hfap.org)
- Community Health Accreditation Program (www.chapinc.org)
- State Departments of Health

Disinfection and Sterilization Recommendations

- ST 79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

- Perioperative Standards and Recommended Practices
  Denver, CO: AORN, Inc, 2012

- CDC Guideline for Decontamination and Sterilization in Healthcare Facilities 2008
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 & A1:2010

- 2010 2nd edition changes:
  - Steam quality requirements,
  - Paper-plastic pouches,
  - Mechanical cleaning equipment,
  - Product quality assurance testing (product families), and
  - Risk analysis.
  - Additional info about Class 6 CIs,
  - Provides a new section on New Product Evaluation.

ST79:2010/A2:2011

- Manufacturer’s written instructions for use = IFU, and
- Hand washing = hand hygiene
Other AAMI Sterile Processing Related Documents

- Recommended practices for sterile processing in HC facilities
  - ANSI/AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
  - ANSI/AAMI ST41 *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*
  - ANSI/AAMI ST58 *Chemical sterilization and high-level disinfection in health care facilities*
  - ANSI/AAMI ST65 *Processing of reusable surgical textiles for use in health care facilities*
  - ANSI/AAMI ST40 *Table-top dry heat (heated air) sterilization and sterility assurance*

Other AAMI Sterile Processing Related Documents

- Standards for sterilization equipment intended for use in HC facilities
  - ANSI/AAMI ST8 *Hospital steam sterilizers*
  - ANSI/AAMI ST55 *Table-top steam sterilizers*
  - ANSI/AAMI ST24 Automatic, general-purpose *ethylene oxide sterilizers* and EtO sterilant sources intended for use in HC facilities
  - ANSI/AAMI ST50 *Dry heat (heated air) sterilizers*
Other AAMI Sterile Processing Related Documents

- Technical information reports (TIR)
  - AAMI TIR12 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities*:
  - AAMI TIR30 *A compendium of processes, materials, test methods, and acceptance criteria* for cleaning reusable medical devices:
  - AAMI TIR31 *Process challenge devices/test packs* for use in healthcare facilities:
  - AAMI TIR34 *Water for the reprocessing of medical devices*

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

Policy and Procedure Template available on CD-Rom

(www.AORN.org)
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CDC Guideline
Decontamination and Sterilization in Healthcare Facilities 2008


CDC Guide

CDC Checklist
Guide to Infection Prevention for Outpatient Settings

- Evidence-based guidelines produced by the CDC and HICPAC
  - Minimum infection prevention expectations
- Infection prevention a priority
- IP gatekeeper to safe patient care

Dedicated IP Resources

- 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

IUSS Position Statement

Preparation for an Accreditation Survey

- Accreditation Preparation Committee
- Accreditation Documents
- Relevant Professional Standards and Recommended Practices

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

Preparation for and Accreditation Survey

- Polices and Procedures
  - Facility design and housekeeping,
  - Personnel – qualifications, training and continuing education,
  - Dress code -PPE,
  - Standard and transmission-based precautions,
  - 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 Knowledge and Education

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Sterile Processing Audit Check List

• Audits and Quality Process Improvements
  – Self audit tool www.seaveyhealthcareconsulting.com
    • Click “SP Audit Check List” (at right)
    • Click “Sterile Processing Best Practices Audit Check List” (at bottom)
    • Click “Open”
  – Introduction followed by a downloadable checklist

Preparation For an Accreditation Survey

• Risk Analysis
  – 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.

• Risk Reduction Tools
  – Root Cause Analysis
  – Failure Modes and Effects Analysis
  – Tracers
Quality Process Improvement

Risk analysis (11.2.2) =
Risk assessment +
Risk management +
Risk communication

Objective is to identify the risks to reduce the likelihood of a sterilization process failure

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 (11.2.2)

- **Risk Management**
  - Determine which of the sterilization process failures are the biggest risk and therefore require management
  - Select and implement the plans or actions needed to ensure those failures are controlled
  - AAMI ST79 describes the accepted means of managing these risks throughout the document

ANSI/AAMI ST79:2010 & A1:2010 Section 11.2.2

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Risk Analysis (11.2.2)

- **Risk Communication**
  - Sterile Processing informs OR and ICP of the risk analysis and the plan of action (recall is an example)
Risk Analysis of the Sterilization Process Resource

- **Risky business: Risk analysis in CSSD**
  - Published in Healthcare Purchasing News - August 2010

- **Worth The Risk: Performing a risk Analysis in CSSD**
  - Published in healthVIE.com - May 2011
    access through [http://www.3M.com//3MSterileU](http://www.3M.com//3MSterileU)

Sue Klacik
(IAHCSMM representative to AAMI and co-chair of the PCD working group)

Sterile Processing Benchmarks

- **New Sterile Processing Benchmarking Solutions**
- Web based platform
- Compare like facilities
- Over 130 measurements
  - Budgeting and financial issues,
  - Sterilization practices,
  - Volume and types of work performed,
  - Compliancy issues, best practices, performance improvement,
  - Purchasing decisions, capital planning and
  - Staffing qualification and much more


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Sterile Processing Certification

• www.iahcsmm.org

• www.sterileprocessing.org

TJC Surveyors

• How often you run a Bowie-Dick test
• How often you run a BI
• BI records in the OR
• BI and control lot numbers match and are recorded
• Documentation for the last recall
• Amount of cleaning agent
• Shelf life of disinfectant
• Quality checks on solutions and test strips
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**TJC Surveys**

- Weight limit on trays
- Loaner instruments
  - Received 24 hours prior
  - Following MFR IFUs
- Reusable rigid containers
- IUSS tracked to the patient
- Using containment devices for IUSS

**TJC Surveyors**

- Fire extinguisher not blocked
- Pull stations were located,
- Adjustable workstations
- Door and pass through window kept closed
- Equipment logs
- Traffic patterns
- Sterile storage shelves were 18 inches
- Bottom shelves solid and 8-10” from floor
- No cardboard shipping boxes

Personnel communications with facilities that have been surveyed by TJC
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TJC Surveyors

- Solid cleanable surfaces
- Solid ceiling tiles
  - No fiberboard
  - No stains
- Temperature, humidity and ventilation records
- 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

TJC Surveyors

- Staff competencies documented
- Professional association,
- Certified staff
- Standardized processes
Survey Hot Buttons

• Laryngoscope blades are semicritical items
  – Sterilization
    • Steam, or
    • Low temperature sterilization
  – High-level disinfection
  – Packaged and Stored to prevent recontamination

• Laryngoscope handles processed between patients

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

ST79 Key Provisions
(Annex G)

• Sections covered
  – Design considerations
  – Personnel considerations
  – Receiving
  – Handling, collection and transport of contaminated items
  – Cleaning and other decontamination processes
  – Packaging, preparation and sterilization
  – Installation, care, and maintenance of sterilizers
  – Quality control
  – Quality process improvement
  – New product evaluation

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Questions?

• To submit a question, please type your question at the bottom of the Q&A box on your screen and press “Enter,” or press *1 on your telephone keypad.

Closing Reminders

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

• Save the date for these upcoming events:
  – January 11: Quality System Concepts Needed for FDA’s Medical Device Data Systems Regulation Webinar
  – February 7: Rigid Sterilization Containers: Best Practices Webinar
  – June 2-4: 2012 AAMI Annual Conference and Expo, Charlotte, NC