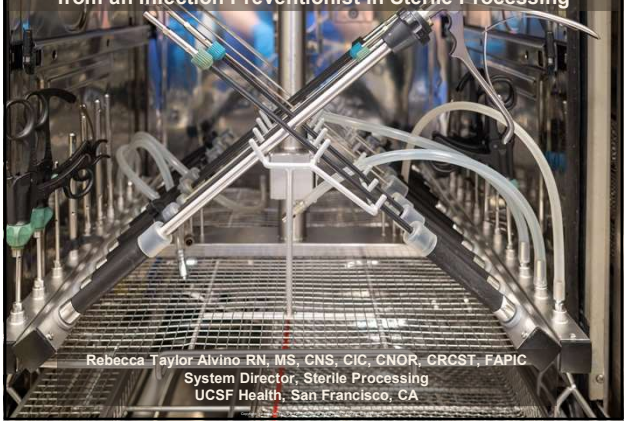
An Overview of Sterile Processing for Infection Preventionists, from an Infection Preventionist in Sterile Processing



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Learning Objectives

1) Discuss updates to AAMI ST91 and relevance to infection preventionists.

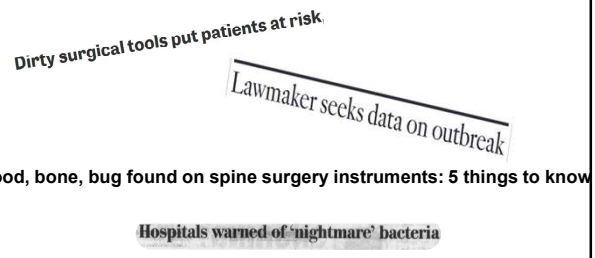
2) Identify key rounding elements for the infection preventionist in sterile processing departments.

3) Describe some of the key performance indicators in sterile processing to guide infection prevention assessment and partnership with sterile processing.

Disclosures

- I have no financial relationships to disclose.

Why is STERILE PROCESSING IMPORTANT TO INFECTION PREVENTION?



Why is STERILE PROCESSING IMPORTANT TO INFECTION PREVENTION?

The Joint Commission Hospital Standard IC 02.02.01

- The hospital reduces risks of infections associated with medical equipment, devices, and supplies
- Five elements of performance that elaborate further on what this standard requires for compliance
- The standard is specific in expecting collaboration between departments and staff when it comes to the activities of infection prevention and control
- This TJC standard is crosswalked with CMS 482.42, 482.51, 482.51(b)

AAMI ST91 Updates

- Consensus document first published in 2015 focusing on reprocessing flexible endoscopes
- Updates to 2022 publication:
  - Additional recommendations for decontamination of flexible endoscopes (three-bay sink is ideal, but two-bay sink or one sink with two basins in minimum standard)
  - Provision for additional space to support delayed reprocessing
  - Recommendation for personnel reprocessing flexible endoscopes to obtain and maintain specialty certification in endoscope reprocessing within two years
  - Recommendation to make steps towards sterilizing flexible endoscopes, when possible
  - Addition of Section 4.3.11, which addresses water quality recommendations for flexible endoscope reprocessing

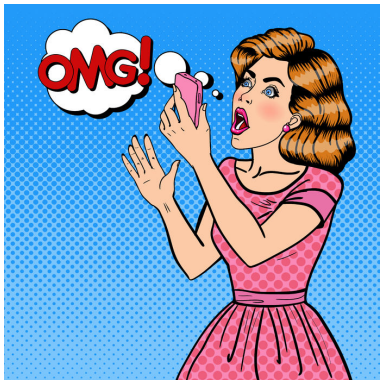
AAMI ST91 Updates

- Updates to 2022 publication:
  - Recommendations to place automated leak testers on calibration schedule
  - Inspect manual and automated leak tester tubing and devices for damage
  - Verification of leak tester pressures each day of use
  - Documentation of leak testing results
  - Single-use endoscope port caps and valves, OR sterilization of reusable endoscope port caps and valves (when validated), OR HLD of caps and valves
  - Cleaning verification to detect debris not directly visualized
  - Formal recommendation to inspect lumens through the use of borescopes
  - Minimum 10 minute drying time post-HLD with pressure-regulated instrument air, or at least HEPA-filtered air; extend drying time if moisture is still observed
  - Storage cabinet recommendations: Drying cabinets or conventional cabinets with positive pressurization of HEPA-filtered or instrument-grade air

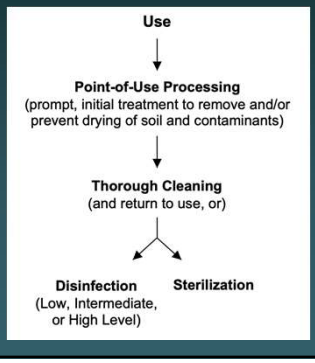
Other AAMI Updates Pertinent to Infection Preventionists and C/SP Professionals

- PB70: "Establishes minimum barrier performance requirements, a classification system, and associated labeling requirements for protective apparel, surgical drapes, and drape accessories intended for use in health care facilities"
- A.4.2.3.6 Decontamination Gowns: "The critical zones include those areas where direct contact with blood, body fluids and OPIM are most likely to occur."
- "Due to the nature of the environment for which decontamination gowns will be worn the critical zones have a minimum barrier performance of at least Level 3."
- *Many thanks to Cheron Roe, Senior Clinical Education Specialist for Healthmark and Co-Chair of AAMI PB70 Workgroup, for sharing this information with me to present*

Uh-oh, Infection Prevention IS HERE!!!



Basic Steps of Reprocessing: High-Level Disinfection and Sterilization



An Infection Preventionist's Perspective to the C/SP Physical Plant

- Are reprocessing areas laid out to support single direction movement through the process?
- Space constructed of non-particulate, non-shedding materials that can withstand frequent cleaning? Surfaces intact?
- Surfaces and equipment clean? Dust and debris accumulation?
- Condensation on the walls?
- Any mold or mildew evident in the space?

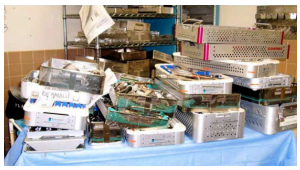
An Infection Preventionist's Perspective to the Physical Plant

- Hand-washing and hand-cleaning facilities (such as waterless hand sanitizer) readily available?
- Eyewash and emergency showers easily accessible by employees?

- Pass-through windows and doors remain closed when not in use?
- Adequate lighting for all staff to perform their work?

An Infection Preventionist's Perspective to the Physical Plant

- Soiled items held inside decontamination areas?
- Three-bay sinks at each decontamination workstation?



- Separate manual decontamination space for delicate (handwash only) and ophthalmic instruments?
- Automated cleaning equipment interiors and exteriors clean?

An Infection Preventionist's Perspective to the Physical Plant

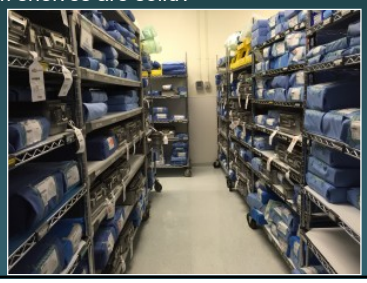
- Critical water source available for final rinses?
- Instrument air source?
- For immersion high-level disinfection (HLD), where does this live?
- Where do automated endoscope reprocessors (AERs) live?
- Do construction projects taking place in reprocessing areas have adequate infection control measures and documentation in place?

An Infection Preventionist's Perspective to the Physical Plant

- Assembly and packaging workstations with appropriate surface disinfectant available?
- Where are packaging materials stored?
- Are shelves and any storage receptacles clean and free of dust/debris?
- Magnifying glasses or other vision-enhancing equipment available?
- Corrugated cardboard or other outside shipping containers present?

An Infection Preventionist's Perspective to the Physical Plant

- Sterile storage areas with items at least 8-10 inches from floor, and top shelf items at least 18 inches from ceiling?
- Bottom shelves are solid?



An Infection Preventionist's Perspective to the Physical Plant

- Wrapped items and rigid container systems placed properly in storage?
- Heavier trays and packages stored for employee safety?
- Peel-packed items stored vertically?
- No expired supplies present?
- Sterilized items in storage are labeled with sterilization information (sterilizer used, cycle number, date of sterilization, and expiration date [if applicable])?

An Infection Preventionist's Perspective to the Physical Plant

Single-space reprocessing areas

- Does the layout support correct movement through the reprocessing steps?
- Unidirectional traffic pattern?
- Adequate space between soiled areas, assembly/packaging areas, high-level disinfection (HLD) and sterilization equipment, and any storage?

An Infection Preventionist's Perspective to Personnel Knowledge and Behaviors

Decontamination

- Soiled items staged for decontamination are not dry?
- Required PPE used during decontamination activities?
- Is PPE intact during decontamination activities?
- Is reusable PPE cleaned between different employee uses and at least every shift?
- What is the process for managing and reporting blood borne pathogen exposures?

An Infection Preventionist's Perspective to Personnel Knowledge, Practices, and Processes

Decontamination

- Correct concentrations of detergents and water mixed at the correct temperatures?
- Decontamination of instruments and endoscopes below the surface of the solution?
- One tray/one endoscope at a time decontaminated?
- Automated washer equipment loaded correctly?
- Movement in this space is from dirty to clean, and never clean back to soiled?
- Are IFUs for decontaminating devices followed?

The Infection Preventionist's Perspective to Personnel Knowledge, Practices, and Processes

Decontamination

- Evidence of efficacy testing for automated cleaning equipment? When is testing of automated cleaning equipment performed?
- Are ophthalmic instruments managed separately, using detergents and chemistries recommended by the instrument manufacturer?
  - American Academy of Ophthalmology (2018) issued guidelines to assist ASCs with cleaning and sterilization of intraocular devices. https://www.aao.org/clinical-statement/guidelines-cleaning-sterilization-intraocular
  - AAMI ST79 (2017) Annex M

What's Wrong With This Picture?

Key Performance Indicators to Consider

Decontamination

- Throughput time: Time from first scan in Decontamination to the next step in the process. Total throughput time is from first scan in Decontamination to time out of sterilizer.
- Acceptable receipt of soiled items from ORs, clinics, and nursing units: Is this captured? If so, where and how is this reported? Who receives these data? Do C/SP know what to look for and how to document acceptable/unacceptable conditions?
- Contaminated trays: How many contaminated products are reaching C/SP assembly areas? How many are reaching ORs or other clinical areas?
- Sharps received:/sharps injuries: Are knife blades, saw blades, or other disposable sharps remaining on instruments during transport to C/SP? Are C/SP injuring themselves with sharp instruments?

Key Performance Indicators to Consider

Decontamination

An Infection Preventionist's Perspective to Personnel Knowledge, Practices, and Processes

Assembly and Packaging/Prep and Pack

- Packaging materiel protected from contamination?
- Chemical integrators stored in a manner to prevent premature change of the indicators?
- Biological indicators stored according to manufacturer IFU?
- How are instrument quality checks performed?
- Tapes, dips, and other instrument identifiers maintained and intact?

An Infection Preventionist's Perspective to Personnel Knowledge, Practices, and Processes

Assembly and Packaging/Prep and Pack

- How are packages labeled? Are packaging materials validated for the sterilization method employed?
- Where are inventory sheets placed on packages, and are they placed before the terminal process or after?
- Are inventory sheets placed before sterilization validated for sterilization?
- Are chemical indicators appropriately placed in instrument trays? Does each layer inside a tray contain a chemical indicator?
- Is packaging materiel used in a compliant manner, as indicated for its use?

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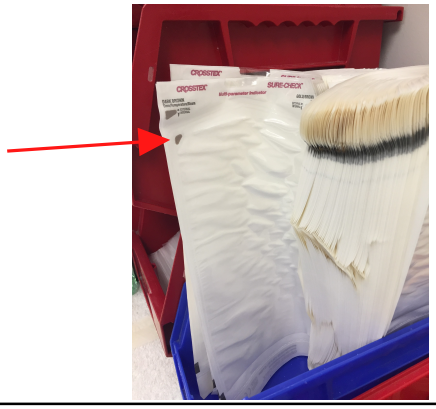

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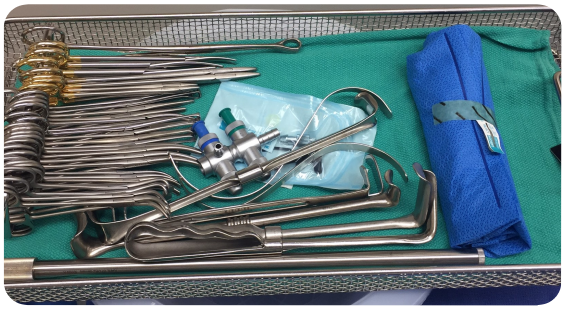


What's Wrong With This Picture?

Key Performance Indicators to Consider

Quality Assurance and More

- Loaned inventory: aka “Loaners”, how many sets are borrowed from vendors or other facilities? What is the compliance for arriving in a timely manner for elective surgeries?
- Error rate: Ideally identified pre-sterilization (before direct impact to patient care), may also be identified in post-sterilization audits (before release to clinical area) or in clinical area. Errors can include missing internal and/or external chemical indicators, filter issues (missing or not secured), or moisture noted in terminally sterilized products

An Infection Preventionist’s Perspective to Personnel Knowledge, Practices, and Processes

High-Level Disinfection and Sterilization

- How often are sterilizers cleaned? What does the manufacturer IFU state the frequency and method should be?
- Evidence of process challenges for each sterilizer on each day of use?
- Are steam sterilizers used for full cycles, or are some cycles IUSS?
- What is the process for returning sterilizers to service after repairs and/or relocation?
- For low-temp gas plasma sterilization, how are hydrogen peroxide cassettes stored?

An Infection Preventionist’s Perspective to Personnel Knowledge, Practices, and Processes

High-Level Disinfection and Sterilization

- Are immersion stations clean? If in use, are filters changed according to IFU?
- Are dates on high-level disinfectants within their expected cycle, and not expired?
- Quality control testing materiel not expired?
- How are items that undergo high-level disinfection or liquid chemical sterilization rinsed?
- High-level disinfectants tested before each use?
- Chemical indicators present for liquid chemical sterilization systems?

High-Level Disinfection and Sterilization

- How often are automated endoscope reprocessors (AERs) cleaned?
- Are AER chambers clean upon inspection?
- Connectors clean?
- Are AERs validated for all flexible endoscopes and TEE probes reprocessed through them?

Are liquid chemical sterilization and high-level disinfection records complete?

Informational source: AAMI ST58 (2013) 9.2.2

Assigned lot number	Name or initials of operator/personnel performing LCS or HLD	Results of biological or spore strip testing, if applicable
Specific contents of the lot or load, including quantity, department, and description of items	Exposure time and temperature, if not provided on the physical monitors	Results of chemical indicator or solution strip testing, if applicable
Patient's name, medical record number, (if available)	Date and time of cycle	Results of MRC or MEC testing, if applicable
Procedure, physician, and serial or other device identification number (if available)	Time, temperature, and chemical concentration (if applicable) during exposure phase of LCS or HLD cycle	Reports of inconclusive or non responsive chemical indicators, or low MRC or MEC testing results
	The shelf-life date, lot number, and date of the original container of LCS/HLD was opened; use-life of open container; date that the product was activated or diluted; pour date of solution into secondary container; and reuse life of solution	

Are steam sterilization records complete?

Informational source: AAMI ST79 (2017) 13.3.3

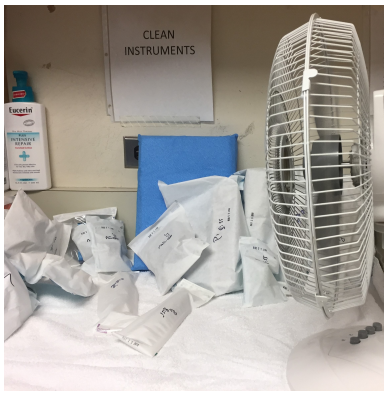
Load number	Specific contents of the lot or load, including quantity, department, and specific description of the items	Exposure time and temperature (if not on sterilizer recording chart)	Operator identification
Results of biological testing, if applicable	Results of Bowie-Dick testing, if applicable	Response of the chemical integrator placed in the process challenge device, if applicable	Reports of inconclusive or non responsive chemical indicators found later in processed devices

What's Wrong With This Picture?

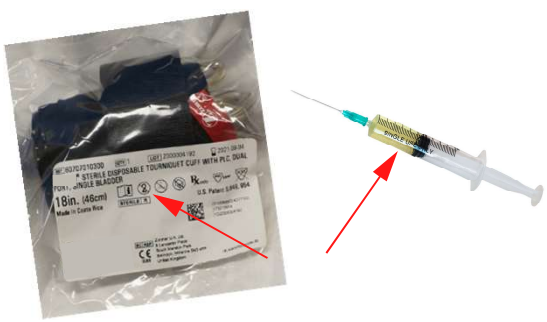
Build-up inside IUSS chamber

Overlapping packages in low-temperature gas plasma sterilization chamber

What's Wrong With This Picture?



The Infection Preventionist's Perspective to Personnel Knowledge and Behaviors



Do Central/Sterile Processing Personnel Need to Be Certified to Work in Sterile Processing?

YES!!!

- The State of New York (as well as a handful other states) require certification to work in sterile processing
- Two certifying bodies for sterile processing:
  - Healthcare Sterile Processing Association (HSPA), formerly the International Association of Healthcare Central Services and Materiel Management
    - Requires continuing education and renewal annually to maintained certifications
  - Certification Board of Sterile Processing and Distribution (CBSPD)
    - Requires continuing education and renewal every five years to maintain certifications

Addition of New Clinical Areas or Acquisition of New Facilities: Are There Disinfection and Sterilization Needs?

- As healthcare networks grow, new clinical spaces and units may be added: C/SP and Infection Prevention must be at the table starting at the concept phases!
- Construction of new buildings and facilities: Who is at the table to discussion reprocessing needs and resources?

Let's Recap!

- The physical plant of C/SP areas should be maintained to the highest standards, like operating rooms, and work must move in one direction
- Assessment of personnel knowledge and behaviors may be performed by the IP

Let's Recap!

- Use CDPH, CMS, and TJC guidance and reference documents, as well as local policies and procedures, to perform frequent assessments
- If it isn't documented, it didn't happen
- Review of high-level disinfection and sterilization records is not off-limits
- Be sure all IFUs are followed, and where there are contradictions reach out to device manufacturers to reconcile **BEFORE** implementation!
- Used single-use devices cannot be reprocessed in C/SP unless specifically licensed to do so

Let's Recap!

- C/SP is a vital service to any healthcare facility, and should be respected as such
- The infection preventionist can be a partner and advocate for C/SP