EDUCATION

STERIS UNIVERSITY

ANSI/AAMI ST58:

Chemical Sterilization and High Level Disinfection in Healthcare Facilities

Part 1 of 2

One Integrated Approach to Healthcare.

STERIS

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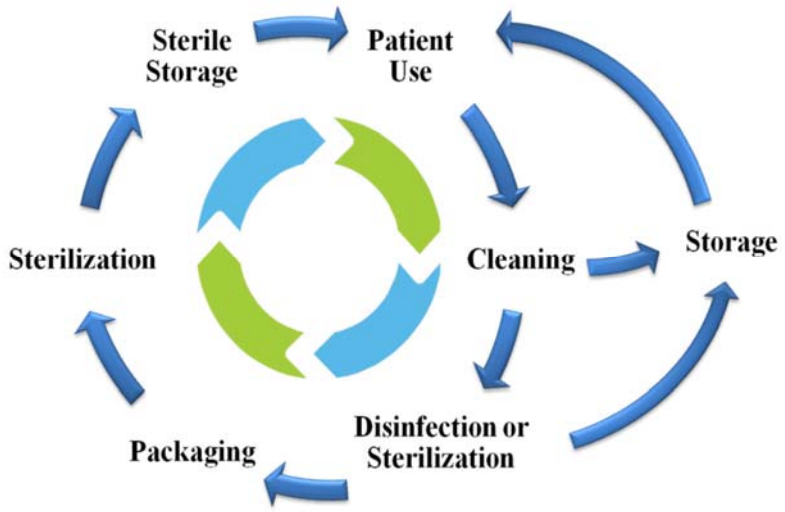
Learning Objectives

Upon completion of this presentation, you will be able to:

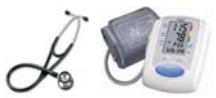
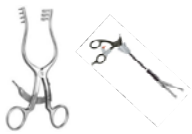
- Understand ANSI/AAMI ST58 regarding chemical high level disinfectants and sterilization processes
- Define key points for safe handling and effective use of chemical sterilants/high level disinfectants for health care workers
- List quality control monitoring methods for chemical sterilization/high level disinfection processes and gaseous sterilization systems

ANSI/AAMI ST58
Part 1 of 2

Typical Reprocessing Cycle



Spaulding Classification

Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Cleaning and/or Low/Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	Cleaning and Sterilization (or High Level Disinfection)
Sterile areas of the body, including blood contact		Critical	Cleaning and Sterilization

Disinfection/Sterilization

Chemical	Thermal
Examples	Examples
• Hydrogen peroxide	• Hot water
• Peracetic acid	• Pasteurization
• Glutaraldehyde	• Steam sterilization
• Ethylene oxide	• Dry heat sterilization

Documents for Device Processing

- ANSI/AAMI ST79: *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 healthcare facilities*
- AAMI Technical Information Report (TIR) 34: - *Water for the reprocessing of medical devices*
- Other Relevant Documents:
  - AORN - *Perioperative standards and recommended practices.*
  - *SGNA - Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes.*
  - CDC/HICPAC - *Guideline for disinfection and sterilization in healthcare facilities.*

What is ANSI/AAMI ST58?

Guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers for use in hospitals and other health care facilities

Definitions for Review

- Processing Area
- Disinfection
- Sterilization

Processing Area

The area of a health care facility where cleaning, disinfection, sterilization is performed.

What is Disinfection?

- Process that kills pathogenic and other microorganisms by physical or chemical means
- High, intermediate or low level
- High level disinfectant (HLD): product that is expected to kill all microbial organisms but not necessarily large numbers of bacterial spores

What is Sterilization?

- Validated process used to render a product free from viable microorganisms
- Chemical sterilization uses a chemical agent for sterilization
- Liquid chemical or gaseous sterilization processes

What Information is in ST58?

- Definitions and abbreviations
- Work area design
- Personnel
- Selection of liquid and gaseous chemical sterilants
- Decontamination and preparation of instruments
- Using chemical sterilants safely and effectively
- Device storage and transport
- Quality control
- Quality process improvement
- Informational annexes

Work Area Design Considerations

- Traffic control, engineering controls, ergonomics, proper equipment installation, operation
- Designated separation of dirty (cleaning) and clean (disinfection/sterilization) activities and work flow
- Separate from patient care areas
- Design for safe use chemicals
- Storage and disposal of chemical
- Restricted, controlled access
- Adequate ventilation

Work Area Design Considerations, continued

- Automated processing equipment for LCS/HLD
  - Designed to reduce exposure to chemical
  - Semi-automatic or automatic
- Considerations
  - Space, appropriate location
  - Manufacturer IFUs for installation
  - Safety features, mid-cycle inspection
  - Special plumbing requirements
  - Filter requirements
  - Heating system
  - Capabilities
  - Means to change and dispose chemical solutions

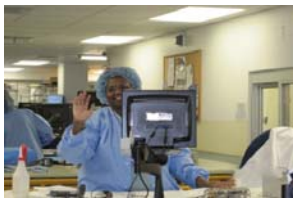
Work Area Design Considerations, continued

- Storage of LCS/HLD
  - Follow IFUs and Safety Data Sheets (SDS)
  - Containers tightly closed, properly marked
  - Store in cool, secure, ventilated area
  - No storage under sinks

- Disposal of LCS/HLD
  - Follow IFU, state and local requirements
  - Label waste container properly
  - Follow IFU for disposal of empty container

Personnel Considerations

- Certification recommended for all personnel
- Follow health and personnel hygiene
- Qualifications
  - Supervisory personnel
    - Specialized training
    - Knowledge and experience
    - Participates in facility and continuing ed.
    - Knowledge of regulations
  - Processing personnel
    - Initial and on-the-job training
    - Training and continuing education
    - Demonstrates skills and competencies



Personnel Considerations, continued

- Hazard training and OSHA Requirements
- PPEs to protect skin, eyes, mucous membranes, clothing
- Protective work practices
- Emergency/exposure procedures
- Consult SDS sheets

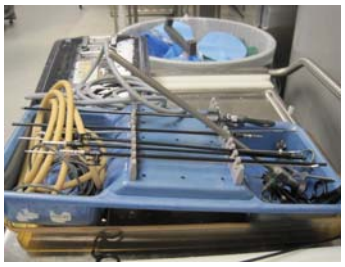
Selection of Liquid, Gaseous Chemical Sterilants and High Level Disinfectants

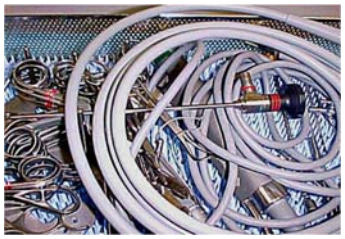
- Categories
  - LCS/HLD
  - Gaseous chemical sterilants
- Effectiveness
- Material compatibility
- Cost effectiveness
- FDA cleared

Decontamination and Preparation of Instruments

- Receiving
  - New or repaired
- Handling and collection
  - Separation of waste
  - Point of use pre-cleaning
  - Safe transport
  - Containment
- Cleaning
  - Facility Policy
  - IFUs
- Transport
  - Contained and segregated
  - On or off site
- Preparation

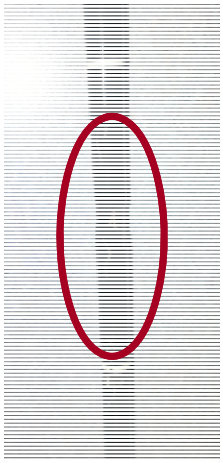
How Damage Occurs





Section 6: Cleaning

Removal of contamination from an item to the extent necessary for further processing or for intended use



Impacts

- Device damage/malfunction
- Inadequate disinfection/sterilization
- Toxicity

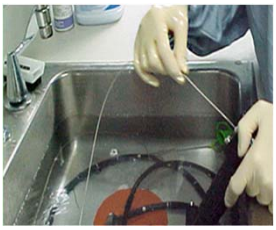
Multi-Step process

- Cleaning (can include various steps)
- Rinsing
- Drying, inspection, verification

Section 6: Cleaning, continued

Variables

- Manufacturer's IFUs
- Water quality
  - AAMI TIR34
- Cleaning chemistry
  - Types and choice
  - Variables for use
  - Concentration, temperature, time

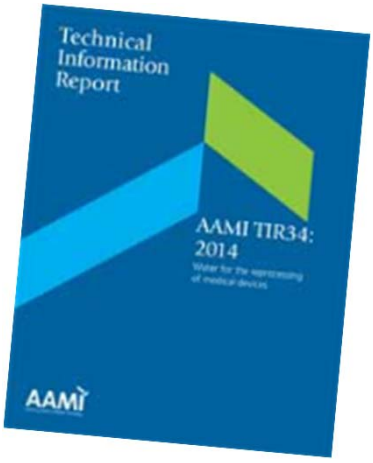


Method

- Manual and/or automated
- Types of automated systems
- Maintenance requirements
- Procedures for specific devices

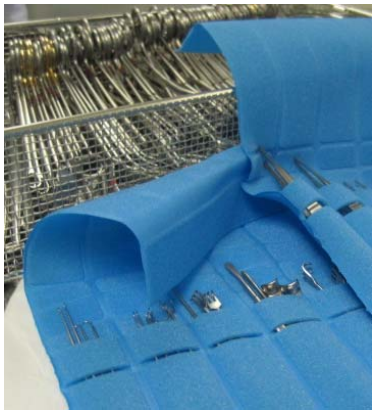
Section 6: Cleaning, continued

- Rinsing
- Inspection
- Verification
  - The process - controlled
    - Temperature
    - Time
    - Chemistry concentration
  - Cleaning indicators
- Devices/loads
  - Visual
  - Other verification methods

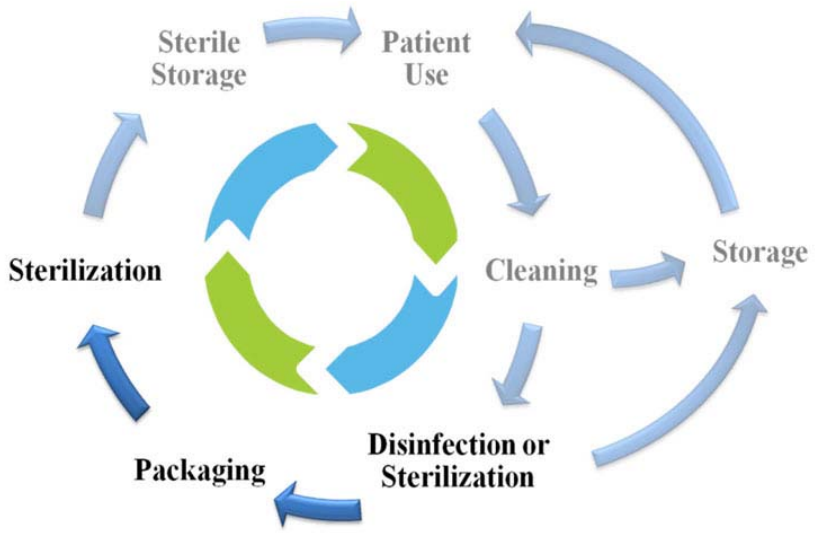


Decontamination and Preparation of Instruments

- Drying (when applicable)
- Packaging (when applicable)
- Validated and specifically labeled for use



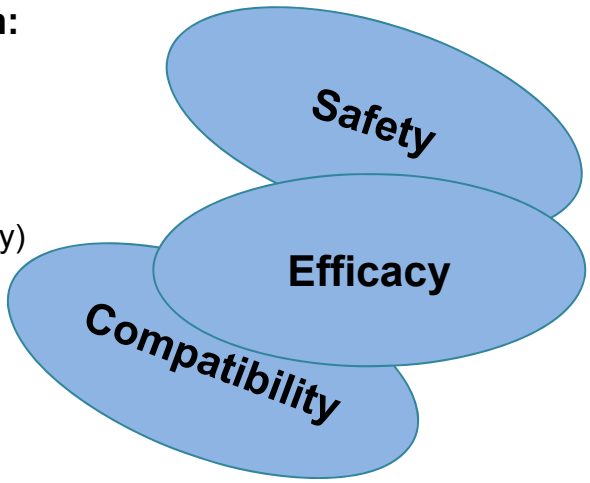
Next Step



Safe and Effective Use

Selection based on:

- Antimicrobial effects
- Device compatibility
- Health effects (toxicity)
  - Patients & Staff
- Labeled instructions



Safe and Effective Use, continued

- Facility policy and procedures
- Include quality, process control and continuous improvement
- Instructions for Use (IFU)
  - Device manufacturer
  - Chemistry manufacturer
  - Process manufacturer
- General safety
  - Specific to chemistry
  - Personnel training
  - (M)SDS library
  - PPE and ventilation
  - Storage
  - Emergency procedures
  - Exposure Response team and plan

Hierarchy of Resistance

Prions *Difficult to remove and inactivate using standard methods.*

Bacterial Spores
Clostridium difficile
Clostridium perfringens
Clostridium botulinum – food poisoning

Sterilization

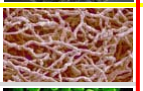
Mycobacteria
Mycobacterium tuberculosis
Mycobacterium chelonae

High Level Disinfection

Non-Enveloped Viruses
Poliovirus
Rhinovirus

Intermediate Level Disinfection

Fungi
Candida albicans – thrush
Trichophyton spp.



Low Level Disinfection

Vegetative Bacteria
Salmonella, ssp.
Staphylococcus, ssp.
E. coli, VRE, MRSA

Enveloped Viruses
Hepatitis A, B & C
Herpes Simplex
HIV, Ebola

Safe and Effective Use

Consideration for selection

- Product labeling (e.g., reuse and single use)
- Importance of formulation and instructions for use
  - Even similar sounding products are very different!
- Preparation, process controls
- Dispensing
- Water quality
  - Dilution and rinsing (AAMI TIR 34)
- Toxicity
- Microbial quality of the device can be compromised
  - e.g., during rinsing following high level disinfection

Safe and Effective Use, continued

Routine Testing and Monitoring

- Physical
  - Time, temperature, leak/diagnostic tests, etc.
- Chemical
  - Solution test strips
  - Chemical indicators
  - Chemical monitoring devices
- Biological
  - Spore test strips
  - Biological indicators
- Documentation

Device Storage and Transport

- Prevention of cross-contamination
- Facility-specific
- Liquid processes
  - Instructions for Use
  - Immediate use or drying-storage
- Gaseous processes
  - Correct storage and inspection

Quality Control

Quality control includes not only product and process monitoring but also involves continuous supervision of personnel performance and work practices and ongoing verification of adherence to established policy and procedures.

Consistent with ST79 and applies to all process types:

- Manual using chemicals
- Automated using chemicals
- Gaseous chemical sterilization

Follow manufacturers guidelines

Quality Control, continued

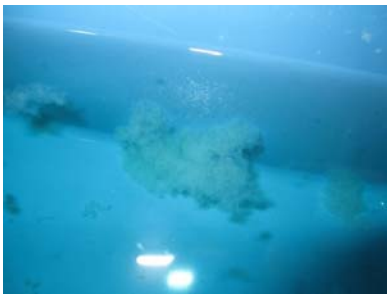
- Monitoring every device or load
  - Includes the use of physical monitors and indicators. Designed to verify an efficient process has been conducted.
- Routine testing
  - This testing should be conducted as often as recommended by the chemical, automated processor or sterilization process manufacturer. Verifies that the chemical or process is operating properly.
- Quality testing after installation or major repair
  - Manufacturer recommended testing to verify that any equipment is operating properly after a major event (such as a repair).
- Periodic product/load quality assurance testing
  - This testing is performed to verify that the expected results are achieved when following the equipment and instrument manufacturer IFUs.

Quality Control, continued

- Product identification and traceability
  - Lot control and expiration dating
  - Cycle identification, documentation and record keeping
    - Parameters met
    - Printout tape documented and maintained
  - Applies to automated and manual HLD processes
- Inadequate processing and troubleshooting
  - Follow IFU to troubleshoot problem
  - Remove from service
  - Notify appropriate personnel and service
  - Retest after issue identified and corrected

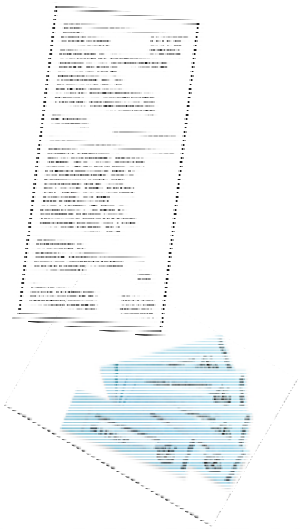
Monitoring Manual Process Using LCS/HLD

- LCS/HLD should be tested prior to each use
- Solution test strips and chemical monitoring devices are used
  - Physical monitors with thermometer and timer
  - Visual Inspection
  - Failure of monitors
- Device not dispensed or used
- Inform supervisor
- Initiate follow-up procedures



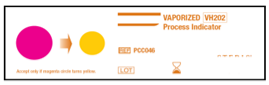
Testing and Monitoring Automated Processes using LCS/HLD

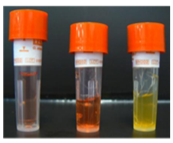
- Physical monitoring with recording capability
- Chemical Process monitoring devices
  - Solution test strips, chemical indicators, or other chemical monitoring device
  - Biological testing

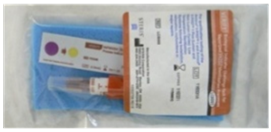


Monitoring Gaseous Sterilization Processes

- As defined by the manufacturer
- Physical monitoring
  - Temperature, concentration, pressure, etc.
- Indicators
  - Chemical indicators
  - Biological indicators
  - Process challenge devices



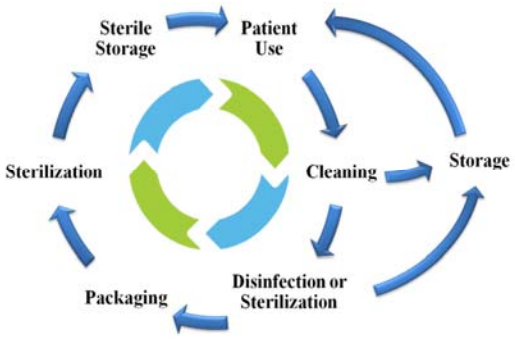




Quality Process

Quality Processes measure objective performance criteria and should be integrated with the overall quality process of the healthcare facility.

The development of a quality process should consider all steps of the full processing cycle.



Quality Process Development

Key Components

- Manufacturers written IFUs
- Guidelines, Recommended Practices and Standards
- Local and facility regulations or requirements
- Written policy and procedures
- Staff training, education and competency

Quality Process Improvement

Risk Analysis

- Identify all critical risks in process steps
- Describe what could reasonably go wrong
- Determine how often it could occur
- Determine the impact of the problem if it occurs
- Implement preventative action to avoid or reduce the risk
- Develop plan to mitigate the risks if something does go wrong
- Communicate plan to all stakeholders

Action Items

- Integrate the requirements recommended in ANSI/AAMI ST58 into facility procedures and policies
  - In parallel with other guidelines, including ST79
- Review and Correct:
  - Work place design
  - Policies and procedures
  - Selection and use of products
  - Safety and efficacy
  - Quality monitoring and testing
  - Risk analysis and quality improvement process

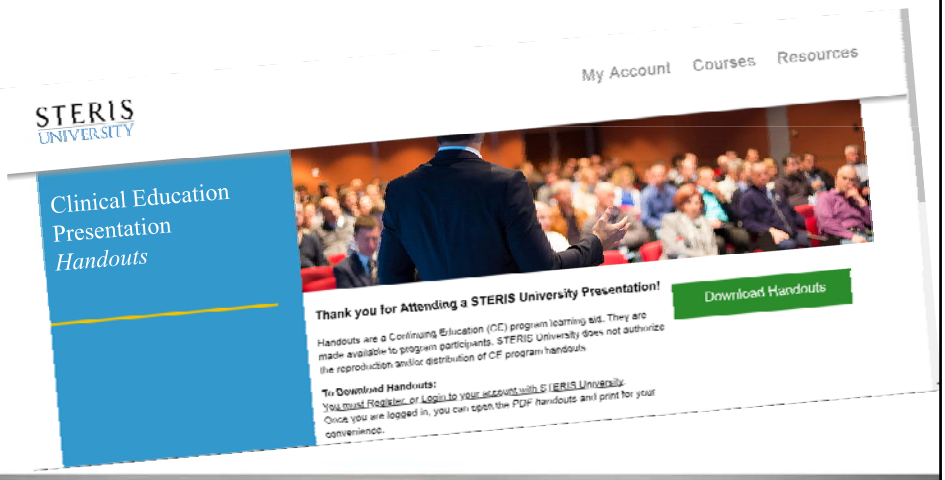
References

- Association for the Advancement of Medical Instrumentation. (2013). *ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities.* Arlington, VA: Author.
- Association of the Advancement of Medical Instrumentation. (2013). *ANSI/AAMI ST79:2017 Comprehensive guide of steam sterilization and sterility assurance in healthcare facilities*. Arlington, VA: Author.
- U. S. Food and Drug Administration (FDA). (2015). Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and food and Drug Administration Staff. Retrieved from http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

Questions

Handouts

To access the handouts for this presentation, go to: university.steris.com/158.



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Revision History

Date	Revisions	Revised By:	Notes
02/12/2018	Slide 45: ST79 reference updated	S. Beauclair	