Understanding ANSI/AAMI ST 91
Flexible and Semi-Rigid Endoscope Reprocessing in Healthcare Facilities
Continuing Education Contact Hours

- Participants must complete the entire presentation/seminar to achieve successful completion and receive contact hour credit. Partial credit will **not** be given.

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Learning Objectives

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

- Provide an overview of the applicable standards and guidelines for flexible endoscope reprocessing
- Understand ANSI/AAMI ST 91, a comprehensive guide to flexible and semi-rigid endoscope reprocessing in healthcare facilities
- Define the key points in the reprocessing of flexible and semi-rigid endoscopes
Processing

Processing (or reprocessing) is a process carried out on a reusable medical device to allow its subsequent safe use, which can include cleaning, disinfection, sterilization and related procedures.
# Spaulding Classification System

<table>
<thead>
<tr>
<th>Spaulding Classification of Devices or Items</th>
<th>Level of Disinfection</th>
<th>Interim Disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical</strong></td>
<td>Sterilant/High Level</td>
<td>Interim Disinfection can be utilized</td>
</tr>
<tr>
<td>(Penetrates the vascular system or sterile areas of the body)</td>
<td>(Sporicidal or High Level = 100% kill of all vegetative organisms)</td>
<td></td>
</tr>
<tr>
<td>Ex: Surgical Instruments</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Semi-Critical</strong></td>
<td>Sterilant/High Level</td>
<td>Interim Disinfection can be utilized</td>
</tr>
<tr>
<td>(To be used on mucous membranes or non-intact skin)</td>
<td>(Sporicidal or High Level = 100% kill of all vegetative organisms)</td>
<td></td>
</tr>
<tr>
<td>Ex: Flexible Endoscopes</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Non-Critical</strong></td>
<td>Intermediate</td>
<td>Interim Disinfection can be utilized</td>
</tr>
<tr>
<td>(Contact intact skin)</td>
<td>(TB-cidal)</td>
<td></td>
</tr>
<tr>
<td>Ex: Blood Pressure Cuff</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Typical Endoscope Reprocessing Cycle

- Storage
- Patient use
- Bedside Procedures
- Leak Test
- Cleaning
- Drying
- Packaging
- Gas Sterilization
- Drying (optional)
- Liquid chemical disinfection or sterilization
Infection and Device Risks

- Device damage
  - Mishandling, inadequate processing
- Toxic substances
  - Chemicals
- Infections
  - Endogenous - Colonized patient’s flora
    - Spread from GI tract to bloodstream/adjacent organs during procedure
  - Exogenous sources
    - Inanimate environmental surfaces
    - Medical equipment, devices
    - Medications and injection equipment
Manual cleaning n = 69; p = 0.001

Ofstead et al., Gastroenterology Nursing, 2010
Current risks are outdated and inaccurate (Ofstead et al, 2013; Dirlam-Langlay et al, 2013)

- Most outbreaks not investigated or published
- Lack of surveillance for post-endoscopic infection
- No central repository for reporting
- Reviews of reprocessing practices show widespread lapses in essential steps
- Risks are greater than just infections (e.g., toxicity with aldehydes)
Regulations, Standards and Guidelines

- **Regulations**
  - Rule or directive made or maintained by an authority
  - Mandatory

- **Standards**
  - Requirements and specifications consistency and fit for purpose
  - Voluntary but can become mandatory

- **Guidelines, Recommended Practices, Technical Information reports**
  - Technical guidance, information or preferred procedures regarding a given topic
  - Voluntary but with interpretation
Examples

- ISO
- Centers for Medicare & Medicaid Services (CMS)
- U.S. Food and Drug Administration (FDA)
- AAMI
- AORN
- APIC
- CDC
- ANSI
- SGNA
- OSHA

Examples of organizations that collaborate in health and safety.
AAMI/ANSI ST 91

Contains comprehensive information and direction for processing devices and accessories

Includes

- Flexible GI endoscopes
- Flexible bronchoscopes
- Surgical flexible endoscopes
- Semi-rigid operative endoscopes
Information in ST 91

- Definitions
- Design of endoscope reprocessing areas
- Personnel considerations
- Cleaning
- High level disinfection
- Automated endoscope reprocessors (AERs)
- Liquid chemical sterilization
- Gaseous chemical sterilization
- Processing accessories
- Storage and transportation to site of use
- Quality control
- Quality process improvement
- Informational annexes
Additional Standards References

1. ANSI/AAMI ST58:2013
   Chemical sterilization and high-level disinfection in health care facilities

2. AAMI TIR34: 2014
   Water for the reprocessing of medical devices

3. American National Standard
   Ethylene oxide sterilization in health care facilities: Safety and effectiveness

4. ANSI/AAMI ST15883-1: 2009/(R)2014
   Human factors engineering for processing medical devices

5. American National Standard
   Technical Information Report
Work Flow Design

• Physical separation from patient care
• Adequate space for all functions
• Unidirectional - dirty → clean (HLD/sterilization) → storage
• Pass-through window (recommended)
• Hand hygiene
• Emergency eyewash
Figure 3. Examples of Endoscopy Processing Room Design

Endoscopy Processing Room - One-Room Design

Endoscopy Processing Room - Two-Room Design: Decontamination Room and Clean Workroom

Note: These examples are conceptual illustrations of one- and two-room design, equipment placement, and traffic flow. They are not intended to represent complete schematic designs.
Decontamination Area

• Sink requirements
  – Two of adequate size
    • Leak testing, manual cleaning
    • Rinsing only
  – Third decontamination sink for treated water rinsing
  – Flushing capabilities
  – Third ‘clean’ sink for rinsing disinfected items
Physical Facilities

- Environmental surfaces
  - Floors, horizontal surfaces cleaned at least daily
- Lighting
- Electricity
- Clean compressed air
- Ventilation
  - Negative in decontamination
  - Positive in clean area
  - 10 exchanges/hour
- Temperature (60-73 F), monitored
- Relative humidity 20%-60%
Personnel

Education, Training, Competency Verification

• Written policies and procedures in place
  – Endoscopes, accessories
  – Guidelines and standards

• Safety requirements
  – OSHA, standard precautions, hand hygiene, PPEs

• Education and training
  – Upon hire, annually, designated intervals, new products or devices introduced
  – Certification recommended

• Competency verification
  – Each processing task
Pre-Cleaning at Point of Use

• Appropriate PPE
• Exterior surfaces wiped with non-lint sponge/cloth
• Flush channel(s) with water/cleaning solution
• Follow manufacturer IFUs
• Separate endoscope from other instruments
  • Avoid damage
• Attach fluid resistant cap
• Prepare for transport
Pre-Cleaning at Point of Use

- Bedside procedure
  - Reduce levels of microorganisms and soil
  - Prevent soil drying
  - Reduce risk of biofilm development
Transport
Closed, labeled transport containers
Biohazard label
Leak testing

- Detects damage
  - Defects harbor microorganisms
- Perform prior to immersion to prevent fluid invasion
- Allow adequate time to identify leaks
  - Scope loosely coiled
  - Manipulate knobs and buttons
- Follow manufacturer IFUs
- Multiple types of testing processes
  - Manual, mechanical
  - Mechanical AER
- Document for records
Manual Cleaning

- Fresh cleaning solution at correct temperature
- Submerge endoscope and accessories to prevent splashing
- Clean surfaces with soft, line-free cloth or sponge
- Attach irrigators to flush all channels
- Select appropriate brush size
- Clean all channels, valves, buttons, cylinders and elevators until no visible soil is seen
- Flush, brush, flush until clean
- Additional mechanical cleaning may be used
Endoscope Accessories

- Reusable accessories, valves, tubing processed per manufacturer IFUs
- Disassembled and cleaned
- Inspect for integrity
- AER manufacturer validates processing
Cleaning Chemistries

• Labeled for endoscopes
• Typically neutral detergents
  – May or may not contain enzymes
  – Follow IFUs for water temperature, dilution rates
• Essential features
  – Optimum cleaning performance
  – Material/device protection
  – Water quality
  – Toxicity validation
Manual Rinse

- Thoroughly rinse with copious amounts of potable water
- Follow AAMI TIR 34 for quality of water
- Rinse all external and internal surfaces
  - Remove residual soils
  - Remove cleaning chemicals
- Purge channels with air to remove residual water
- Dry exterior with lint-free cloth
- Keep detachable valves, buttons together with endoscope as a set
Definitions

High level disinfectant

- A product that should inactivate all microbial pathogens, except large numbers of bacterial spores, *when used according to labeling*
- A HLD is often a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass an FDA-defined spore inactivation test

High Level Disinfection

- Product that should kill all microbial pathogens but not necessarily high numbers of bacterial spores
- Disinfection and rinsing need to be controlled

Liquid chemical sterilant

- Product validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim

Sterilization

- Validated process used to render a product free from viable microorganisms, including bacterial spores.
- Liquid or gaseous process
# High Level Disinfectant/Sterilant Examples

<table>
<thead>
<tr>
<th>Chemicals</th>
<th>Sterilant</th>
<th>High Level Disinfection</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4% glutaraldehyde</td>
<td>8 hours at 20°C</td>
<td>10 mins at 20°C</td>
<td>Requires activation 3 rinses following exposure</td>
</tr>
<tr>
<td>20.1% isopropanol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2% hydrogen peroxide</td>
<td>6 hours at 20°C</td>
<td>8 mins at 20°C</td>
<td>No activation 1 rinse</td>
</tr>
<tr>
<td>0.575% OPA</td>
<td>No claim (passes sporicidal test at 32 hours at 20°C)</td>
<td>10 mins at 20°C</td>
<td>No activation 3 rinses</td>
</tr>
<tr>
<td>2.4% glutaraldehyde</td>
<td>10 hours at 25°C</td>
<td>45 mins at 25°C</td>
<td>Requires activation 3 rinses following exposure</td>
</tr>
<tr>
<td>3.4% glutaraldehyde</td>
<td>10 hours at 25°C</td>
<td>90 mins at 25°C</td>
<td>Requires activation ‘Thoroughly’ rinse following exposure</td>
</tr>
</tbody>
</table>

[www.fda.gov](http://www.fda.gov)
Key Points with Disinfection

Label claims can vary
- Safety, preparation, contact time, numbers or rinsing etc
- Request specifics from manufacturers (e.g., ‘rinse thoroughly’)

Single use or multiple use
- Use of solution test strips to verify minimum recommended concentration (MRC)

Multiple use disinfectants
- Closely follow label claims, including maximum reuse life
- NO topping off

All surfaces of the device should be in contact

Rinsing
- Correct water quality (bacteria-free; AAMI TIR34)
- Fresh water for every rinse (by immersion)
- Correct number of rinses
High Level Disinfection Steps

Preparation
(if applicable, e.g., activation)

Immersion/Flow
(ensure all parts/lumens exposed)

Remove Device, Purge all Lumens

Rinsing
(each rinse timed and repeated as necessary in fresh water)
Manual and Automated Cleaning / Reprocessing
Automated Endoscope Reprocessors

Review claims and instructions for use carefully
- FDA clearance
- Note limitations

Provide
- More efficient process
- Less user exposure to chemicals
- Ensure standardized results

Repeat cycle if interrupted

Correct use of cleaning detergents and/or disinfectants

Adequate ventilation

Rinse water control (filtered)

Routine maintenance
Liquid Chemical Sterilization

- One system cleared (in the USA) as a liquid chemical sterilant processing system for heat sensitive devices
- Liquid chemical sterilization with a peracetic acid sterilant process
  - Controlled rinsing with extensively treated water
  - Removal of bacteria, viruses, fungi, protozoa
  - Quick cycle time
- After processing, devices should be used immediately
Endoscope Drying

- Essential to prevent bacterial/fungal growth or biofilm development over time
- ‘Hanging to dry’ or ‘drip dry’ is NOT effective
- Compressed air
  - Most AERs ‘purge’ water from the endoscope lumens do not ‘dry’
  - Air pressure and quality of air through channels
  - Alcohol flush facilitates drying
  - Dry all removable parts and keep with endoscope
Sterilization Essentials

- Sterilization is dependant on adequate cleaning, rinsing and device preparation
  - Drying may also be essential
  - Packaging considerations (if applicable)
- Modality claims are product specific, controlled processes
  - Steam (AAMI ST 79)
  - Ethylene oxide (AAMI ST 41)
  - Vaporized Hydrogen peroxide (AAMI ST 58)
  - Ozone (AAMI ST 58)
- Correct equipment installation, maintenance
Terminal Sterilization

• Processes for flexible and semi-rigid endoscopes
• Recommended for devices entering sterile body cavities
• Required for all endoscope accessories that penetrate mucosa
  • Biopsy forceps, sphincterotomes, etc.
• Claims are product specific
  • Controlled processes
• Monitoring required for all systems
Ethylene Oxide

- Devices are clean and dry
  - ETO is sensitive to the presence of residual soil
- Low pressure (vacuum) systems
  - Venting cap required
- Sterilization parameters validated by endoscope manufacturer
  - Conditioning, sterilization and aeration
- Post-sterilization aeration is essential
  - Processing time typically >18 hours
- May have a limited number of cycles before requiring extensive repair
Hydrogen Peroxide Gas

- Processes with and without ‘plasma’
  - Vacuum processes require device venting
  - Packaging requirements

- Claims (lumen length and diameter restrictions) product specific
  - Generally critical flexible endoscopes
  - Some systems include claims for single/multiple lumen devices, with or without an additional load and bronchoscopes

- No GI endoscope claims

- Typical sterilization time ~30 mins

- Devices clean and dry before sterilization
Protective Microbial Barriers

• Sheaths are designed as an accessory for certain types of endoscopes and vary in design

• Two categories
  • Intended to reduce the level of soiling
  • Intended to prevent endoscope soiling

• Follow instructions for use carefully
  • Requirement for periodic reprocessing
  • Application and removal
  • Inspection (e.g., if compromised)
Storage

General considerations

• Dry prior to storage
• Prevent coiling or kinking (hanging preferred)
• Well ventilated, clean area
• No risk of contamination
• Angulation locks in free position
• All removable parts detached, kept with endoscope
• Label or tag affixed to identify endoscope has been processed
• Tracking and traceability
Storage

- Liquid chemical sterilization process
  - Drying with cleaned pressurized air
  - Reduce risks of contamination
  - Follow manufacturer IFUs
- Gaseous sterilization
  - sterilized endoscopes stored in container in which they were sterilized
  - Sterile storage conditions (AAMI ST 58)
- ‘Hang’ time
  - Perform risk assessment (facility specific)
  - Develop policy and procedure
Risk Assessment for Hang Time

• Perform assessment to determine length of storage time
• Consider:
  • Complexity of device
  • Condition after processing
  • Transportation methods
  • Conditions of storage environment
  • Handling during storage
  • Manufacturer IFUs
  • Professional organization guidelines
  • Current research studies
• Develop policy and procedure
Storage, Terminal Sterilization

- Storage conditions are monitored according to ANSI/AAMI ST79
- Endoscopes are rotated according to policy
- Endoscopes are identified and labeled
Quality Control Plan

- Policies follow standards and guidelines, manufacturer IFUs
  - May conflict or be periodically updated
- Reprocessing policy
  - Facility
    - Reprocessing area design
    - Essential requirements
  - Department
    - Detailed work instructions
    - Safety and essential steps
    - Recalls
- Staff training and demonstrated competency
  - Periodic auditing of practices
- Documentation
Quality Control Plan

• Verification points*
  • Physical: exposure times, temperature, volumes, shelf-life, number of uses, etc
  • Chemical: test strips and chemical indicators
  • Biological (when appropriate): spore test strips and biological indicators

• Standards recommend
  • Monitoring every device/load
  • Routine (equipment) testing
  • Following installation or major repair
  • Periodic (load) testing

*Specific for each product/process
Quality Control Plan, continued

• **Cleaning**
  - Preparation (dilution, temperature) and use (contact time)
  - Visual and another method (e.g., protein, ATP detection)

• **Disinfection**
  - Preparation and use (contact time, reuse criteria)
  - Solution test strips (indicators)

• **Sterilization**
  - Pressure, temperature, time
  - Chemical, biological and spore test indicators

• **Documentation**
Quality Control Program

Cleaning Verification

• Retained soil causes patient infections!
• Manufacturers required to validate cleaning instructions
• Visual inspection combined with other verification methods
• Biochemical testing
• Cleaning efficacy of mechanical equipment
• Monitoring cleaning parameters (e.g., temperature)
• Repeat cleaning if soil present
Cleaning Verification

**ATP**
- an energy molecule found in all living things
- Test Enzyme Solution + ATP = Light
- Luminometer measure Relative Light Unit output
  - Higher RLU= Higher ATP

**Hemoglobin**
- Tests for blood residues
- Too specific and can be too sensitive

**Carbohydrate**
- Tests for sugar and starches
- Currently in combination with protein and hemoglobin testing in one test

**Protein**
- Tests for protein residues

**TYPES OF TESTS**
Quality Control Plan

Microbiological Surveillance Testing

• Limited information for guidance of surveillance cultures
• Surveillance cultures to assess adequacy of reprocessing
• Culture results delayed 2-3 days
• Quarantine endoscopes/accessories/AER?
• Is there a cutoff to define proper disinfection?
• What endoscopes are cultured/sampling?
• Areas cultured?
• Protocol for culturing correctly
• Real time testing
Risk Analysis and Mitigation

- Stage 1: Risk identification
- Stage 2: Risk assessment
- Stage 3: Risk mitigation
- Stage 4: Maintenance (quality control) and Quality Process Improvement
Risk Identification: Examples
Action Items

• Obtain copies of applicable standards and guidelines for flexible endoscope reprocessing

• Understand ANSI/AAMI ST91, a comprehensive guide to flexible and semi-rigid endoscope reprocessing in healthcare facilities

• Develop appropriate policy and procedures the equipment used.
Questions
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To help you achieve your career vision for tomorrow
Useful References

- AAMI/ANSI ST 58. Chemical sterilization and high-level disinfection. 3rd edition (2013)
- AAMI/ANSI ST91. Flexible and semi-rigid endoscope processing in health care facilities (2015)
- AAMI TIR34 Water for the reprocessing of medical devices (2014)
- ASGE/SHEA/SGNA/APIC: Multi-society guideline on reprocessing flexible gastrointestinal endoscopes (2011)