Advanced Sterilization Products™

ANSI/AAMI ST58: 2024

Updates for Enhanced Safety and Compliance with Chemical Sterilization and High Level Disinfection

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LET’S DISCUSS

Objectives

01 Identify changes made to ANSI/AAMI ST58: 2024 from the 2018 revision.

02 Discuss considerations in selection of liquid chemical sterilization, high level disinfection, and gasesous chemical sterilization systems.

03 Discuss recommendations for effective use of vaporized hydrogen peroxide sterilizers.

American National Standard

ANSI/AAMI ST58:2024

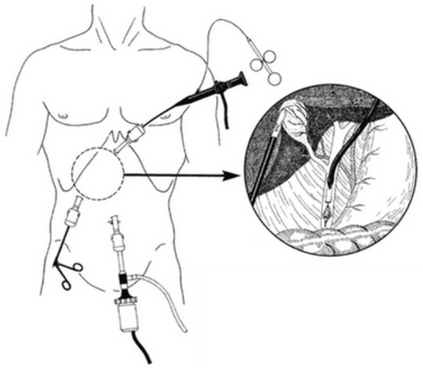
Chemical sterilization and high-level disinfection in health care facilities

AAMI
Advancing Safety in Health Technology

Changes from ANSI/AAMI ST58: 2013/(R)2018

- Document sections reorganized
- Annexes were added and rearranged
- Added EO to the document
- Updates and language to align with AAMI ST108, ST91 and ST79

Spaulding Classification



CRITICAL

Instrumentation
enters sterile tissue or body cavities

Example: Choledochoscope

SEMI-CRITICAL

Instrumentation
comes into contact with mucous membranes

Example: Endoscopes

AAMI ST58 only includes critical and semi-critical devices.

9.2.2 Risk Analysis: The Spaulding classification of a device will determine the level of disinfection required

(Rutala & Weber, 2013)

SCOPE: Major Additions in 2024

Ethylene Oxide (EO) Sterilization

- EO sterilization moved from ST41
- Updated EO guidance in ST58
- No language for separate aeration chamber, only single chamber sterilizer/aerator
- Updated ventilation and new EPA regulations

Chemical Sterilant

- Added a 3rd category
    1. Liquid chemical sterilants /high level disinfectants
    2. Gaseous chemical sterilants
    3. Foam or gel-there is only 1 foam HLD product on the market, refer to IFUs

Section 2 Definitions

ST58: 2024 37 Definitions Added

- Calibration
- Challenge test pack
- Cleaning
- Contaminated
- Critical Water
- Culture
- Culture medium
- Cycle time
- Cycle, sterilization
- Decontamination room
- Dedicated exhaust line
- Diffusion restrictor
- Disinfectant
- Door capture zone
- Enhanced visualization
- Excursion limit
- Exhaust duct
- Expiration date
- Expiration statement
- Gram's method of staining

Section 2 Definitions

ST58: 2024 37 Definitions Added

- Gram –negative bacteria
- Gross soil
- Huck Towel
- Lot/load control number
- Muslin
- Operational qualification
- Performance qualification
- Qualification
- Quality assurance test
- Sterile processing department/area
- Sterilizer

Gram –positive bacteria

Health care – associated infections (HAIs)

Instrument air

Mechanical cleaning

NFPA – National Fire protection Agency

Point of use treatment

Pyrogen

Qualification test

Restricted area

Sterile storage area

Section 3 Work Area Design Considerations

3.1 General Considerations

3.2 Processing Area

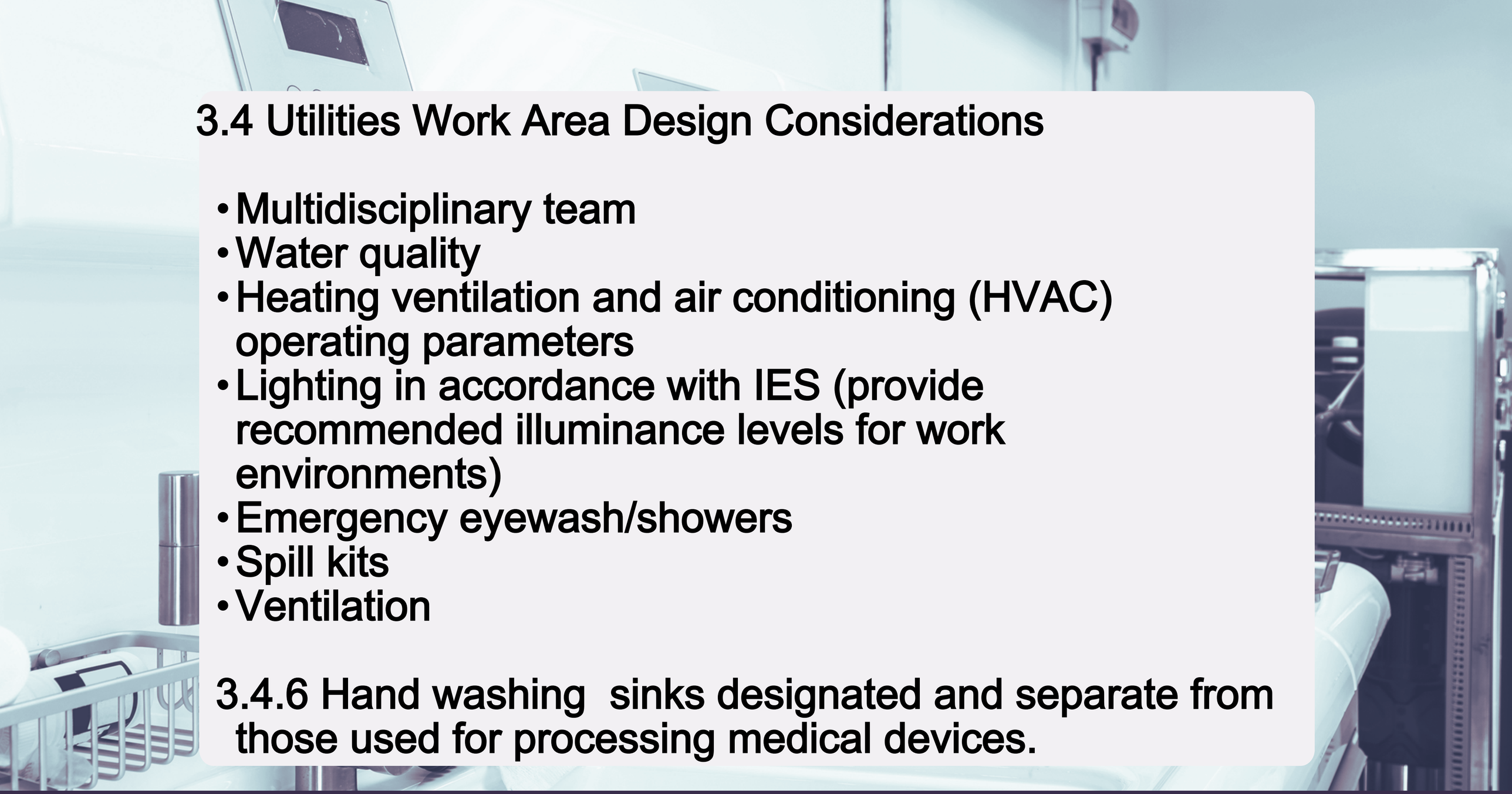
- Adequate space for cleaning
- Separate space for processing
- One-way directional workflow
- Solid wall barriers
- Floors, walls and ceiling surfaces

3.2.1 Environmental Cleaning

- Routine scheduled cleaning

3.3 Traffic Control

- Segregated space with controlled access
- Traffic enforcement



3.4 Utilities Work Area Design Considerations

- Multidisciplinary team
- Water quality
- Heating ventilation and air conditioning (HVAC) operating parameters
- Lighting in accordance with IES (provide recommended illuminance levels for work environments)
- Emergency eyewash/showers
- Spill kits
- Ventilation

3.4.6 Hand washing sinks designated and separate from those used for processing medical devices.

Automated Processing Equipment for Liquid Chemical Sterilant/High -Level Disinfectants

3.5 Selection of Equipment

- Considerations for equipment installation
- Load capacity
- Changing and disposal of chemicals
- Plumbing
- Proper ventilation
- Appropriate storage of supplies and chemicals

Automated Processing Equipment for Liquid Chemical Sterilant/High -Level Disinfectants

3.5 Selection of Equipment

- Safety Features
- Water quality requirements
- Digital recording documentation
- Equipment location

Work Area Design Considerations

3.6 Gaseous Chemical Sterilizer Equipment

- Regulatory requirements
- Ventilation requirements
- Accessibility for use and servicing
- Device validations
- Load capcity

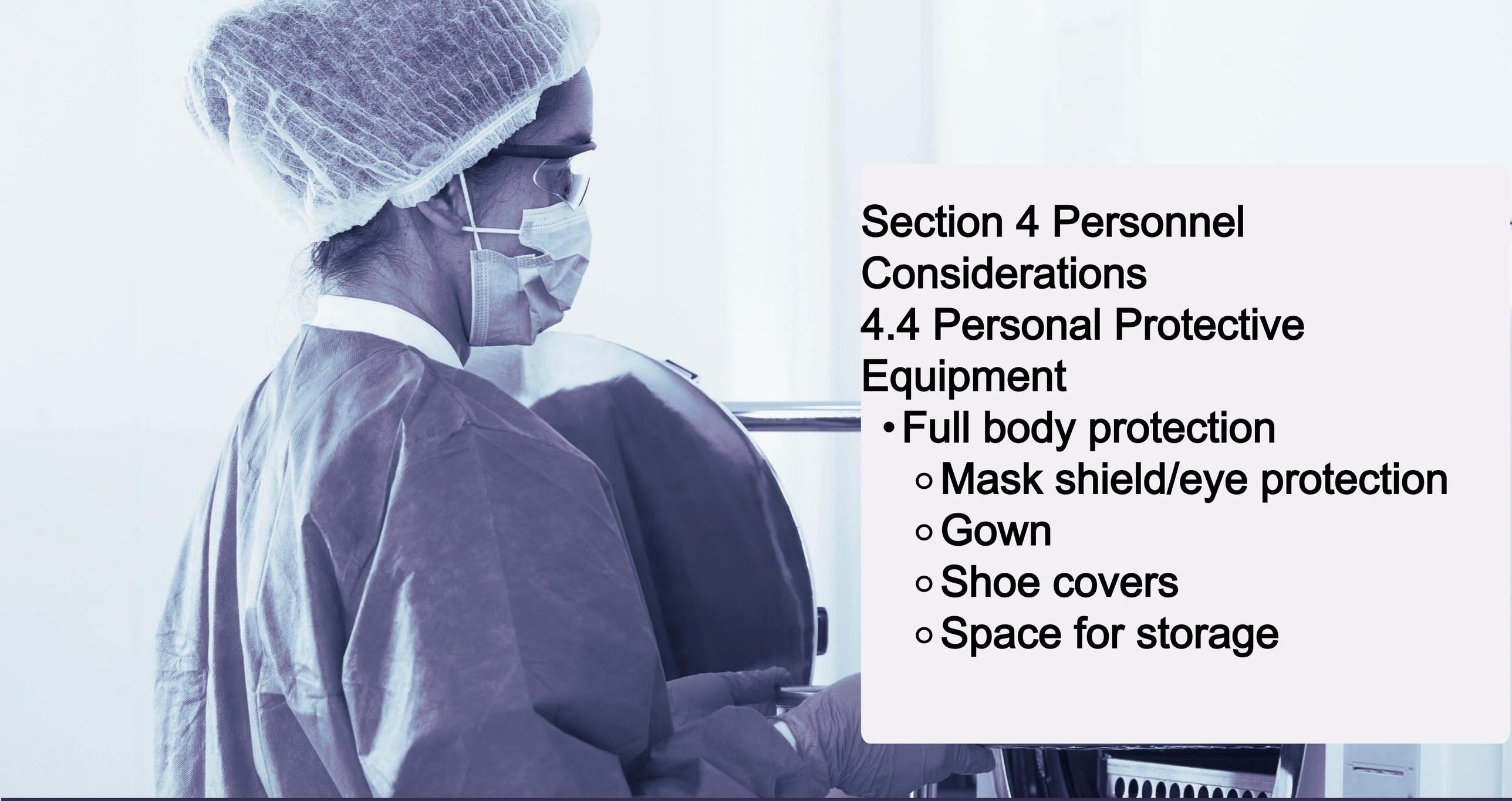
Section 4 Personnel Considerations

4.2 Qualifications

- Certifications
- Competency
  - Orientation

4.3 Training & Continuing Education

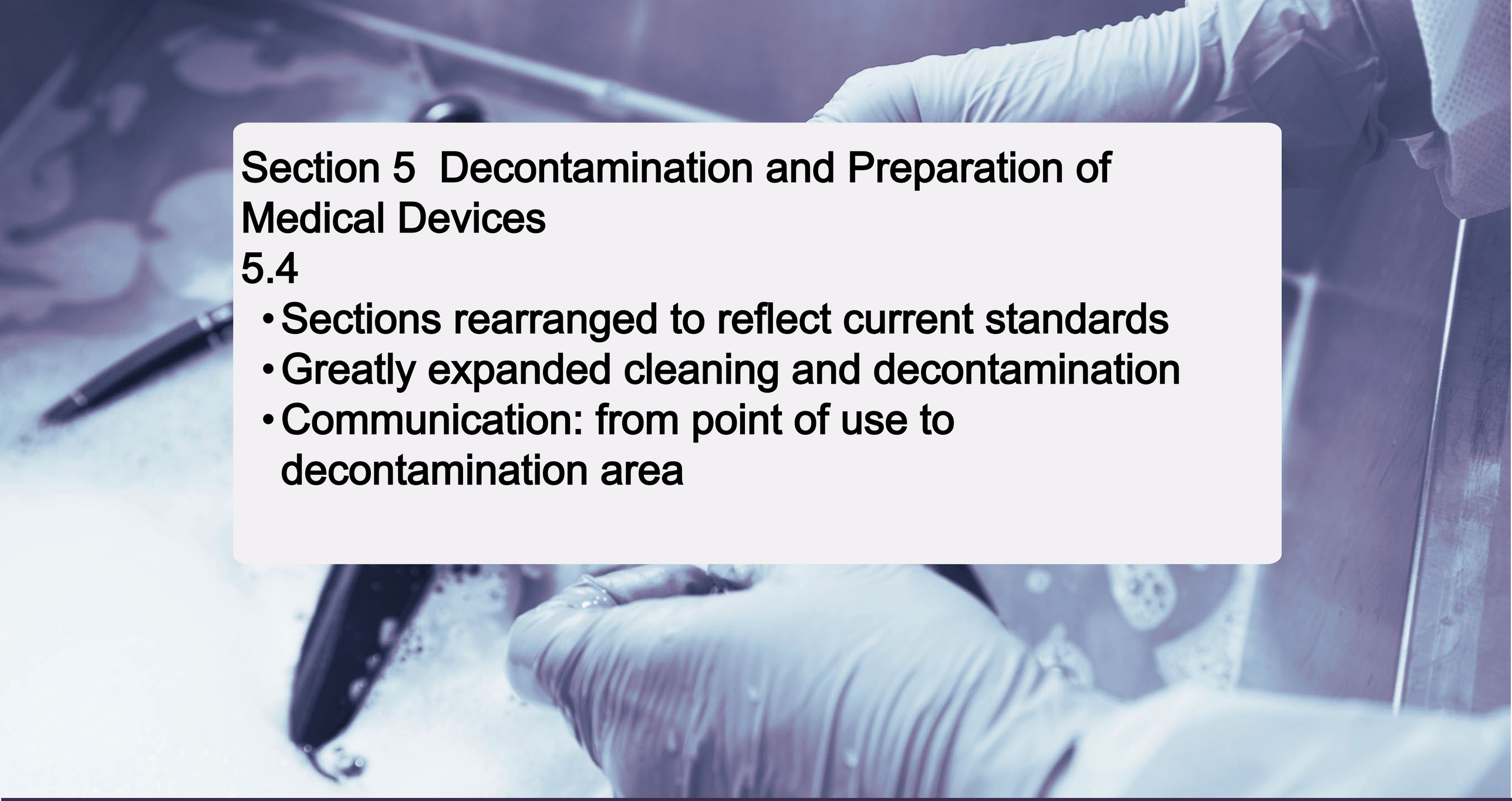
- Continuing education
- Verified annual competence



Section 4 Personnel Considerations

4.4 Personal Protective Equipment

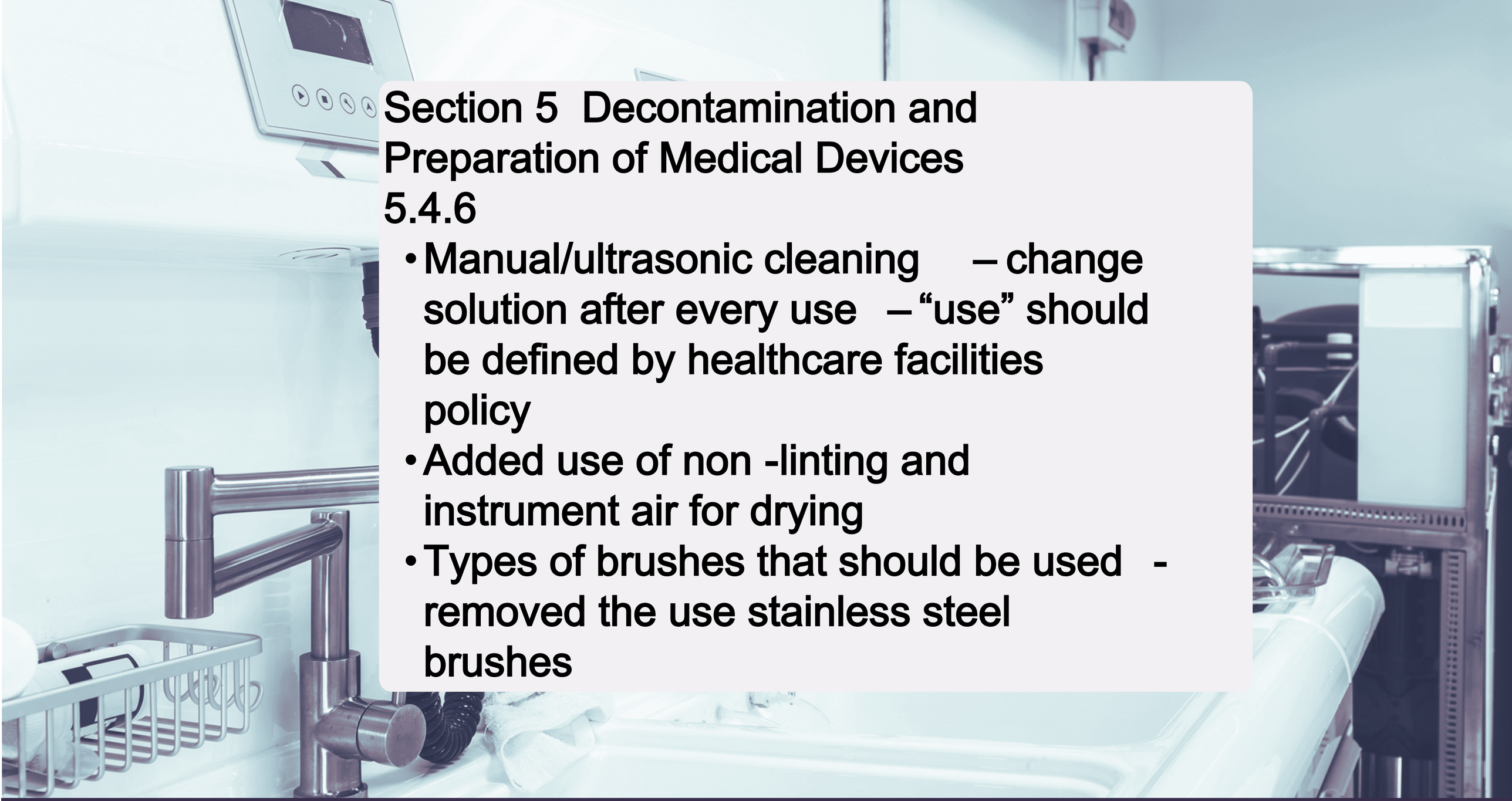
- Full body protection
  - Mask shield/eye protection
  - Gown
  - Shoe covers
  - Space for storage



Section 5 Decontamination and Preparation of Medical Devices

5.4

- Sections rearranged to reflect current standards
- Greatly expanded cleaning and decontamination
- Communication: from point of use to decontamination area



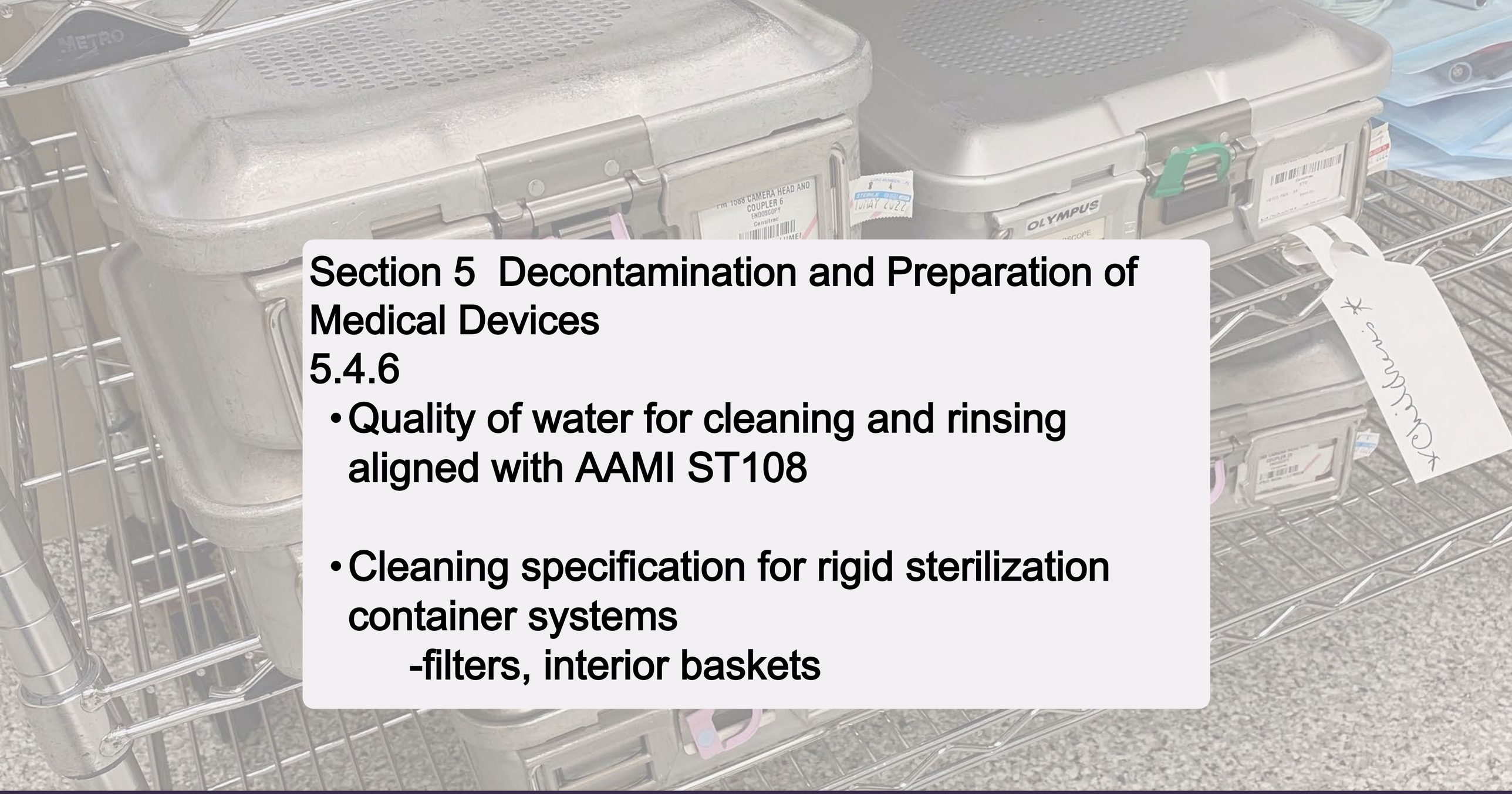
Section 5 Decontamination and Preparation of Medical Devices 5.4.6

- Manual/ultrasonic cleaning – change solution after every use – “use” should be defined by healthcare facilities policy
- Added use of non -linting and instrument air for drying
- Types of brushes that should be used - removed the use stainless steel brushes

Section 5.4.5.2.2 Rigid Sterilization Container Systems

- Container shall be compatible with the proposed sterilization system
  - Low Temperature Vaporized Hydrogen Peroxide, EO, etc.

- Only use cleaning agents intended for cleaning rigid sterilization containers
- Not contraindicated in the device manufacturer's validated IFU should be used



Section 5 Decontamination and Preparation of Medical Devices

5.4.6

- Quality of water for cleaning and rinsing aligned with AAMI ST108

- Cleaning specification for rigid sterilization container systems
  -filters, interior baskets

5.4.5.2.2.1

- Some cleaning agents can cause corrosion or deterioration of container surfaces, such as discoloration or stress cracking

- Detergents that do not have a neutral pH might corrode more sensitive metals, and specific additives can adversely affect some plastics and gasket materials.

5.4.5.2.2.1

- Thorough rinsing is essential for removal of detergent and other residues.
- Damaged components of container systems could interfere with the sterilization process.

5.4.6.3.2 Manual Cleaning

- Follow the detergent manufacturer's written IFU
  - Water hardness and pH
  - Temperature
  - Type(s) of soil the detergent is suitable for removing
- Thoroughly perform final rinse using critical water
- Dry devices using a non -linting cloth or instrument air

5.4.6.3.2 Manual Cleaning

- Thorough rinsing removes residual cleaning agent
- Residual cleaning agent might affect the efficacy of the LCS/HLD or the gaseous chemical sterilant
- Proper drying of devices prior to gaseous sterilization prevents cycle abortion and potential exposure to sterilant post -cycle

Section 5 Decontamination and Preparation of Medical Devices

5.4.7

- Borescope examination added
- Periodic cleaning verification of manually cleaned items
- Daily testing of mechanical equipment

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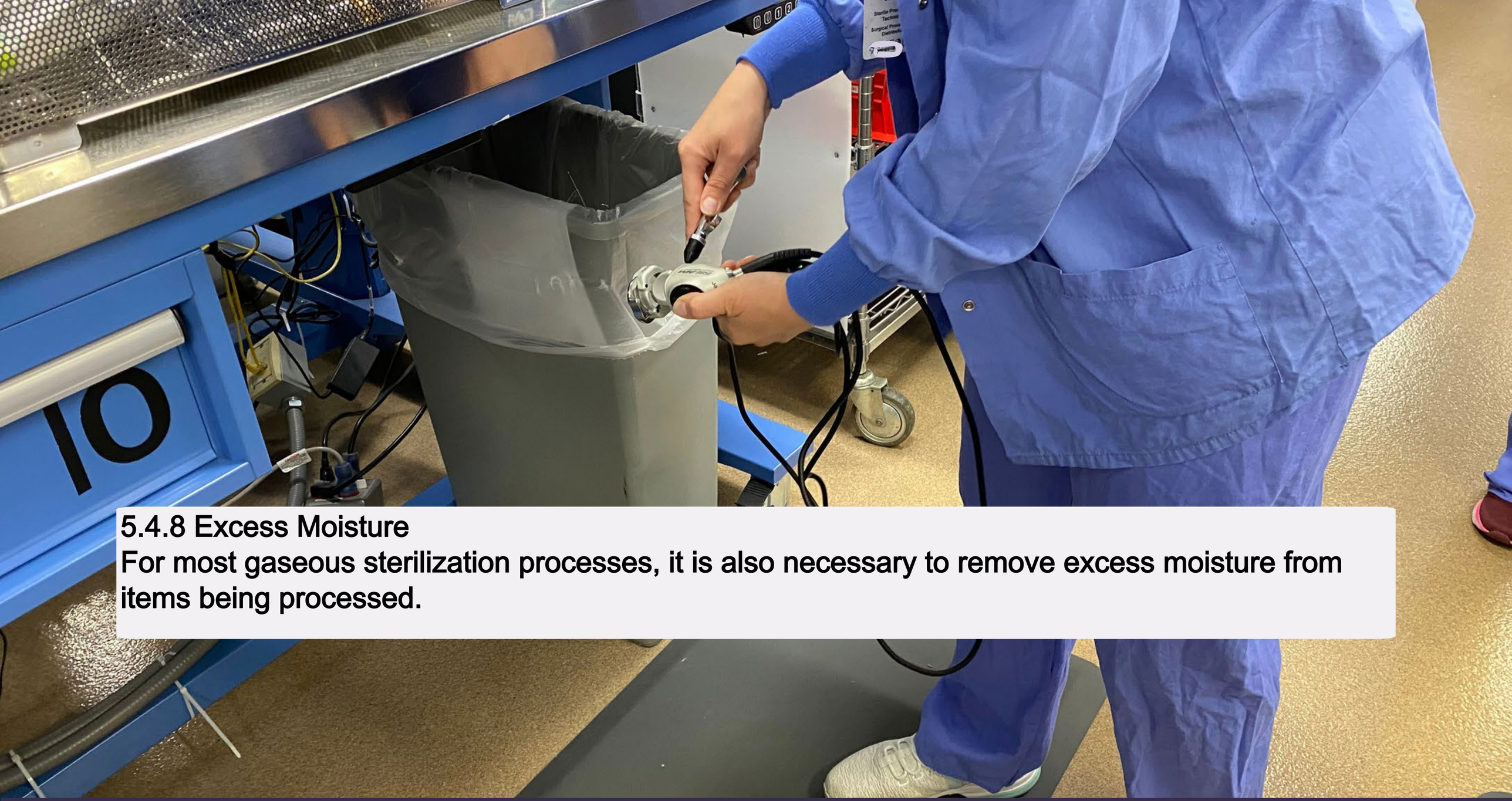


5.4.8 Excess Moisture

For most gaseous sterilization processes, it is also necessary to remove excess moisture from items being processed.

5.4.8 Excess Moisture Gaseous Chemical Sterilants

- Excess moisture can cause cycle cancellation.
- Evaporation of excessive moisture during the air removal stage may cause localized cold spots in the load which may result in condensation of the gaseous sterilant resulting in cancelled cycles and failed monitoring products.
- Residual water droplets have the potential to cause residual chemicals to be present in a liquid form at the conclusion of the sterilization cycle, which may cause exposure to the chemical.

5.4.8 Excess Moisture

- LCSs/HLDs can be diluted by water remaining on surfaces and lumens of items
- Concentration of HLD active ingredient can be reduced to a level too low to be effective.

- If there is significant dilution of LCS/HLD determined by MEC monitoring, the solution should be discarded even if it has not reached the manufacturer’s reuse time

Section 6
Safe and Effective Use of Liquid Chemical Sterilant/High -level Disinfectants and Equipment

Use of syringes or hand held compressed air gun for drying channels is not recommended

6.5.1

- Water references updated to meet AAMI ST108
  - Potable water=utility water
  - Fresh water for each rinse
  - Critical water for final rinse

6.5.2

- Storage of chemicals
  - Container labeled: Description of contents and Expiration Date
  - Solution should be tested each time used

OPA 10-05-25

Manual vs. Automated HLD/LCS Practices

- Manual not recommended
  - Variability and inconsistency

- Automated
  - Programmed cycles:
    - Solution dosage, exposure time and rinses
  - Consistency and efficiency

Section 7
Safe and Effective Use of Gaseous Chemical Sterilizers

7.1 General Considerations

- Personnel
- OSHA
- Emergency Procedures

7.2 Gaseous Chemical Sterilization Types

- Low temp vaporized hydrogen peroxide
- Ethylene oxide (New)
- Chemical vapor sterilant using alcohol and formadehyde
- Hydrogen peroxide -ozone
- (ANNEX B Table B1 has complete list)

Sterilization is Preferred over HLD

- Some pathogens are resistant to high -level disinfection.
- Medical devices and instructions for use are more complex
- The introduction of new low temperature modalities are same amount of time as HLD or less

(Foreword)

Safe and Effective Use of Gaseous Chemical Sterilizers

7.3 Manufacturer’s IFU

- Cleaning and maintenance
- Loading and unloading
- Load temperature
- Spill containment and clean up
- Methods to monitor efficiency of process

7.4 Sterilizer Maintenance

- Calibration
- Filter changes
- Emission control systems
- Record keeping

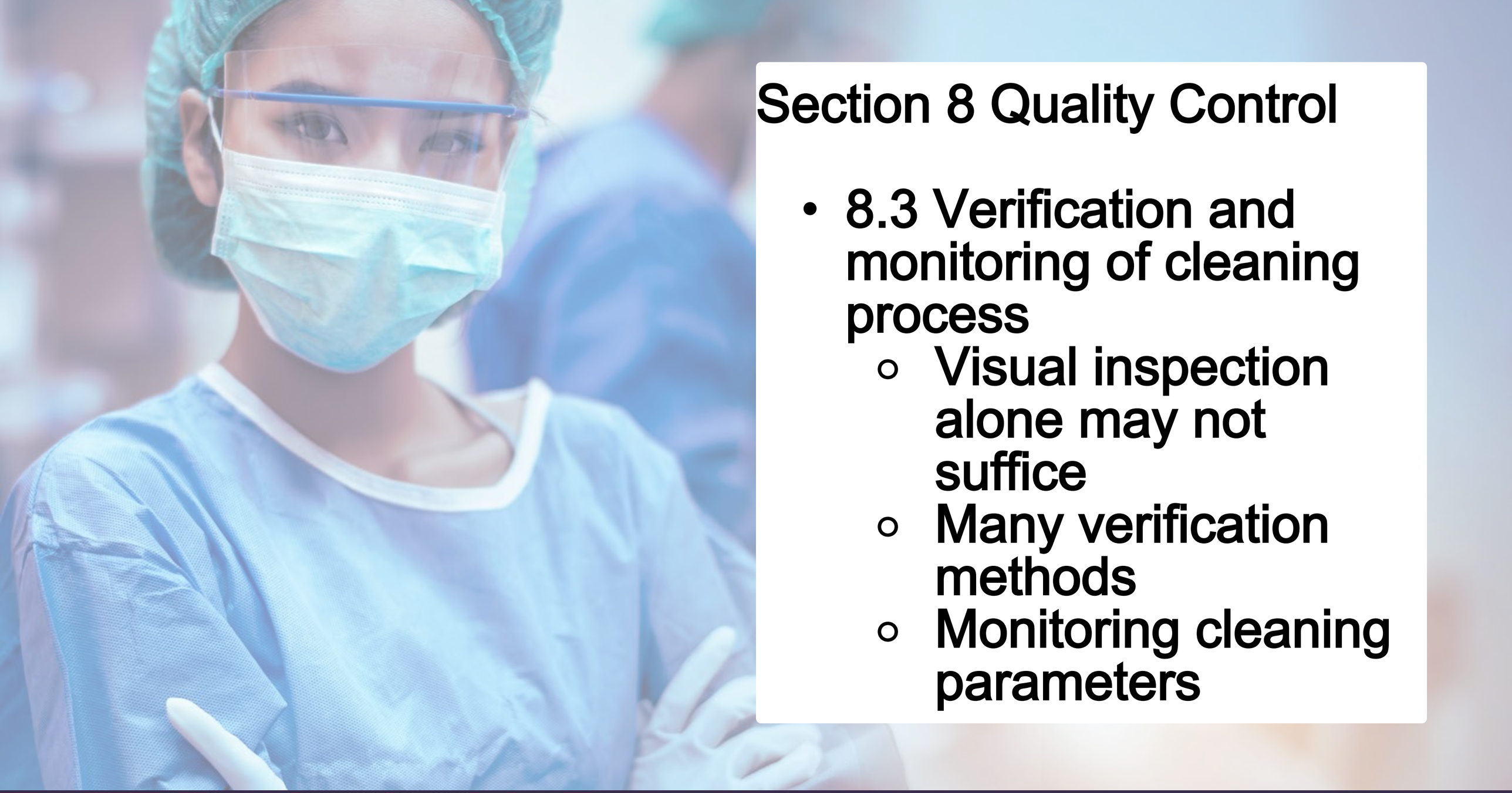
Packaging, Preparation, & Sterilization

7.5.1 Selection of Sterile Barrier Systems

- Must be FDA cleared for sterilization method selected.
- The selected cycles must be listed on indication for use of the barrier system.

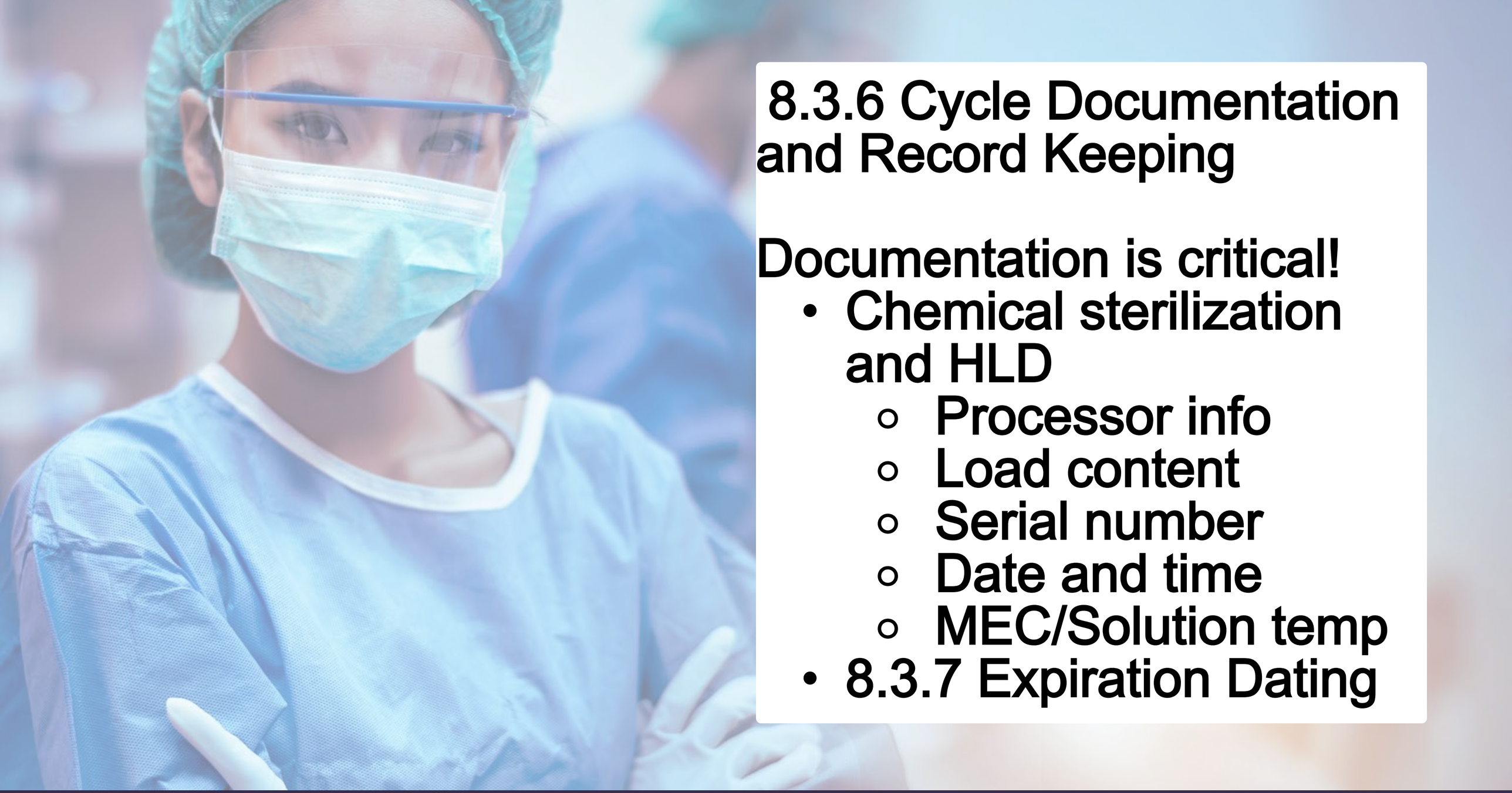
7.5.3
Post-process handling of wrapped sets

- Avoid dragging, sliding, or crushing processed items to avoid puncturing wraps, and to prolong package integrity.



Section 8 Quality Control

- 8.3 Verification and monitoring of cleaning process
  - Visual inspection alone may not suffice
  - Many verification methods
  - Monitoring cleaning parameters



8.3.6 Cycle Documentation and Record Keeping

Documentation is critical!

- Chemical sterilization and HLD
  - Processor info
  - Load content
  - Serial number
  - Date and time
  - MEC/Solution temp
- 8.3.7 Expiration Dating

Updated Safety Recommendations for Chemical sterilization and HLD

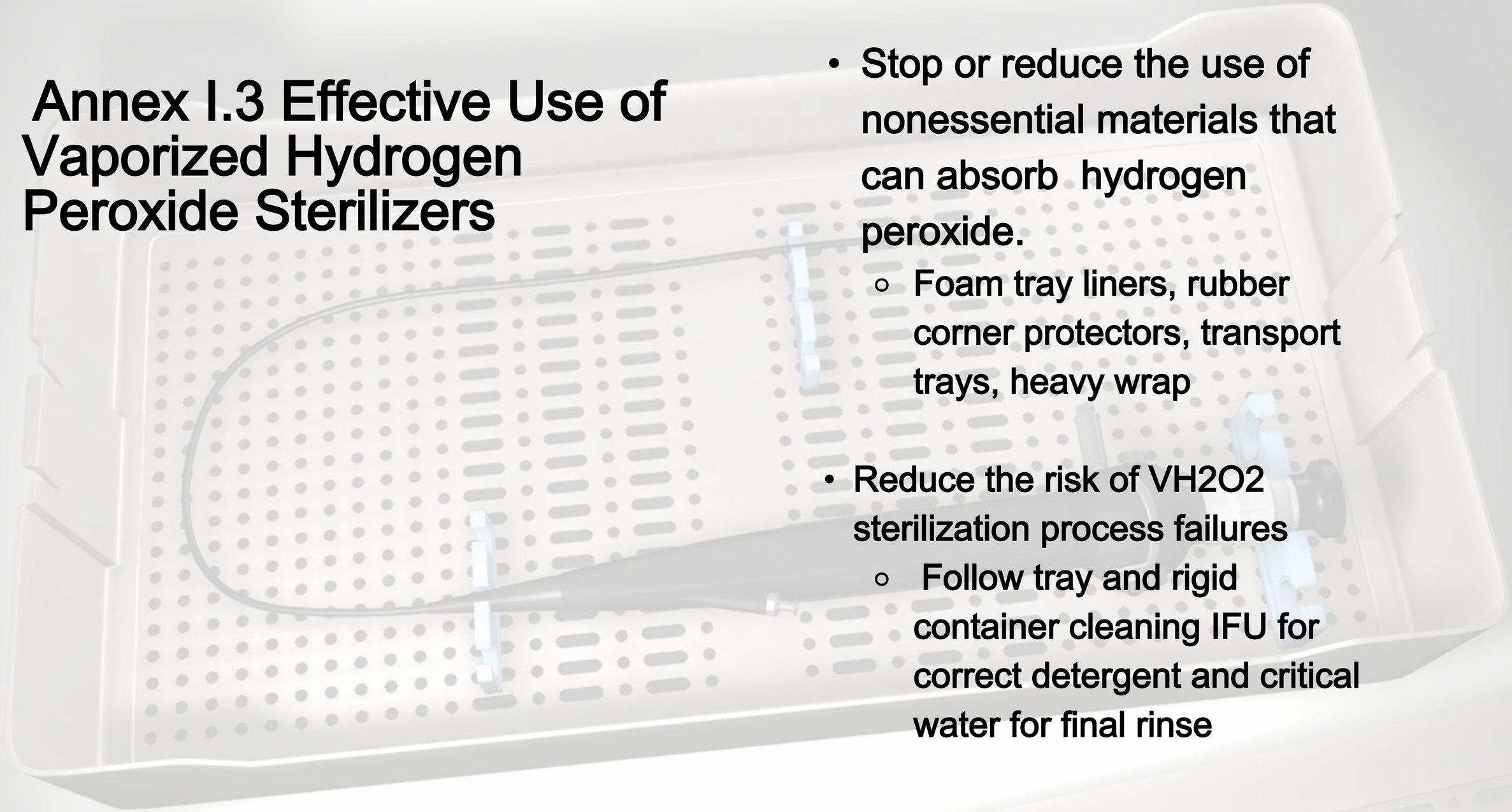
- EO Sterilization: Annex S
- Vaporized Hydrogen Peroxide: Annex I
- Workplace safety controls

Annex I
I.3 Effective Use of Vaporized Hydrogen Peroxide Sterilizers

- The medical device and/or sterilizer manufacturer IFU should be consulted to determine compatibility of device

- Load weights and correct loading of chamber - No stacking

Annex I.3 Effective Use of Vaporized Hydrogen Peroxide Sterilizers



- Stop or reduce the use of nonessential materials that can absorb hydrogen peroxide.
  - Foam tray liners, rubber corner protectors, transport trays, heavy wrap
- Reduce the risk of VH2O2 sterilization process failures
  - Follow tray and rigid container cleaning IFU for correct detergent and critical water for final rinse

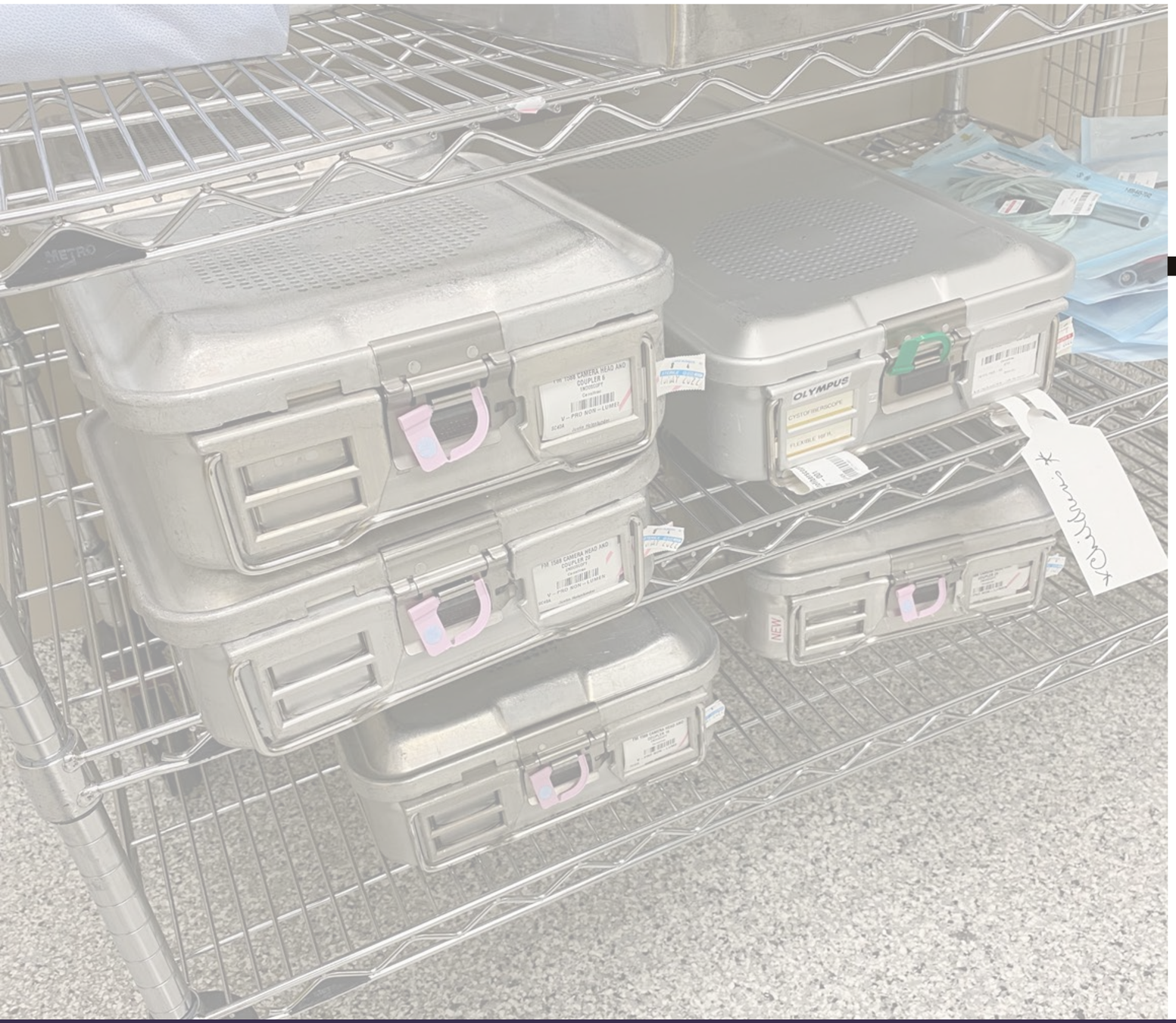
I.7 Vapor Monitoring - Vaporized Hydrogen Peroxide

Vapor monitoring is recommended if there is potential for the hydrogen peroxide vapor concentration to exceed OSHA recommended permissible exposure limits (PEL)

Annex P
Gas and Vapor Monitoring

Summary of technologies used for detection of gas and v apors of HLD and sterilization chemicals.

- monitoring methods
- frequency
- procedure
- record keeping
- selection of equipment



8.6.1 General Considerations

- Sterilization process monitoring devices include
  - -Physical monitors
  - -Chemical indicators
  - -Biological indicators

- Each of these devices plays a distinct and specific role in sterilization process monitoring, and each is indispensable to sterility assurance.

Annex I
I.3 Effective Use of Vaporized Hydrogen Peroxide Sterilizers

Use of multivariable chemical indicators

- Monitors 2 or more parameters
- Can provide additional quality assurance
  - complex devices
  - surgical trays
  - rigid containers

9.3 Quality Process Improvement

Examples of a CQI program areas include:

- Training, continuing education, and competency assessments
- Product identification and traceability (i.e., lot control numbers and load records)
- Monitoring manual processes that use LCSs/HLDs
- Monitoring automated processes that use LCSs/HLDs
- Monitoring gaseous chemical sterilization processes
- Product testing
- Product recalls

9.4 Implementation of Product & Process Improvements

- Should be customized to your facility.
- All members of the team should be included.
- Collection of data is vital to the success of the program.
- Can consist of all variables such as:
  - items processed
  - physical parameters failures,
  - chemical failures
  - PM failures
  - Locating products for recalls
  - Completeness of test records

Reference Articles

Sterilization

- Rutala, W. A, et al. (2020). Comparative evaluation of the microbicidal activity of low-temperature sterilization technologies to steam sterilization. *Infection Control & Hospital Epidemiology*, 41*(4)*, 391-395. DOI: 10.1017/ice.2020.2

- Ofstead, C., et al. (2025). Endoscope processing effectiveness: A reality check and call to action for infection preventionists and clinicians. *American Journal of Infection Contro*l. 53*(7).* 785-793. https://doi.org/10.1016/j.ajic.2025.04.003

- Ofstead, C., et al. (2020). Challenges in achieving effective high-level disinfection in endoscope reprocessing. *American Journal If Infection Control.* 48*(3).* 309-315. *DOI: 10.1016/j.ajic.2019.09.013*

Importance of Drying Endoscope

- Ofstead, C., et al. (2024). Fluid retention in endoscopes: A real-world study on drying effectiveness. *American Journal of Infection Control.* 6(*52*).635-643. https://doi.org/10.1016/j.ajic.2024.02.015

Reference Articles

Vapor Monitoring

- Cornelia, R. & Warburton, R. P. (2017). Assessing hydrogen peroxide vapor exposure from hospital sterilizers. *Journal of Occupational and Environmental Hygiene.* 14*(9).* 150-157. DOI: 10.1080/15459624.2017.1335401

Boroscope Inspection

- Ofstead, C., et al. (2025). Unseen threats: Lumens 2.0 study reveals the hidden challenges of cleaning lumened surgical instruments. *American Journal of Infection Control.* 53*(5).* 537-547. DOI: 10.1016/j.ajic.2025.02.003

Questions?

Thank You

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