

# Surveying a Sterile Processing Department - ASC

# Disclosures

1. **Successful completion:** Participants must complete the entire program and submit required documentation. No partial credit will be given.
2. **Conflict of interest:** Employee of STERIS.
3. **Commercial company support:** Fees are underwritten by education funding provided by STERIS.
4. **Non-commercial company support:** None.
5. **Alternative/Complementary therapy:** None.

# Continuing Education

- STERIS Corporation is an approved provider of continuing nursing education by **CBRN** – provider # CEP 11681 and an approved Administrator Education Unit (AEU) and Infection Prevention Control (IPCH) provider by **BASC** – provider # 1417.
- This program is approved for:
  - 0 hour(s) of GI Specific content credit by **ABCGN** (American Board of Certification for Gastroenterology Nurses),
  - 1.5 AEU(s) & 1.5 IPCH(s) by **BASC** (Board of Ambulatory Surgery Certification), and
  - 1.5 contact hour(s) of continuing education credit
    - **CBRN** (California Board of Registered Nursing);
    - **CBSPD** (Certified Board for Sterile Processing and Distribution); and
    - **HSPA** (Healthcare Sterile Processing Association).



Through a partnership with CCI®, it also meets CNOR® and CSSM® recertification requirements for perioperative nurses.



# Learning Objectives

- Review infection prevention challenges specific to ASCs
- Identify areas for improvement that focus on decreasing healthcare infections

# Common Processing Challenges for ASCs

- Space constraints
- Caseload vs. reprocessing speed
- No dedicated SPD staff
- Lack of education or competency





**60%**

**Noncompliant to NPSG  
Standard IC.02.02.01**

The organization reduces the risk of infections associated with medical equipment, devices, and supplies.

The Joint Commission 2018

# Top 10 Health Technology Hazards for 2020

1. Surgical stapler misuse.
2. Point-of-care ultrasound.
3. Sterile processing errors in medical and dental offices.
4. Central venous catheter risk in at-home hemodialysis.
5. Unproven surgical robotic procedures.
6. Alarm, alert and notification overload.
7. Connected home healthcare security risks.
8. Missing implant data and MRIs.
9. Medication timing errors in EHRs.
10. Loose nuts and bolts in devices.

# Infection Control Plan

Surveillance  
and Disease  
Reporting

Hand Hygiene

PPE

Injection  
Safety

Respiratory/  
Cough  
Hygiene

Environmental  
Cleaning

Transmission  
based  
precautions

Reprocessing  
of Medical  
Devices



A microscopic image showing a metallic surgical instrument, possibly a retractor system, heavily encrusted with a thick, yellowish-brown biofilm. The biofilm is uneven and porous, covering the entire visible surface of the metal. The background is dark and out of focus.

**“Do not get complacent about proper sterilization.”**

**Dotty Bollinger RN, JD, CASC, LHRM (2012)  
COO, Laser Spine Institute**

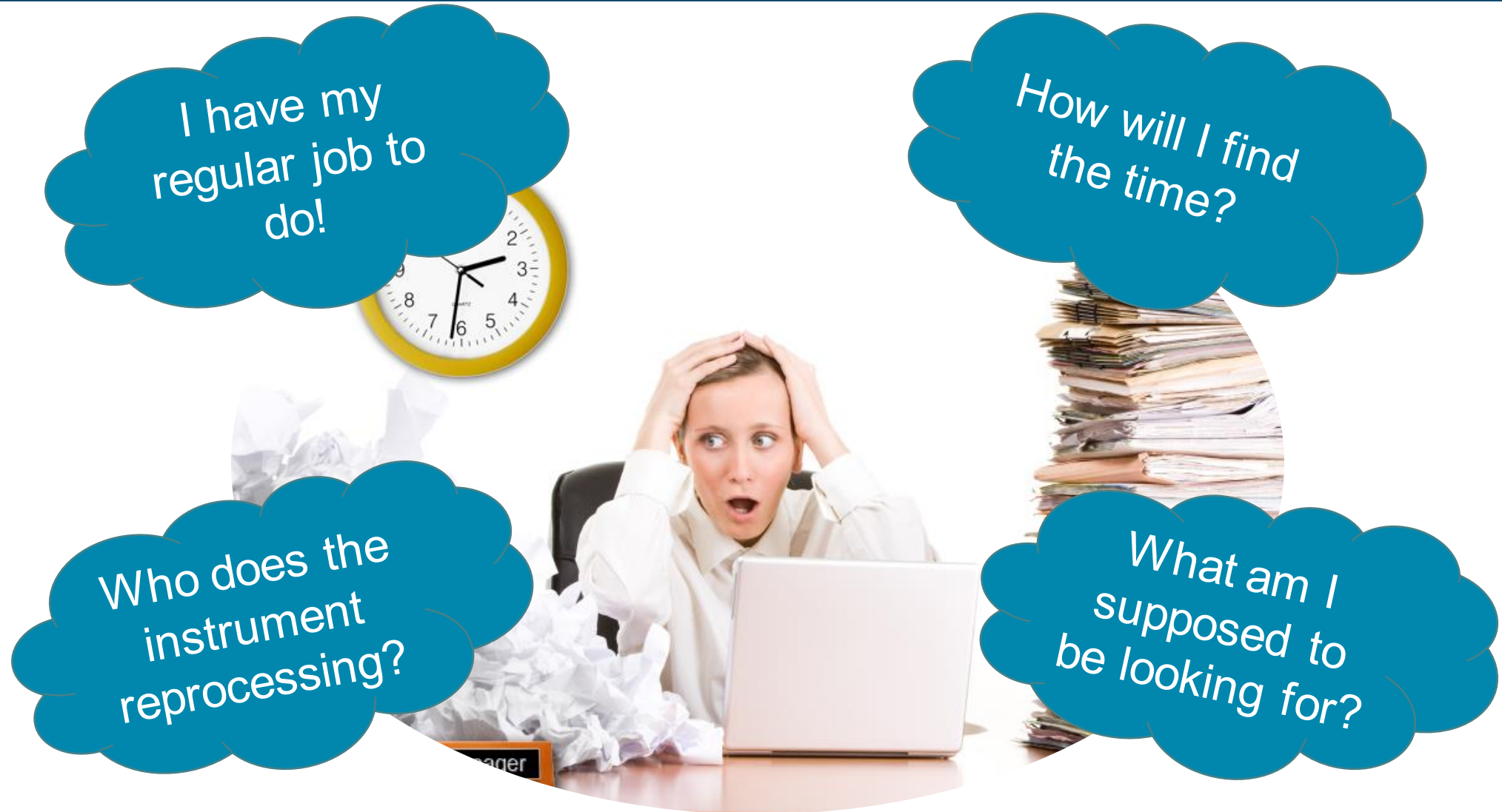
- **Qualified infection prevention specialist**
- **Staff education**
- **Focus on plan basics**
- **Regular Surveys and Audits**

# Infection Control Audit

- Direct observation
- Confirms compliance
- Identifies areas for improvement

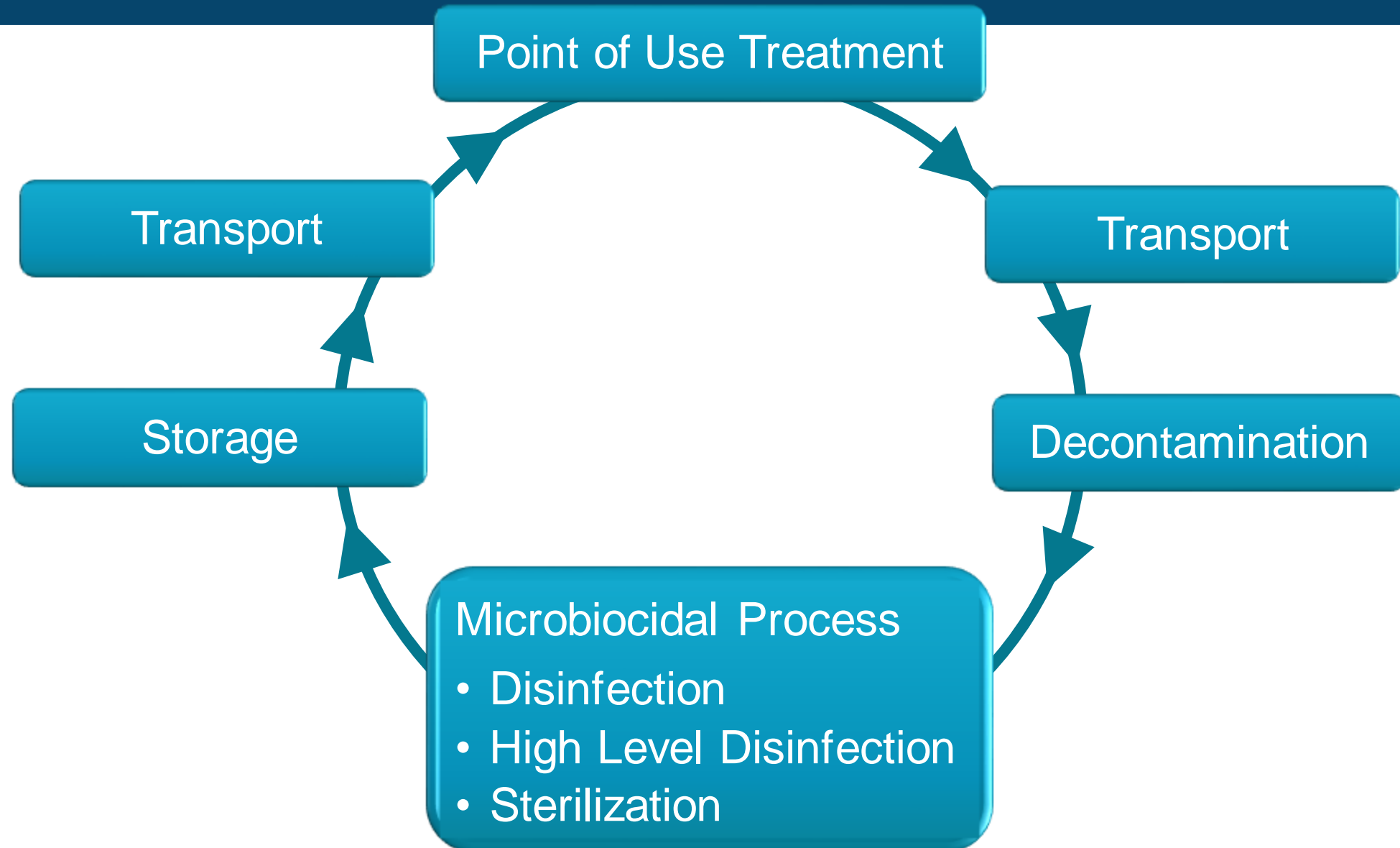
Tools to get better!

# Auditing Challenges





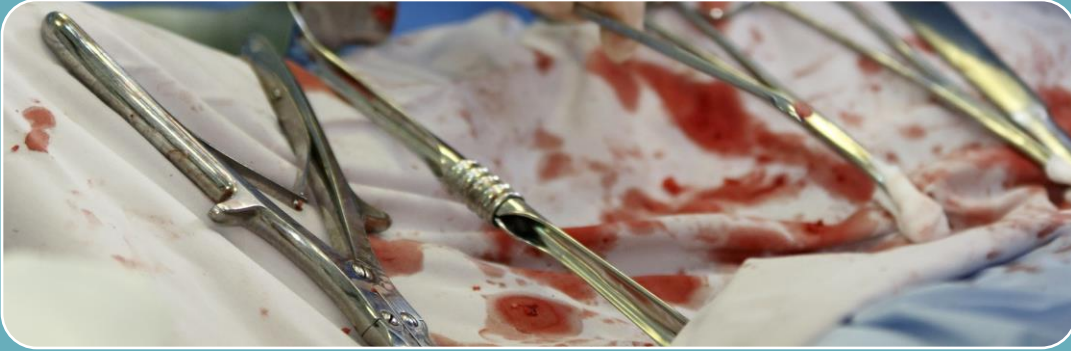
# Medical Device Reprocessing Loop





# Point-of-Use and Transport

# Point of Use Treatment



## During Procedure

- Remove gross soil
- Keep Moist
- No saline



## Post Procedure

- Remove gross soil
- Discard waste
- Disassemble per IFU
- Keep moist for transport



# Soiled Transport – O.R.

- Puncture-proof container with lid or case cart
- Instruments kept moist
- Labeled BIOHAZARD
- As soon after procedure as possible

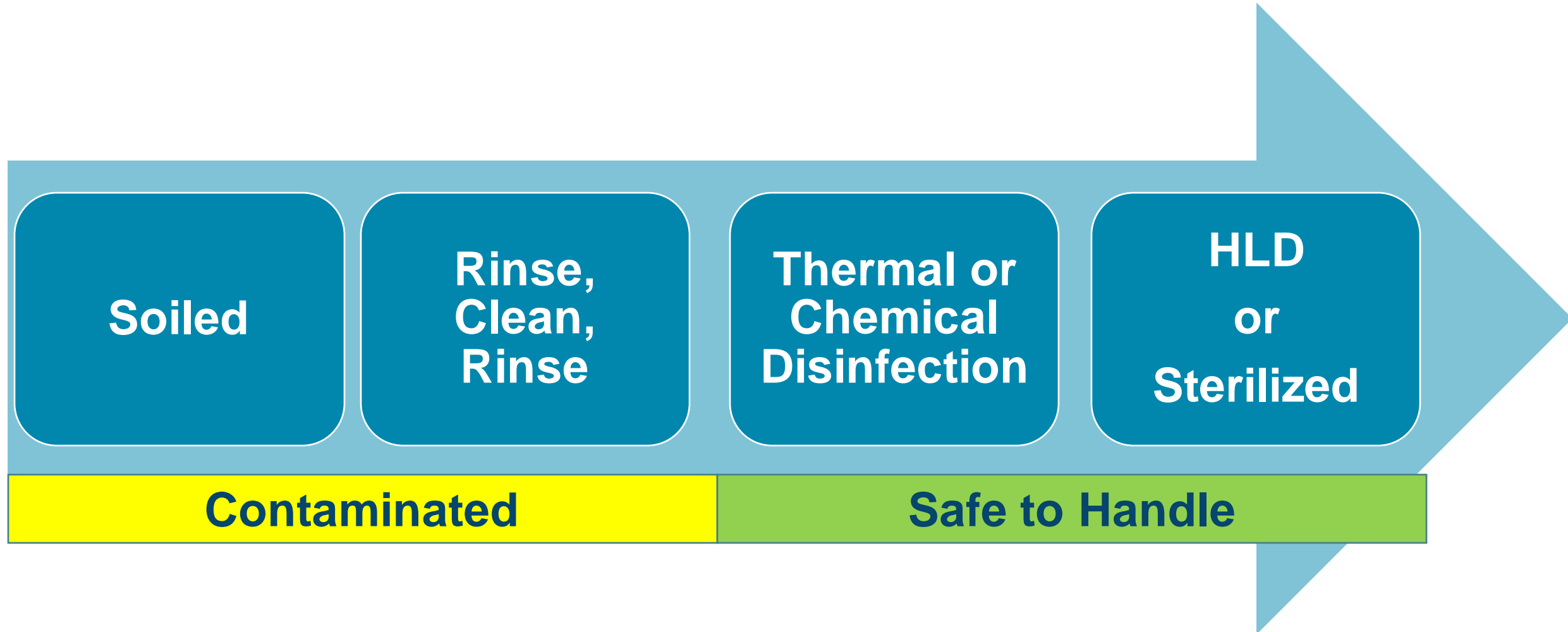


# Decontamination

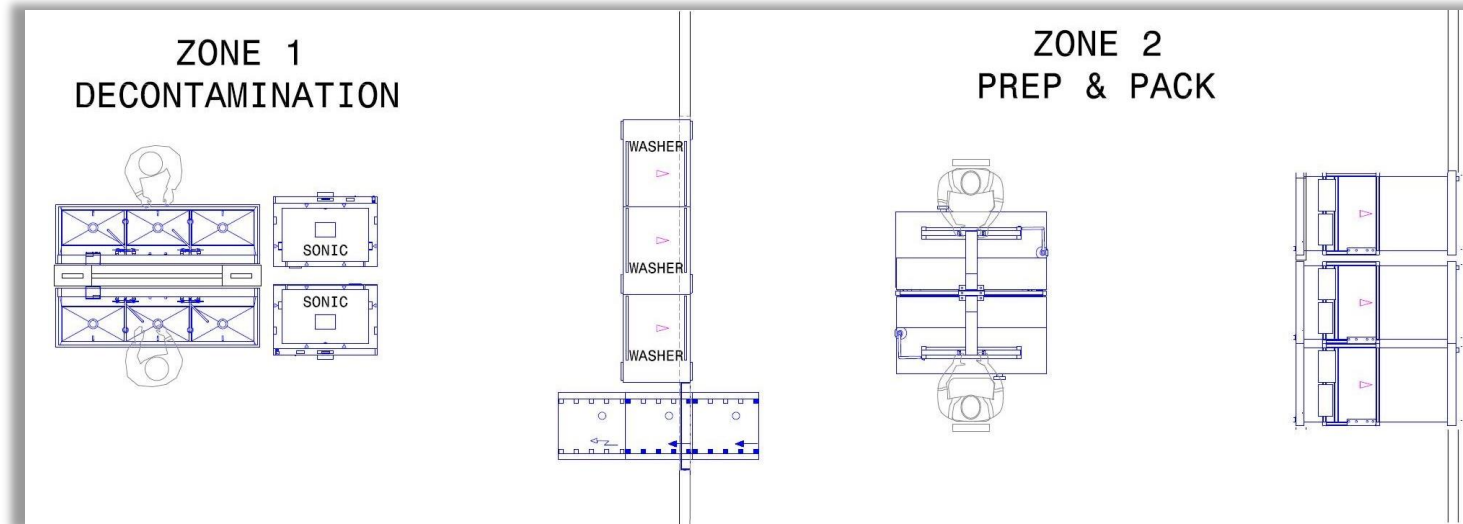
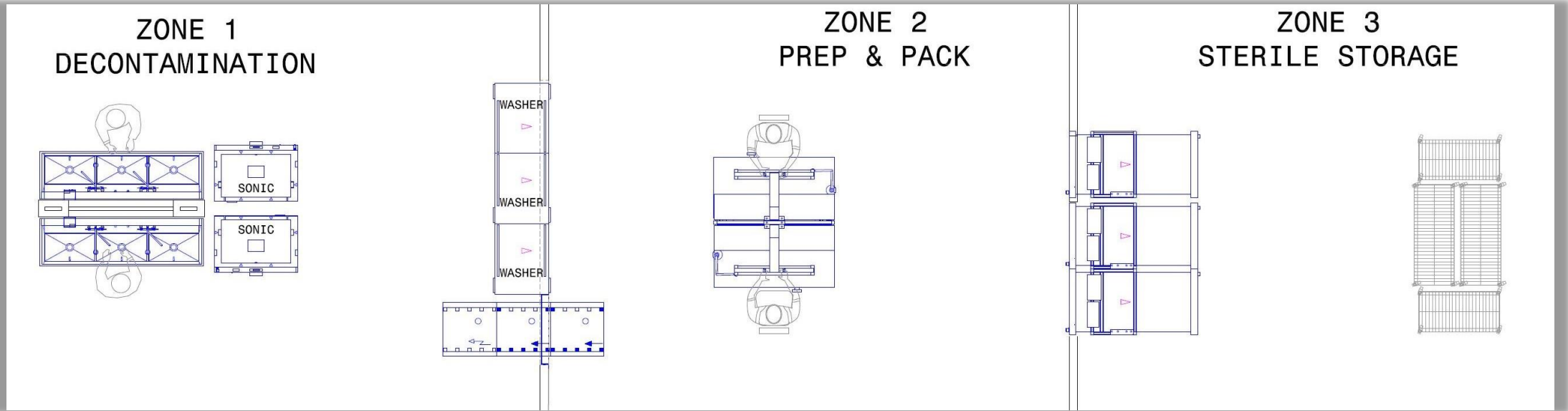




# Reprocessing Workflow

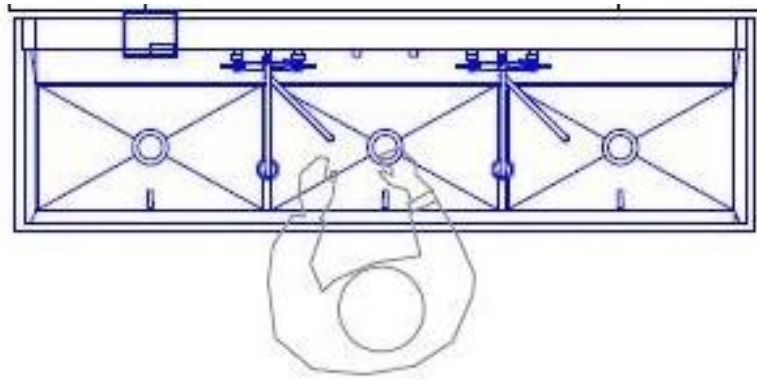


# 3-Zone and 2-Zone Workflow



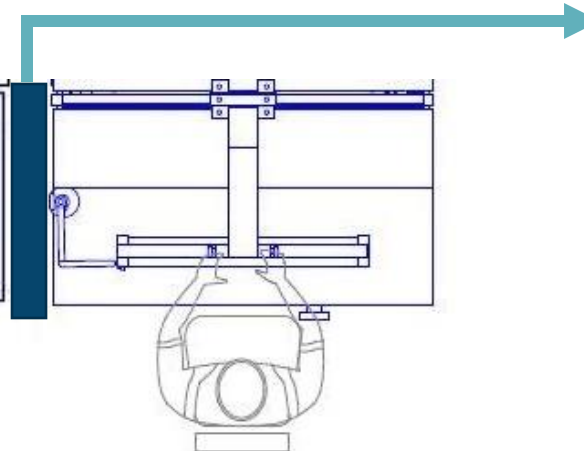
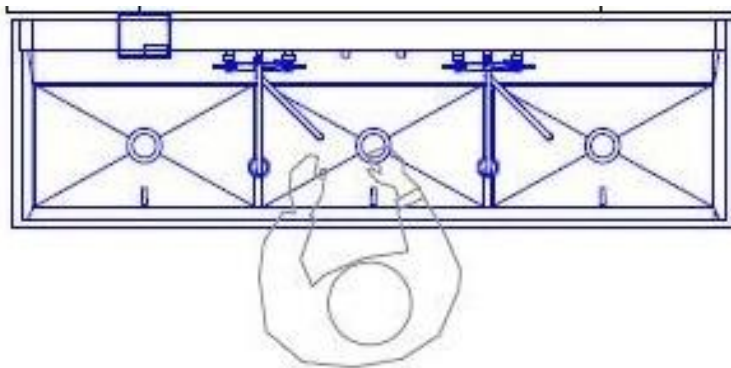
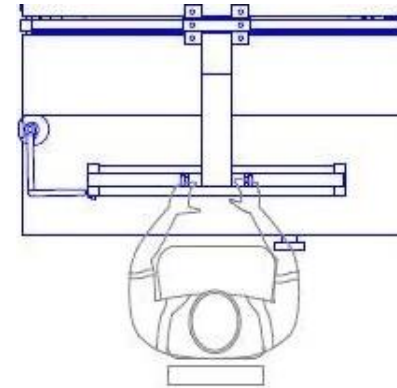
# Single Zone Reprocessing

## Cleaning & Rinsing



4  
Feet

## Assembly



## Cleaning & Rinsing

## Assembly

### Things to Check

- Is workflow from dirty to clean
- Are physical distancing or barriers in place



### Things to Check

- Are there delays
- Enough reprocessing staff
- Are IFUs followed for delays

**Dried Soil**

**Biofilm Formation**

**Decontamination Delay**

**Damage to coated surfaces**

**Damage to Passivation Layer**

# Manual Cleaning & Decontamination Steps

**Cold  
Water  
Rinse**

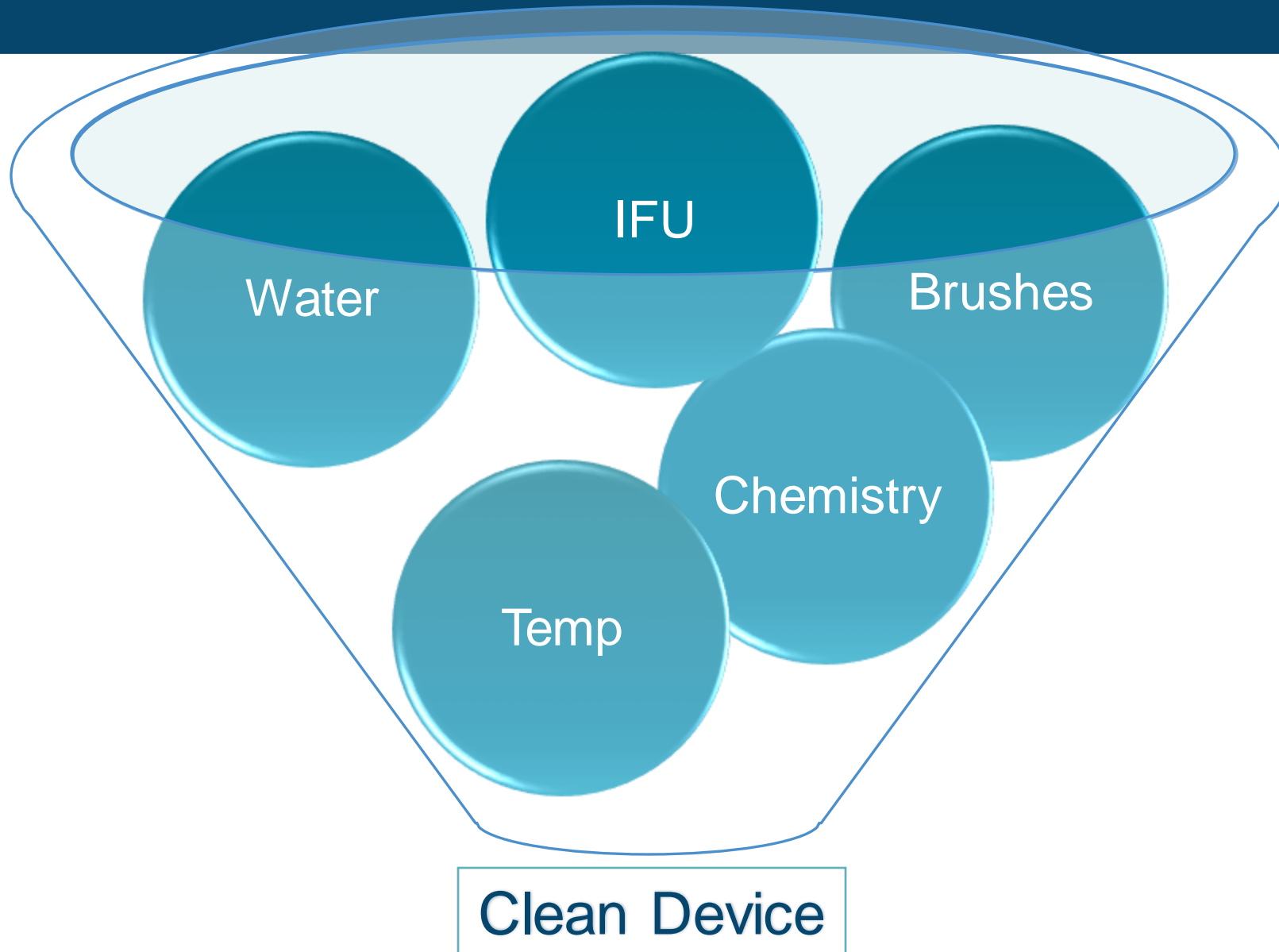
**Soak**

**Brush &  
Flush**

**Treated  
Water  
Rinse**



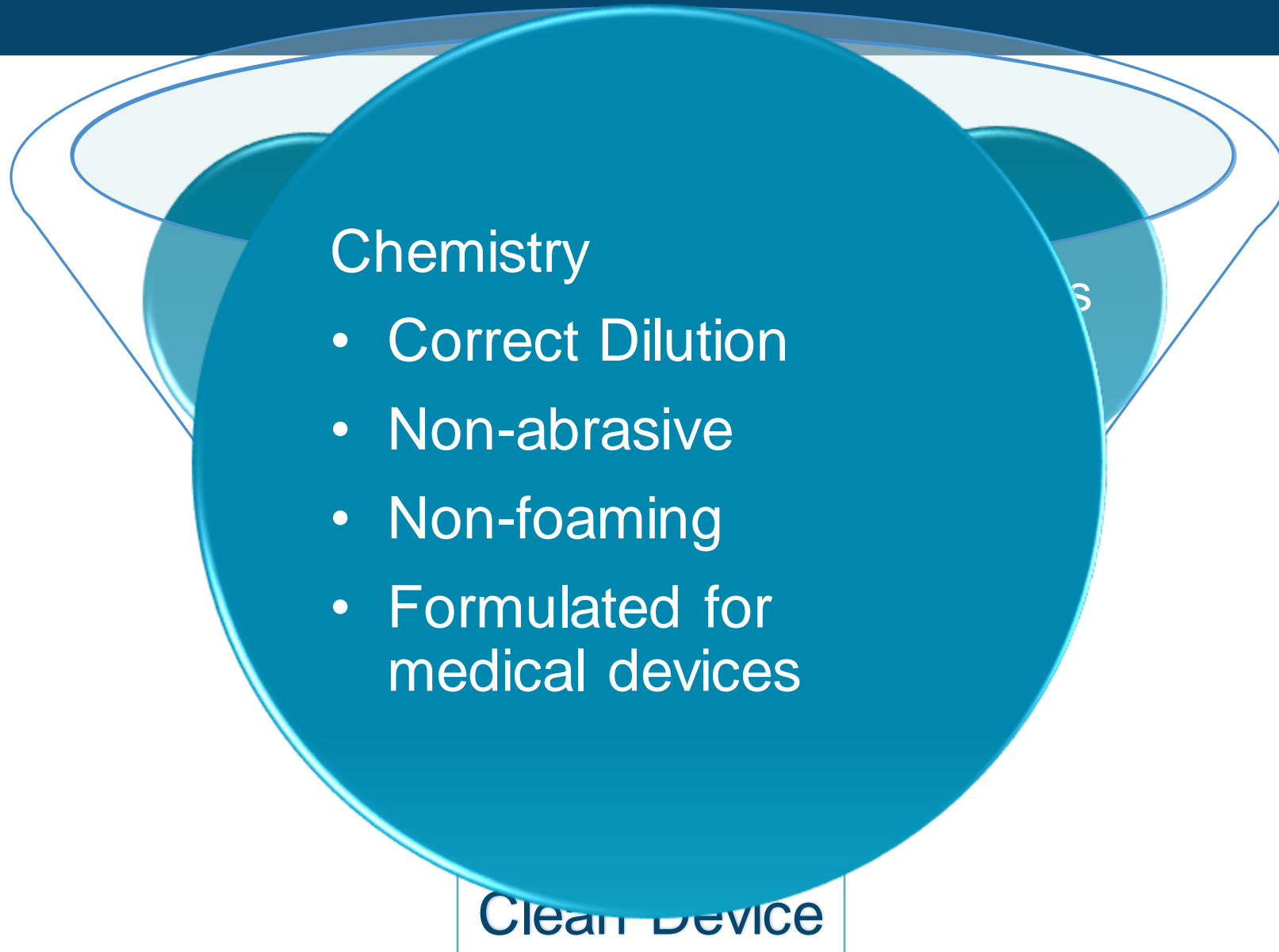
# Manual Cleaning & Decontamination



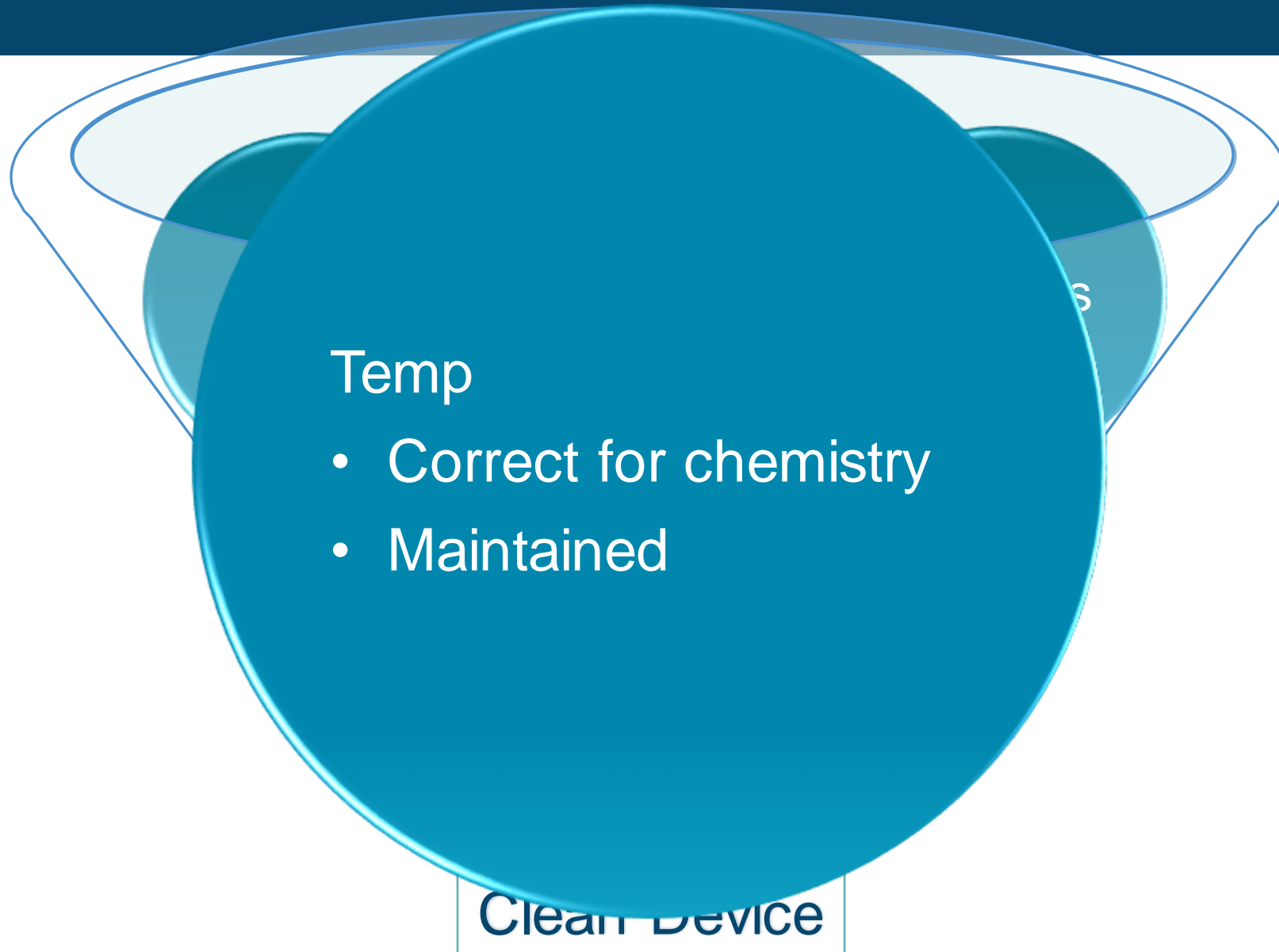
# Manual Cleaning & Decontamination



# Manual Cleaning & Decontamination



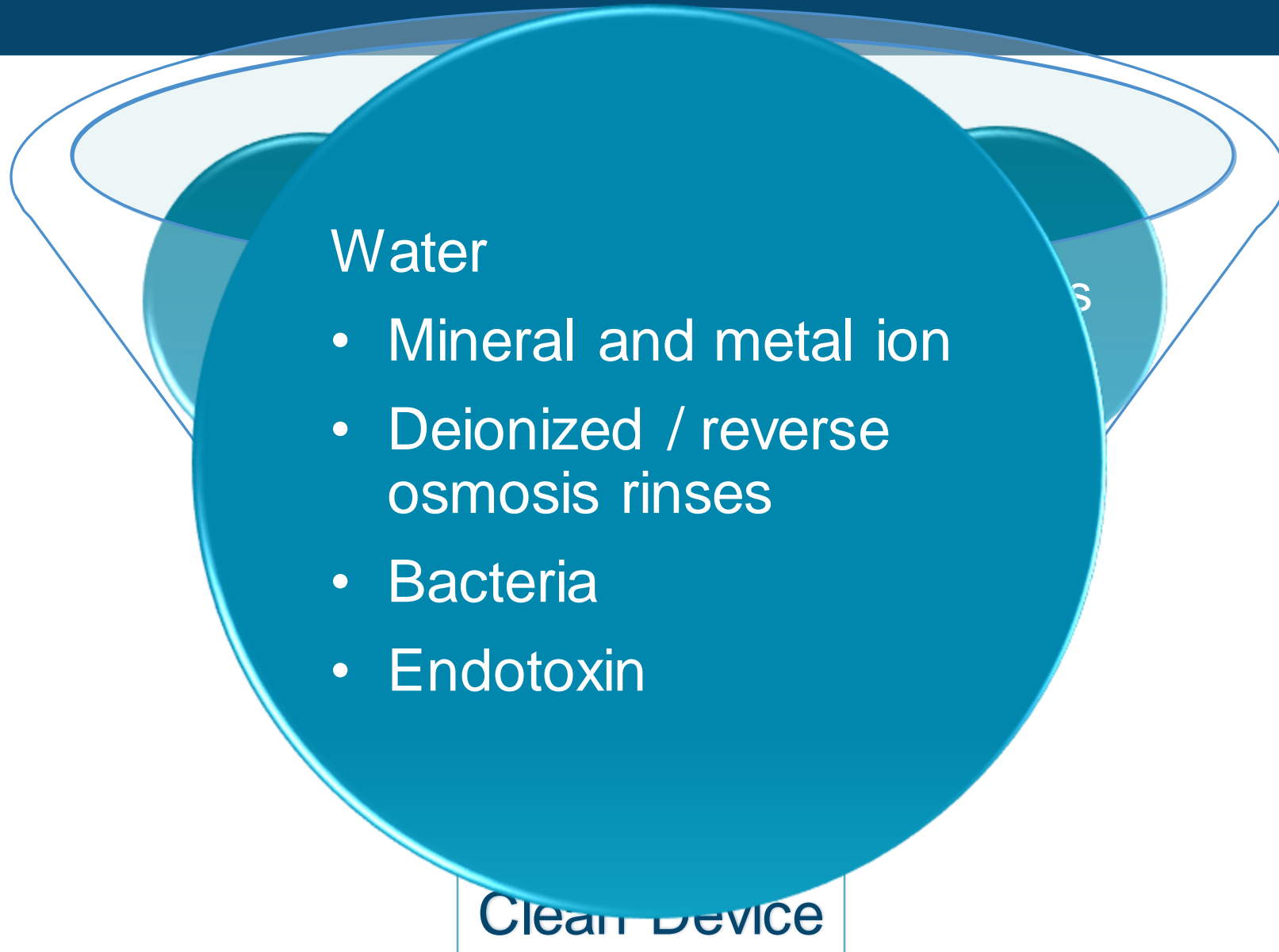
# Manual Cleaning & Decontamination



# Manual Cleaning & Decontamination



# Manual Cleaning & Decontamination





# Manual Cleaning & Decontamination

## Things to Check

- Make IFU available
- Staff educated and competent
- Right cleaning tools available

Water

## Things to Check

- Bacterial and Endotoxin water testing
- Ensure DI or RO water is used for rinses

Brushes

## Things to Check

- Confirm dilution rates and temps
- Confirm chemistry is right for the devices and water quality of the facility

Clean Device

# Automated Cleaning

**Cold Water  
Rinse**

**Soak**

**Manual  
Cleaning**

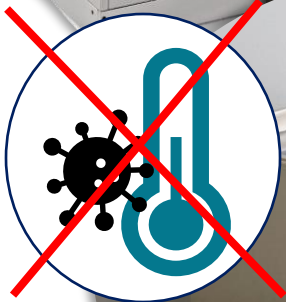
**Automated  
Cleaning**



# Automated Cleaning



Ultrasonics



Washers



# Automated Cleaning Equipment

- Water & cleaning chemistry
- Dilution rates
- Lumen flow & adapters
- Daily performance testing
- Cleaning & disinfection schedule
- Preventative maintenance

## Things to Check

- Confirm the right cleaning chemistry
- Check dilution rates
- Flow connectors used
- Verify performance testing
- Confirm disinfection schedule
- Review PM records

# Drying

**Manual  
Cleaning**



**Automated  
Cleaning**



**Air Purge**

**Drying  
Cabinet**

# Pass Through

- Maintain positive pressure flow
- Drying station
- Cleaning & disinfection schedule
- Preventative maintenance



## Things to Check

- Observe that the window is kept close
- Regularly replace absorbent material
- Check completion of cleaning and disinfection
- Review PM records



# Drying Cabinets

- Temperature control
- HEPA filter air
- Lumen adapters / connectors
- Cleaning & disinfection schedule
- Preventative maintenance

## Things to Check

- Check temperature requirements and monitoring log
- Check adaptors and connectors
- Review filter & PM records



# Inspection for Residual Soil

- Lighted magnified inspection
- Borescope
- Residual soil tests
  - Many types
  - Frequency and scope determined by factors
  - Risk assessment

## Things to Check

- Check lighted magnification
- How and when the borescope is used
- Residual soil testing in risk assessment
- Review soil testing records





# Assembly / Prep & Pack

# Assembly / Prep and Pack



**Inspect**

**Assemble &  
Lubricate**

**Pack**



## Workstation

- Organized / clean
- No food, lotions, drinks, etc.



# Inspection

- Lighted magnification / borescope
- Visible soil & soil tests
- Moisture
- Device damage
- Functional testing
- Lubrication, if applicable



## Things to Check

- Lighted magnification and borescope
- Residual soil testing is completed
- Review the damage device process
- Confirm medical grade lubricants

# Assembly Prepares Device & Device Sets



High Level  
Disinfection



Liquid  
Chemical  
Sterilization



Terminal  
Sterilization

# Assembly - Steam

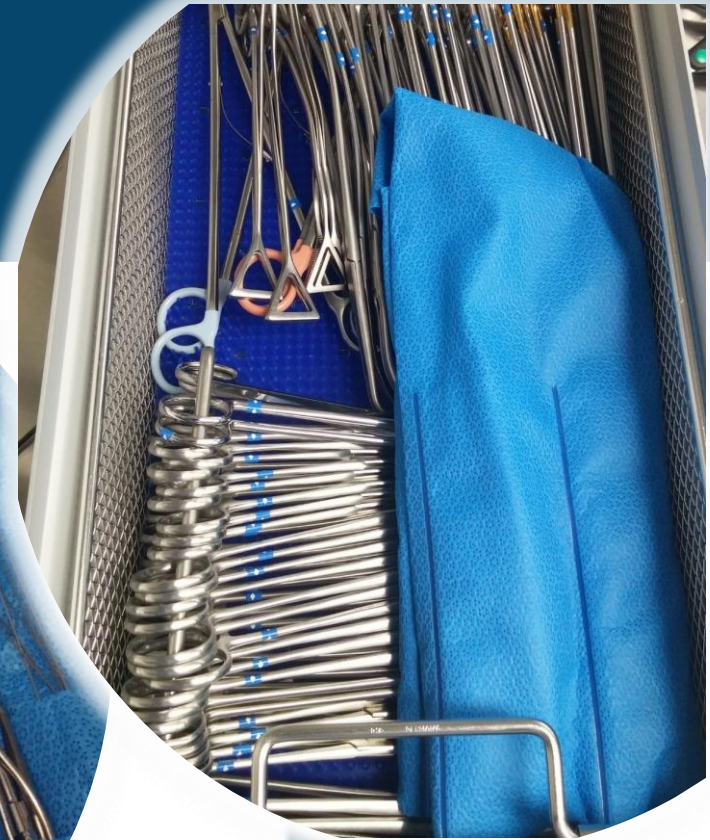
- Instrument Labeling
- Instrument positioning
- Set weight
- Water





# Assembly – Instrument Protection

- Instrument holders / pouches
- Tip protectors
- Mats







### Things to Check

- Staff competency
- Reconcile IFU for set weights

### Things to Check

- Compatibility for accessories, devices and containment devices

### Things to Check

- Tip protector and matt use
- Check on water and personal items

# Packaging & Labeling



Small  
Light-weight  
Items  
Use before  
Expiration  
Date



Correct  
Weight &  
Size  
Inspect for  
Defects  
Store per  
IFU



Correct  
Filters &  
Accessories  
Inspect for  
Damage &  
Cleanliness



Non-toxic ink



Load label



Tamper arrow



Packaging  
tape



# Sterilization



# Assembly / Prep and Pack



**Loading**

**Sterilization**

**Release &  
Storage**



**Loading,  
Product ID,  
Traceability**

**Sterilization**

**Testing and  
Monitoring**

**Load Release,  
Failures**

**Preventative  
Maintenance**

# Sterilization Processes



Steam



Vaporized  
Hydrogen  
Peroxide



Ethylene  
Oxide



# Steam Cycle Choice

## Gravity

- 30 min exposure at 250°F
- 15 min exposure at 270°F

## Prevacuum

- 4 min exposure at 270°F
- 3 min exposure at 275°F

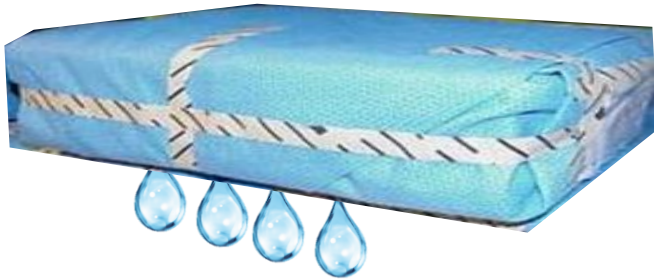
## Steam-Flush Pressure-Pulse (SFPP)

- 4 min exposure at 270°F
- 3 min exposure at 275°F

## Things to Check

- Long time
- Load Weight
- Extended cycles
- Few cycles
- Few assurance products

# Loading - Steam



- Pouches and textiles on edge
- Containers and trays flat
- Basins tilted to drain
- Heavy on the bottom

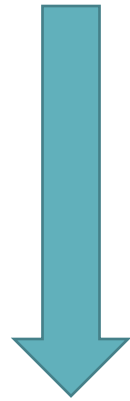


# Unloading

- Low traffic area
- Away from vents

# Immediate-Use Steam Sterilization

**Urgent** Clinical Situations



**Immediate** Use

## Things to Check

- IFU available and followed
- Competencies complete
- Container validated of IUSS
- Volume and reasons are consistent with CMS guidelines

# VHP Cycle Choice

## Lumen Cycles

- Lumen or cannulated devices
- Mixed loads

## Non Lumen Cycles

- No lumens or cannulation

## Flexible Cycles

- Flexible endoscopes
- Mixed loads

### Things to Check

- Right cycle
  - Compatible
  - IFU / Device Matrix
- St
  - G
  - V



# Loading - VHP

- Placed flat
- Do not touch plasma coil
- Follow loading charts



Plasma Coil

## Standard Cycle



**47-minute**  
for most surgical  
instruments



← Place biological indicator at the back of

## Express Cycle



**24-minute**  
for fast turnaround  
endoscopes  
and many other  
instruments



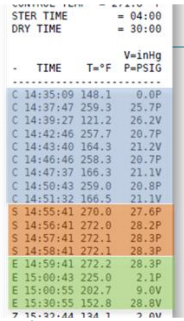




# Unloading

- Use gloves

# Sterilization Process Monitoring

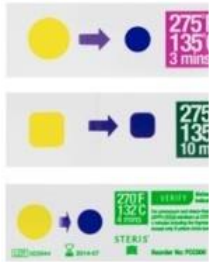


TIME	Ta°F	V=InHg	P=PSIG
C 14:35:09	148.1	0.0P	
C 14:37:47	259.3	25.7P	
C 14:39:27	121.2	26.2V	
C 14:42:46	257.7	20.7P	
C 14:43:40	164.3	21.2V	
C 14:46:46	258.3	20.7P	
C 14:47:37	166.3	21.1V	
C 14:50:43	259.0	20.8P	
C 14:51:32	166.5	21.1V	
S 14:55:41	270.0	27.6P	
S 14:56:41	272.0	28.2P	
S 14:57:41	272.1	28.3P	
S 14:58:41	272.1	28.3P	
E 14:59:41	272.2	28.3P	
E 15:00:43	225.0	2.1P	
E 15:00:55	202.7	9.0V	
E 15:30:55	152.8	28.8V	
7 15:35:44	124.1	9.0V	

Cycle print out



External chemical indicators



Internal chemical indicators



Biological indicators



Process challenge device



Special tests

# Sterility Assurance



Qualification

Routine monitoring

Load release

Package release



Product quality assurance testing

## Things to Check

- Qualification test records
- Routine and load monitoring standards
- Product testing?

# When is Qualification Needed?



Installation



Relocation  
and changes  
in utilities



Sterilization  
malfunctions or  
failures



Major  
repairs

- 3 consecutive test cycles
- Process Challenge Device (PCD)
- Special Tests, if applicable



# Option

Chemical  
Process  
Challenge  
Device

Biological  
Process  
Challenge  
Device

## Things to Check

- Implant load monitoring
- Record complete
- Are loads quarantined

Physical  
Monitors

External  
Chemical  
Indicators

# Emergency Release

- Documented medical exception
- Exception not rule
- Policy and procedures
- Trending

## Things to Check

- Trending
- Actively reducing IUSS usage





# Documentation Needs

# Equipment Records, continued

Tests	
• Equipment cleaning & verification	
• Leak test	
• Bowie-Dick test	
• Routine biological indicator	
• Qualification test results	
• Product testing test results	

# Equipment Records

## Service & Maintenance

- Daily maintenance activities
- Preventative maintenance records
- Repair records
- Calibration records
- Installation records
- Relocation records
- Changes to equipment parameters settings

# Facility Records

## Maintenance

- Corrective actions for steam delivery system
- HVAC parameters by room for the department

## Tests

- Assessment of steam quality
- Assessment of water quality (tap and treated)
- Routine testing of safety equipment, such as eyewash stations

# Sterilization Records

## Records

- Load/lot number identification
- Detailed load content list
- Sterilizer cycle printout
- Sterilization cycle parameters
- Operator identification
- Biological indicator PCD results
- Chemical indicator PCD results

# Sterilization Records cont'd

## Records

- Reports of inconclusive or non-responsive chemical indicators
- Emergency release documentation
- Traceable



# Administrative Records

## Records

- Competencies
- Audit findings and corrective actions
- Additional medical device instructions
- Failure tracking and corrective actions
- Recall records
- Critical supplier communications / recall
- Loaned equipment transactions
- Continuous quality improvement records

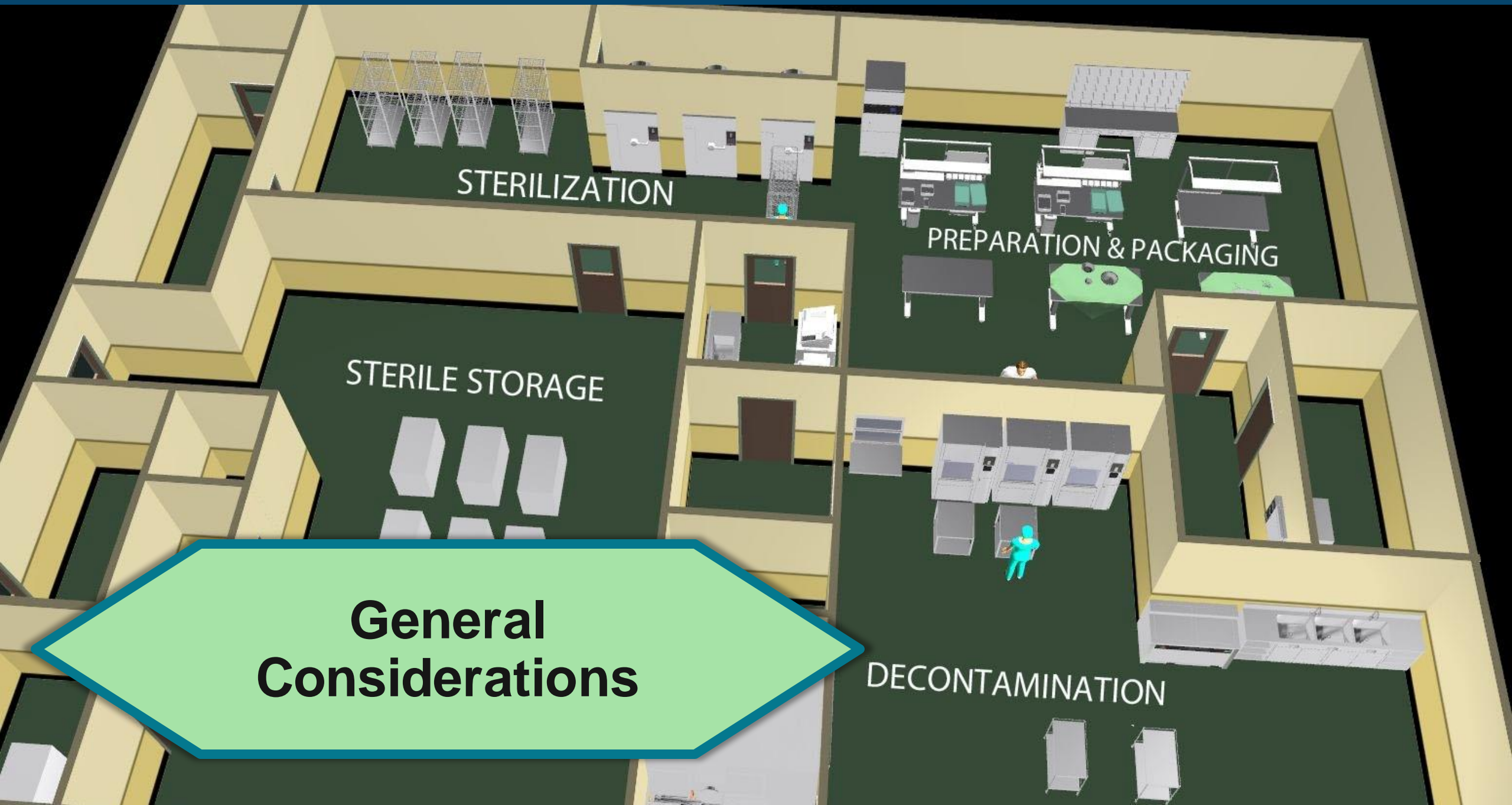
### Things to Check

- Audit documentation
- Compare against the standards

# Types of Electronic Documentation Systems

- Document management systems (DM)
- Semi-automated systems (SAS)
- Workflow management systems (WMS)





STERILIZATION

PREPARATION & PACKAGING

STERILE STORAGE

DECONTAMINATION

**General  
Considerations**

# Personal Protective Equipment (PPE)

Dirty Side



- Face shield
- Surgical mask
- Fluid resistant gown
- Chemical gloves

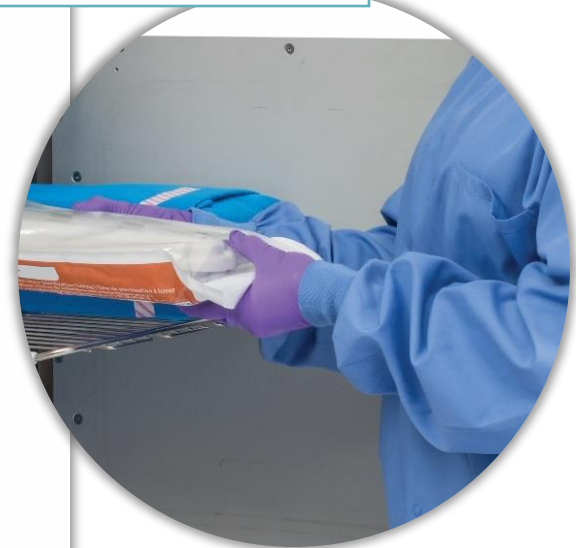


## Things to Check

- Right PPE for the job
- Observe use
- Donning and doffing

covers

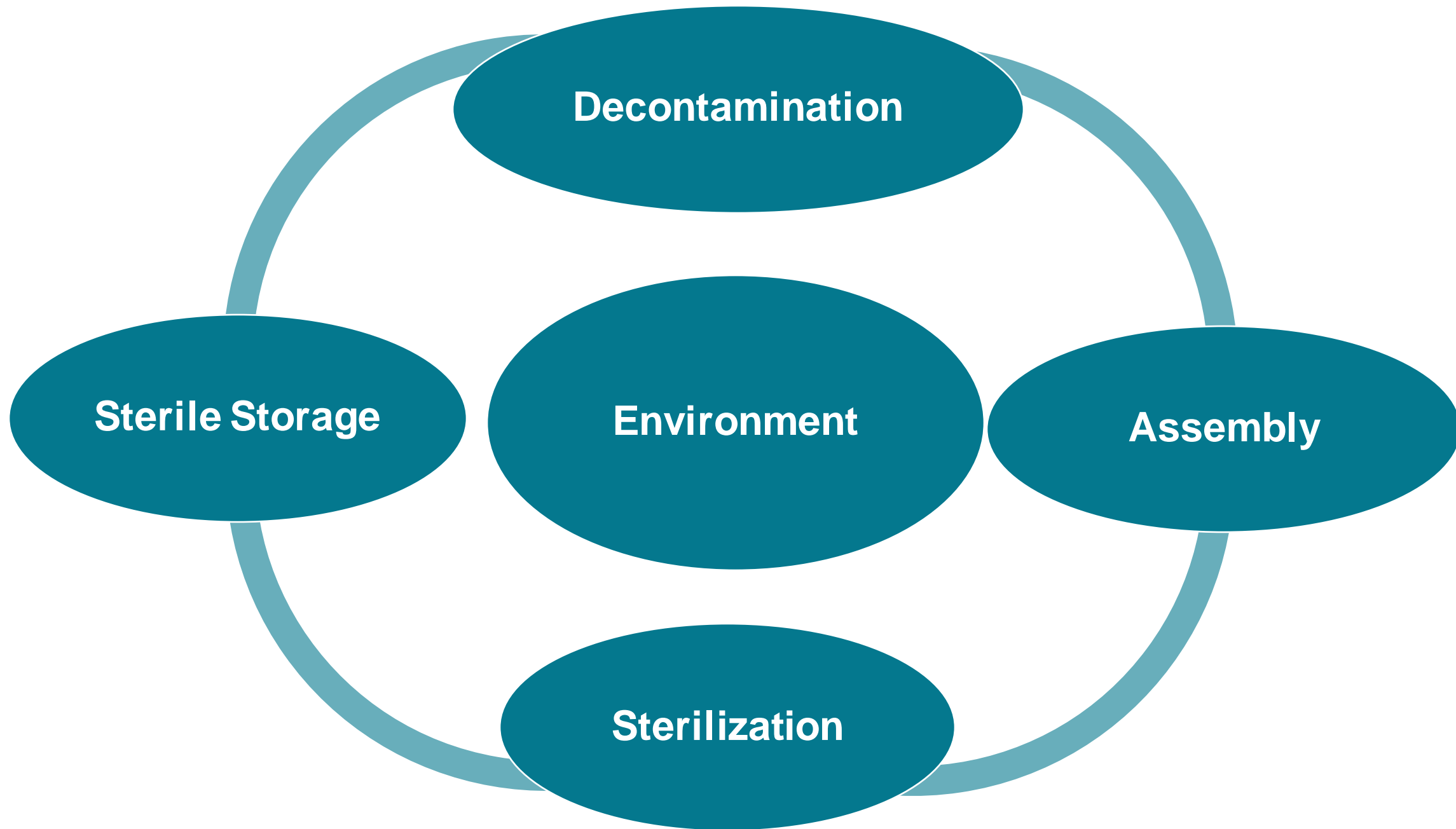
Clean Side



- Chemical gloves
- Thermal resistant gloves
- Safety goggles / glasses









# Traffic Patterns - Decontamination

Emergency  
Eye Wash

Keep Area Clear  
Test Emergency Equipment

ACTIVATE SWITCH  
TO OPERATE



**"PPE" IS REQUIRED  
IN DECONTAM  
DURING ACTIVE  
DECONTAMINATION**

FLEXIBLE  
LEAK TEST

FLEXIBLE  
EYE INSTR. D  
TO BE CLEANED IN  
PUSHE LOCK WYTH

# Lighting

Task  
Lighting

No  
Shadows



## STANDARD

## Ventilation of Health Care Facilities

ISSN 1041-2336





# Hand Hygiene



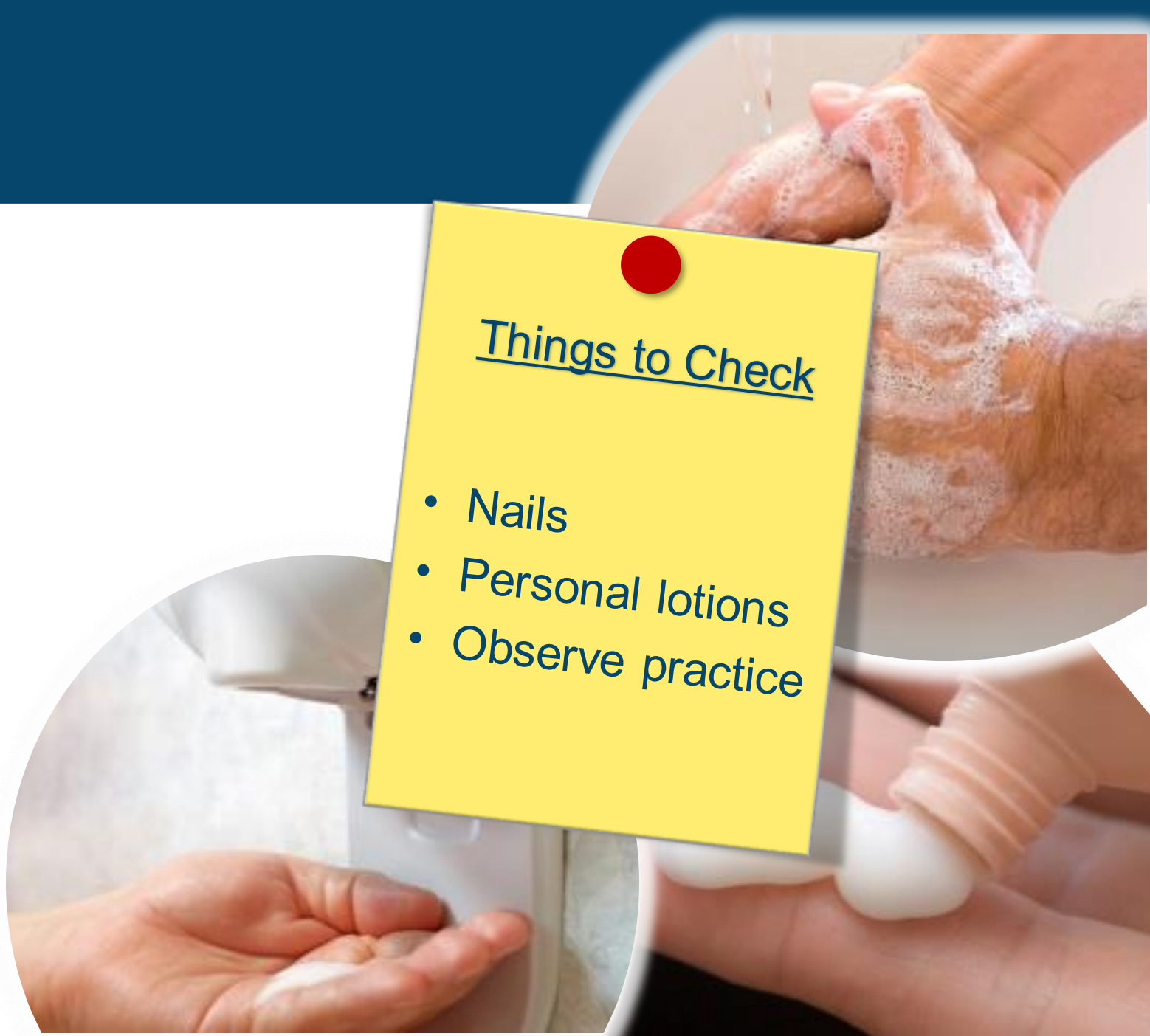
# Hand Hygiene

- Wash hands
- Medical grade lotions
- Alcohol-based product
- Hand washing stations



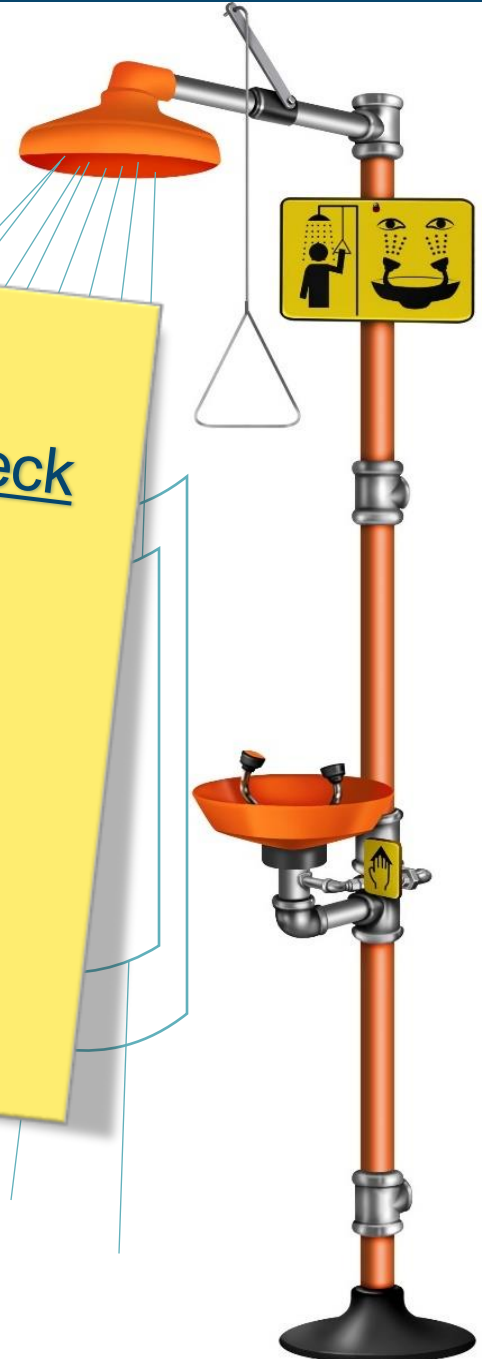
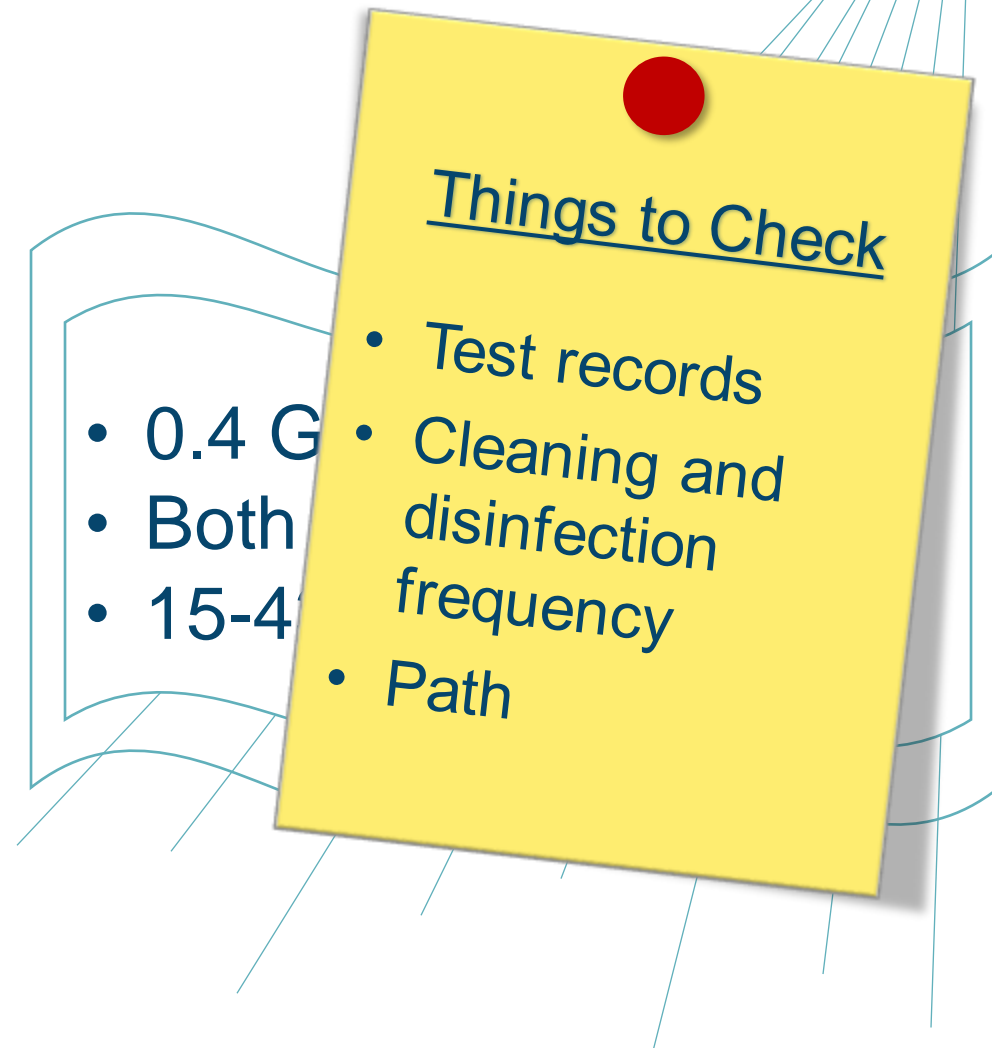
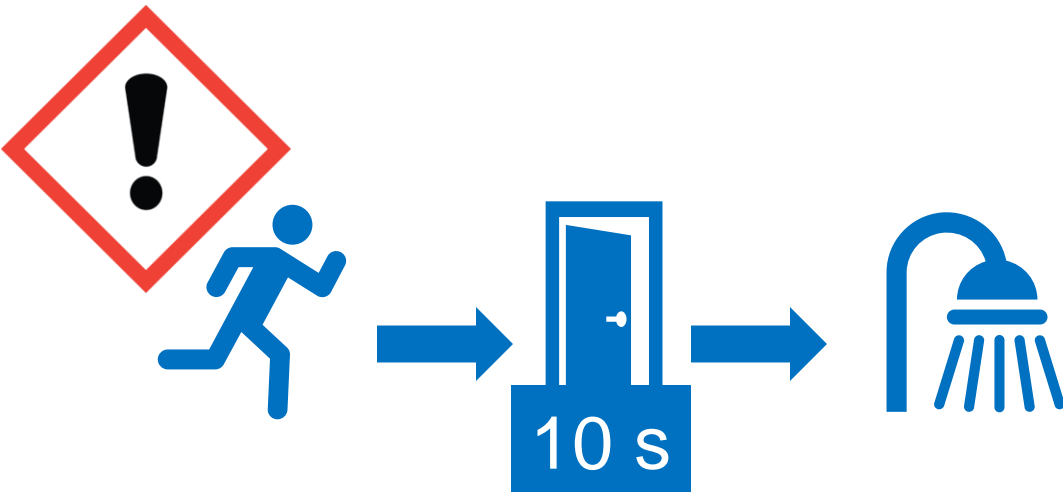
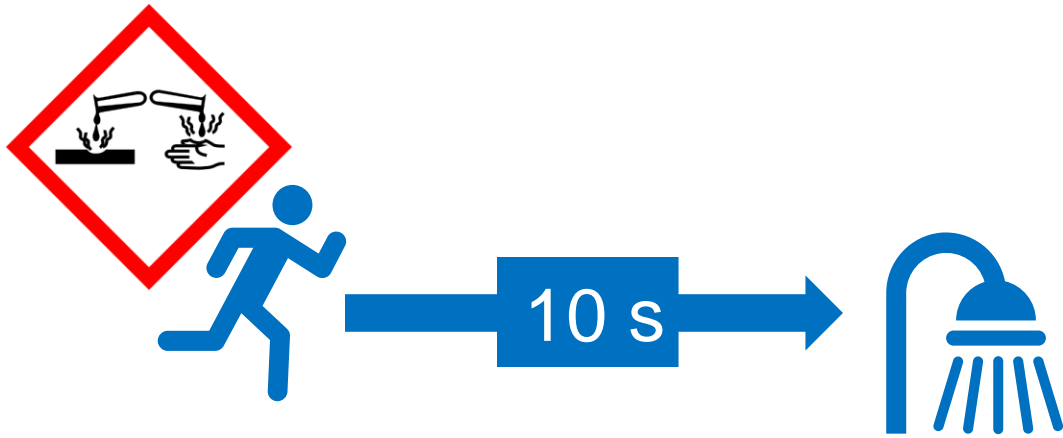
## Things to Check

- Nails
- Personal lotions
- Observe practice





# Emergency Eye Wash Station



# Surfaces



## Have:

- Smooth
- Nonporous
- Compatible



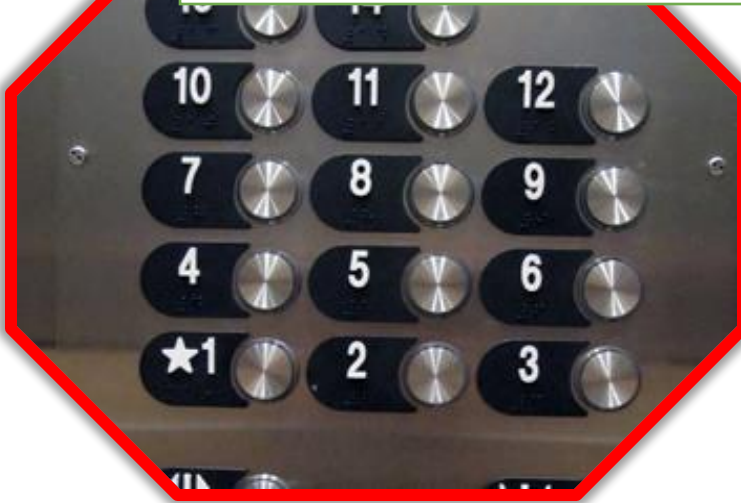
## Avoid:

- Textured
- Porous
- Non-compatible





## Sources of Environmental Contamination





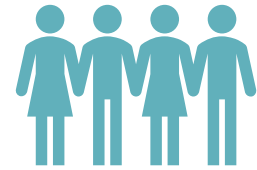
# Environmental Services (EVS) in SPD



Cleaning protocol for  
each area

## Things to Check

- Trash & Linen Schedule
- PPE and Attire
- Cleaning Chemistry
- Disinfectants



EVS staff  
competency



# Storage



# Sterile Storage



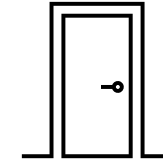
- Clean and organized
- Restricted access
- Environment monitored
- Cleaned regularly



### Things to Check

- Storage
- Hang time records
- Hang Time risk Assessment

Vertical  
ge

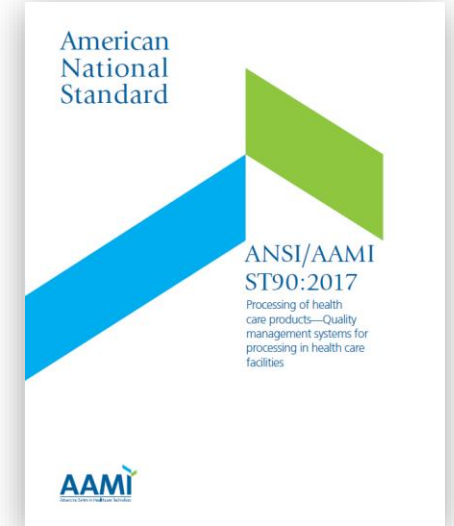
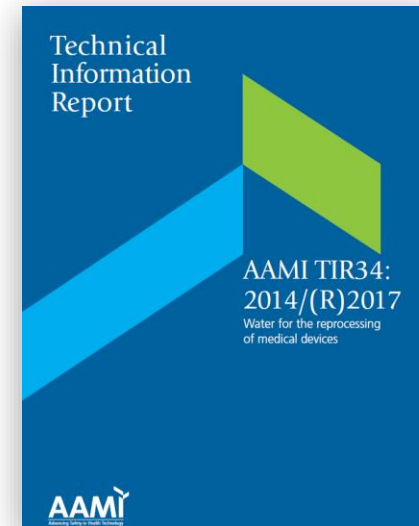
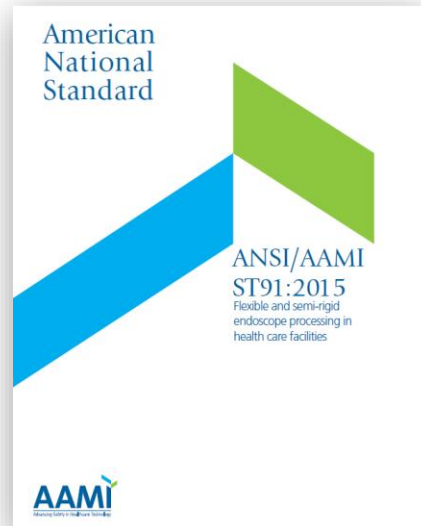
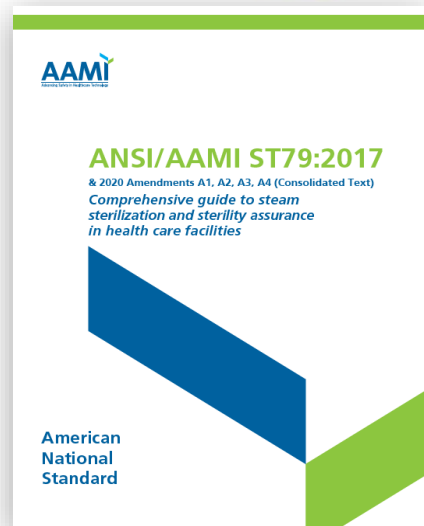
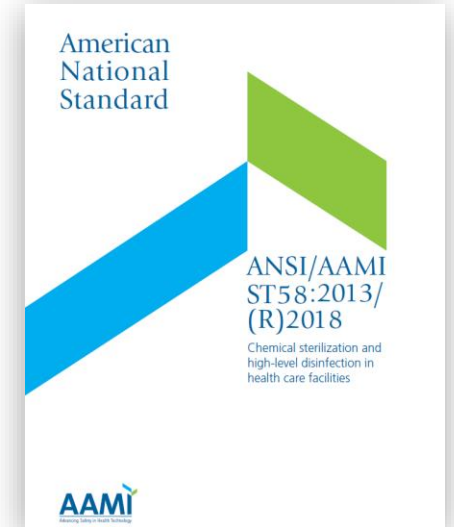
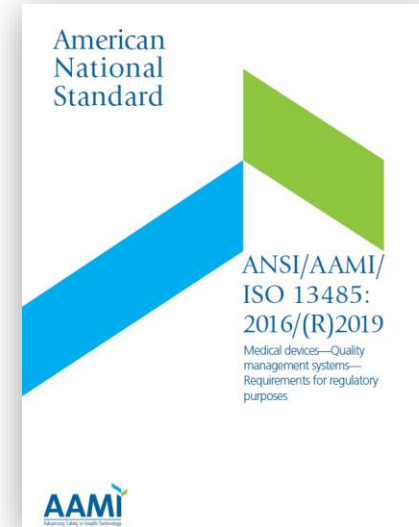
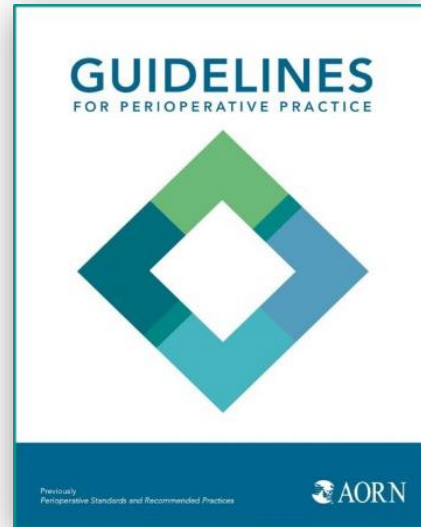


Closed  
cabinet



Filtered air  
circulation

# Resources



# Action Items

- Survey the SPD
- Develop a plan to address gaps
- Educate, train and assess





Infection Prevention...  
It's **Everyone's** Responsibility



# References

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Questions?



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