Applying ST108 for Bioburden Control and Sterility Assurance

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NEPHROS

because water matters℠

Bioburden Control and Sterility Assurance

Published analyses estimate that

20-30% of HAIs involve device contamination or use of contaminated fluids [during reprocessing]

Source: Centers for Disease Control and Prevention (CDC). Healthcare-Associated Infections (HAI) Data Portal. Available at: https://www.cdc.gov/hai/data/index.html; Rutala WA, Weber DJ. Disinfection and Sterilization in Health Care Facilities: What Clinicians Need to Know. Clin Infect Dis. 2016;63(2):233-238

Impact of Sterilization Failure

- More than 100 surgeries were **postponed** following hard-water-related sterilization system failure[1]
- Multiple outbreaks have been documented from **inadequate decontamination or sterilization**, including endoscope-related transmission[2, 3]
- Contaminated **devices, rinse water, and water-associated equipment** are recognized sources of healthcare-associated infection[4]
- Reprocessed **duodenoscopes** have been linked to outbreaks **despite adherence** to manufacturers' cleaning and disinfection or sterilization instructions[5]
- A systematic review and meta-analysis estimated **15.25% contamination** among "patient-ready" reprocessed duodenoscopes across published studies[6]
- Potable-water rinses and **biofilm within reprocessor water paths** have been implicated in Gram-negative contamination[7, 8]
- Biofilm was found in an automated reprocessor's **detergent tank, inlet water hose, and air vents**, with standard disinfection failing until root causes were corrected[7, 8]

(1) Hospital News. (2) Rutala WA, Weber DJ. *Disinfection and Sterilization in Health Care Facilities* (Clin Infect Dis review; open-access on PMC). (3) CDC. *Guideline for Disinfection and Sterilization in Healthcare Facilities* (2008 guideline with 2023–2024 updates). (4) CDC. *Water, Environmental Infection Control.* (5) FDA. *Infections Associated with Reprocessed Duodenoscopes.* (6) Larsen S, et al. *Rate and impact of duodenoscope contamination.* (7) Kanamori H, et al. *Healthcare Outbreaks Associated With a Water Reservoir and Infection Prevention Strategies* (Clin Infect Dis). (8) CDC MMWR. *Nosocomial Infection and Pseudoinfection from Automated Endoscope Reprocessor* .

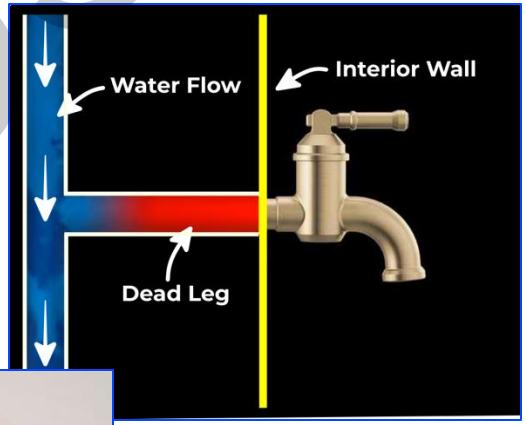
Blind Spot: Point-of-Use Outlets

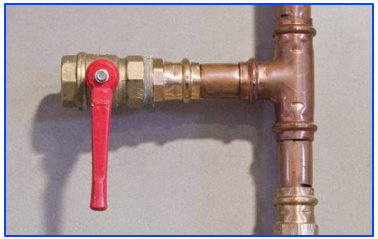
- Faucet aerators, spray guns, and washers' final rinse **nozzles can harbor and release bacteria and endotoxins**
- **Scale buildup** can restrict flow and support biofilm growth
- Warm, moist surfaces can harbor and promote pathogens like *Legionella*, NTM, and *Pseudomonas*
- Sterile processing departments & facilities should **include distal or point-of-use outlets where water contacts devices in their risk analysis and monitoring**

Source: ANSI/AAMI ST108:2023, Section 6.3 (Routine Monitoring) and Annex G & H (Sampling locations; corrective actions for distal points and outlets).

Blind Spot: Dead Legs / Dead Ends

- Dead ends and dead legs (unused or capped branches) provide areas for water to become stagnant
- These sections are **highly susceptible to biofilm** formation
- Dead legs are especially difficult to treat
- Sterile processing departments & facilities should **minimize or eliminate such sections to maintain water quality control**





Source: ANSI/AAMI ST108:2023, Annex G and Annex H (guidance on loop design and monitoring)

Blind Spot: External Events

- **Construction and weather can mobilize *Legionella*** and other soilborne contaminants, introducing microbial hazards into water supply
- Wildfire treatment and physical environment disruptions can introduce **chemicals which leach into groundwater**
- Building shutdowns **promote microbial growth**
- Chemical treatment to reopen buildings can **dislodge biofilm**
- Sterile processing departments & facilities should maintain a **documented plan for response to water quality excursions or system disruptions**

Source: ANSI/AAMI ST108:2023, Section 4 (Water Management Program), Section 6.3 Water Quality Requirements and Table 2, Annex D/E (chemical contaminant control and water treatment technologies), and Annex H (Maintaining Microbiological Quality — Corrective Actions & Response to System Events)

ANSI/AAMI ST108:2023

ST108 specifies:

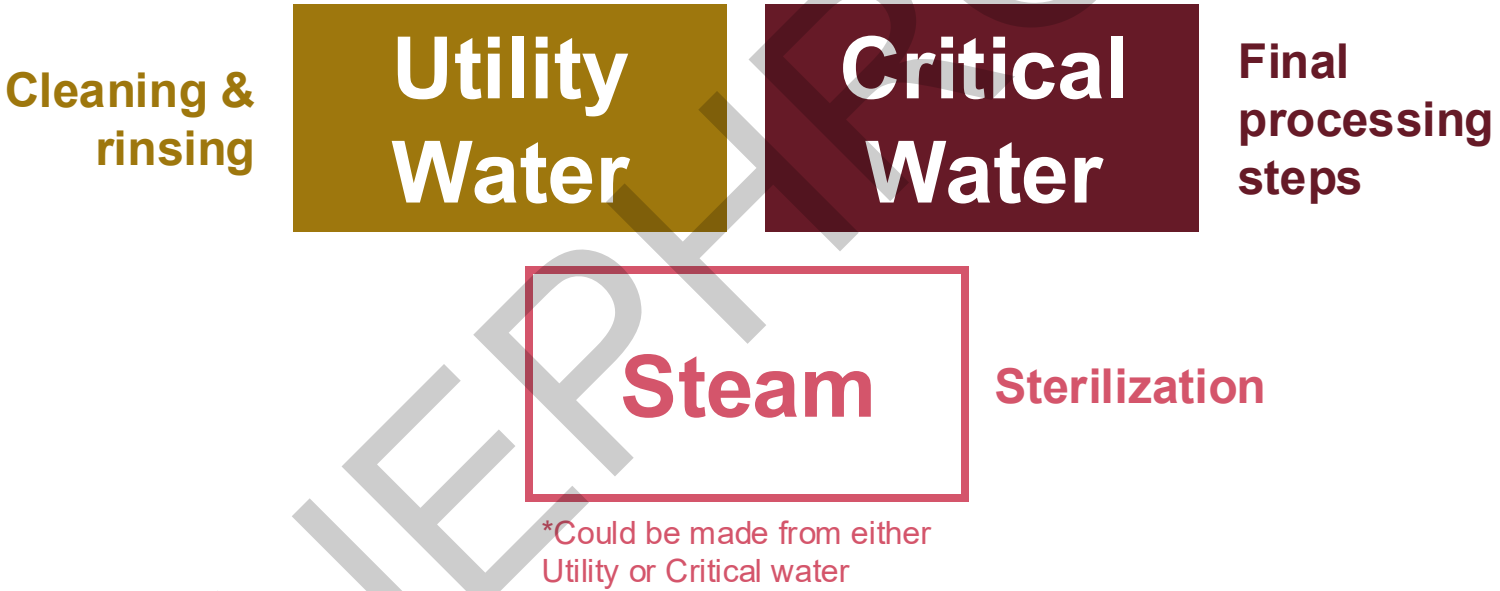
"specifies minimum water quality requirements and verification methods for all water used in processing reusable medical devices…"

AAMI TIR34 vs. ANSI/AAMI ST108

- **AAMI TIR34** and **ANSI / AAMI ST108** are two released standards which specifically address water in sterile processing environments

  - **ST108** expands upon [and replaces] the guidance of TIR34 to offer **a comprehensive approach to water quality in the entire processing cycle** of reusable medical devices

ST108 Water Categories



Water Quality Guidance For Processing Stages

Utility Water Acceptable

- **Point-of-Use Treatment***
- **Cleaning with Cleaning Agent**
- **Ultrasonic Cleaners**
- **Post-Wash Rinse**

*If conducted on sterile field, sterile water is required

Critical water should be used for the final stages of device processing and equipment requiring high-level disinfection

Critical Water Recommended

- **Final Rinse**
- **Thermal Disinfection** or **Pasteurization**
- **Steam Sterilization**

For local steam generation, the condensate pH should be 5.0 to 7.5.

For boiler-treated steam, most boilers should be treated to maintain a condensate pH of 7.5 to 9.2

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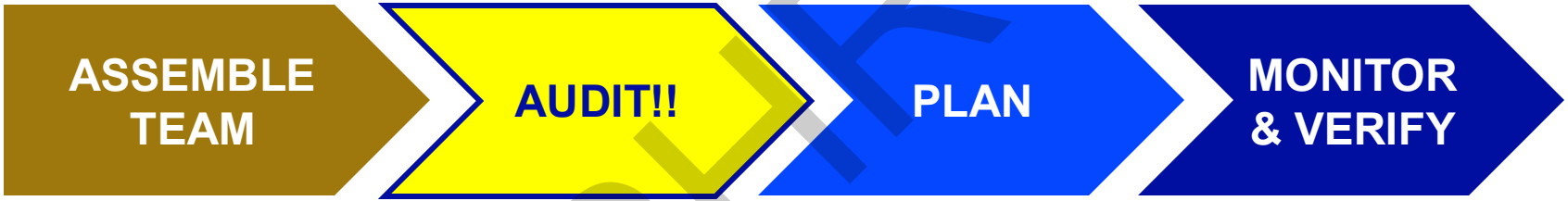
Requirements and Recommendations

Steps To Implementation



A successful plan of execution is impossible without an accurate and thorough assessment of your current setup

ST108 Water Management Framework

- **Multidisciplinary Team** Oversight
- System Description & Process Mapping
- Risk Assessment & Hazard Identification
- Water Quality Specifications & Acceptance Criteria
- Monitoring and Sampling Plan
- Corrective Actions & Emergency Response
- Documentation, Trending & Review

Sterile Processing Personnel

Infection Prevention and Control Professionals

Facilities/Plant Operations

Clinical/Biomedical Engineering

Water Treatment Experts or Vendors

Surgical Staff (when applicable)

Facility Executives or Leadership

Categories & Quality Standards

Contaminant Testing Categories ⟷ Quality Standards

- Microbial Testing
- Chemical Testing
- Physical Testing

ST108 defines required testing categories to verify that water quality meets established performance limits **[defined in Table 2]**

Table 2—Categories and performance qualification levels of water quality for medical device processing

Water Quality Measurement	Units	Utility Water	Critical Water	Steam
pH @ 25 °C:	pH	6.5 – 9.5	5.0 – 7.5	5.0 – 9.2**
Total Alkalinity	mg $CaCO_3$/L	<400	<8	<8
Bacteria	CFU/mL	<500***	<10	N/A
Endotoxin	EU/mL	N/A***	<10	N/A
Total Organic Carbon (TOC)	mg/L (ppm)	N/A	<1.0	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment
Ionic Contaminants				
Aluminum	mg/L	<0.1	<0.1	<0.1
Chloride	mg/L	<250	<1	<1
Conductivity	µS/cm	<500	<10	<10
Copper	mg/L	<0.1	<0.1	<0.1
Iron	mg/L	<0.1	<0.1	<0.1
Manganese	mg/L	<0.1	<0.1	<0.1
Nitrate	mg/L	<10	<1	<1
Phosphate	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Total Hardness	mg $CaCO_3$/L	<150****	<1	<1
Zinc	mg/L	<0.1	<0.1	<0.1

ST108 Water Testing Frequency

ST108 REQUIRES routine testing on monthly and/or quarterly basis

*Multiple tests may be done using same sample

Table 5—Frequency for water quality monitoring at water generation system

Water quality measurement	Type of testing	Routine monitoring sampling site	Minimum frequency of testing*	
			Utility Water	Critical Water
pH	pH meter** or Colorimetric dipsticks (sample tested within 15 minutes)	After the last treatment step	Quarterly	Monthly
Conductivity	Conductivity meter (in line or by measurement of a collected sample)	After the last treatment step, Storage tanks (if used)	Quarterly	Daily
Total Alkalinity	Colorimetric dipsticks Alkalinity test kit**	After the last treatment step, storage tanks (if used)	Quarterly	Monthly
Total Hardness	Determination of ppm as $CaCO_3$ by Colorimetric dipsticks, Titration kit**, or Handheld meter**	After the last treatment step	Quarterly	Monthly
Bacteria	Heterotrophic plate count (see Annex H)	Loop out and loop return points	N/A	Monthly
Endotoxin	LAL test (see Annex H)	Loop out and loop return points	N/A	Monthly

Table 6—Frequency for water quality monitoring at point-of-water-use

Water quality measurement	Type of testing	Routine monitoring sampling site	Minimum frequency of testing*		
			Utility Water	Critical Water	Steam
pH	pH meter** or Colorimetric dipsticks (sample tested within 15 minutes)	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Conductivity	Conductivity meter** or Colorimetric dipsticks	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Total Alkalinity	Colorimetric dipsticks or Alkalinity test kit**	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Total hardness	Determination of ppm as $CaCO_3$ by Colorimetric dipsticks, Titration kit** ,or Handheld meter**	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Bacteria	Heterotrophic plate count (see Annex H)	Each location of point-of-use in department	Quarterly	Monthly	N/A
Endotoxin	LAL test (see Annex H)	Each location of point-of-use in department	N/A	Monthly	N/A
Visual Inspection	Visual Inspection of inside of equipment - Look for residue, staining, scaling, and discoloration (Annex I)	Spray Arms/Inside Chamber Walls/Inside Interior of Machine	Daily	Daily	Daily

Impact of Chemical and Organic Contaminants

Total Organic Carbon (TOC) — supports biofilm growth; reduces disinfectant effectiveness

Chlorine, Chloramine — corrode metals; degrade medical devices and membranes

Iron, Manganese, Copper, Zinc — stain/discolor; cause scaling and fouling

Sodium, Dissolved Salts — interfere with detergents; alter water chemistry and cleaning

Hardness (Calcium, Magnesium) — causes scaling and deposits; reduces cleaning efficacy; damages instruments

pH (high or low) — promotes corrosion; affects detergent stability

Conductivity — indicator of total dissolved ions; helps detect elevated salts/metals that harm cleaning and devices

CASE STUDY: Sterilization Failure Due to Hard Water

165 surgeries postponed

Source: https://hospitalnews.com/sterilization-failure-halts-surgeries-offers-lessons-for-hospitals-nationwide

Notes On Disinfection

- The frequency of disinfection will vary with system design...
  - Should be performed **at least** monthly

- If biofilm has formed, disinfection might be more effective if the pipes are treated with a descaling agent before disinfection is performed.

Also…

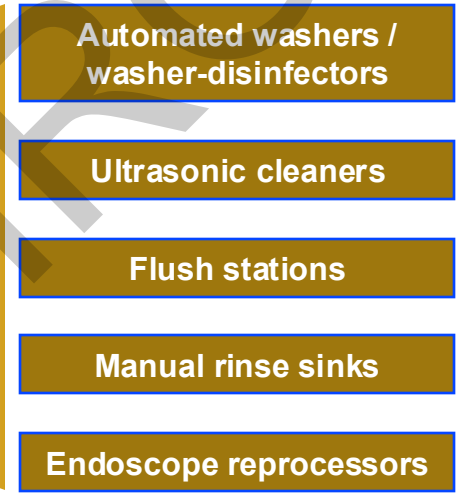
A storage tank can harbor bacteria
*> They are **not** recommended unless frequently drained and adequately disinfected*

For critical devices, pyrogenic reactions are a significant consideration [endotoxins]

"Monitoring bacteria and endotoxin levels serves to demonstrate that the disinfection program is effective, not to indicate when disinfection should be performed"

ST108 Water Sampling Recommendations

Sampling locations shall be chosen to provide a representative microbial and chemical quality picture of the system including points at or near device contact and at distribution loop termini; additional points may be added if risk analysis identifies vulnerabilities



(the final rinse water connection is considered a point where water contacts devices)

(explicitly referenced in Annex C)

Source: ANSI/AAMI ST108:2023, Section 6.3 Routine Monitoring and Annex G (guidance on selecting sampling locations)

FOCUS: Defining "Point-Of-Use"

Point-of-Use Treatment

Occurs immediately after patient use and can include:
- rinsing,
- flushing,
- wiping,
- disconnecting accessories,
- preparing for transport,
- placing it in container

Point-of-Water Use

The closest point in the distribution loop where water is exposed to a medical device during processing

Point-of-Water Use System

Water treatment system in which purification (usually filtration) takes place just before a single water supply outlet

> **EXs:** a filter in the line leading to the faucet or attached to end of faucet

NOTE: **Biofilm can develop after just 20 minutes!!**

Notes On Water Sampling

Sample Collection

- Samples should be collected from several locations within the distribution system to provide a representative microbial water quality of the system
  - In general, samples should be collected at the **beginning** and **end** of the water distribution loop
  - Where any storage tank is used, water should be sampled at the **end of the purification process** and the **exit of the storage tank**

Sampling Technique

- Sampling should be consistent in procedure and location
- Samples should always be collected **before disinfection** of the water treatment system
- Sample points should be **flushed** prior to sampling
  - For at least 60 seconds
- **Sampling locations**
  - Should not be a stagnant water environment when not in use
  - Must be accessible to the distribution loop disinfection process

Sample Containers

- Appropriate containers must be used
  - A sterile & pyrogen-free (endotoxin-free)
- Must not introduce or allow contamination into the test sample

FOCUS: Sample Ports

- **From Annex G:**
  - “Sampling locations should be selected to represent the water used for device processing and to verify control of the distribution system (eg, distal outlets, end of loops).”
- **From Annex H:**
  - “Dead legs and unused branches should be minimized or eliminated to prevent stagnation and biofilm formation. When they cannot be eliminated, appropriate control measures and monitoring should be implemented.”
- **From Section 6.3, Annex D/E; EN285 practice:**
  - Facilities are required to verify steam quality (chemical and microbial safety).
    - While ST108 does not prescribe a specific sampling method, accepted practice (per AAMI ST79 and EN 285) is to collect **condensed steam under controlled conditions** so dryness fraction, non-condensable gases (NCG), and conductivity results are valid

ANSI/AAMI ST108:2023

Implementation

COMPARISON: Reverse Osmosis (RO)

Benefits

- Removes most dissolved salts, minerals, and many chemical contaminants with semipermeable membranes
- Produces high-purity water suitable for Critical Water supply
- Permeate can be slightly acidic due to dissolved CO_2
- Available in a wide range of flow capacities (eg, 30-100+ gpm)

Challenges

- *Requires downstream control and monitoring to reinforce endotoxin control*
- *Rejects 25–75% of feed water (waste stream)*
- *Membranes foul and degrade; require maintenance and sanitization*
- *Bacteria and biofilm can develop if system is idle or poorly disinfected*

COMPARISON: De-Ionization (DI)

Benefits:

- Purifies through ion exchange (NO membrane)
- Removes most dissolved salts and ionic contaminants
- Rapid swap-and-go resin cylinders; no on-site chemicals
- Achieves high chemical purity (very low conductivity)
- More efficient (less wastewater) than RO

Challenges:

- ***Does not address bacteria or endotoxins***
- *Resin fouling is a risk and can promote microbial growth*
- *Does not remove non-ionic organics or particulates; dissolved gases (oxygen, CO_2) remain*

COMPARISON: Ultraviolet Light (UV)

Benefits:

- Non-chemical microbial reduction (eg, removes bacteria, viruses, protozoa)
- Immediate on-demand disinfection without adding heat or chemicals
- Minimal footprint

Challenges:

- *No residual effects (water can be recontaminated downstream)*
- *Efficacy declines with turbidity or high TOC*
- *Lamps require monitoring and replacement*
- ***Does not address endotoxins***

FOCUS: Endotoxin Filtration

- [Steam] Sterilization may not eliminate endotoxin presence – test before and after sterilizer to ensure safety
- Dedicated endotoxin filtration can address gaps in other water purification steps
- **Not all endotoxin filtration is the same!** Retention via positively charged membranes vs. size exclusion:

Charged membrane filtration	Size exclusion filtration
Higher flow rate	Lower flow rate
Less effective endotoxin retention	Highly effective endotoxin retention
Prone to clogging / fouling; shorter filter life	Consistent performance throughout filter life
Expensive, specialized materials	Cost-effective and easy to maintain

Size exclusion endotoxin filtration is more effective, reliable, and long-lasting

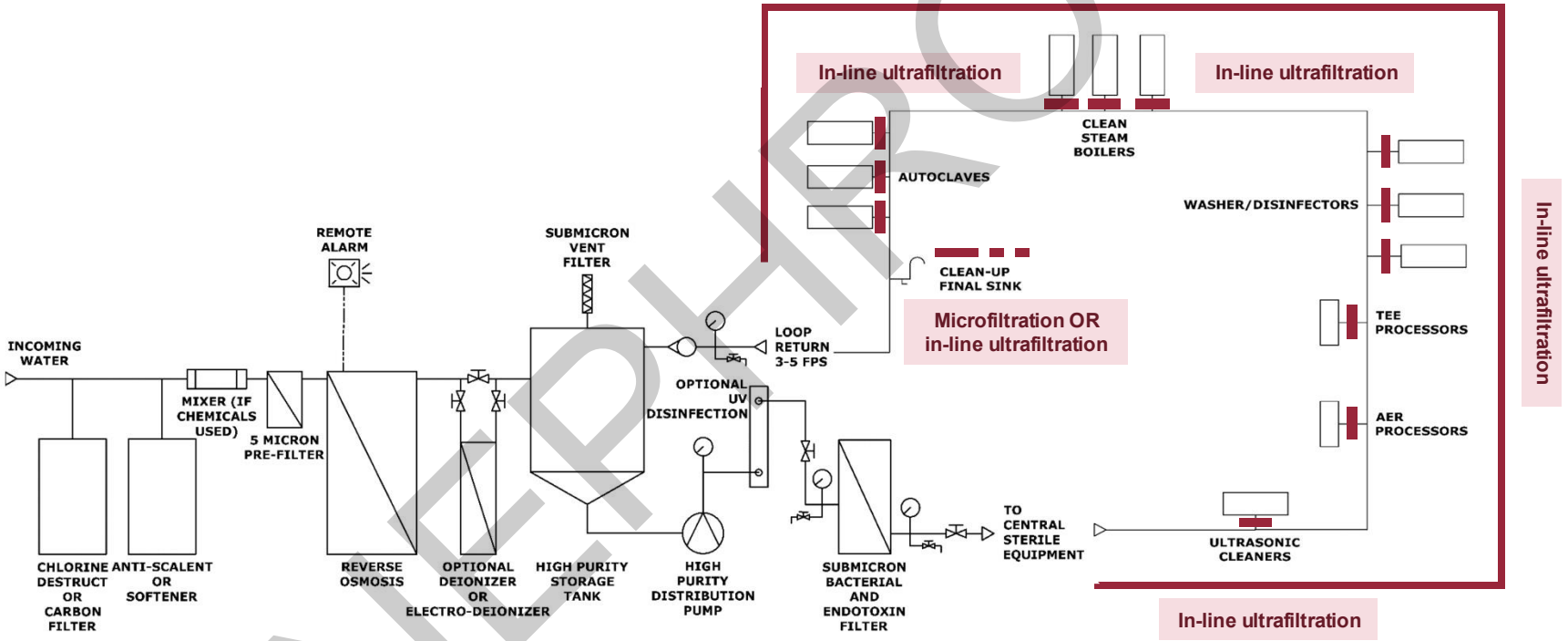
ANSI/AAMI ST108:2023

Micro- And Ultrafilter Solutions For Compliance And Water Safety

ANSI/AAMI ST108 references filtration as a key microbial hazard control strategy, especially at, or near, the point-of-use

For superior water safety support within sterile processing, **size exclusion**-powered **micro-** and **ultrafilters** can act as **physical barriers to biological contaminants**

Nephros Water Filter Applications In SAMPLE Sterile Processing Loop



Examples

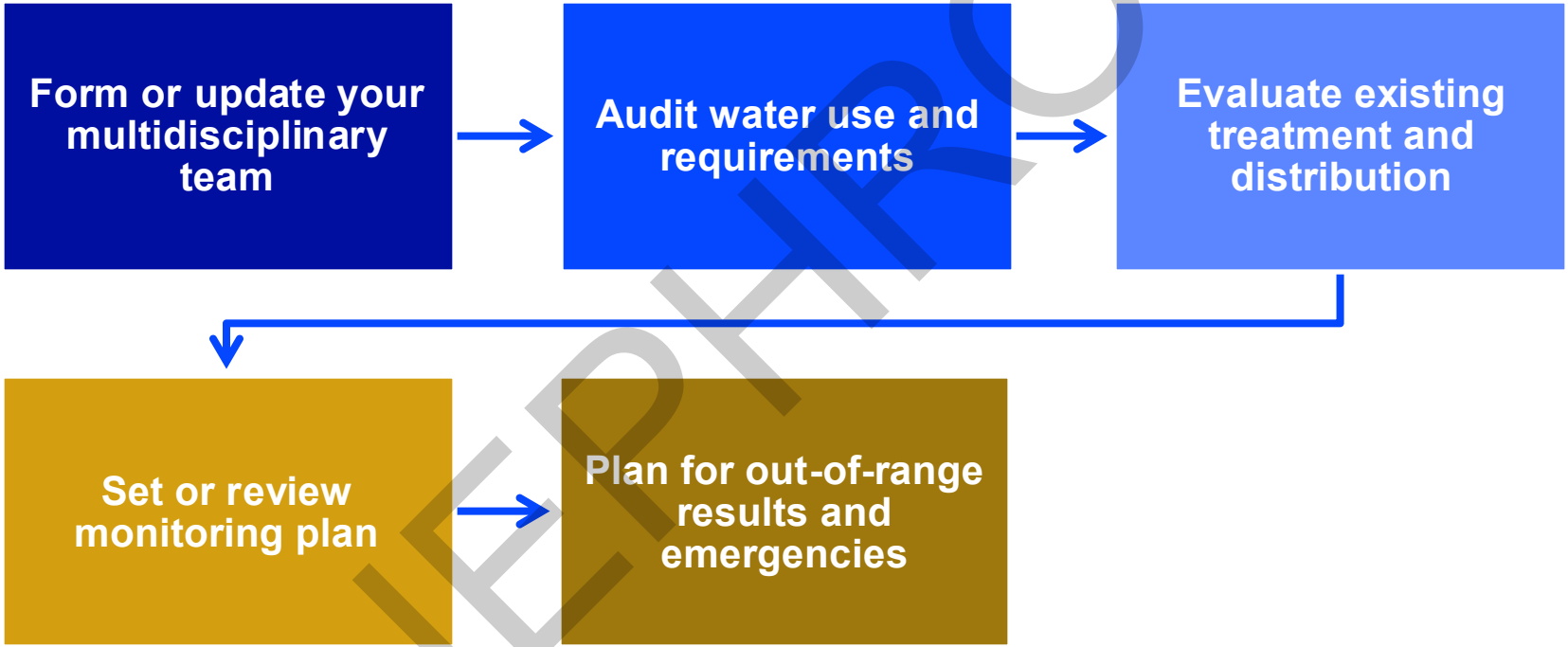
CRITICAL WATER

Takeaways

ST108 Summary

- ST108 addresses three categories of water: **Utility**, **Critical**, and **Steam**
- New & updated water quality considerations address **endotoxins**, alkalinity, total organic compounds (TOC), and ionic contaminants
- Water testing requirements bring **stricter oversight of bacteria presence**
- Ultra- and microfiltration solutions are ideal for multiple placements within both **Utility** and **Critical** water treatment
  - Leveraging water filters in the sterile processing loop **address process gaps** and ensures optimal water quality

Where to Start



Source: ANSI/AAMI ST108:2023 — Section 4 (Water Management Program), Section 6.3 (Water Quality Requirements & Monitoring), Annex B, G, H.

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