AAMI STANDARD 108

What It Is and What It Means for Your Sterile Processing Department

JAMIE MUNDA

- Water Safety Specialist (2019)
- Water Safety Industry Technical Consultant (2017)
- Dow Chemical – Senior Microbiologist / Industrial Hygiene Auditor (2006)
- University of Illinois – B.S. Molecular Cellular Biology
- Avid Baseball Fan
- Married to Steve
- Mom to 3

PURPOSE, PROCESS, PAYOFF

PURPOSE

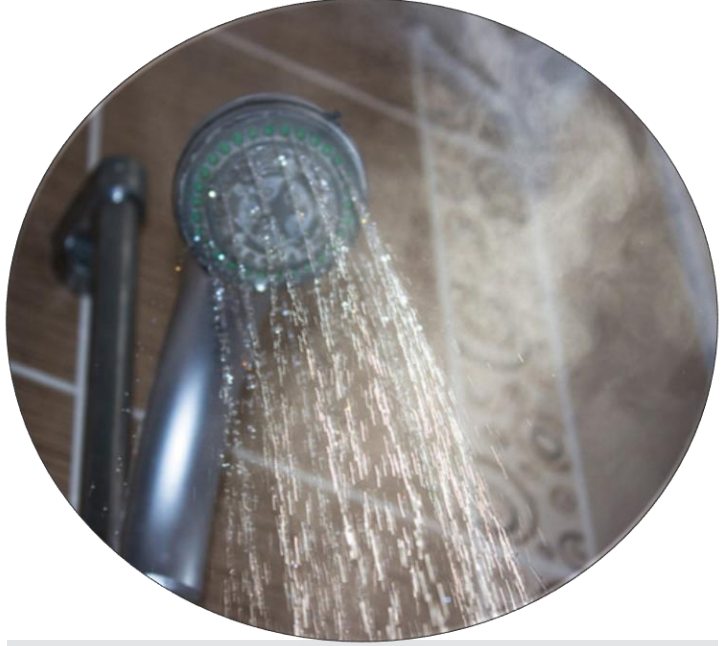
To discuss the new AAMI Standard for Sterile Processing and how it will impact Sterile Processing/Central Sterile Departments

PROCESS

Review Guideline (TIR34) as well as the requirements outlined in the new Standard (ST108)

PAYOFF

Provide awareness of the necessary steps to bring the monitoring of your Hospital's Sterile Processing Department into compliance with the new Standard to achieve your Water Safety goals



1

DOMESTIC

35%

2

HVAC

20%

3

MEDICAL DEVICE REPROCESSING

15%

WATER USE IN HOSPITALS

Source: New Mexico Office of the State Engineer, American Water Works Association (AWWA), AWWA Research Foundation, and East Bay Municipal Utility District.

WHY IS WATER IMPORTANT?

In Medical Device Reprocessing…

- Water is involved in nearly every part of instrument reprocessing:
  - Pre-cleaning
  - Manual cleaning
  - Ultrasonic
  - Washer/Disinfector
  - Rinsing
  - Steam Sterilizer/ Autoclave
  - Cart Washer
- Water spotting and staining cause questions about instrument cleanliness
- Water quality can affect instrument longevity and function
- Mineral deposits can hinder sterilization effectiveness
- Waterborne pathogens can be a source of HAIs & SSIs

FACTORS AFFECTING DEVICE PERFORMANCE, CLEANLINESS & DISINFECTION

- TOC
  - Interferes with efficiency of enzymatic detergents, disinfectants & sterilants
  - Provides nutrition to microorganisms; can contribute to microbial growth & discolor devices
- Dissolved Salts (Na, Mg, Ca, P, Zn)
  - Decreases performance of washers/disinfectors and effectiveness of detergents
- Ionic Molecules (Cl, Mn, Cu, Fe)
  - Main cause of pitting to instruments
- pH
  - Pitting and Corrosion of devices; decreases effectiveness of detergents
- Bacterial Endotoxin
  - Causes fever, meningitis, hypotension. Sterile devices must have endotoxin levels within specific limits

ROLE OF SPD IN INFECTION PREVENTION

"The importance of this [SPD] role in the prevention of nosocomial [HAIs] is clear: **reusable medical devices improperly handled, disinfected, or sterilized provide a source of contamination and increase the risk of transmission of infection to both patients and the staff involved in reprocessing procedures.**"

Pugliese, Gina and Hunstiger. Central Services, Linens and Laundry. In Hospital Infections. Edited by John V. Bennett and Philip S. Brachman. 3rd ed.

CURRENT GUIDELINES FOR WATER QUALITY

AAMI- The Association for the Advancement of Medical Instrumentation

- AAMI ST79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI TIR34 - Water for the reprocessing of medical devices
- AAMI ST108 – Water for the processing of medical devices
- AAMI TIR110 – Working Group; intended to provide guidance for healthcare facilities concerning the technical information, testing and qualification of water systems defined by and built to meet the requirements of ST108

VHA Directive 1116(2) Sterile Processing Services

Equipment Manufacturers IFUs (instructions for use)

AAMI "**Technical Information Reports**" are a review of technical issues relevant to a particular technology and statement of expert opinion. A TIR contains guidelines rather than requirements.

AAMI "**Standards**" are consensus documents that provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

AAMI ST108:2023

Water for the processing of medical devices

- Published August 2023
- Revises and replaces TIR34
- Developed to provide requirements – versus guidance – for water used in the processing of medical devices.

INDUSTRY STANDARD

What is driving this change?

FDA has identified cases in which

Healthcare-Associated Infections (HAIs) affect **5-10%** of hospitalized patients, with **1.7 million HAIs** per year – resulting in **99,000 deaths** and **billion** per year in the USA. Surgical ons accounts for **20%** of those HAIs, most costly HAI type with an annual

Per the Joint Commission – *the cleaning of medical equipment ranks in the Top 10 of compliance issues.* (IC02.02.01 standard helps organizations reduc of infections associated with m equipment, devices and suppl

CMS reports that 1/3 of hospitals have reprocessing deficiencies.

CMS lists SSIs as “Never Events” & costs will not be reimbursed by Medicare.

INDUSTRY STANDARD

Experience of Loss Due to Inferior Water Quality?

"Surgical procedures account for more than 60% of the operating costs of a hospital and about 15% of those costs – or roughly 9% of total hospital operating costs – are spent on surgical instrume
For a medium-sized hospital, that's $4 million t
million per year in total surgical instrumen
spending."

Improved water quality can theoretically extend instrument life by 5%, and a medium-sized hospital could save $200-$350K per year.

INDUSTRY STANDARD

Requirements…Who is enforcing this?

- Does your hospital have an internal policy that defines their SPD requirements? Are any guidelines/standards currently being followed? Does it reference TIR34?
- The FDA and CDC both reference TIR34…
  - FDA: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff
    - "We recommend that you refer to the current version of AAMI TIR34 "Water for the reprocessing of medical devices" for more information on final rinse water quality and to establish the optimal water quality for final rinses…"
  - CDC: Lists AAMI TIR34 under "Applicable Standards, Guidelines, and Regulations"
- The Joint Commission
  - Facilities must use evidence-based guidelines and standards (EBG) when developing infection prevention and control activities (IC.01.05.01)
  - Environment of Care
- DNV
  - Advanced Sterile Processing Certification (ASPC) Requirements – Revision 23-0

AAMI ST108:2023

Water for the processing of medical devices

What to Expect with the new AAMI Standard 108?

- Sets three categories of water used in processing (Utility, Critical & Steam)
- Provides guidance for when and where to use water of each category
- Provides information on how to ensure water continues to meet those quality requirements, at a minimum
- Sets performance criteria for a water treatment/delivery system & monitoring program

ROLES AND RESPONSIBILITIES

ST108, Section 4.3 – Multidisciplinary Team Roles

"Facilities engineering personnel are responsible for the water system installation, qualification, validation for the appropriate water quality for device processing and water system maintenance."

"Medical Device Processing Personnel are responsible for the cleaning, disinfection, inspection and sterilization of medical devices….they are responsible for monitoring processing equipment and medical devices being processed…."

ROLES AND RESPONSIBILITIES

ST108, Section 4.3.3 – Infection Prevention and Control Personnel

- Review the water management program
- Perform ongoing surveillance monitoring of patients who were potentially exposed to waterborne pathogens carried by instruments
- Review water monitoring test results
- Facilitate/perform risk assessment related to water quality impacting the Medical Device Processing Department
- Bring concerns/issues to the Infection Prevention & Control Committee, escalate as needed.

AAMI ST108

Categories of Water

UTILITY	Water as it comes from the tap. Mainly used for flushing, washing & intermediate rinsing. **May require further treatment to achieve the specifications.
CRITICAL	Water that has undergone extensive treatment to remove inorganic and organic matter as well as microorganisms. This usually requires a multistep process involving a combination of the following: softening, carbon bed, deionization, reverse osmosis and/or distillation. This water is used for final rinses after high level disinfection and/or critical devices prior to sterilization. **Using critical water for all stages of medical device processing may be unnecessary and costly and can cause damage to equipment.
STEAM	Vaporized water produced by a centralized boiler or generator at the point-of-use. When the steam is tested as condensate, it should meet the criteria for the specific described. **Critical water may not be compatible with iron boilers.

WATER QUALITY SELECTION & REQUIREMENTS

Categories of Medical Devices

Critical	Semi-Critical	Non-Critical
Instruments or objects that are introduced directly into the human body, and products with sterile fluid pathways. Items present a high degree of risk of transmission of infection if contaminated.	Instruments or objects that contact intact mucosal membranes or nonintact skin. Semi-critical devices should be sterilized – if feasible – or minimally subjected to high-level disinfection.	Instruments or objects that usually contact only the intact skin. These items rarely, if ever, transmit infections directly to patients.

THINK PROCESS VALIDATION…

Installation Qualification / Operation Qualification / Performance Qualification

Performance Qualification demonstrating that the process will consistently produce acceptable results under normal operating conditions.

Water Quality Measurement	Units	Utility	Critical	Steam
pH @ 25C	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 & Turbidity	Visual	Colorless, Clear, no residues	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	µSiemens/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

RISK ASSESSMENT

AAMI ST 108, Section 5: Risk Assessment

- TJC Water Management Standard (EC.02.05.02, EPs 1-4) & CMS Requirement QSO17-30
  - Both require health care facilities to have a WMP with an individual or team responsible for oversight and implementation of the program and provide requirements for water quality production including a risk assessment. Other accrediting agencies have similar requirements.
  - AAMI ST108 assists in increasing the awareness of health care personnel on the gross indicators that suggest that there may be problems with water quality. Monitoring water quality is a process meant to confirm that control strategies are working properly.

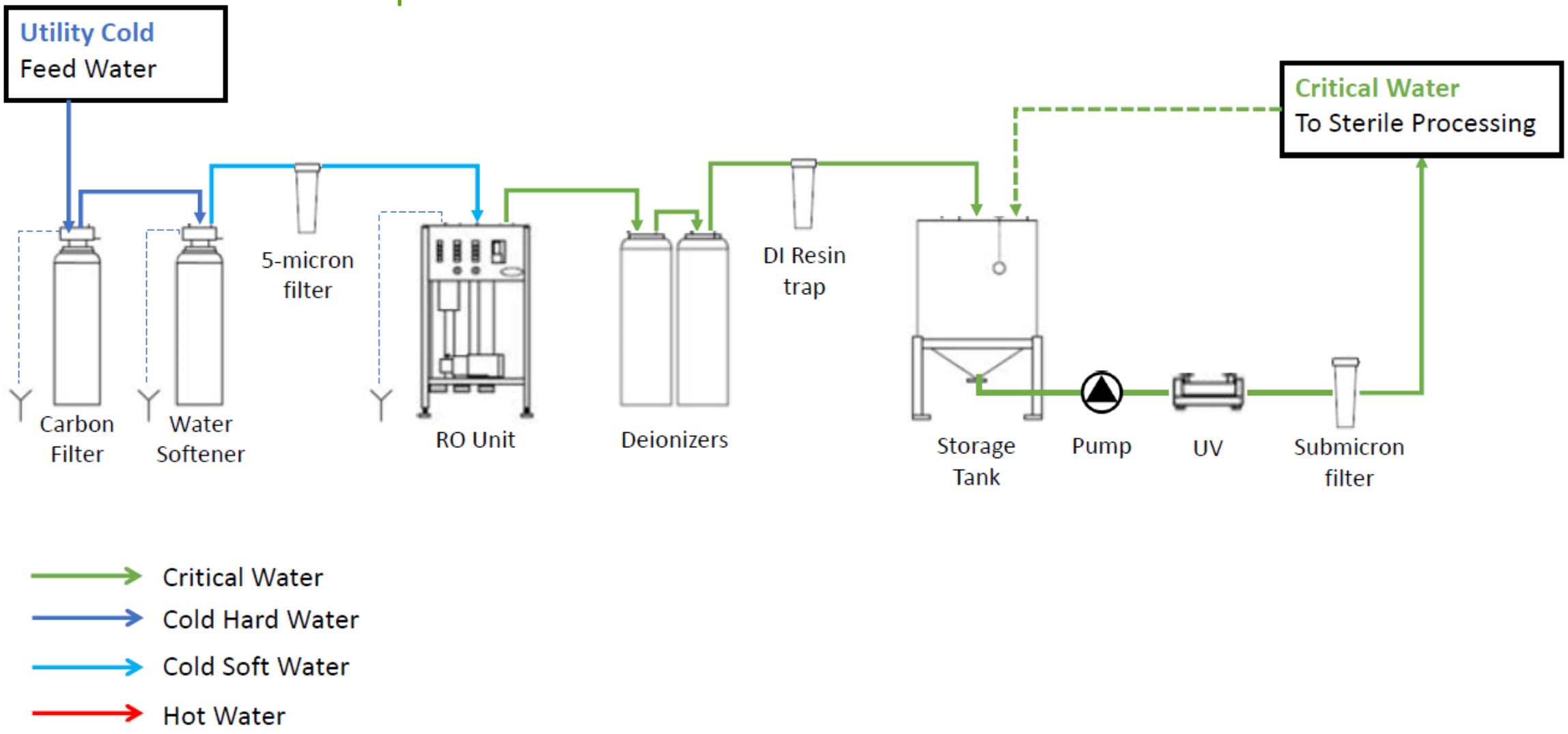
RISK ASSESSMENT

Equipment Identification

- Capture all the types of equipment that use water within your Department
  - Examples include, but are not limited to…
    - Decontamination Sinks
    - Ultrasonic
    - Washer/Disinfectors
    - High Level Disinfection & Rinsing
    - Sterilizers/Autoclaves
    - Cart Washers
- Specify which water quality is used at each piece of equipment
  - Note - some equipment may utilize multiple water qualities

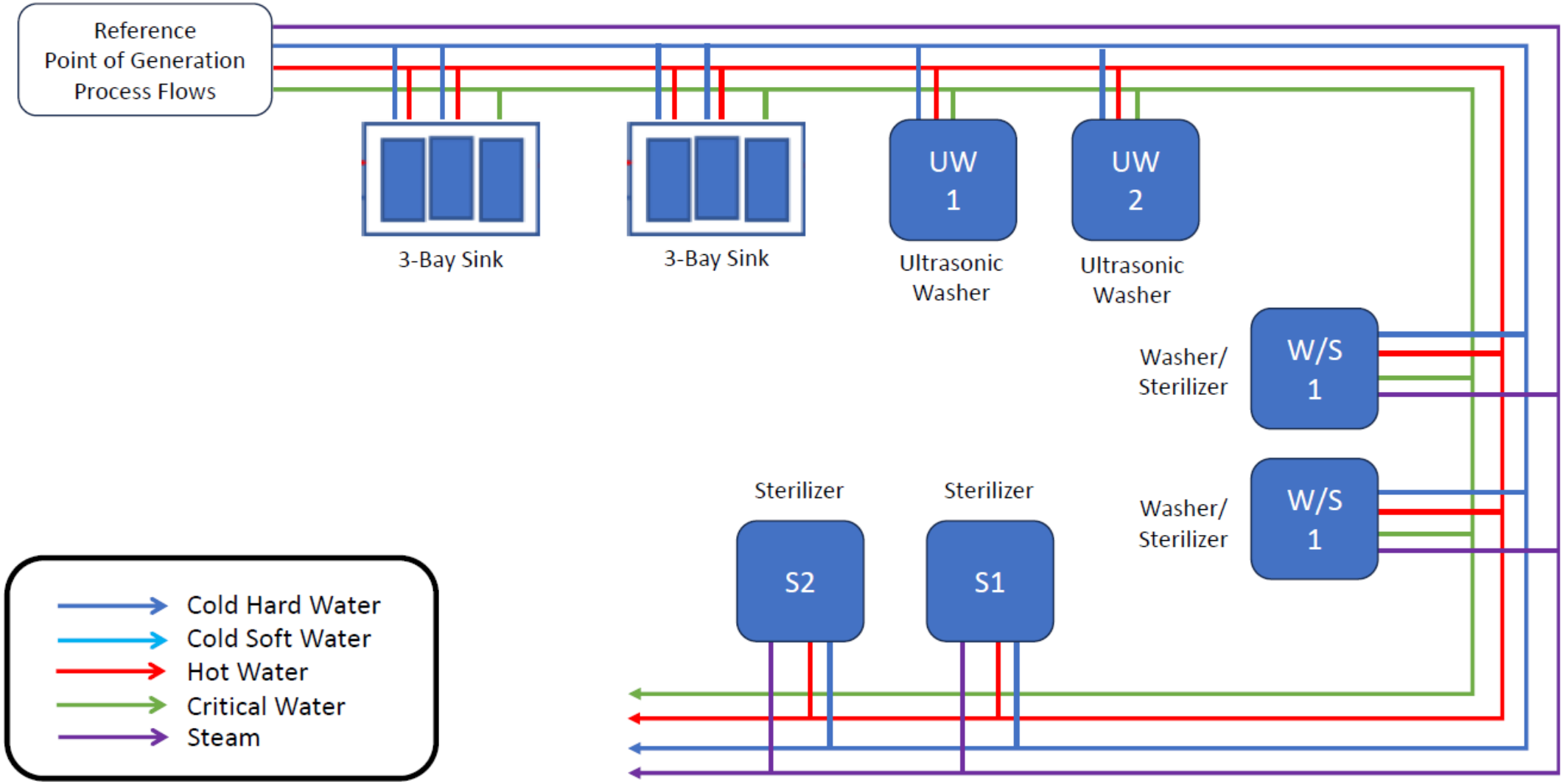
RISK ASSESSMENT

SPD Process Flow Example



RISK ASSESSMENT

SPD Process Flow Example



ROUTINE MONITORING

Ongoing monitoring is performed to verify that the water quality is maintained and does not deteriorate over time. If water quality is not monitored, the water treatment system could become heavily contaminated with microorganisms or other contaminants and could contribute to corrosion, staining, and increased microbial levels after processing.

Parameter	Units	Utility Water	Critical Water	Steam
pH @ 25C	pH	6.5 – 9.5	5.0 – 7.5	5.0 – 9.2
Conductivity	µSiemens/cm	<500	<10	<10
Total Alkalinity	mg CaCO3/L	<400	<8	<8
Total Hardness	mg CaCO3/L	<150	<1	<1
Bacteria	CFU/mL	<500	<10	N/A
Endotoxin	EU/mL	N/A	<10	N/A

ROUTINE MONITORING

Minimum Frequency for Monitoring at Water Generation Systems

Parameter	Type of Testing	Sampling Site	Minimum Frequency of Testing	
			Utility Water	Critical Water
pH	pH meter or colorimetric dipsticks	After last treatment step	Quarterly	Monthly
Conductivity	conductivity meter	After last treatment step, Storage Tanks (if used)	Quarterly	Daily
Total Alkalinity	colorimetric dipsticks	After last treatment step	Quarterly	Monthly
Total Hardness	ppm CaCO3 or colorimetric dipsticks	After last treatment step	Quarterly	Monthly
Bacteria	Heterotrophic plate count	After last treatment step, Storage Tanks (if used)	N/A	Monthly
Endotoxin	LAL test	After last treatment step, Storage Tanks (if used)	N/A	Monthly

ROUTINE MONITORING

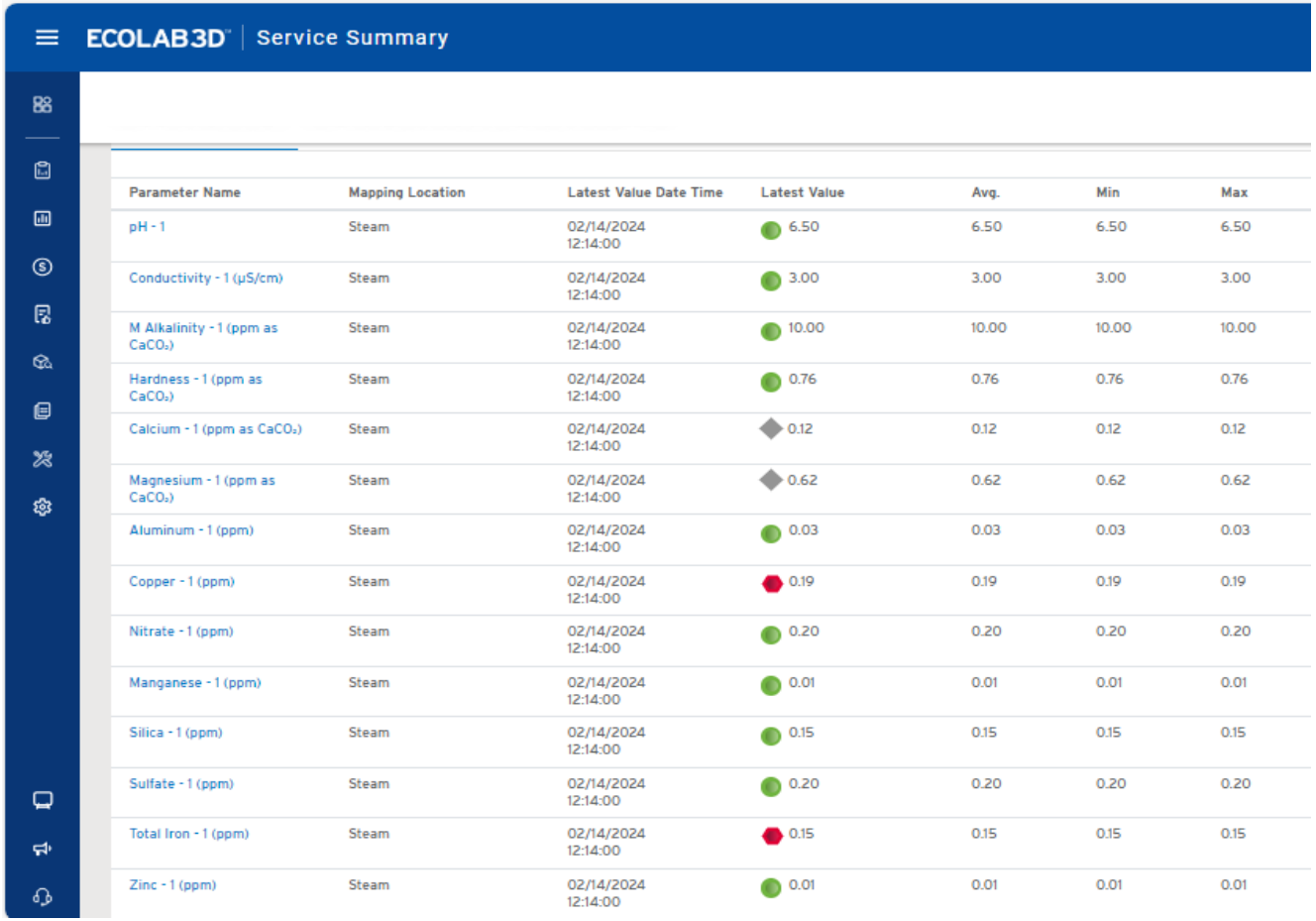
Minimum Frequency for Monitoring at Point-of-Use

Parameter	Type of Testing	Sampling Site	Minimum Frequency of Testing		
			Utility Water	Critical Water	Steam
pH	pH meter or colorimetric dipsticks	First POU on distribution loop	Quarterly	Monthly	Quarterly
Conductivity	conductivity meter	First POU on distribution loop	Quarterly	Monthly	Quarterly
Total Alkalinity	colorimetric dipsticks	First POU on distribution loop	Quarterly	Monthly	Quarterly
Total Hardness	ppm CaCO3 or colorimetric dipsticks	First POU on distribution loop	Quarterly	Monthly	Quarterly
Bacteria	Heterotrophic plate count	Each location of POU in department	Quarterly	Monthly	N/A
Endotoxin	LAL test	Each location of POU in department	N/A	Monthly	N/A
Visual Inspection	Visually inspect inside of equipment	Spray arms / inside chamber walls / inside machine	Daily*	Daily*	Daily*

WHAT DO I DO WITH ALL THIS DATA?

Analyzing Trends & Setting Alert Levels

- Trending baseline data and setting an **alert level** can give you early indication of the water quality trend. This trend can be used for early warning of issues that may impact that water quality.
- When data is outside the upper or lower alert levels, it is an **excursion**. Excursions can be identified as warning of potential issues and should prompt investigation to find the assignable causes. The monitoring program is an opportunity to address potential problematic issues prior to failing of specifications during routine monitoring.



Parameter Name	Mapping Location	Latest Value Date Time	Latest Value	Avg.	Min	Max
pH - 1	Steam	02/14/2024 12:14:00	6.50	6.50	6.50	6.50
Conductivity - 1 (µS/cm)	Steam	02/14/2024 12:14:00	3.00	3.00	3.00	3.00
M Alkalinity - 1 (ppm as $CaCO_3$)	Steam	02/14/2024 12:14:00	10.00	10.00	10.00	10.00
Hardness - 1 (ppm as $CaCO_3$)	Steam	02/14/2024 12:14:00	0.76	0.76	0.76	0.76
Calcium - 1 (ppm as $CaCO_3$)	Steam	02/14/2024 12:14:00	0.12	0.12	0.12	0.12
Magnesium - 1 (ppm as $CaCO_3$)	Steam	02/14/2024 12:14:00	0.62	0.62	0.62	0.62
Aluminum - 1 (ppm)	Steam	02/14/2024 12:14:00	0.03	0.03	0.03	0.03
Copper - 1 (ppm)	Steam	02/14/2024 12:14:00	0.19	0.19	0.19	0.19
Nitrate - 1 (ppm)	Steam	02/14/2024 12:14:00	0.20	0.20	0.20	0.20
Manganese - 1 (ppm)	Steam	02/14/2024 12:14:00	0.01	0.01	0.01	0.01
Silica - 1 (ppm)	Steam	02/14/2024 12:14:00	0.15	0.15	0.15	0.15
Sulfate - 1 (ppm)	Steam	02/14/2024 12:14:00	0.20	0.20	0.20	0.20
Total Iron - 1 (ppm)	Steam	02/14/2024 12:14:00	0.15	0.15	0.15	0.15
Zinc - 1 (ppm)	Steam	02/14/2024 12:14:00	0.01	0.01	0.01	0.01

WHERE DO I START?

Steps you can take now

- Start the conversation
- Assess current water categories

- Develop a plan to incorporate any necessary process/equipment changes
- Perform a Risk Assessment & develop a WMP specific to Sterile Processing

  - Understand current monitoring program & determine what other monitoring may be needed to achieve compliance

Pathway Toward Compliance

IN SUMMARY…

- Sterile Processing Departments play a vital role in minimizing the risk of infection
- The new AAMI Standard contains a lot of information and is intended to assist in the selection of the appropriate water quality needed for cleaning, disinfecting and sterilizing medical devices.
- Understanding key elements within AAMI Standard 108 & developing a path toward compliance are important next steps.

Jamie Munda
Nalco Water, an Ecolab Company Water Safety Specialist

jamie.munda@ecolab.com
331-230-0331


ECOLAB®
NALCO Water