AAMI STANDARD 108

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

MITCH LUKEN

- Water Safety Specialist (2022)
- Waterborne Pathogen Consultation
- ST108 Compliance
- Heidelberg University – B.S. Biology and Environmental Science
- Living in Cincinnati, OH
- Married to Olivia

PURPOSE, PROCESS, PAYOFF

PURPOSE

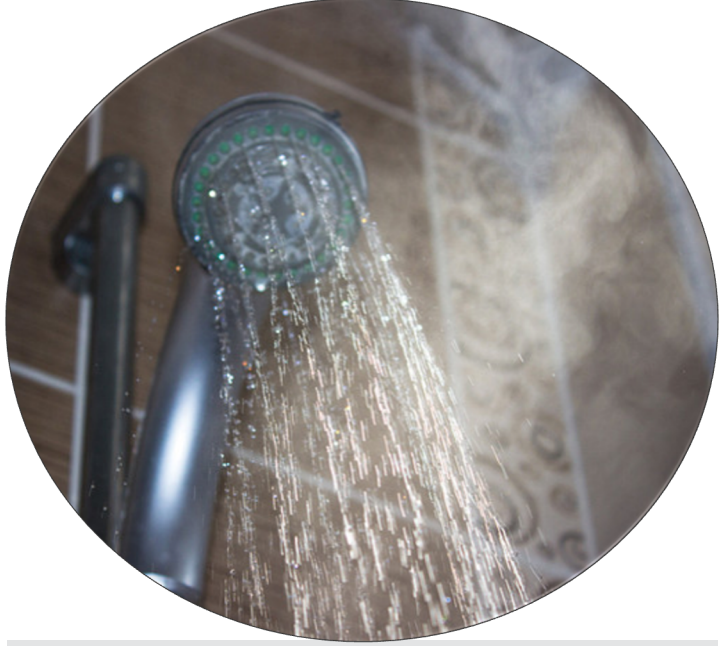
To discuss the new AAMI Standard for Sterile Processing and how it will impact Sterile Processing/Central Sterile Departments

PROCESS

Review the requirements outlined in the new Standard (ST108) and discuss potential avenues for implementation

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 STATE OF MARKET

- SPD is regulated, process and compliance-based
  - FDA (medical devices)
  - Instructions for Use (IFUs)
- ~20-30% SPDs have no water treatment – use city water for critical water
- Lack of understanding of what category of water serves what area
- Little collaboration/communication between hospital personnel and water treatment personnel
- Who is responsible for water? Sterile Processing or Facilities?
- Little or no routine monitoring of water quality
- Instrument failure/staining is common
- Blame game & root cause analysis: water, chemistry, equipment

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)

WHO IS AAMI?

AAMI - Association for the Advancement of Medical Instrumentation

- Standards and Guidelines from AAMI provide consensus and performance-based recommendations and requirements for Sterile Processing to help ensure safe processing practices and that medical and surgical devices are well functioning and available for patient care.
- AAMI Guidance documents are also referenced by accreditation agencies – including the Joint Commission (TJC) & DNV – during facility surveys.
- AAMI is compromised of a diverse community of experts in healthcare, medical device manufacturers, government and consumer representatives that develop and issue sterilization and disinfection standards as a consensus body.
- AAMI develops Technical Information Reports (TIRs), which are publications that address specific aspects of medical technology. TIRs are often developed in response to a current safety or performance issue and a standard may follow.

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 supp

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

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

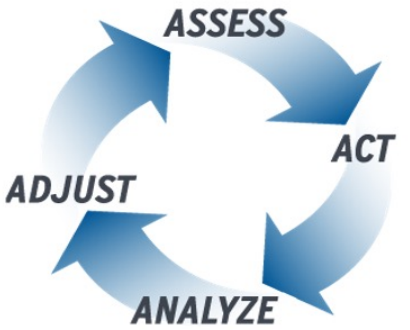
Critical	Semi-Critical	Non-Critical
Instruments or objects that are introduced directly into the human body, and products with sterile fluid pathways. Items present a high degree of risk of transmission of infection if contaminated.	Instruments or objects that contact intact mucosal membranes or nonintact 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.

THE STERILE PROCESSING WMP

Key Elements mirror ASHRAE ST188 for Domestic WMPs

- Team: roles and responsibilities
- Risk Analysis
- Categories of water quality and selection
- Validation Plan
  - Water quality and operating parameters
  - Equipment
  - Process flow diagram
  - Monitoring
  - Alert/Action levels
  - Periodic review

1. **Organize a Program Team**
   Development & Implementation
2. **Describe Your Water Systems & Flow Diagrams**
3. **Analyze System Hazards**
4. **Define Control Measures & Monitor Them**
5. **Intervene When Control Limits are Not Met**
6. **Review & Confirm the Program**
7. **Document, Communicate & Adjust**



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.

WATER FOR DEVICE PROCESSING

SPDs are typically divided into four major areas

- **Decontamination** – Initial sorting, soaking and washing
- **Prep & pack**– instruments assembled onto trays for organization and packaging
- **Sterilization** – instruments undergo sterilization using steam sterilizers
- **Cart Assembly & Storage** – instruments loaded onto carts and transported in preparation for surgical procedures

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.

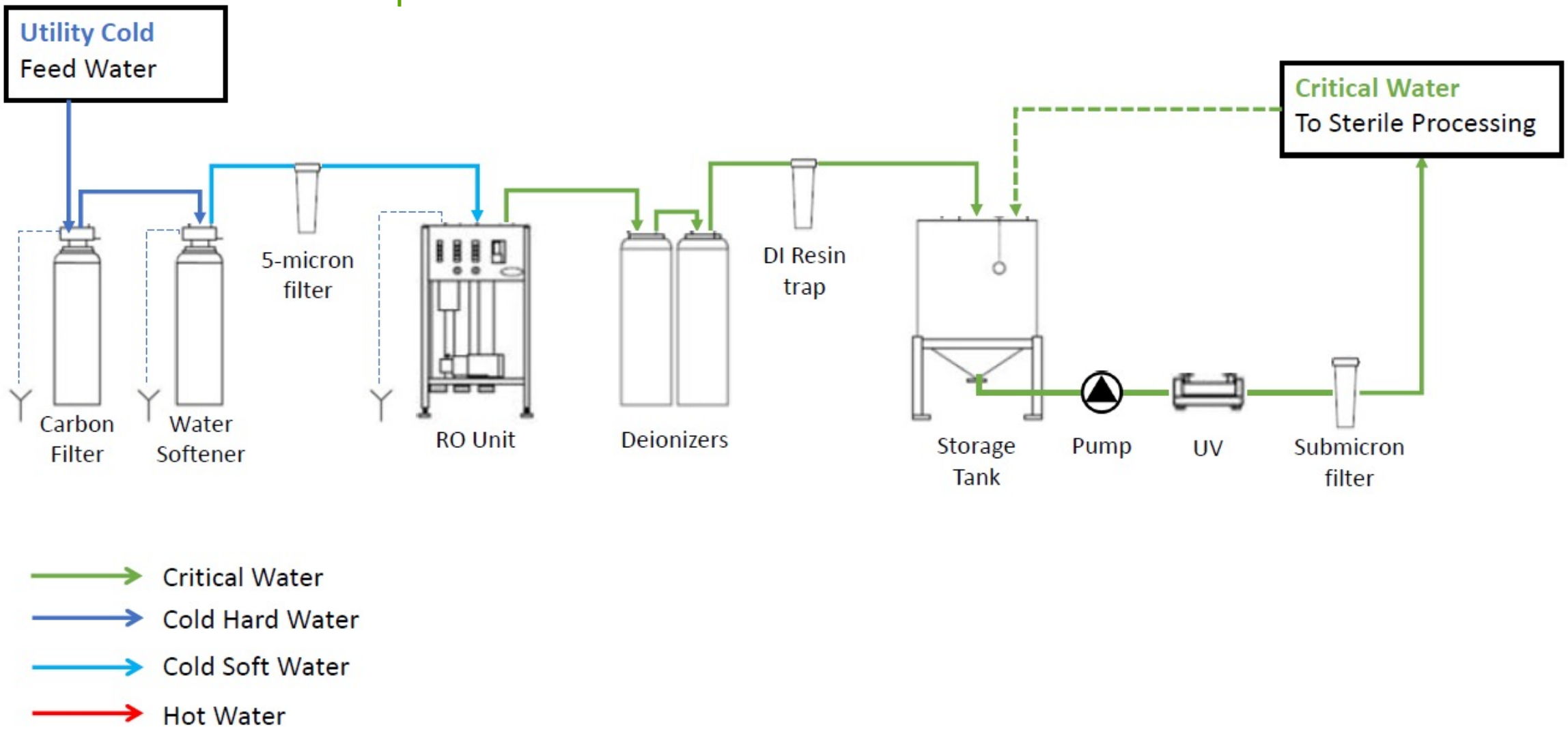
RISK ASSESSMENT

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

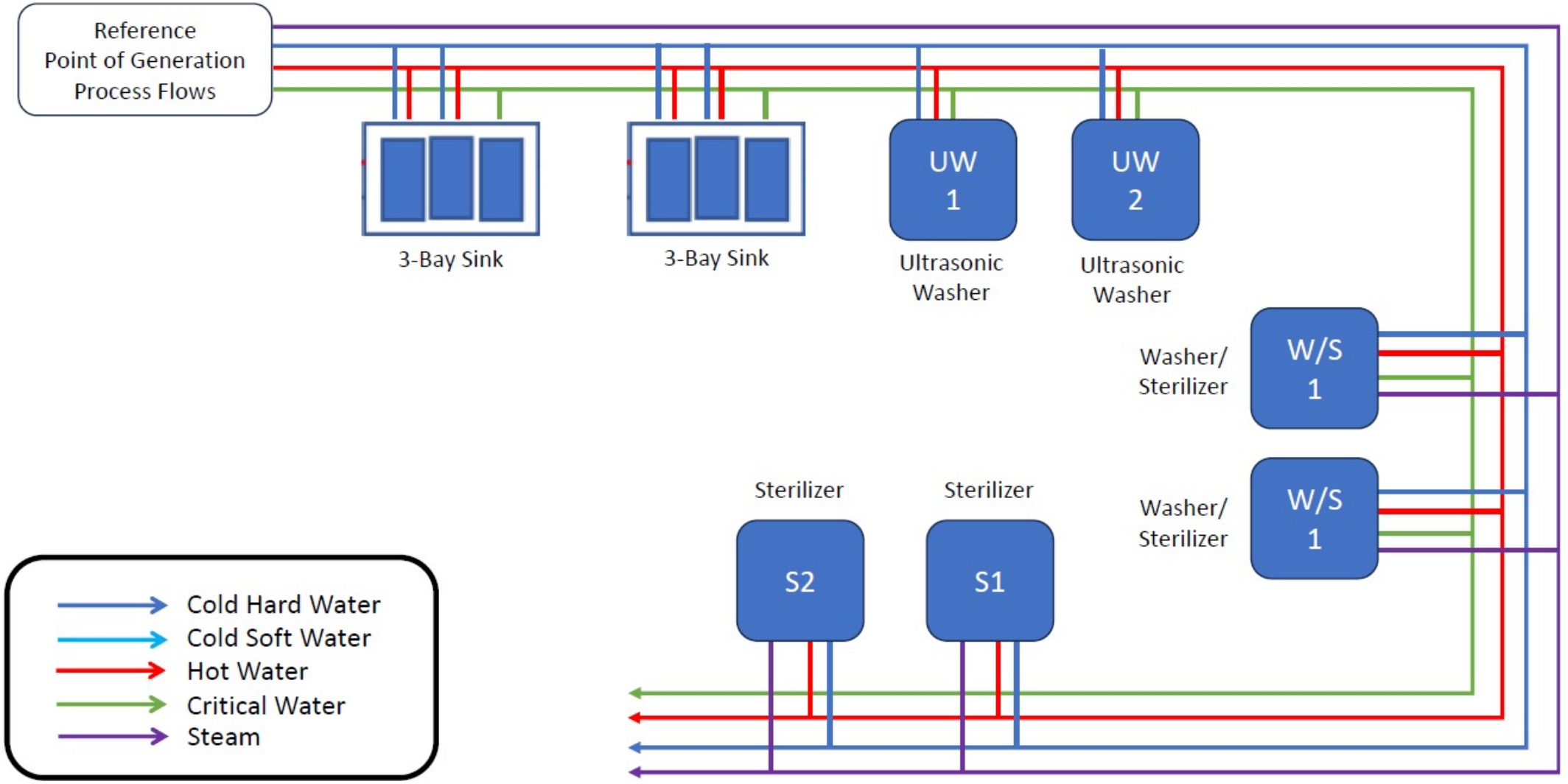
RISK ASSESSMENT

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

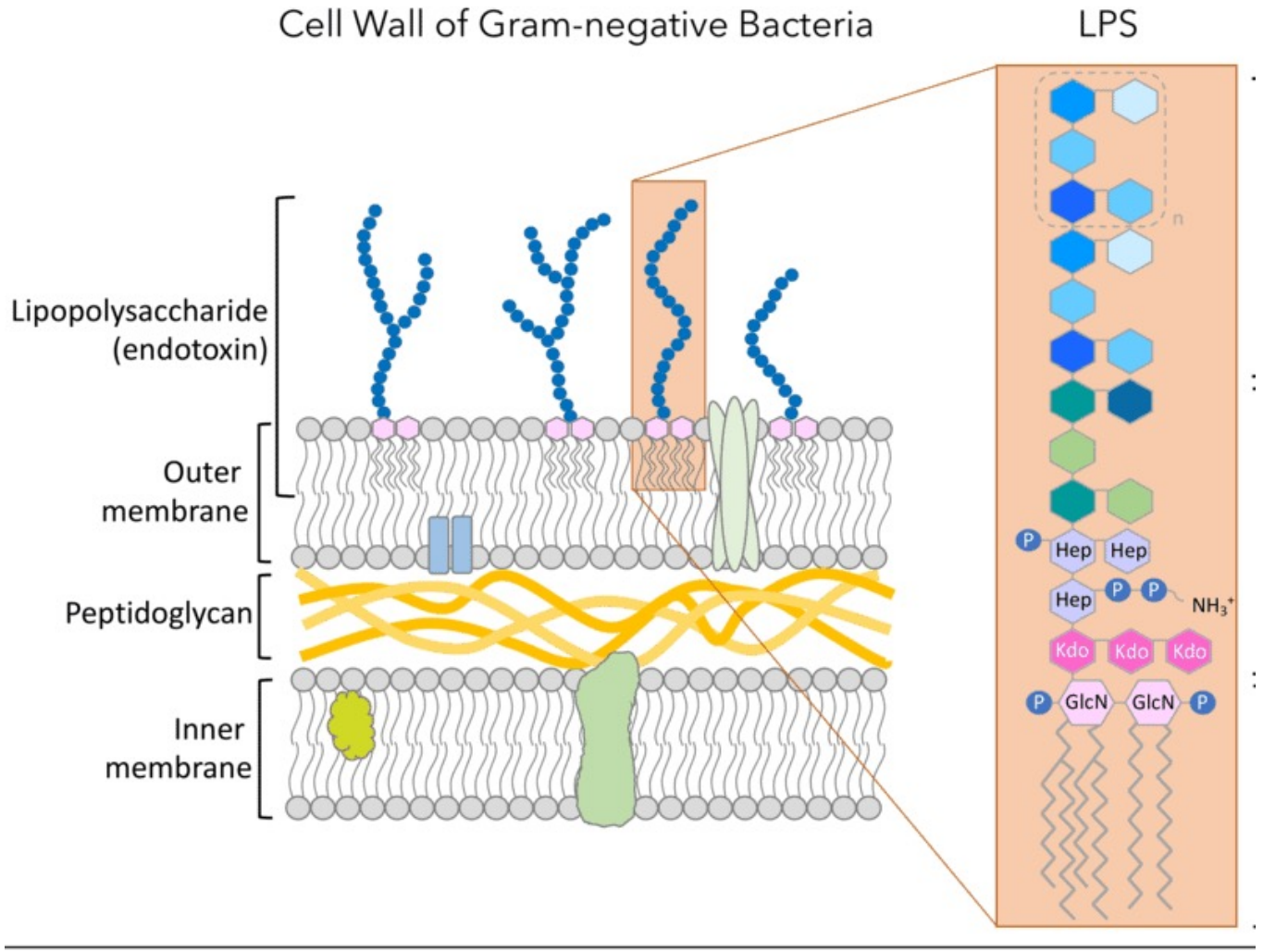
Minimum Frequency for Monitoring at Point-of-Use

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 $CaCO_3$ 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 ARE WE MONITORING?

Bacterial Endotoxin

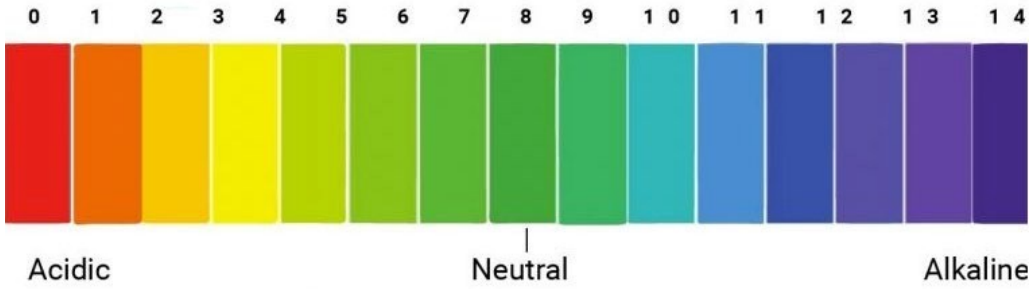
- What are Endotoxins?
  - High molecular-weight complex that contains lipopolysaccharide (LPS) protein and phospholipid originating from the outer membrane of Gram-Negative bacteria.
- Why are Endotoxins a concern?
  - The LPS protein is released when Gram-Negative bacteria divide or lyse.
  - This can cause fever, meningitis, and a rapid fall in blood pressure
  - Sterile devices mush have endotoxin levels within specified limits, per the FDA.



WHAT ARE WE MONITORING?

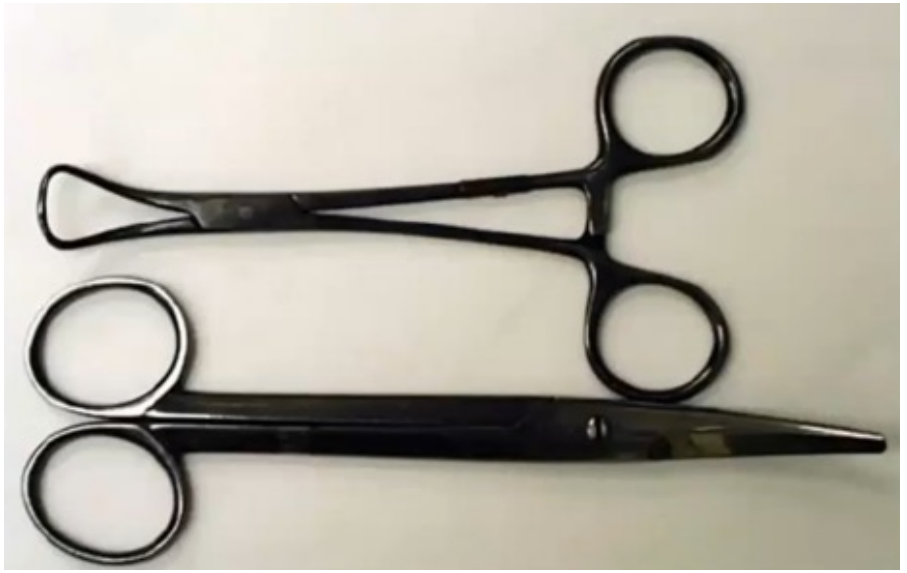
Total Organic Carbon (TOC)

- Water residuals can discolor devices
- TOC can interfere with the effectiveness of detergents, disinfectants or sterilants
- TOC can provide nutrition to microorganisms and contribute to microbial growth



pH

- Can affect detergent effectiveness
- Can cause device pitting or corrosion
- Black instruments can be an indication of pH residuals



WHAT ARE WE MONITORING?

Dissolved Salts

- Utility Water: Hardness < 150 mg/L
- Salts in hard water may deposit on instruments
- Decrease the effectiveness of most detergents / disinfectants
- Decrease the performance of washers / disinfectors
- Circles on instruments can indicate hard water

WHAT ARE WE MONITORING?

Ionic Molecules

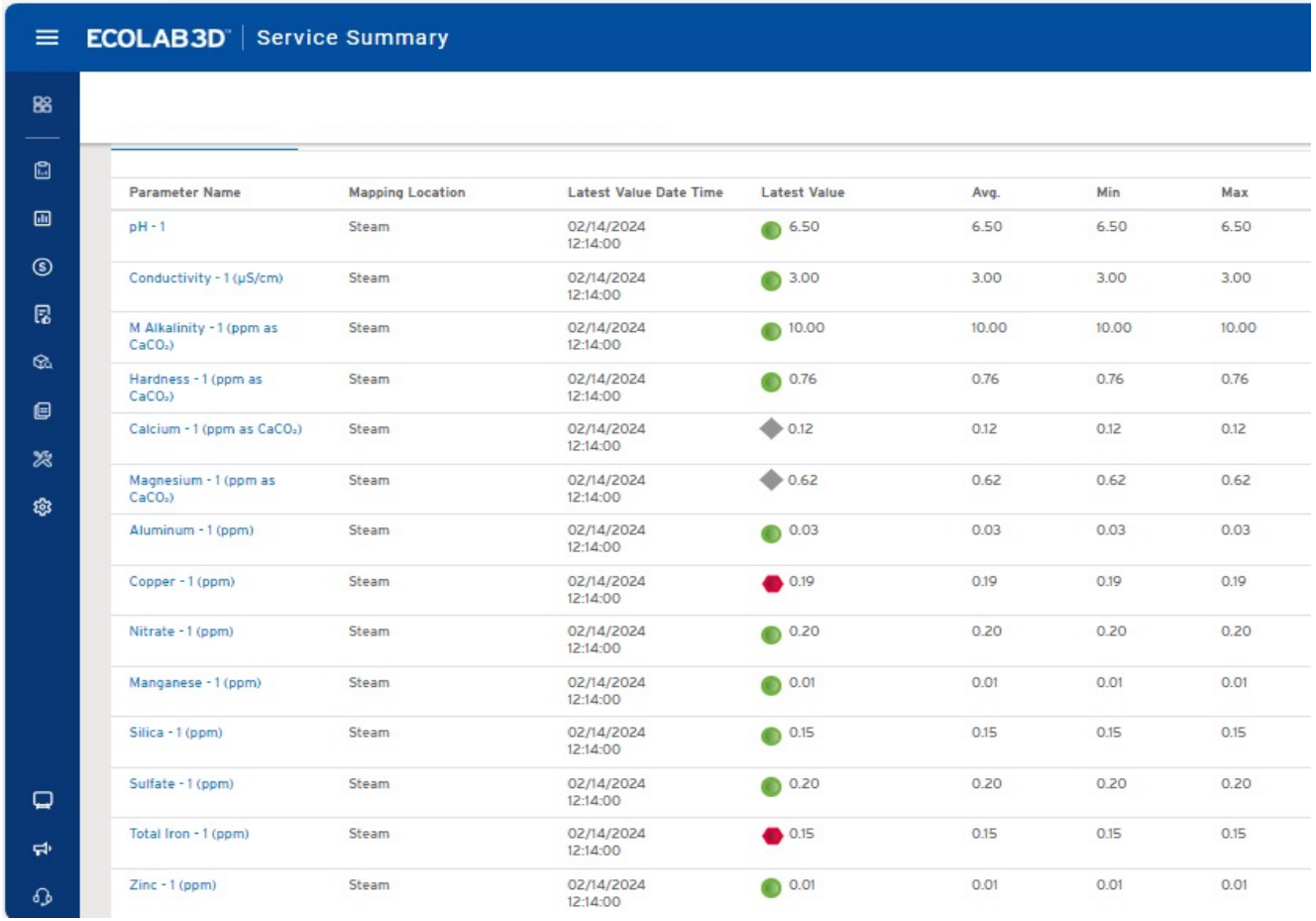
- Rainbow Gold color inside washer is not intended, and is an indicator of ionic molecules in water
- Critical Water (final rinse):

  Conductivity < 10 µS/cm
- Excessive ions can damage device surfaces and increase pitting
- Ions can discolor instruments when they are exposed to heat

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

WHAT IF THERE'S AN EXCURSION?

Performance Qualifications

- Remember, this is one data point
  - Seasonal water quality changes
  - Consider taking additional samples before making decisions/changes
- Data – even out of spec – is giving us information
  - Make sure we are looking at the correct data sets (Utility~Critical~Steam)
  - Verify samples were taken from the correct location
  - Will a process change help?
  - Do we need to install new equipment?
  - Does existing equipment need to be serviced/fixed?

WHAT IF THERE'S AN EXCURSION?

Routine Monitoring

ACTION	REASON
Reference your Water Quality Monitoring Program	This is why you created a Program specific for SPD
Discuss with your Team	Make sure everyone is aware of the issue – stack hands on how to proceed
Determine if this is a microbiological issue or a chemical attribute issue (e.g., pH, conductivity, alkalinity, hardness)?	Contamination of the water system that will change the microbiological quality of the water will be more readily apparent than changes of physical attributes.
Determine if this is a one-off issue, or a recurring pattern?	Outlier due to seasonal issue, construction, repair – or indicative of need to repair/replace water treatment equipment or process.

REMEDIATION EXAMPLES

Addressing Excursions or Alerts

- Clean/Disinfect Sample Port Location, Resample
- Flush System, Resample
- Sterilize Water System and Distribution, Resample
- For critical loop, sample after each treatment step to determine root cause of issue

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.

Mitch Luken
Nalco Water, an Ecolab Company Water Safety Specialist
Mitchell.luken@ecolab.com
513-687-7947

Jamie Munda
Nalco Water, an Ecolab Company Water Safety Specialist

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


ECOLAB®
NALCO Water