EDUCATIONAL MEETING: Understanding AAMI ST108 for Water Quality in Sterile Processing

SMSHE October 2024

NALCO Water
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INTRODUCTIONS

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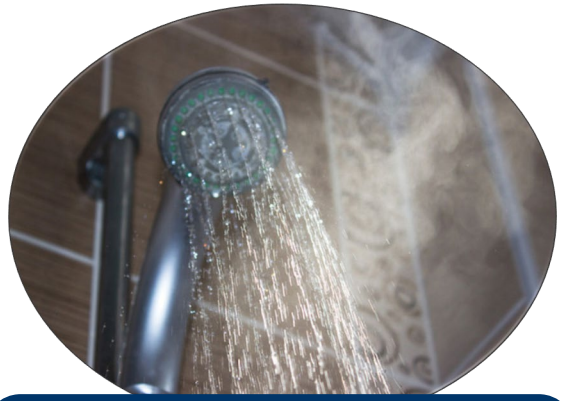
AGENDA

- Importance of water in medical device processing
- Review ANSI/AAMI ST108
  - Water Management Programs
  - Pretreatment systems
  - Routine Monitoring
- Q+A

WATER USE IN HOSPITALS



1. Domestic: 35%

Water use includes toilets, showers, baths, faucets, etc

Water Management Programs:
- ✓ ANSI/ASHRAE 188 – 2018
- ✓ CMS Memo – 2017
- ✓ ASHRAE Guideline 12 – 2023
- ✓ TJC Standard EC.02.05.02 – 2022
- ✓ ANSI/ASHRAE 514 – 2023 ***NEW***

2. HVAC: 20%

Water used for heating and cooling the facility (Cooling towers, boilers)

Water Management Programs:
- ✓ ANSI/ASHRAE 188 – 2018

Water Treatment/Sustainability:
- ✓ TJC Sustainable Healthcare Certification ***NEW***

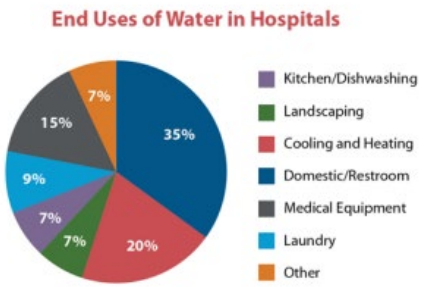
3. Medical Device Reprocessing: 15%

Water used for medical instrument reprocessing in the sterile processing department

Water Management Programs:
- ✓ AAMI ST108

4. Other: 30%

Water used for kitchen/dishwashing, landscaping, and laundry



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

WATER USES IN MEDICAL DEVICE PROCESSING

Water is involved in nearly every part of instrument processing:

- Pre-cleaning
- Manual cleaning
- Ultrasonic
- Washer/Disinfector
- Rinsing
- Steam Sterilizer/ Autoclave
- Cart Washer

- INEFFECTIVE CLEANING – Water spotting and staining cause questions about instrument cleanliness
- DEVICE MALFUNCTION – Water quality can affect instrument longevity and function
- STEAM STERILIZATION PURITY – Mineral deposits can hinder sterilization effectiveness
- TOXIC EFFECTS – Tissue irritation resulting from residuals
- PATIENT INFECTION – Waterborne pathogens can be a source of HAI's and SSI's

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.**"

- Approximately **300,000** surgical site infections (SSIs) in US
  - SSIs occur in **2-5%** of patients going undergoing inpatient surgery
  - SSI is now the most common and costly HAI
- SSIs result in an additional **7-11** postoperative hospital-days
- SSI patient is **2-11X** higher risk of death
- SSI are preventable and will not be reimbursed by Medicare (CMMS)
  - Additional costs of SSI vary $10K - $100K
  - **$3.5 billion to $10 billion** in additional expenditures

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

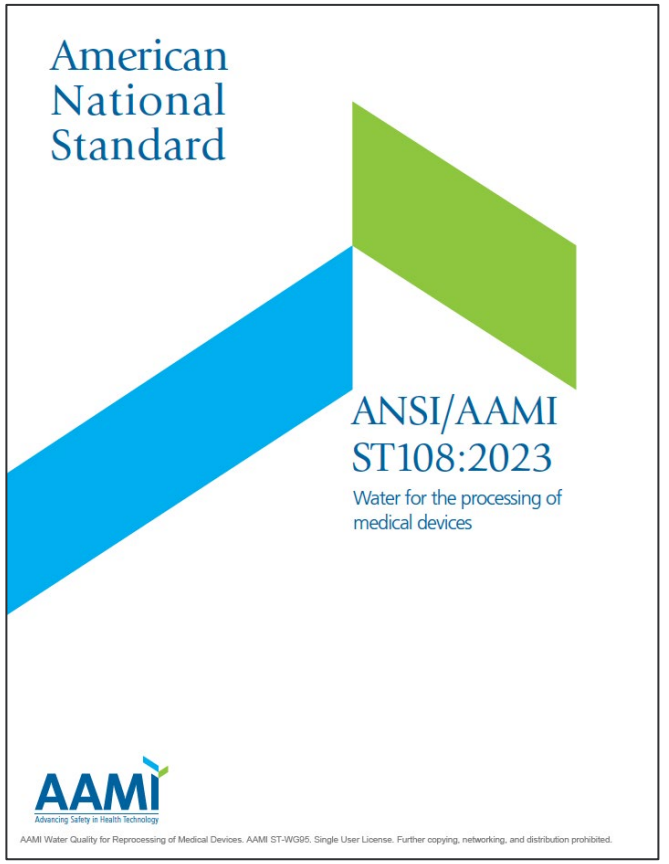
AAMI – The Association for the Advancement of Medical Instrumentation

- **ANSI/AAMI ST79:2017** – Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- **ANSI/AAMI ST108:2023** – Water for the processing of medical devices ***NEW***
  - Replaced **AAMI TIR34:2014/(R)2021**
- Equipment Manufacturers **IFUs** (instructions for use)
- **VHA Directive 1116(2)** Sterile Processing Services

MARKET EVENT: NEW STANDARD

AAMI ST108 – Water for the processing of medical devices

- Replaces AAMI TIR34
- Approved June 30th, 2023 by AAMI, Approved August 4th, 2023 by ANSI
- Standard focuses on minimum requirements of water quality requirements for processing medical devices
- Sets different categories of water used in processing
  - Utility water, critical water, and steam
  - When and where to use water of each category
  - Provides information on how to ensure that the water continues to meet those requirements at a minimum
  - Sets performance criteria for a water treatment/delivery system and monitoring program



IMPACT OF A STANDARD TO THE INDUSTRY

2015 ASHRAE Standard 188 Published

NEW YORK STATE OF OPPORTUNITY. Department of Health

2016 NY City & State adopt regulations

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Ref:

2017 Centers for Medicare & Medicaid Services QSO-17-30 Issued

Environment of Care
Standard EC.02.05.02

2021 The Joint Commission New Standard for Water Management

Understanding AAMI ST108

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ANSI/AAMI STANDARD 108

Minimum Standard of Care

Primary objectives

Overview of water quality & reasons for ST108

Roles & responsibilities of multidisciplinary team

Risk analysis

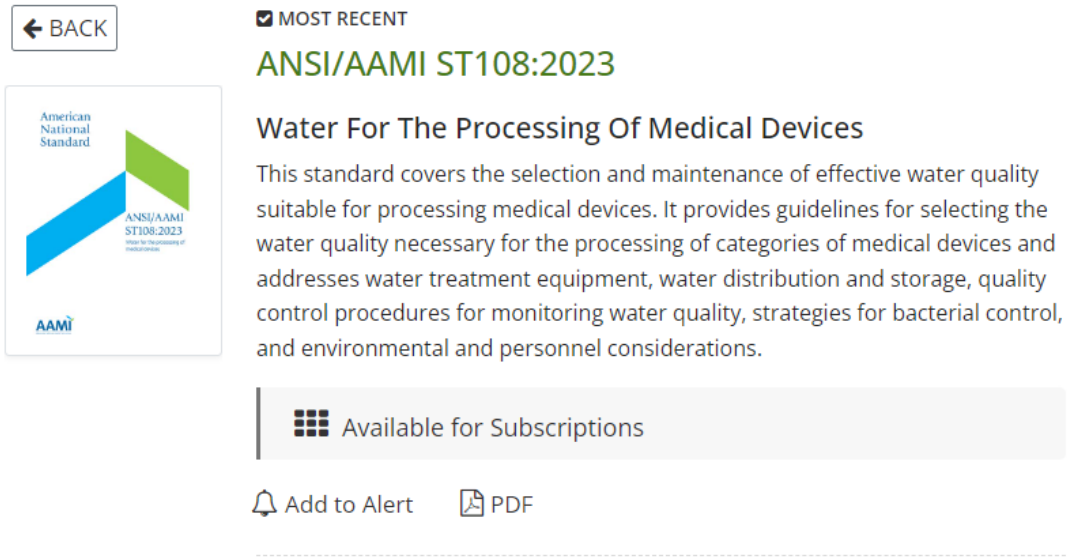
Categories of water and why

Water quality selection

How to get the water you need (Water Treatment Systems)

Maintaining water treatment systems

Annexes of AAMI ST108



ANSI/AAMI STANDARD 108

Informative Section

Annex A Guidance on the application of the normative requirements

Annex B Risk analysis

Annex C Automated Endoscope Reprocessor (AER)

Annex D Water used in cleaning and moist heat processes

Annex E Water treatment technologies

Annex F Water treatment system design

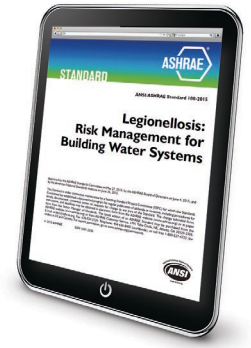
Annex G Routine monitoring of water treatment equipment

Annex H Maintaining microbiological quality

Annex I Typical Presentation of water quality issues during the processing of medical devices

ANSI/ASHRAE Standard 188

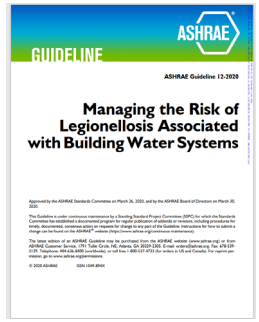
(Published in 2015, Updated in 2018 & 2021)



- ✓ **Requirements for developing and implementing a WMP**

ASHRAE Guideline 12

(Published in 2000, Updated in 2020 & 2023)



- ✓ **Risk management strategies to help mitigate risk**

ST108: WATER FOR THE PROCESSING OF MEDICAL DEVICES

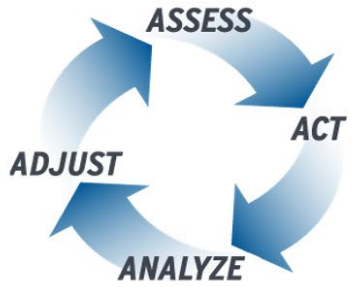
Water Management Program

- 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

KEY ELEMENTS OF A WATER MANAGEMENT PROGRAMS

PER ASHRAE STANDARD 188 & CDC TOOL KIT

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**



Water Safety is a Continuous Process

WHO IS ON YOUR TEAM?

FACILITIES

EXECUTIVE LEADERSHIP

STERILE PROCESSING

INFECTION PREVENTION

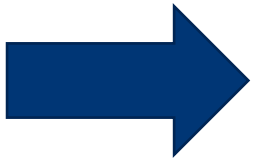
HEALTH & SAFETY

THIRD-PARTY VENDORS

RISK ANALYSIS

Understand impact of water

- Effect on the medical device
- Effect on the process
- Effect on patient (indirect)
- Effect to personnel



Water characteristics need to be considered

- Physical appearance – sediment/turbidity
  - Inorganic and organic contaminants
  - Microbial level
  - pH
  - Conductivity

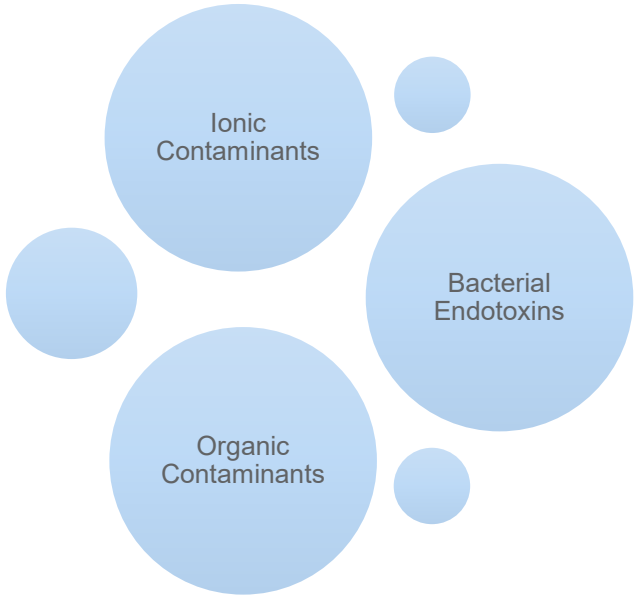
CATEGORIES OF WATER

Water Quality Selection

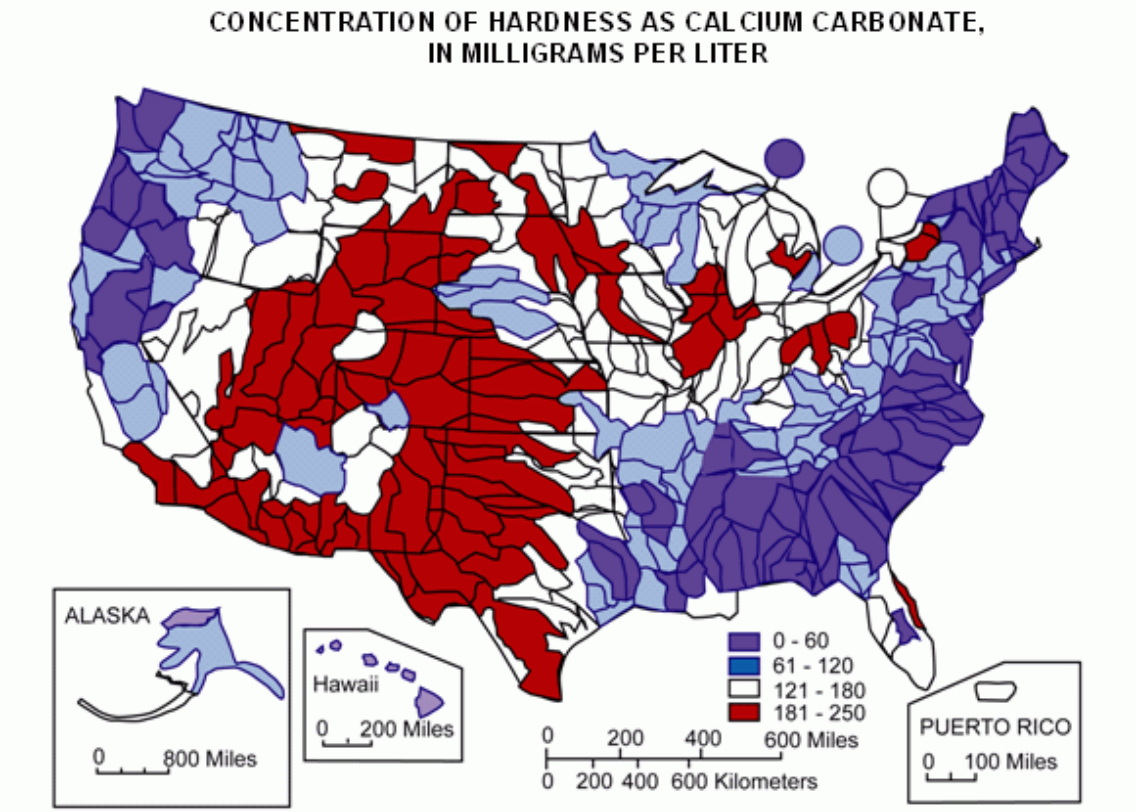
UTILITY WATER	Mainly used for flushing, washing & intermediate rinsing. **May require further treatment to achieve the specifications.
CRITICAL WATER	This water is used for final rinses after high-level disinfection and/or critical devices prior to sterilization. **Using critical water for all stages of medical device processing may be unnecessary and costly and can cause damage to equipment.
STEAM	Vaporized water used for sterilization

MUNICIPAL FEED WATER QUALTIY

Different Based on Source Water/Geographical Region



Municipal Feed Water



IMPURITIES IN WATER

Impurities	Types	Examples
Ionic	• Salts • Acids • Bases	Silicates, chlorides, calcium, fluorides, magnesium, phosphates, bicarbonates, sulphates, nitrates and ferrous
Organic	• Alcohols • Ketones • Aldehydes • Phenols	Pesticides, herbicides, plant/animal decay, industrial/domestic waste
Particulate	• Microbiological • Suspended solids • Colloidal material	Bacteria, viruses, endotoxins, sand, dust, pollen, resin
Gases	• Carbon Dioxide • Oxygen • Nitrogen • Chlorine • Chloramines	

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

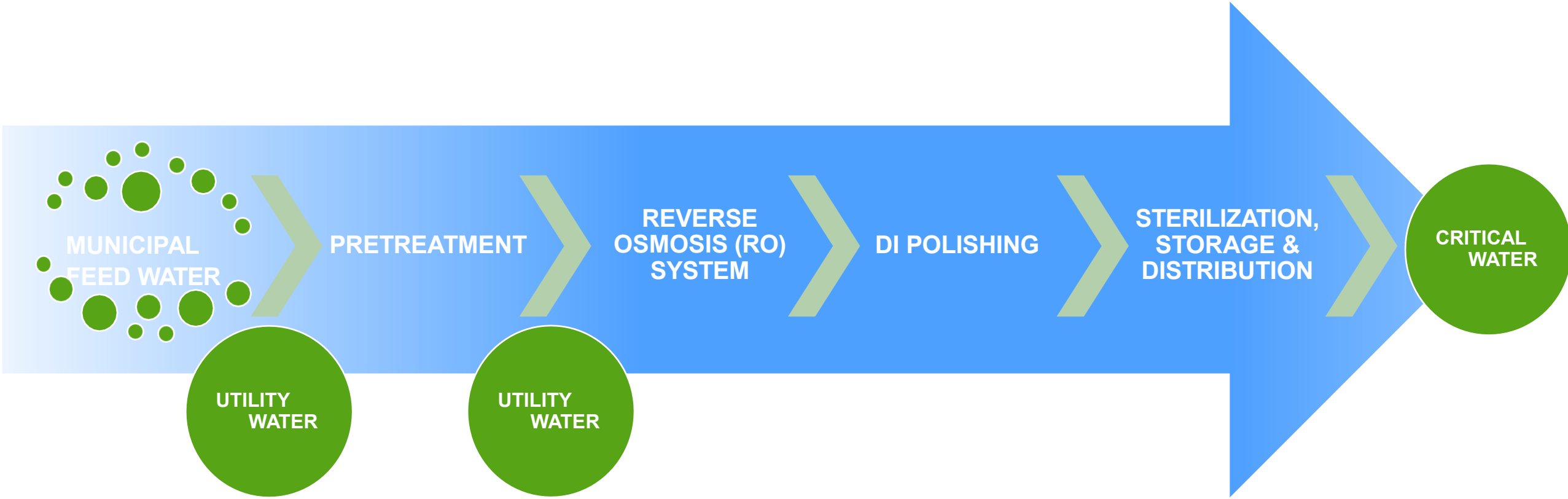
Water Quality Measurement	Units	Utility	Critical	Steam
pH @ 25C	pH	6.5 - 9.5	5.0 - 7.5	5.0 - 9.2
Total Alkalinity	mg $CaCO_3$/L	<400	<8	<8
Bacteria	CFU/mL	<500	<10	N/A
Endotoxin	EU/mL	N/A	<10	N/A
Total Organic Carbon (TOC)	mg/L (ppm)	N/A	<1.0	N/A
Color & Turbidity	Visual	Colorless, Clear, no residues	Colorless, Clear, without sediment	Colorless, Clear, without sediment
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

REMOVING IMPURITIES IN WATER

IMPURITY	WATER TREATMENT METHODS*
Ionic	• Deionization • Water Softening • Reverse Osmosis
Organic	• Cartridge Filtration • Carbon Filtration • Reverse Osmosis
Particulate	• Cartridge Filtration • Multimedia Filtration
Microbial	• Reverse Osmosis • Ultraviolet Sterilization • Final Filtration • Chemical Sanitization
Gases	• Carbon Filtration • pH adjustment pre-RO

*there are additional water treatment methods, both chemical and mechanical, but are removed to keep specific to SPD systems

EXAMPLE WATER TREATMENT STEPS

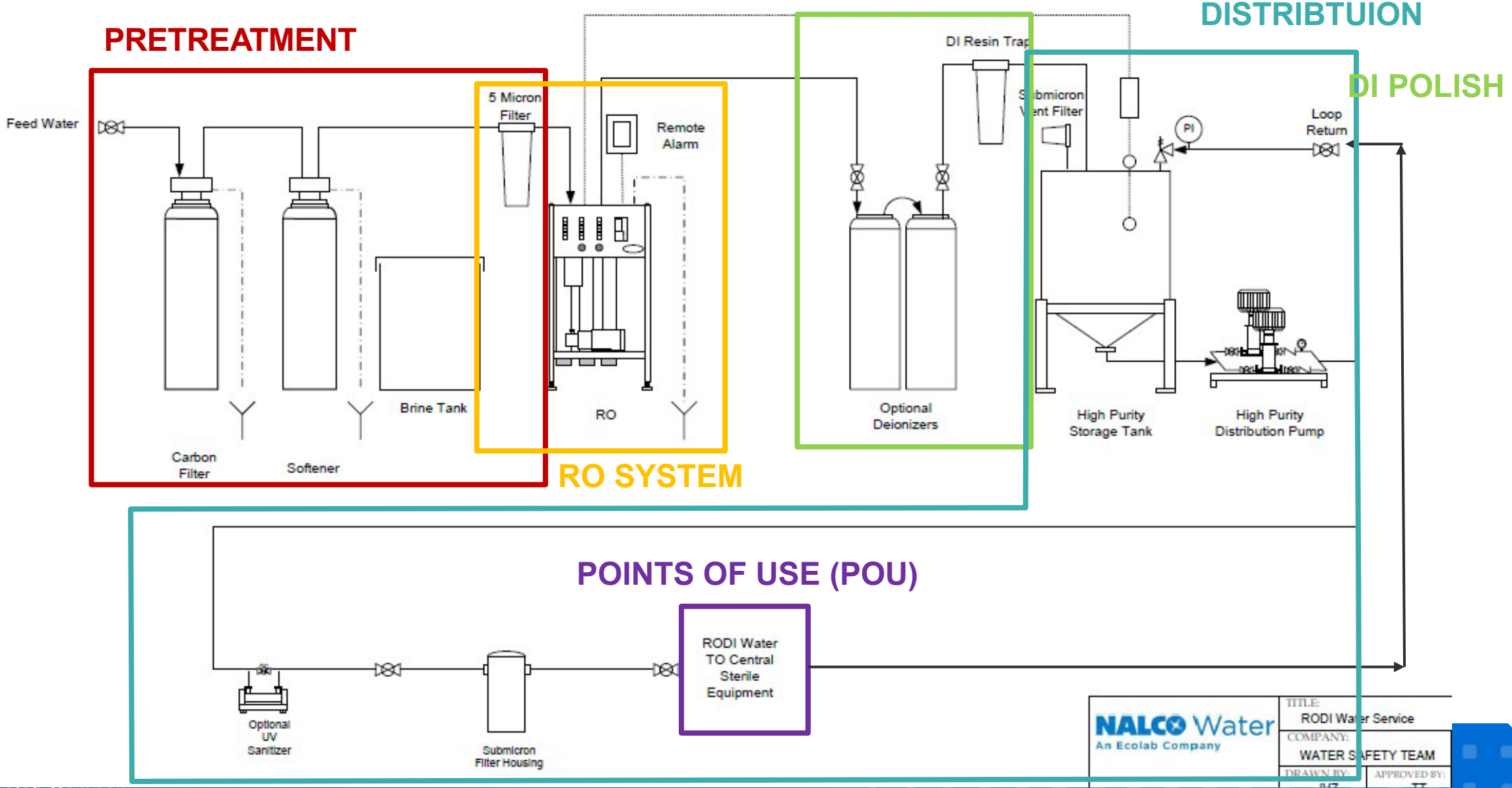


WATER TREATMENT SYSTEMS

STERILIZATION, STORAGE & DISTRIBTUION

PRETREATMENT

DI POLISH



WATER TREATMENT SYSTEMS

Installation and Operation Qualification

Installation Qualification

process of establishing that all key aspects of the process equipment and ancillary system installation comply with the approved specification

Examples
- Plumbing material for high purity should be SCH 80 PVC, polypro, high-density polyethelene.
- Systems must be on a fully recirculating loop with a fully drainable tank (3-5fps)
- System must be free of dead legs and free draining (sloped)
- Storage tank should be conical and vented with hydrophobic submicron vent filter
- Sample Ports: after each purification step

Operational Qualification

process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

Examples
- Monitor product conductivity after RO
- Monitor water flow rate
- Monitor pressure drop across filter
- Filter expiration dates
- DI Tank exchange schedule

WATER SAMPLING – 2 STEPS

(Step 1) Performance Qualification (PQ) & (Step 2 & Ongoing) Routine Monitoring

Monitoring water quality is a prospective process meant to confirm that control strategies are functioning as expected and is performed in order to detect when control strategies might require review or remedial action.

WATER SAMPLING

Performance Qualification (PQ)

- Performance Qualification = demonstrating that the process will consistently produce acceptable results under normal operating conditions
- During performance qualification, the entire water treatment system should be assessed (Reference Table 2)
  - Ionic (aluminum, chloride, conductivity, copper, iron, manganese, nitrate, phosphate, sulfate, silicate, hardness, zinc)
  - Organic (total organic carbon)
  - Microbial (Bacteria, Endotoxin)
- The following sampling locations should be evaluated:
  - Incoming water
  - Following each treatment step
  - At the point-of-use for Utility Water, Critical Water & Steam Condensate

WATER SAMPLING

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.

Areas for Monitoring:

- Water Generation (At Make Up)
- Water Point of Uses (sinks, washers, etc)

Frequency by Category:

- Critical Water – Monthly
- Utility Water – Quarterly
- Steam – Quarterly

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)	Quarterly	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 in order to find the assignable causes. The monitoring program is an opportunity to address potential problematic issues **prior** to failing of specifications during routine monitoring.

WHAT TO DO IF THERE IS AN EXCURSION OR ALERT?

Alert levels can occur - Don’t Panic

Fluctuations in the incoming water quality, maintenance of components of the critical water system, longevity of the consumables, flow rate of the water (channeling), biofilm in distribution

1. Connect Multidisciplinary Team – Internal & External Partners
2. Reference your WMP
3. Example Remediation - Flush System, Resample
4. Example Remediation - Disinfection of water system and distribution
5. Recurring Issues: Evaluation of Critical Water system treatment steps
6. Consider pretreatment water system for Utility Water (softening or filtration)

Next Steps

- Start the conversation
- Assess current water categories
- Understand current monitoring program
- Develop a plan to incorporate any necessary process/equipment changes
  - Risk Assessment to develop an SPD specific Water Management Program
  - Determine what is needed to meet compliance with the standard

IN SUMMARY…

- Water is critical to patient & staff safety
- SPD play a vital role in minimizing the risk of infection
- ST108 is the roadmap for Sterile Processing Departments

NALCO WATER THE WATER SAFETY EXPERT

Global
Experts in
Water Safety
25+ years

Research
Microbiologists,
Scientists & Engineers

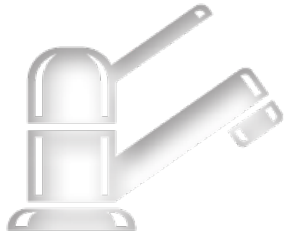
Our *Legionella* lab is a charter member of CDC-ELITE proficiency program

Starting in 1999

120,000+ tests/year globally

We have boots on the ground everywhere.
Local service delivered by sales & service associates worldwide.

15,000+
Water Safety Plans Implemented Globally
Healthcare, Lodging, Education, Commercial, F&B, Manufacturing, Industrial



Disinfection of 3 billion+ gallons
of potable & non-potable water annually

EXPERTISE AND SOLUTIONS THAT MAKE THE WORLD CLEANER, SAFER AND HEALTHIER

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QUESTIONS?

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