ANSI/AAMI ST108-2023: Water for the Processing of Medical Devices ST108

Sterile Processing Water
Use, Requirements, and Testing

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Introduction

Miranda Haramia, Project Advisor for San Diego Region

- Primary Account Specialist for South San Diego Since 2021
- Involved in All Field Work & Reporting
- Water Management Program Development & Verification
- Water Safety *Legionella* Sampling
- Central Sterile Processing Water Sampling

Andi Wade, Regional Manager for Southwest Region

- Over 9 years experience in Healthcare and Facilities Management
- Regional Manager for Southwest Territory
- Expert in Water Management and *Legionella* Safety
- Development and Implements comprehensive Water Management Programs

WHAT'S OUR GAME PLAN TODAY!

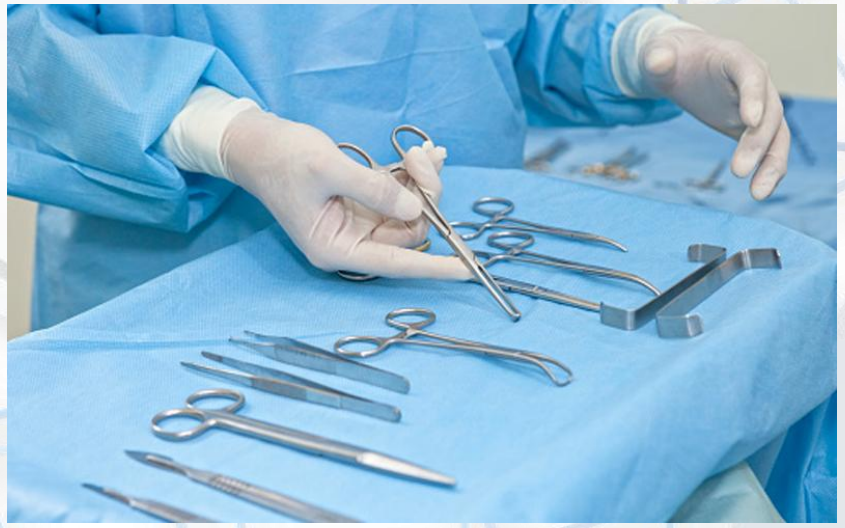
- **Review** the Importance of the Sterile Processing Department (SPD)
- **Review** evolution of **AAMI TIR34** into the **ANSI/AAMI ST108** standard
- **Understand** how water quality impacts Sterile Processing.
  - Learning Points on Water Chemistry Tests, and How Water is Refined
- **Explain** the requirements for a SPD testing program aligns with the ANSI/AAMI ST108 standard.
- **Discuss** the Current State of ST108 and Survey Expectations

What is Central Sterile Processing?

- Department for the Decontamination, Disinfection, Sterilization, Storage & Distribution of reusable surgical instruments

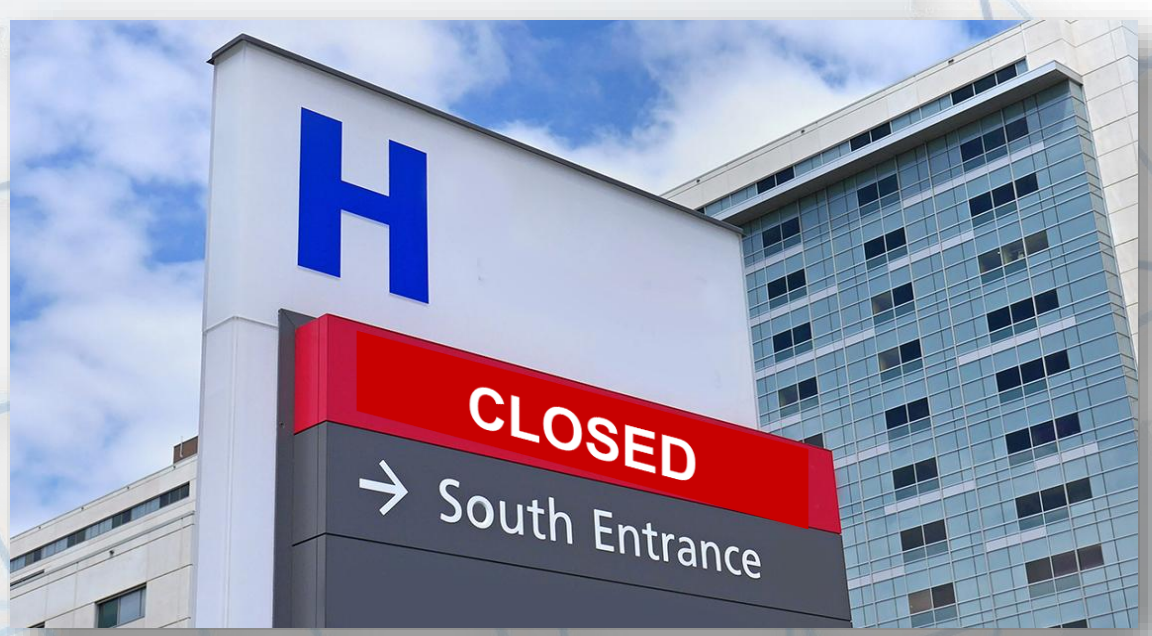
- SPD Provides the tools for **the most profitable department $$$**

Surgery

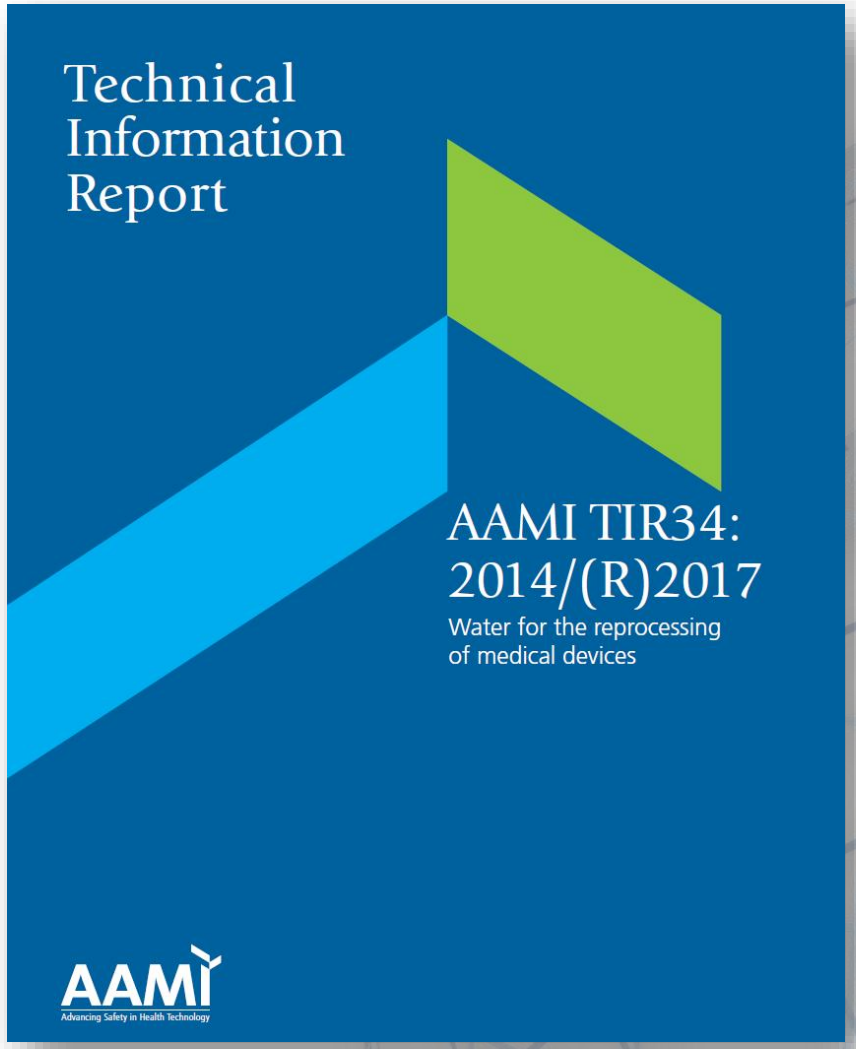


Why is Central Sterile Processing Critical?

- No Instruments → No Surgeries → NO $$$$$$
- Must Reduce Corrosion and Deposits in Surgical Equipment – Maintain Tool Integrity
- Essential to Control & Reduce the Patient Risk of Infection
  - Surgical Site Infection: *Staphylococcus, Streptococcus, Pseudomonas*, Endotoxins



What is AAMI TIR34:2017?



- ✓ TIR = Technical Information Report
- ✓ Guideline Advised
- ✓ Water for Reprocessing of Medical Devices (Sterile Processing)
- ✓ Ensures Adequate Water Quality in Washing & Rinsing Medical Equipment
- ✓ Updated to Standard (ST108) in Aug 2023

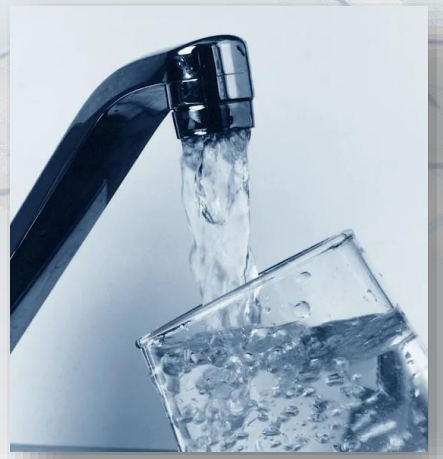
Why Make it a Standard?

Rally Compliance When Many Facilities Currently Did Nothing

SPD Water Quality Categories

1) UTILITY WATER

- Water Used for Flushing, Washing and Rinsing
- Water from the tap that might require further treatment to achieve the specifications (cold & hot)



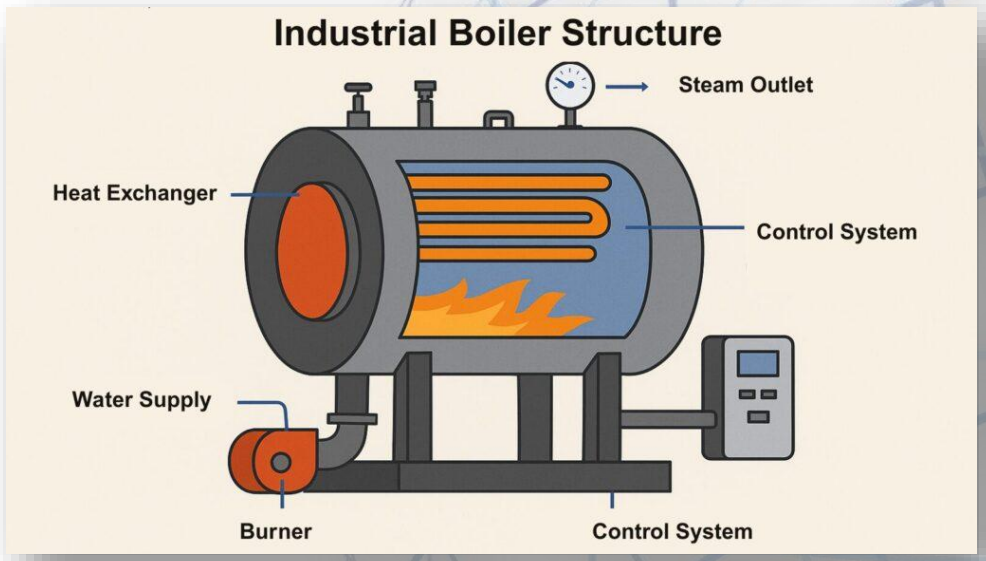
2) CRITICAL WATER

- Water Used for Final Rinsing
- Purified, typically by Reverse Osmosis (RO), Deionization System (DI), or Both
- Purification ensures that microorganisms and inorganic/organic materials are removed

SPD Water Quality Categories

3) STEAM

- Water used for Steam Sterilization of medical devices
- Heated via a Boiler or Steam Generator
  - Steam can be fed from a central location such as a boiler plant
  - Steam can also be created via a steam generator within a sterilizer
- Plant steam is used for MANY things, not just at SPD (Hot Water & Comfort Heat)



Basic AAMI Analyses For Purity

Hardness – Can leave deposits on instruments, or damage RO membranes

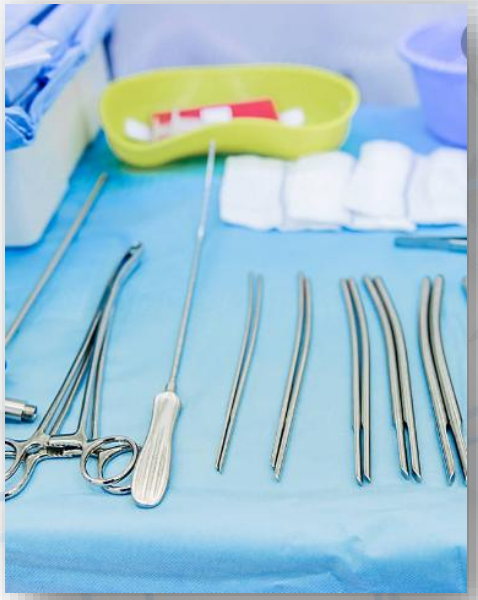
Conductivity (uS/cm) – or Total Dissolved Solids

pH – Can cause pitting of instruments

Alkalinity – Can also cause pitting

Bacteria (Plate Count) – General water quality

Endotoxins – Component of a cell membrane that can cause ill effects with exposure



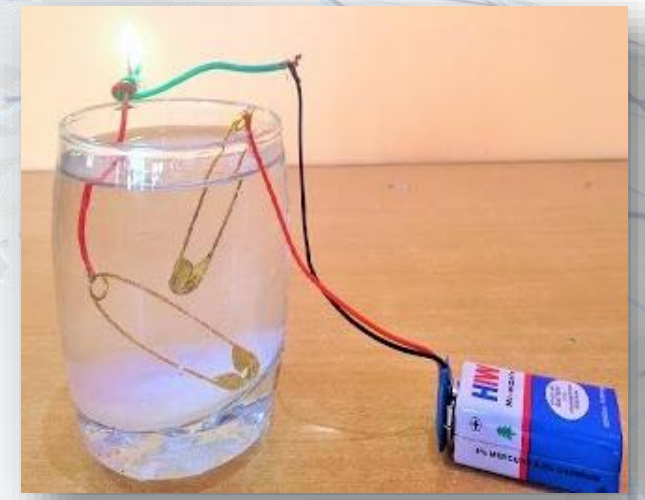
What is Hardness?

- Hardness is Calcium (Ca) and Magnesium (Mg) Salts
- Can cause scale/deposits: Calcium Carbonate ($CaCO_3$), Magnesium Carbonate ($MgCO_3$)
- Water Softeners remove Ca and Mg, but:
  - ✓ Does not remove anything else
  - ✓ Does not decrease TDS or Conductivity (may increase it)
- Water softeners should be used for Utility Water
- Softened water will reduce costs of Deionized and Reverse Osmosis

What is Conductivity?

- Conductivity is a measure of water's capability to pass electrical flow
  - ✓ Water with dissolved salts & inorganic materials
- Lower conductivity = Less dissolved ions
- Typical City Water Conductivity:
  - ✓ SoCal: 500-750 µS/cm
  - ✓ Bay Area: 40-120 µS/cm
- AAMI Goals:
  - ✓ Utility Water: <500 µS/cm
  - ✓ Critical Water: < 10 µS/cm

  (< 10 µS/cm cannot be achieved without RO/DI in place)

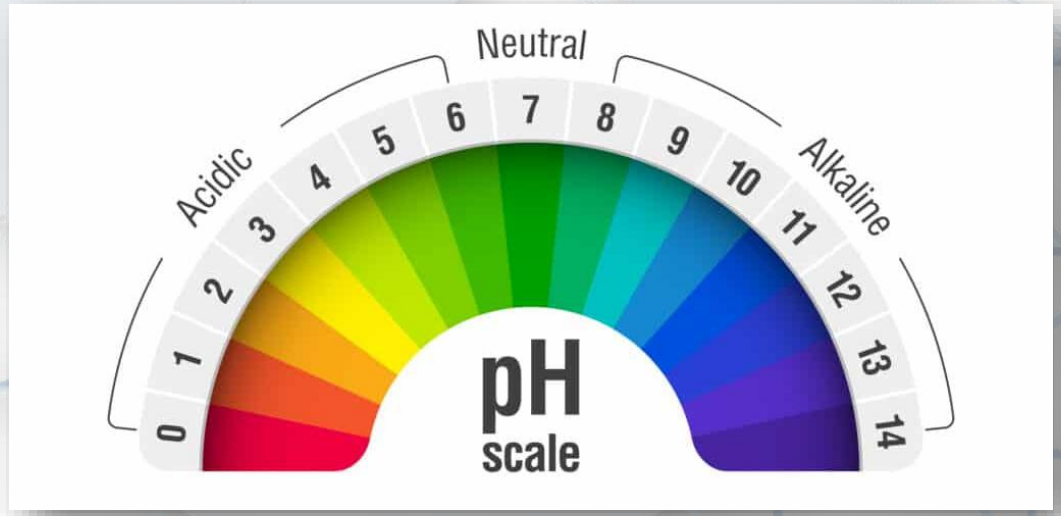


How do you Lower Conductivity???

(more on this later)

What is pH & Alkalinity?

- pH is a Scale for how acidic or alkaline (basic) a solution is
- Both High pH and Low pH can cause pitting of device surfaces
  - ✓ Utility Water: pH range of 6.5-9.5
  - ✓ Critical Water: pH range 5.0-7.5



  - ✓ Utility Water: Alkalinity <400ppm
  - ✓ Critical Water: Alkalinity <8ppm

PLEASE NOTE: pH is not easily manipulated or changed in water

Bacteria
Heterotrophic Plate Count

- Critical Water: Goal <10cfu/ml

  S*hould be* ZERO at the point of generation

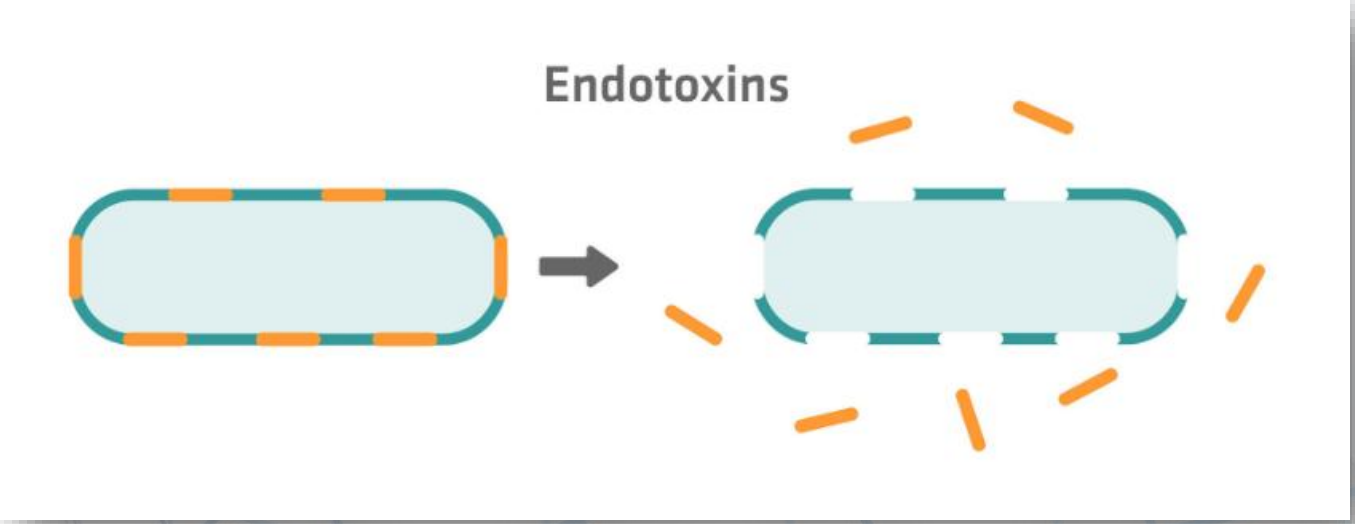
- Utility Water: Goal <500cfu/ml

  City Water Supply

  High Purity Not Necessary for Washing

Endotoxins

- Toxin bound to the bacterial cell membrane & released upon cell death
- Even in very small amounts, endotoxins can cause deadly effects
- Only Critical Water is made by a process expected to remove endotoxins
  - ❑ Critical Water: Goal <10 EU/mL



Summary of Target Levels to Achieve

Summary of Recommended Water Quality Levels for Medical Device Processing in Accordance with ST108-2023				
Analyte	**Units**	**Utility Water Flushing/Washing**	**Critical Water Final Rinse**	**Steam* (if Used)**
		Target Level	**Target Level**	**Target Level**
pH	Units	6.5-9.5	5.0-7.5	5.0-9.22**
Conductivity	µS/cm	< 500	< 10	<10
Alkalinity	mg/L	< 400	< 8	<8
Hardness	mg/L	< 150	< 1	<1
Bacteria	cfu/ml	< 500	< 10	N/A
Endotoxin	EU/ml	N/A	< 10	N/A
Color & Turbidity	Visual	Colorless, clear, no sediment		

*Steam sampled as condensate

**The pH range for steam is wider than for critical water as some steam may not be generated locally but from a central system. The need for treatment chemicals in the boiler at a distant location (plant) may result in higher pH requirements. pH <7.5 should be avoided.

Endotoxin Is Required to Be Tested In What Types of Water Systems?

A. Patient Sinks and Showers
B. Sterile Processing Utility Water
C. Sterile Processing Critical Water
D. Cooling Towers

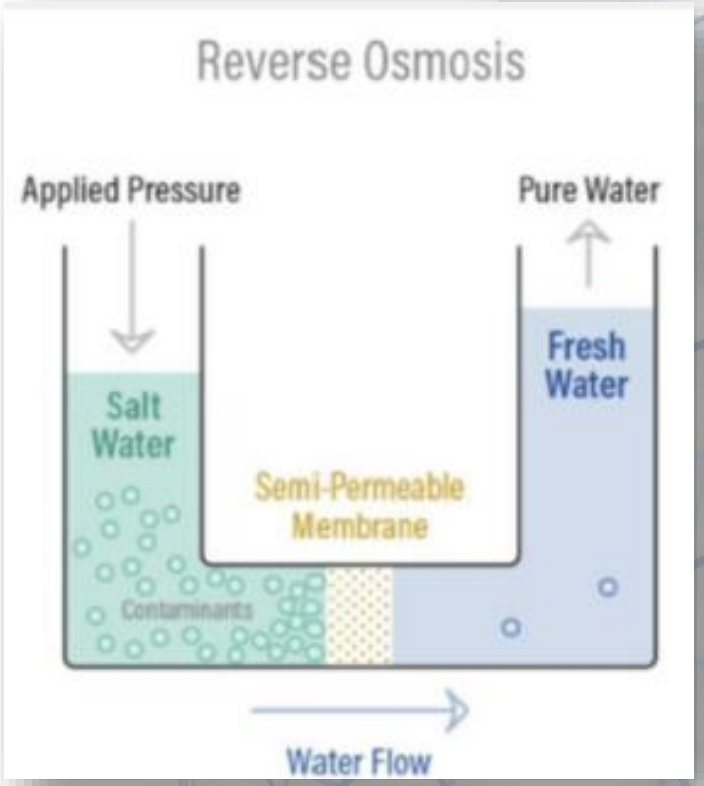
Answer: C- Critical Water

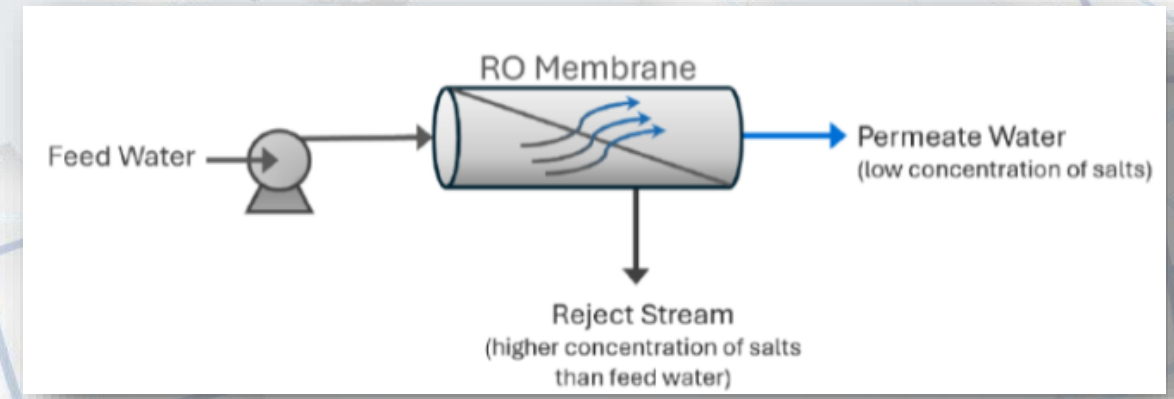
Solutions for Out-of-Range Results

- ✓ Elevated Hardness? **Install Softener System**
- ✓ Elevated Conductivity? **Water Purification Such as RO or DI or Both**
- ✓ Elevated Bacteria/HPC? **Flush, or Install Micro Rated Filter**
- ✓ Elevated Endotoxins? **Flush, or Install Endotoxin Filter**

Technical Review: How Do You Reduce Conductivity?

1. Remove Dissolved Solids & Contaminants with Reverse Osmosis

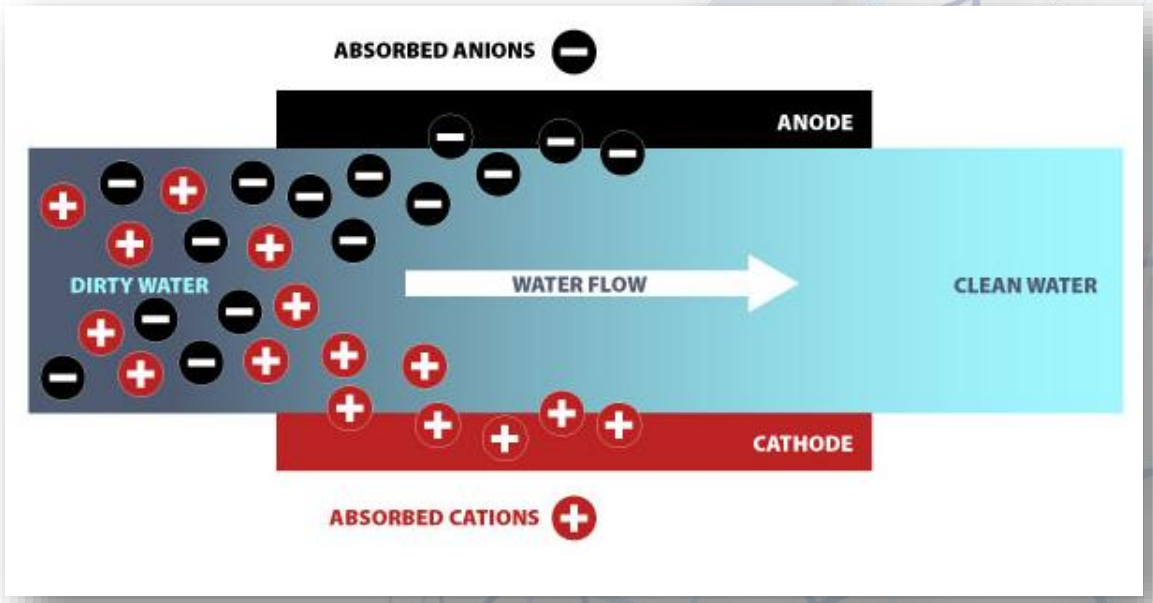


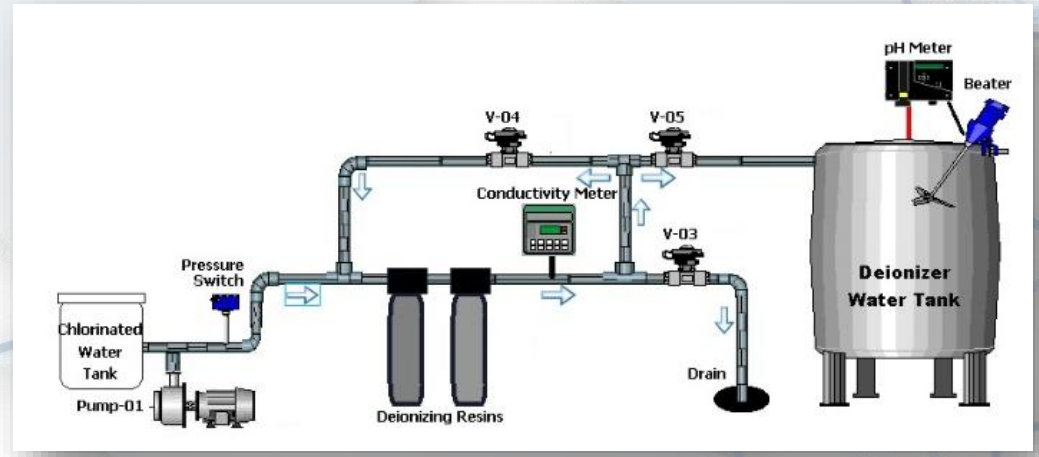


- Removes Dissolved Solids
- Some Ions & Impurities Still Pass Through

How Do You Further Reduce Conductivity?

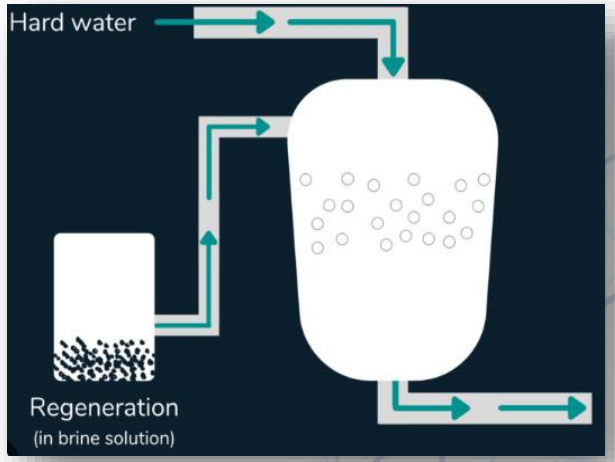
2. Remove Ions with De-Ionization (Ion Exchange)



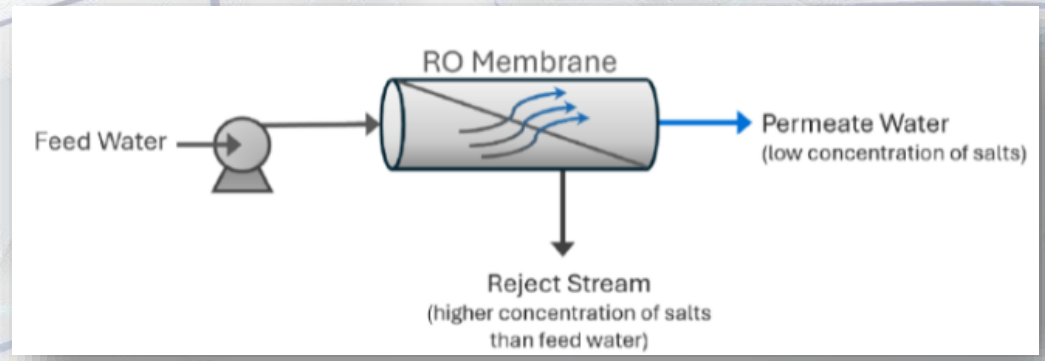


A Typical Critical Water Production Using RO/DI

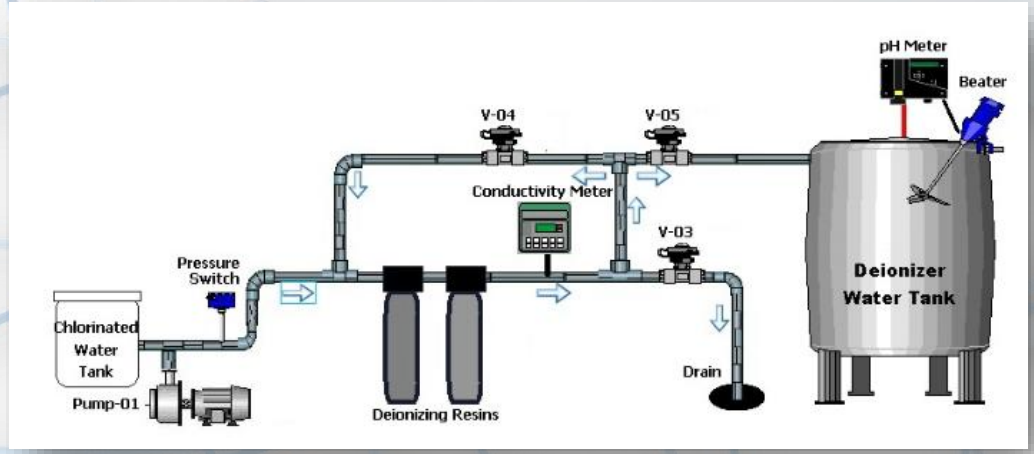
STEP 1: Softener



STEP 2: Reverse Osmosis



STEP 3: De-Ionization



ST108 Water Testing – What is “Required”?

ST108 “Requires” Routine Testing, but Systemically Uses the Word “Recommends”

- Daily, Monthly & Quarterly Specifications
- Testing at Generation Sites, & Points of Use

ST108 Testing & Frequency at Point of Generation

Table 5 and Table 6 describe the water quality monitoring that shall be performed as part of a quality improvement process within their area. Continuous quality improvement involves conducting risk analyses (see Clause 5).

Table 5

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

Yes, this is a lot of testing, and this is only at the Point of GENERATION!

ST108 Testing & Frequency at Point of Use

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

*NOTE 1 The recommendations for frequency of testing in this table are the recommended minimum frequency. If problems or issues arise with the water quality, it may be necessary to increase the frequency until they are resolved.

**NOTE 2 Test type needed to measure Critical Water and Steam levels. Steam condensate must be filled to the brim, sealed, and allowed to cool before testing to prevent carbon dioxide absorption.

Yes, this is even more testing at the Final Points of Use!

Some Questions & Answers of Interest

Q1) Has The Joint Commission Adopted ST108 Yet? Are They Surveying?

- **NO** not Officially…
- Not Yet, but Expected to Be Adopted in the Near Future
- May Depend on Surveyor, Hospital, Overall Conditions
- TJC Considers ST108 as a “Best Practice”

Q2) When They Do Adopt it, What Will Be the Expectation?

- Unsure, but it’s Unrealistic to Expect Full Compliance. Almost NO Hospital Does
- Significant Investment in Water Refinement Processes Necessary to Meet Specs!
- (Equipment Vendors are Licking Their Chops!)

Some Questions and Answers of Interest

Q3) Is Current Testing Completely Aligned with ST108 Recommendations?

- **Probably Not**. ST108 Puts Forth a Very Robust Sampling Regime
- There is Industry Push Back on the Expectation
- Conservative Start Leaves Room to Expand When Necessary

Q4) Does SPD Department Do Testing In House?

- Weekly, Monthly Testing – Handheld Meters are Acceptable
- SPD, IP, and Facilities Need to Work Together
- Localized Log Book in Department a Good Idea

Some Questions and Answers of Interest

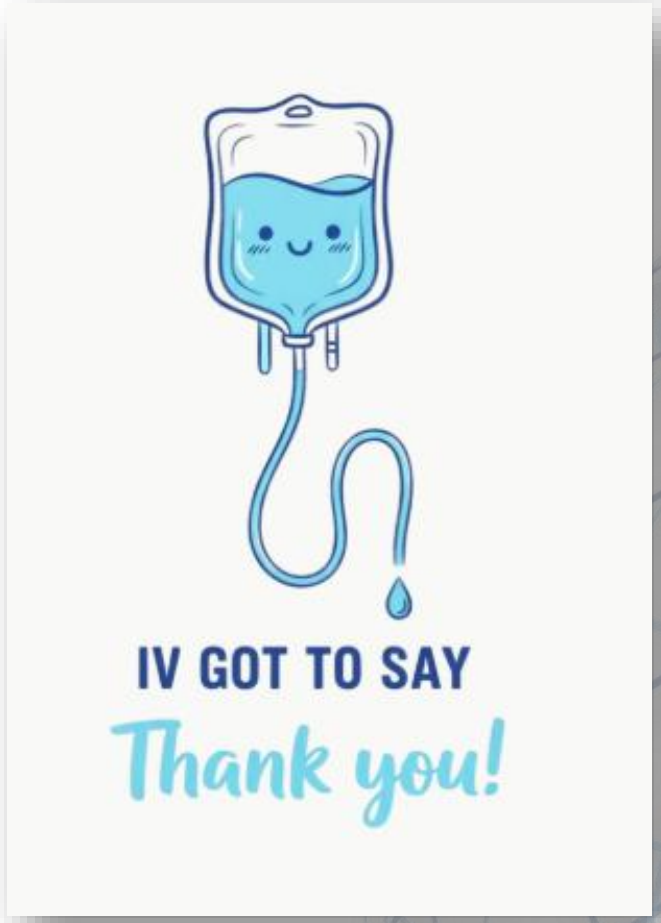
Q5) What are the Benefits of Beginning Testing Before It's Being Enforced?

- Patient Safety
- Good Water Quality in SPD Results in Reliable Department Operations
- Reduce Impact on Surgical Operations
- Meet Instructions for Use for Medical Equipment Requiring Specific Water Qualities
- Get Ahead of the Survey Expectation

Coming Soon: TIR 119/ED-1: Water Quality for Reprocessing Medical Devices

TAKE AWAYS

- Sterile Processing Department (SPD) is a Critical Department for Hospitals
- Goal of **ANSI/AAMI ST108** is to Improve Water Quality Used in SPD Operations
- Improving Utility & Critical Water Quality Requires Mechanical Refinement Processes – New Equipment Installation and Investments
- Work Towards Aligning with ST108 Testing with a Vendor Partner *as well as* In-House Testing



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