DEMYSTIFYING ANSI/AAMI ST108:
AN APPROACH TO STANDARD COMPLIANCE

ADDRESSING COMMON MISCONCEPTIONS AND BEST PRACTICES FOR WATER MANAGEMENT IN NEW JERSEY'S STERILE PROCESSING DEPARTMENTS

HAVE YOU EVER BEEN REALLY SICK?

HOW WOULD TAKING YOUR TEMPERATURE HAVE PREVENTED IT?

Testing is not prevention:

- Testing water quality doesn't equal compliance
- The ST108 objective is to guard against "sick" water and know how to treat it if it happens

TOPICS WE WILL COVER TODAY

UNPACKING THE RUSSIAN NESTING DOLLS OF WATER MANAGEMENT

1) The basics of ANSI/AAMI ST108

- Impact of Poor Water Quality
- Why Water Quality Should Be on Every SPD Manager's Radar

2) What You're Actually Responsible For

- Common Misconceptions
- The Three Water Classifications

3) The cross-functional team required to comply

- Who Needs to Be Involved
- Best Practices

SECTION 1

The Basics of

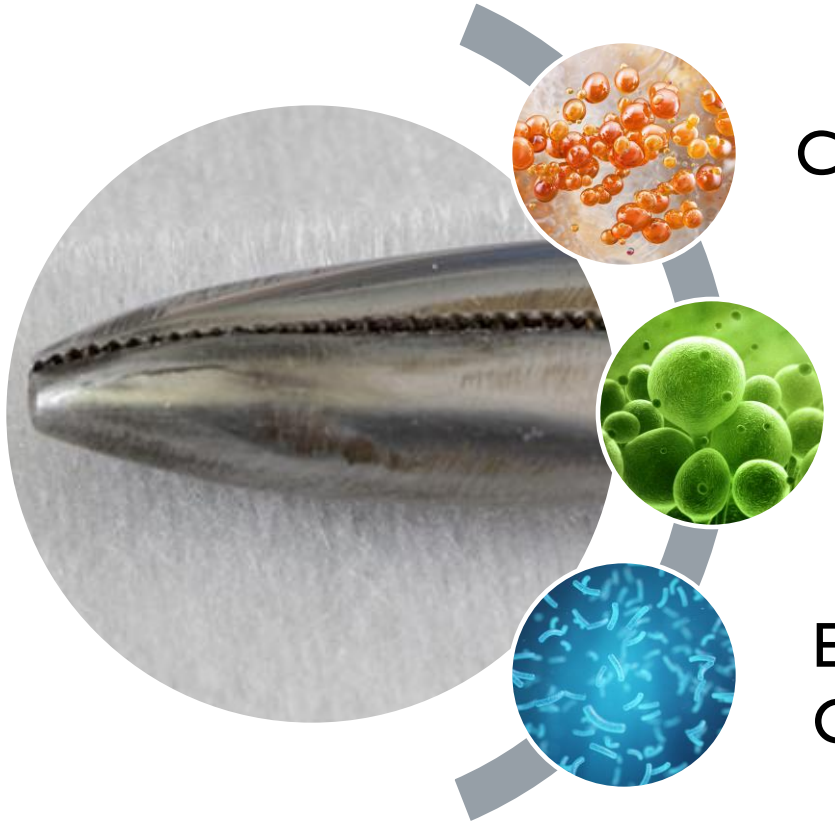
ANSI/AAMI ST108

IMPACT OF POOR WATER QUALITY

WHEN WATER GOES WRONG: RISKS YOU CAN'T IGNORE

Water quality directly affects:

- Sterilization Outcomes
- Instrument Integrity
- Patient Safety



Corrosion

Biofilm Formation

Endotoxin Contamination

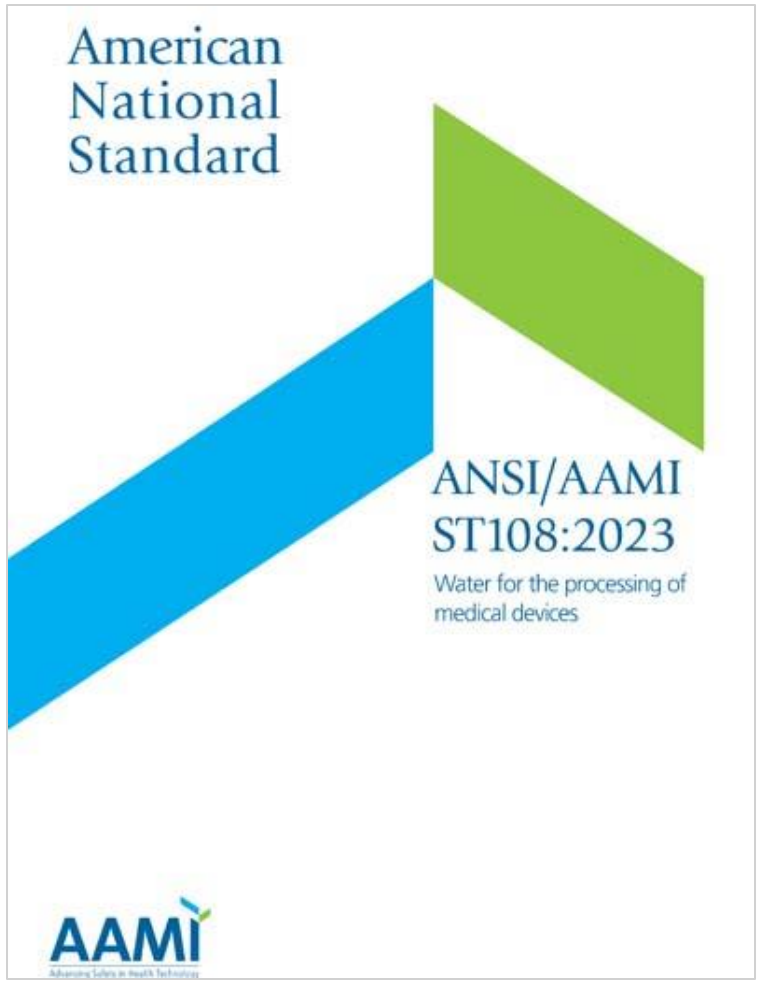
ANSI/AAMI ST108:
THE BASICS

What It Is:

- A U.S. national standard (2023) that sets minimum water quality requirements for cleaning, rinsing, disinfecting, and sterilizing medical devices.
- Replaces earlier guidance (AAMI TIR34) with clearer requirements for compliance.

Why It Matters:

- Poor water quality can cause corrosion, biofilm, staining, and ineffective cleaning of instruments.
- Direct impact on patient safety (SSIs) and instrument performance.



ANSI/AAMI ST108:
THE BASICS

Core Requirements:

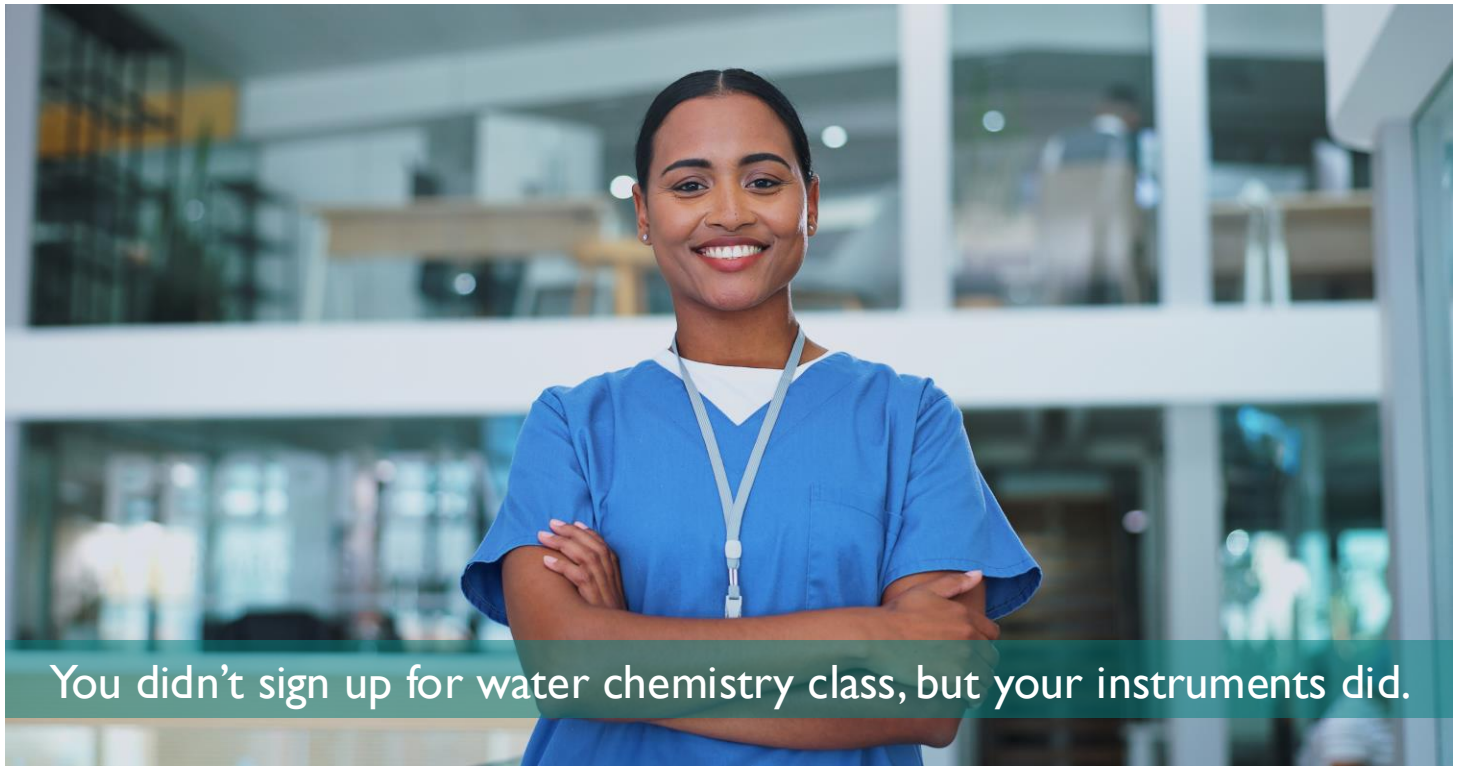
- Risk Assessment – facilities must evaluate water systems and risks to processing
- Defined Water Types:
  1. Utility Water – used for flushing, washing, initial rinsing
  2. Critical Water – purified for final rinse before sterilization/disinfection
  3. Steam – must meet purity requirements when condensed
- Ongoing Monitoring & Maintenance – routine testing, documentation, and corrective action if limits are exceeded

Big Takeaway for SPD Teams:

- ST108 makes water quality a compliance objective, not just a best practice. Following it protects patients, extends instrument life, and keeps facilities inspection-ready.

WHY WATER QUALITY SHOULD BE ON EVERY SPD MANAGER'S RADAR

YOUR INSTRUMENTS NOTICE. YOUR PATIENTS NOTICE. YOU SHOULD TOO



Regulatory Compliance:

- ST108 is now a key standard for SPD water management.

Operational Impact:

- Testing, maintenance, and monitoring affect instrument turnover and workflow.

Patient Safety:

- Reducing risk of SSIs and ensuring sterilization efficacy.

SECTION 2

What You're Actually Responsible For

COMMON MISCONCEPTIONS ABOUT ST108 COMPLIANCE

DEBUNKING THE MYTHS

Misconception 1:
"Water is water; quality can't impact sterilization."

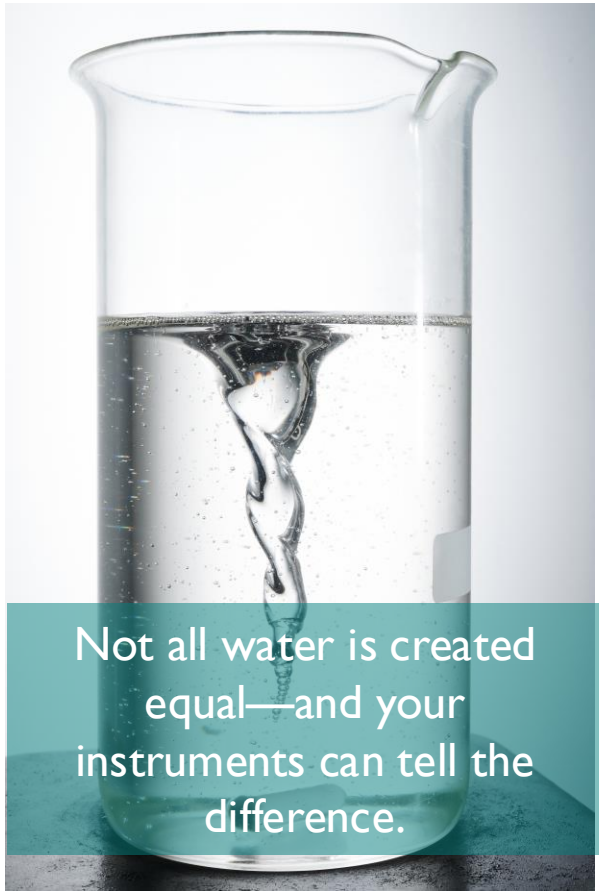
Misconception 2:
"I've got an RO system, I'm good to go."

Misconception 3:
"Testing once a year is sufficient."

THE THREE WATER CLASSIFICATIONS DEFINED IN ST108

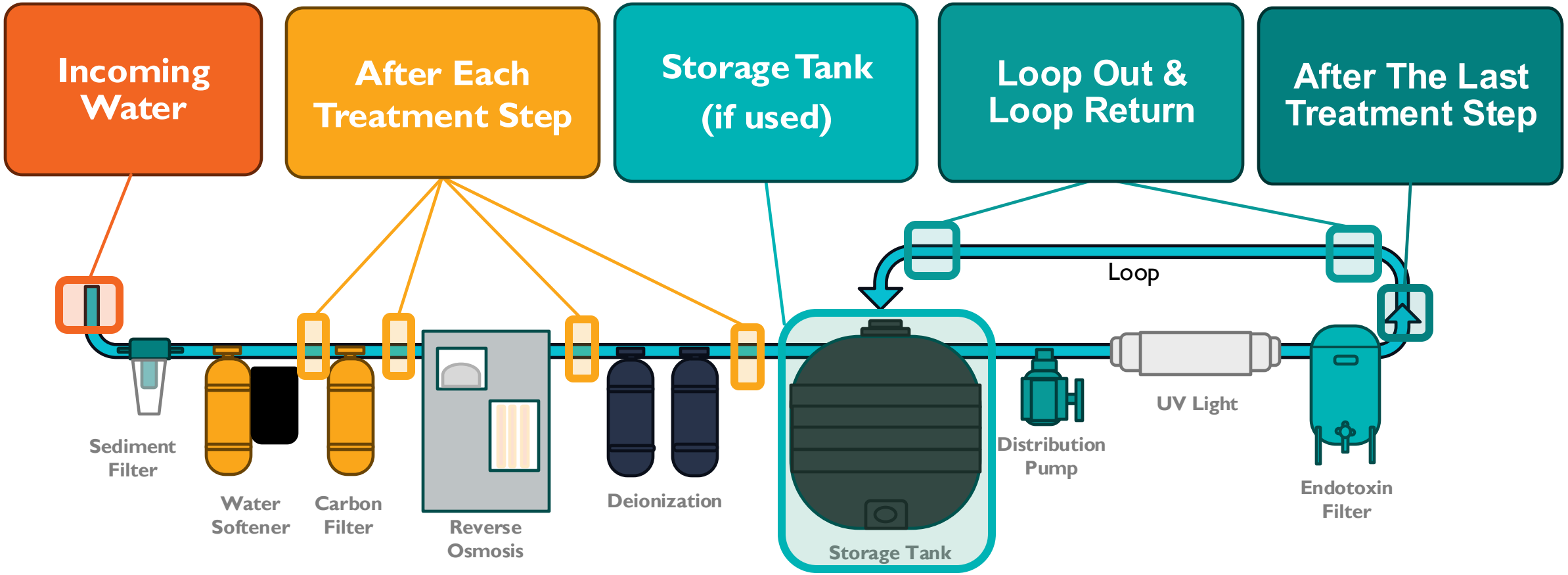
1. Based on:
    - What is the water used for? What is it used in?
    - Equipment and Manufacturer Instructions for Use (IFUs)
    - ST108 water quality tables (e.g., microbial, chemical limits)
2. Water Categories:

3. Threshold Levels – Alert and Action



IDENTIFYING KEY MONITORING LOCATIONS

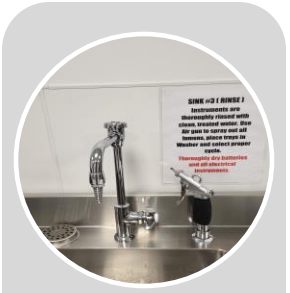
WATER GENERATION SYSTEM

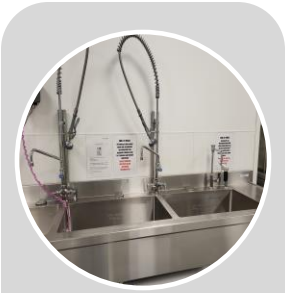


IDENTIFYING WATER QUALITY SAMPLING LOCATIONS

AFTER THE TREATMENT SYSTEM

- **Sample at point where distribution loop enters SPD OR first point of use on the loop**
- **Each location point of use in the department**


Critical Faucets


Utility Faucets


Washers


Sterilizers

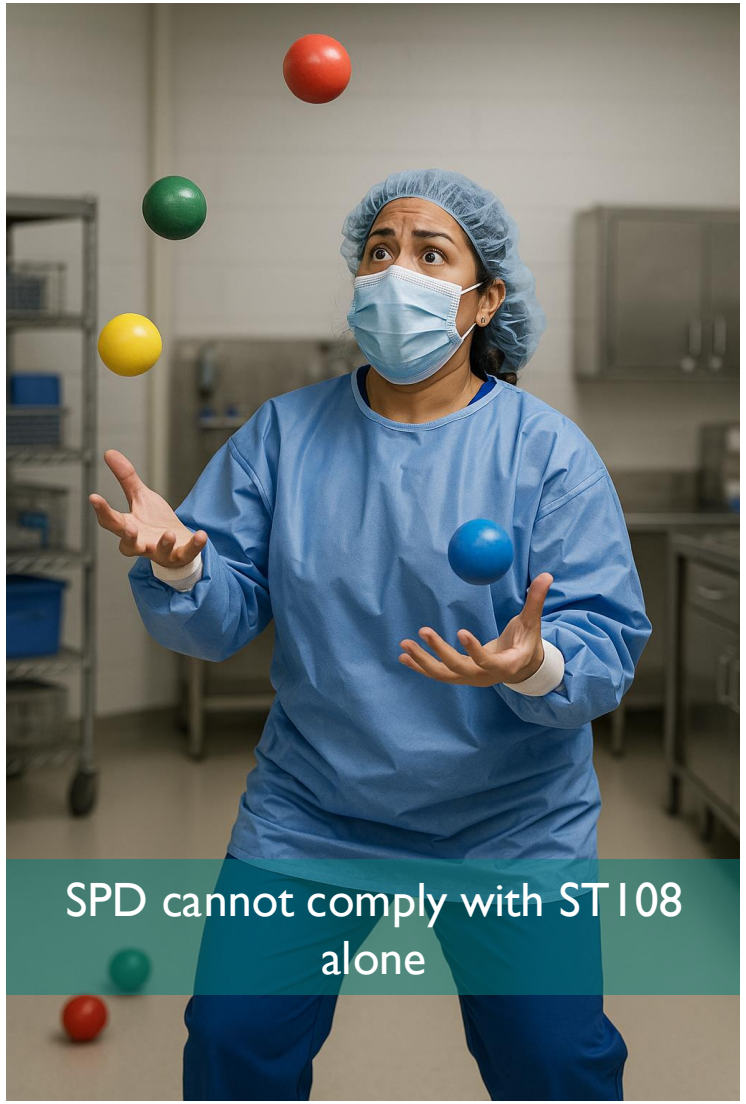

Ultrasonics

BEST PRACTICES FOR WATER MANAGEMENT IN SPDS

- Establishing routine testing and monitoring schedules.
- Documenting results to ensure audit readiness.
- Communication strategies for cross-functional team coordination.
- Handling municipal water source changes or seasonal variations.

SECTION 3

The Cross-Functional Team Required to Successfully Comply



A CROSS-FUNCTIONAL TEAM IS REQUIRED FOR SUCCESSFUL COMPLIANCE

WATER IMPACTS PATIENT OUTCOMES

Plumbing Dead Legs

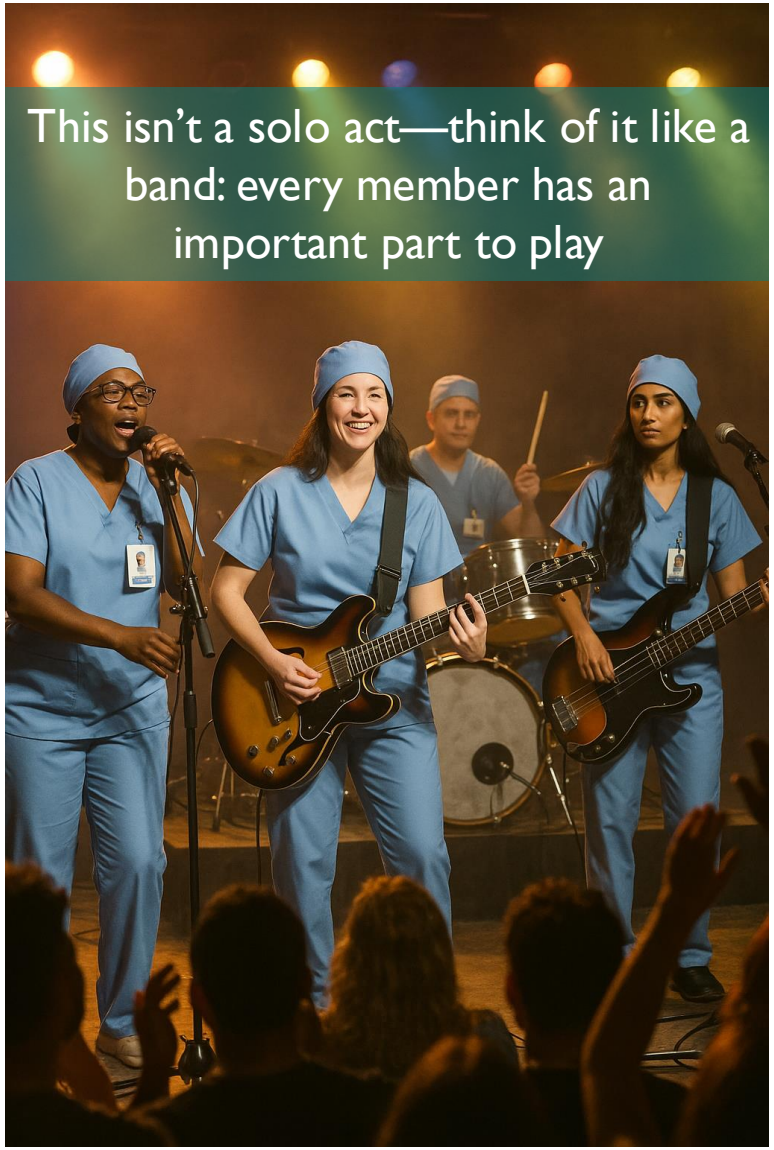
Biofilm Build-up

SSIs

WHO NEEDS TO BE INVOLVED

ASSEMBLE THE AQUA AVENGERS (WATER MANAGEMENT TEAM)

Includes Internal and External Members



EDUCATION, REVIEW, AND CONTINUOUS IMPROVEMENTS

BUILDING A CULTURE OF WATER QUALITY

1. Staff training on water quality basics

2. Annual review of the water management program

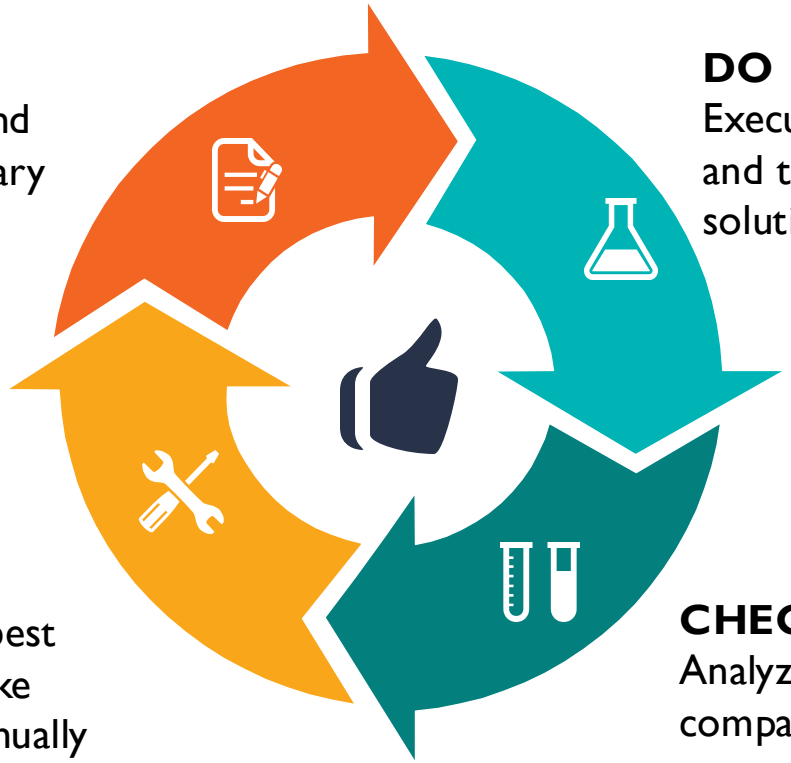
3. Revise based on:
    - New equipment
    - Changes in water source or treatment
    - Nonconformances or adverse effects

WATER MANAGEMENT PROGRAM

WHAT GOOD LOOKS LIKE

PLAN
Identify needs and establish necessary objectives

DO
Execute the plan and test potential solutions



CHECK
Analyze results in comparison with the expected results

ACT
Implement the best solutions and take actions to continually improve performance

1. Optimize water quality
2. Bolster the effectiveness of sterile processing

- Multi-step process
- Requires an understanding of all areas where reprocessing occurs
- Routinely review and document
- "Living Plan" adaptable with adjustments informed by documented monitoring data

CASE STUDY: "IT WASN'T MAGIC – IT WAS A PLAN"

HOW ONE MEDICAL CENTER BUILT A HIGH-PERFORMING WATER MANAGEMENT PLAN

CONSISTENCY
Monthly Testing = Real Insights

OWNERSHIP
Visible Wins = Stronger Buy-in

RECOGNITION
Appreciation = Culture Change

AUTHORITY
Empowered Staff =
Faster Problem Solving

THANK YOU

Send questions or comments to:

- Kenneth Mayer
- Director of Marketing
- kmayer@mmicmedical.com
- linkedin.com/in/kenneth-mayer
- https://verdawater.com