



SUPPORTING WATER QUALITY IN STERILE PROCESSING:

A Practical Guide to AAMI TIR119

A preview on the expanding guidance
on water quality in sterile processing



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AGENDA

Learning Objectives

01 Understand the importance of managing water in Sterile Processing

The role of water quality

02 Review the water quality specifications of an ST108-aligned program

The water quality specifications set out by AAMI

03 Identify the new guidance for WMSP operations in TIR119

What is new in the guidance and how does it interaction with ST108?

04 Evaluate key considerations for water management teams on implementing guidance

Questions to ask today.



01

UNDERSTANDING THE "WHY"

The Role of Water Quality

THE ROLE OF WATER QUALITY

The Why = Successful Patient Outcomes



Surgeries are the **key source revenue** for a hospital



Sterile processing relies on water to supply surgeries with **safe** instruments at a **cost-effective rate**

THE ROLE OF WATER QUALITY

The Why = Successful Patient Outcomes



The goal of an ST108 program is to **prevent water from being a limiting factor in this cycle.**

THE ROLE OF WATER QUALITY

Water as a limiting factor: Rust / damage to instruments



Staining on an eye caliper



Eye scissor with rust build up



Bone clamp with fractures and staining

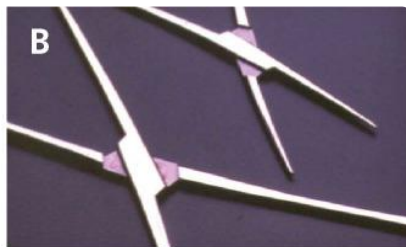
THE ROLE OF WATER QUALITY

Water as a limiting factor: staining / risking SSI's



Multicolored (rainbow) staining

**Excessive Heat / too much
amines in the steam**



Black staining

**Acidic Detergent
Residues**



Gold Brown staining

Galvanic corrosion



White / Chalky staining

Mineral Build Up

THE ROLE OF WATER QUALITY

Water as a limiting factor: Fabric Contamination

Mineral contaminants in water and or steam resulted in staining of liners used inside rigid sterilization containers— kits rejected



THE ROLE OF WATER QUALITY

Water as a limiting factor: Damage to capital assets / costly maintenance or reduced output.



Scale build-up on inline filters that were not properly serviced



Hard water build up in feedwater pipe—had to be replaced and serviced regularly at \$15,000/yr



Algae contamination in a Reverse-Osmosis System Rotameter

THE ROLE OF WATER QUALITY

A Quick Review of ST108 — 1 of 2



DEFINES Water Quality Specifications

Parameters to monitor and maintain, at start-up and routine operations



REQUIRES a Team to manage the program

Multidisciplinary, similar in structure to those found in ASHRAE Std. 188



ADVOCATES for a Risk Assessment based on data

Objective information on your system's health should drive program scope

THE ROLE OF WATER QUALITY

The Three Water Types, as defined by AAMI



Utility Water

- Initial Rinse
- Manual Cleaning
- Minimal treatment, usually tap water



Critical Water

- High Purity Final Rinse
- Extensive water treatment and filtration to produce
- Highly sensitive, highest risk



Steam

- Sterilization
- Pumped from utility plant or created within equipment

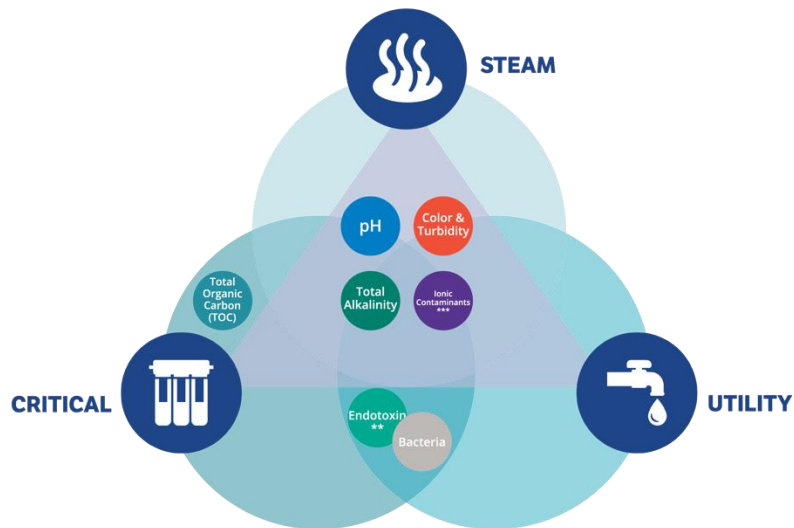
THE ROLE OF WATER QUALITY

A Quick Review of ST108

ST108 defines **WHAT** and **HOW OFTEN** to test, but does not provide guidance on implementation or response when parameters pass control limits

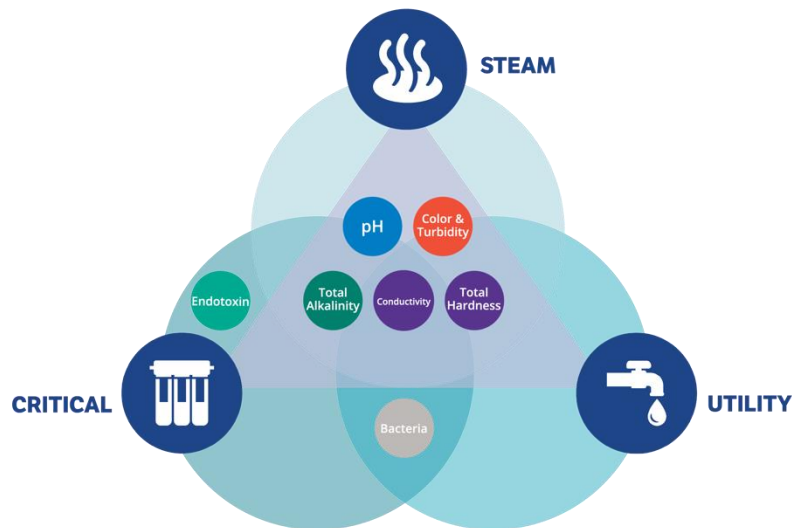
QUALIFICATION

Table 2



ROUTINE

Table 4

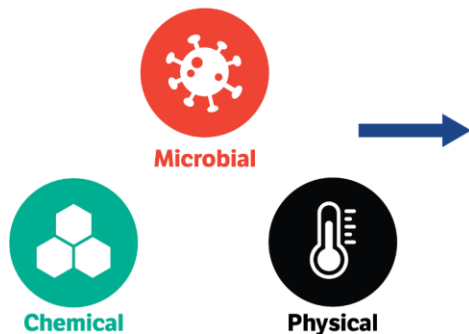


THE ROLE OF WATER QUALITY

Comparing Risk Assessment vs a typical *Legionella* Program

ANSI/ASHRAE Stds. 188 & 514

Hazard-Focused



**Patient
Safety**

ANSI/AAMI ST108

Delivery of Care



EXPANDING ON ANSI/AAMI ST108

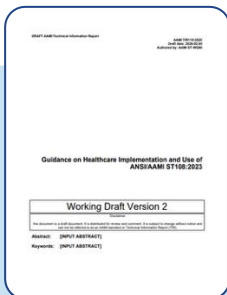
Distinguishing the Role of TIR119

THE ROLE OF TIR119

Defining TIR119

AAMI TIR119

- Is a Technical Information Report (TIR)
- Supplements the information from ST108 by providing guidance
- Supports healthcare facilities in implementing and using ST108



ANSI/AAMI ST108

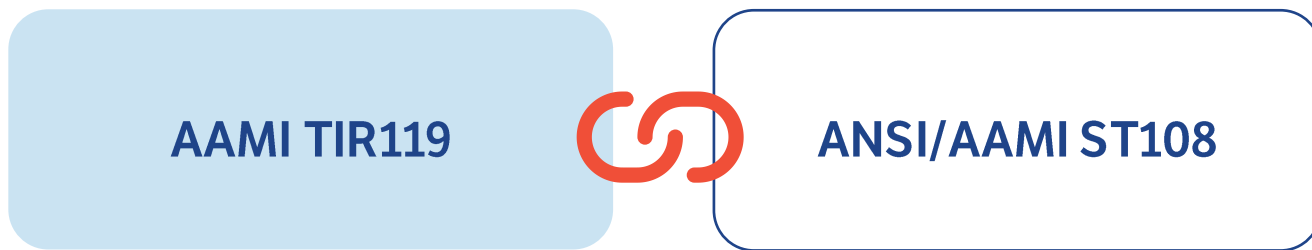
- Is a National Standard; first published in 2023
- Outlines the required water characteristics for different stages of medical device reprocessing
- Defines water types based on the qualities possessed



THE ROLE OF TIR119

ST108 Support

- TIR119 **exists to support** healthcare facilities in understanding and implementing ST108.
- The goal of this document is to **complement and explain ST108**, making it easier to align.
- **TIR119 does not replace or modify ST108.**



THE ROLE OF TIR119

TIR119 Scope

- Applies to healthcare centers such as hospitals, surgical centers, mobile units, dental offices, and **ANY facility where reusable medical devices are cleaned.**
- Offers practical tools, checklists, and examples for testing, qualification, and risk management.
- **Reinforces the need for a Sterile Processing Water Management Program** as the best way to align to ST108.



Key Elements of TIR119

KEY ELEMENTS

MDT Formation & Responsibilities

Multidisciplinary Team (MDT) in TIR119 is synonymous with Water Management Team (WMT) from ANSI/ASHRAE Std. 188

The recommended personnel are largely the same as in your Std. 188-aligned program:



**Sterile
Processing**



**Facilities/
Ops**



**Water
Treatment**



**Biomed
Engineering**



**Infection
Prevention**



**Risk
Management**



**Leadership/
Admin**



01

KEY ELEMENTS

MDT Formation & Responsibilities

TIR119 suggests **integrating a Sterile Processing Multidisciplinary Team into an existing WMT from an ANSI/ASHRAE Standard 188-aligned program.**
(Section 6.3)

The team is **in control of all decisions** of the Sterile Processing Water System, including equipment qualification and installation.



KEY ELEMENTS

MDT Formation & Responsibilities

Team **must** assemble experts in water system design, device processing, infection control, and engineering.

Responsible for assessing existing systems, planning upgrades, and overseeing monitoring and corrective actions.

KEY ELEMENTS

Implementing a Sampling Strategy



QUALIFICATION TESTING

To establish a baseline



ROUTINE MONITORING

Transition based on risk assessment
and system performance.



ALIGNMENT WITH ST108

MDT oversees all actions, ensuring
alignment with ANSI/AAMI ST108:2023.

KEY ELEMENTS

Documentation

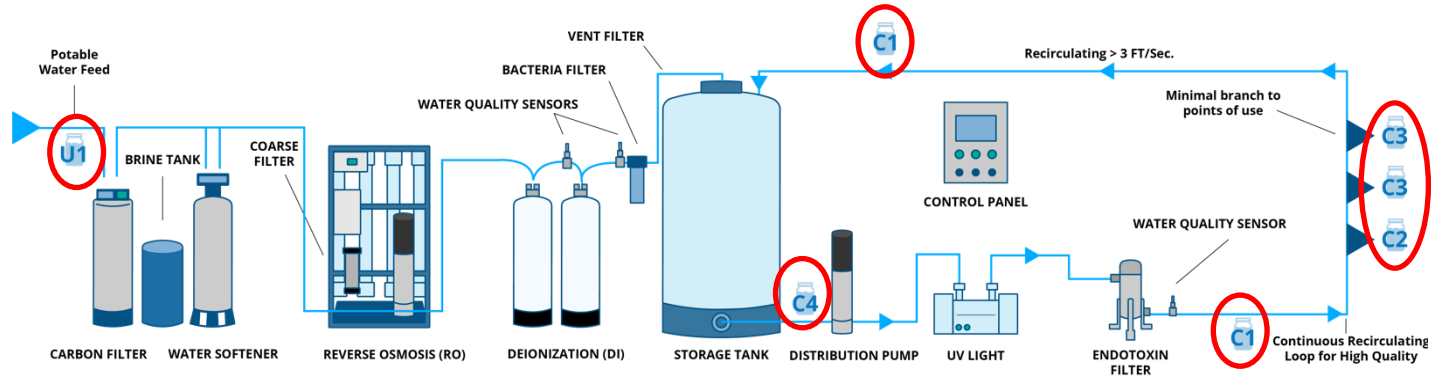
- TIR119 emphasizes documentation and recordkeeping to support the defensibility of the overall program. (Section 12).
- Documentation also supports risk-informed decision-making.
- Annual reassessment is recommended
- ST108 requires requalification is needed periodically or when major system changes occur.

If you didn't document it, you didn't do it.

KEY ELEMENTS

Sampling Plan

- **A written sampling plan is recommended** as part of your records. (Section 12.3.3)
- **TIR119 enforces the importance of splitting sampling** into Point-of-Generation (POG) and Point-of-Use (POU) locations.
- It confirms that the MDT has **a great degree of latitude to choose sample locations**.



KEY ELEMENTS

Qualification Steps

01

Design Qualification (DQ)

Ensure system design meets water quality needs.

02

Installation Qualification (IQ)

Verify correct installation of equipment.

03

Operational Qualification (OQ)

Confirm system operates within expected parameters.

04

Performance Qualification (PQ)

Demonstrate consistent production of water meeting specifications. The minimum recommended amount is 4 tests over 1 month

ALL are the responsibility of the MDT

KEY ELEMENTS

Routine Monitoring

- **Testing requirements from ST108 Table 4 still apply.**
- **Not all deviations require immediate corrective action.**
Documentation of rationale supports consistency and defensibility.
 - **Alert Level** – Indicates a result is within range but is changed from baseline.
 - **Action Levels** - Indicates a result exceeds set threshold.
- Level thresholds can be refined with historical data.
- TIR119 recommends MDT set thresholds below ST108 limits to trigger early intervention.

KEY ELEMENTS

Additional Guidance

- TIR119 highlights the importance of **capturing seasonal water quality changes.**
- Equipment MIFU (Manufacturer's Instructions for Use) **must be reviewed and considered.**
- Utility water can fail to meet standards but **meet IFUs.**
- Examples of multiple case studies highlight real-world failures due to poor design or oversight.



KEY ELEMENTS

Implementing a Sampling Strategy



FREQUENCY OF TESTING

Semiannual disinfection set as recommended minimum. Monthly disinfection is recommended for Critical Water systems.



ROUTINE MONITORING

Transition based on risk assessment and system performance.

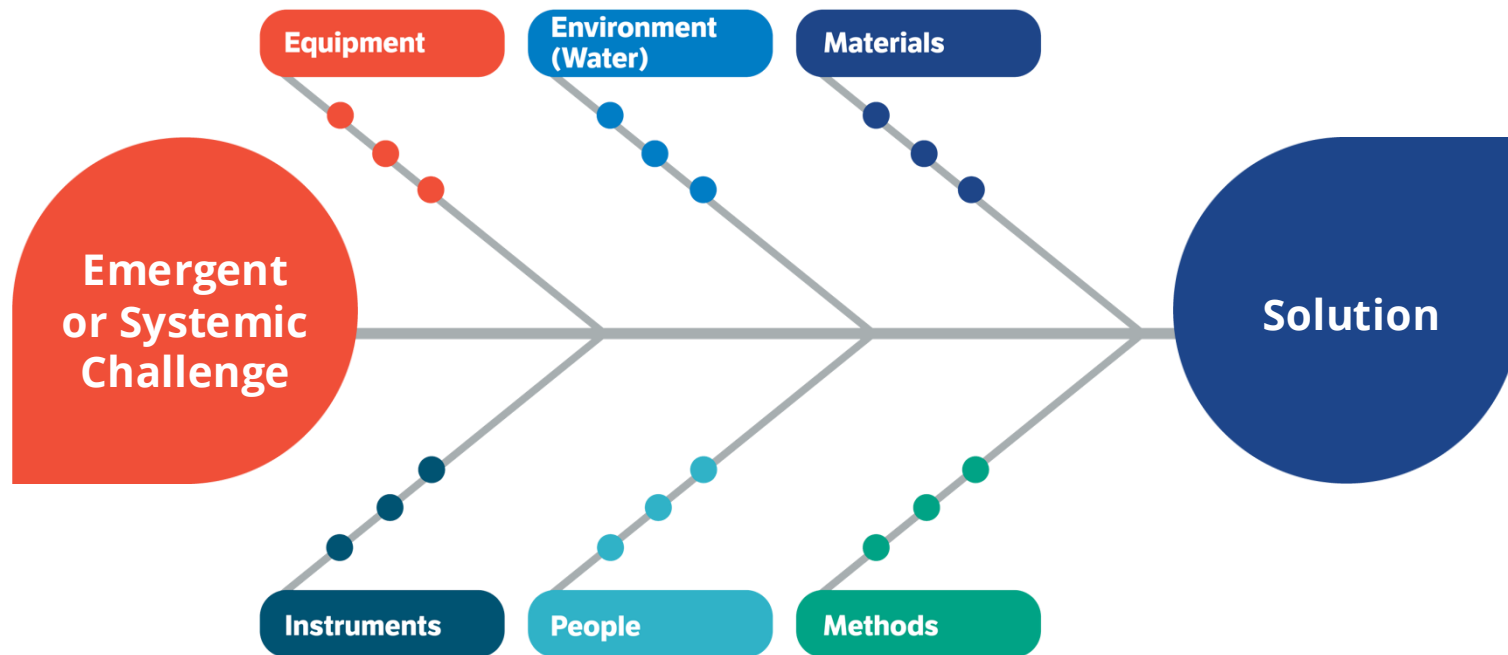


ALIGNMENT WITH ST108

MDT oversees all actions, ensuring alignment with ANSI/AAMI ST108:2023.

KEY ELEMENTS

Root Cause Analysis



KEY ELEMENTS

Root Cause Analysis— Example 1:

Identifying the source of a blue stain on endoscopes

Environment:

- Does your normal water quality meet equipment needs?
- Does routine monitoring indicate any change in water quality?

People:

- How is pre-treatment being managed?
- Was this properly cleaned during manual washing?

Materials:

- Are there any known reactions that occur with the detergent?

Equipment:

- After what piece of equipment was the stain identified?

Methods:

- Was the instrument processed appropriately/per its IFU?

KEY ELEMENTS

Root Cause Analysis— Example 1:

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- Are there any known reactions that occur with the detergent? →

Equipment:

- After what piece of equipment was the stain identified?

Methods:

- Was the instrument processed appropriately/per its IFU?

According to the detergent manufacturer FAQ, the detergent is **known to stain if there are proteins on the materials.**

This also pointed to the need to **reassess manual washing procedures** which were allowing proteins to remain on the instruments. Corrections implemented by the endoscopy team.

KEY ELEMENTS

Root Cause Analysis— Example 2:

Finding the source of black flecks on instruments

Environment:

- Does your normal water quality meet equipment needs?
- Does routine monitoring indicate any change in water quality?

People:

- How is pre-treatment being managed?
- Was this properly cleaned during manual washing?

Materials:

- What are the flecks made of, e.g. are they magnetic?

Equipment:

- After what piece of equipment was the black flecks identified?

Methods:

- Was the instrument processed appropriately/per its IFU?

KEY ELEMENTS

Root Cause Analysis— Example 2:

Finding the source of black flecks on instruments

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- Does your normal water quality meet equipment needs?
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Materials:

- What are the flecks made of, e.g. are they magnetic?

Equipment:

- After what piece of equipment was the black flecks identified?

Methods:

- Was the instrument processed appropriately/per its IFU?

Found after the steam sterilizer— prompted **review of preventative maintenance** logs and procedures.

Identified that **steam filters had never been changed +** gaskets were breaking down. Corrections done by facility team.

Questions for Teams

QUESTIONS FOR THE TEAM

Water Management for Sterile Processing



Do we have the expertise to do a full gap analysis?

Having all the stakeholders is key



What processes already exist in our Std. 188 program?

No need to start from scratch



When was the last full program review?

Scope, controls, monitoring, etc



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Q&A



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