APEX

Navigating ST108: What Health Care Facilities Need to Know

Water Quality Requirements for Medical Device Reprocessing

Contents

What is ANSI/AAMI ST108?

ANSI/AAMI ST108 is the first comprehensive American National Standard outlining water quality and steam purity requirements for processing reusable medical devices. Introduced in 2023, the standard replaces previous TIR34 guidance, changing the landscape of health care water management by transitioning water quality from a “utility” concern to a critical, formal “standard of care” mandate.

Moving from Guidance to Enforcement

Replacing TIR34 with ST108 moves water quality oversight from voluntary guidance to a structured, enforceable framework with direct implications for organizational compliance:

ACCREDITATION IMPACT

Accrediting bodies such as The Joint Commission, DNV and ACHC now evaluate water management through the lens of governance, expecting a structure program that demonstrates measurable control over water quality.

CMS CONDITIONS OF PARTICIPATION (COP)

While CMS may not explicitly name ST108, its requirements are embedded within the Conditions of Participation related to infection prevention, environment of care and governing body oversight.

REGULATORY DEFENSIBILITY

Adherence to this recognized national standard establishes the baseline for legal defensibility. Failure to comply creates significant liability exposure in the event of adverse patient outcomes or surgical site infection investigations.

Making the Distinction between ST108 and ASHRAE 188 & 514

ASHRAE 188, ASHRAE 514 and ST108 are critical, often overlapping, water management standards. ASHRAE 188 & 514 govern building-wide water safety, *Legionella* risk management, and additional physical, chemical & microbial hazards, while ST108 focuses exclusively on water used for medical device reprocessing. ST108 is considered a specialized component within a broader ASHRAE 188 & 514 Water Management Program, as failures at the building level increase the burden on device-level treatment systems.

Strategic Risk Synthesis

Non-compliance with ST108 isn't merely a technical issue – it presents direct risk to operational continuity and patient safety:

CLINICAL FAILURES

Poor water quality can result in sterilization failures, endotoxin contamination of "clean" instruments and the transmission of waterborne pathogens.

LEGAL AND FINANCIAL EXPOSURE

Failure to demonstrate compliance with a recognized national standard increases liability during adverse event investigations.

ASSET DEGRADATION

Substandard water irreversibly damages surgical instruments and shortens the lifespan of sterilization infrastructure.

OPERATIONAL DISRUPTION

System failures or regulatory citations can lead to immediate suspension of surgical services, impacting revenue and reputation.

Defining Water Types and Quality Standards

ST108 requires water quality be matched to the risk profile of the medical device being processed.

ST108 Water Quality Classifications

Water Type	Description / Typical Uses	Testing Frequency
Utility Water	Potable water used for initial rinsing, washing and intermediate rinse cycles. Must meet defined chemical and microbial limits.	Quarterly (final treatment step and point of use)
Critical Water	High-purity water required for final rinses before sterilization or after high-level disinfection, with endotoxin and microbial control.	Monthly lab testing; daily conductivity monitoring
Steam	Feedwater for steam sterilization. Condensate must meet purity limits similar to Critical Water.	Quarterly (sterilizer point of use) *Note: Routine microbial/ endotoxin testing of condensate not required*

ANSI/AAMI ST108 Water Quality Recommendations for Medical Device Reprocessing

					Minimum Monitoring Frequency		
Metric	Units	Utility Water	Critical Water	Steam	Utility Water	Critical Water	Steam
Water Use		Flushing, Washing & Rinsing	Final Rinse & Steam	Sterilizers			
pH		6.5 - 9.5	5 - 7.5	5.0 - 9.2	Quarterly	Monthly	Quarterly
Total Alkalinity	Mg CaCO3/L	< 400	< 8	< 8	Quarterly	Monthly	Quarterly
Bacteria	CFU/mL	< 500	< 10	N/A	Quarterly	Monthly	N/A
Endotoxin	EU/mL	N/A	< 10	N/A	N/A	Monthly	N/A
Total Organic Carbon	ppm	N/A	< 1	N/A	N/A	Annually	N/A
Color & Turbidity	Visual	Colorless, clear, without sediment			Daily		
Aluminum	ppm	< 0.1			Annually	Annually	N/A
Chloride	ppm	< 250	< 1	< 1	Annually	Annually	N/A
Conductivity	uS/cm	< 500	< 10	< 10	Quarterly	Daily	Quarterly
Copper	ppm	< 0.1			Annually	Annually	N/A
Iron	ppm	< 0.1			Annually	Annually	N/A
Manganese	ppm	< 0.1			Annually	Annually	N/A
Nitrate	ppm	< 10	< 1	< 1	Annually	Annually	N/A
Phosphate	ppm	< 5	< 1	< 1	Annually	Annually	N/A
Sulfate	ppm	< 150	< 1	< 1	Annually	Annually	N/A
Silicate	ppm	< 50	< 1	< 1	Annually	Annually	N/A
Total Hardness	ppm	< 150	< 1	< 1	Quarterly	Monthly	Quarterly
Zinc	ppm	< 0.1			Annually	Annually	N/A

Mapping Device Risk Levels

Water quality requirements are dictated by the Spaulding Classification and device contact risk:

1. **Critical devices**
   Come in contact with sterile tissue or bloodstream (e.g., surgical sets); require a final rinse with Critical Water before sterilization.

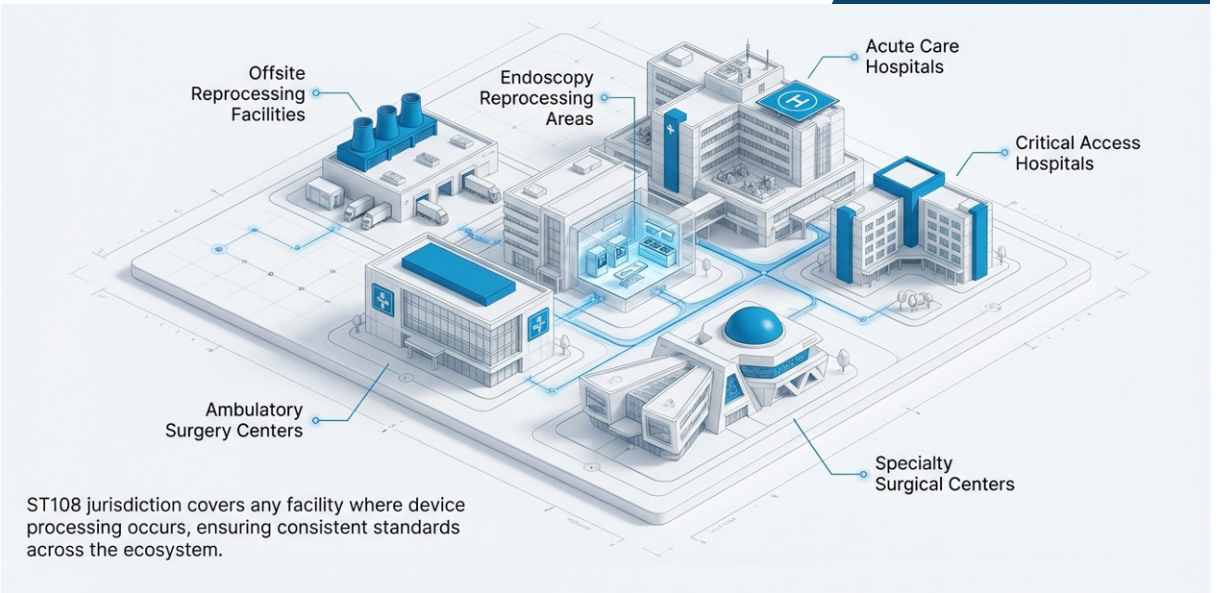
2. **Semi-critical devices**
   Come in contact with mucous membranes (e.g., endoscopes); require Critical Water after high-level disinfection.

3. **Non-critical devices**
   Come in contact with intact skin; Utility Water is generally acceptable.

Applicable Health Care Facilities

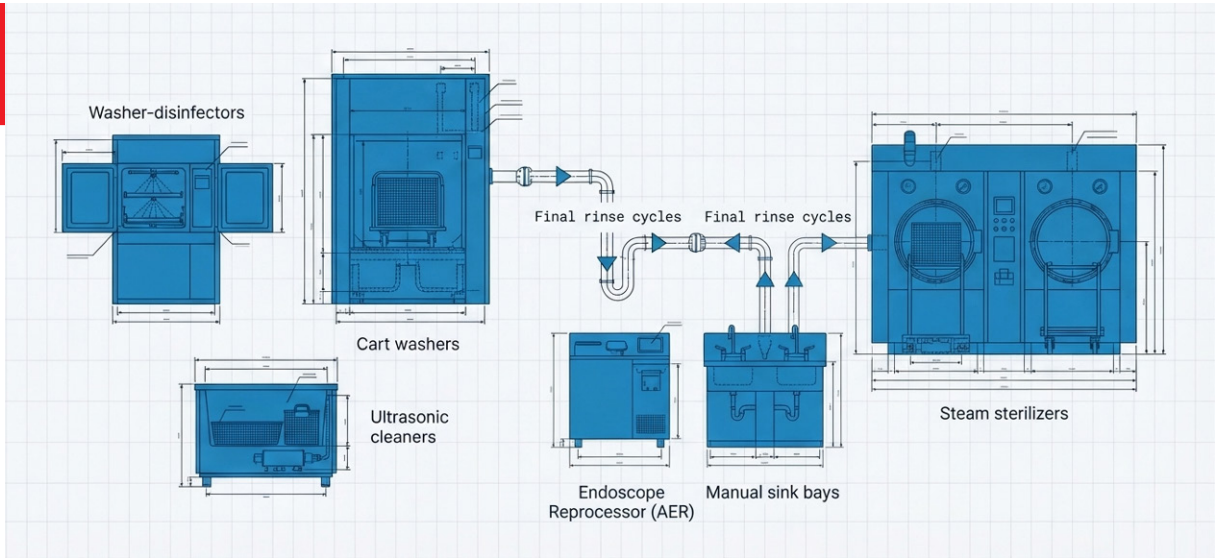
ST108 applies to any clinical environment where reusable medical devices are processed, including acute care and critical access hospitals, ambulatory surgery centers, offsite reprocessing hubs and endoscope reprocessing suites. Covered equipment includes washer-disinfectors, cart washers, steam sterilizers, ultrasonic cleaners and manual sink bay final rinses.

The Operational Environment



ST108 jurisdiction covers any facility where device processing occurs, ensuring consistent standards across the ecosystem.

Critical Systems & Cycles



The Multidisciplinary Governance Model

Water quality management must be governed as a cross-functional leadership responsibility to mitigate operational risk and maintain regulatory readiness.

Functional Accountabilities

Department	Primary Responsibilities
Sterile processing	Daily performance monitoring; point-of-use application; alarm response and reports
Facilities engineering	Infrastructure maintenance; system reliability; preventive maintenance
Infection prevention	Clinical risk assessments; pathogen oversight
Quality/clinical engineering	Device integration; performance verification

The Oversight Mandate

Governance teams must demonstrate measurable control through a documented Water Quality Management Program that supports survey readiness and continuous compliance.

Engineered for Compliance

ST108-compliant systems are intentionally engineered to deliver consistent, validated water quality and eliminate conditions that enable pathogen growth.

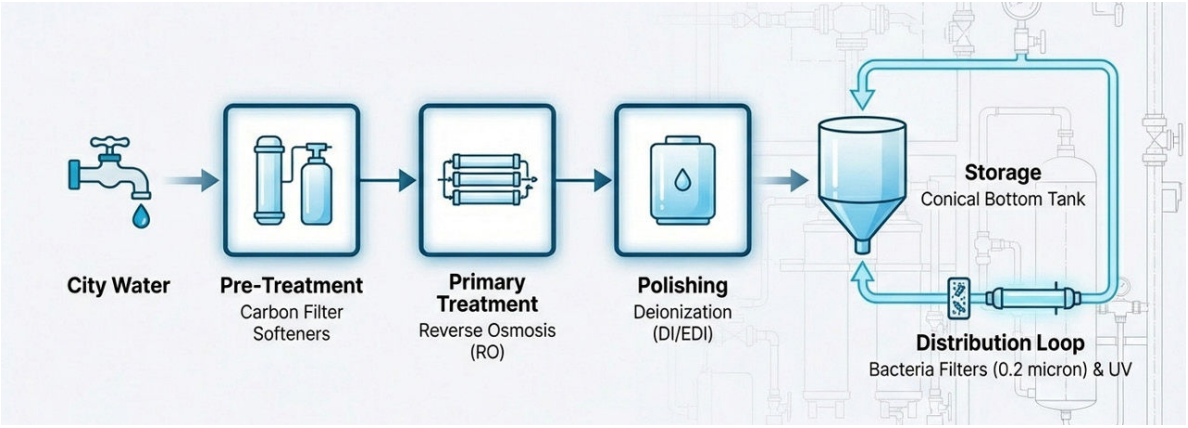
System Component Deconstruction

Pretreatment:
Remove chlorine, chloramines and hardness

RO/Deionization or EDI:
Reduces dissolved solids, microbes and conductivity

Sanitary storage and distribution:
Closed tanks and continuous recirculation loops

System Design: The Ideal Process Flow



The Path to ST108 Compliance: Six Essential Steps

Achieving sustained compliance requires a structured, multi-phased approach that integrates technical validation with organizational oversight.

THE PATH TO ST108 COMPLIANCE: SIX ESSENTIAL STEPS

1

Define and identify:
Map water types and clinical points of use.

2

Establish limits
Set chemical and microbial targets with ST108.

3

Monitor and trend
Analyze performance data to detect early drift.

4

Validate (IQ/OQ/PQ)
Confirm reliable system installation, operation and performance.

5

Formalize governance
Embed responsibilities into a structured oversight framework.

6

Document everything
Maintain comprehensive, survey-ready records.

The Risk Assessment Layer

Initial risk assessments identify specific contamination points, stagnation risks and dead legs within the distribution loop to focus monitoring on areas most vulnerable to biofilm formation.

Sustained Surveillance and Remediation Protocols

Compliance requires continuous verification through disciplined monitoring programs.

The Surveillance Framework

- **Continuous:** Real-time tracking of conductivity, temperature and pressure
- **Daily/Weekly:** Visual inspections for color, clarity and turbidity
- **Monthly:** Microbial and endotoxin testing (Critical Water)
- **Quarterly/Annually:** Chemical and microbial validation

The Corrective Action Cycle (Remediation)

When quality limits are exceeded, organizations must follow a formal response cycle:

1. **Investigate root cause**
2. **Correct the issue**
3. **Verify restored control**
4. **Document all actions**

Frequently Asked Questions

Frequently Asked Questions

What is AAMI ST108, and why is it critical to our organization?

AAMI ST108 is a national standard that defines water quality requirements for processing reusable medical devices. Adopted in 2023 to replace TIR34, it elevated guidance to a formal standard. Compliance is critical to prevent infection risk, sterilization failures, equipment damage, operational disruption and legal threat. It's also increasingly viewed as a standard of care during surveys.

Does ST108 apply to our ambulatory surgery center or specific departments?

Yes, ST108 applies anywhere water is used to process reusable medical devices, including ASCs, hospitals, specialty centers and endoscopy areas. It covers equipment like washer-disinfectors and sterilizers, but not general building water systems, which fall under standards like ASHRAE 188 & 514.

What types of water quality does ST108 require us to manage?

ST108 establishes three water quality categories: Utility Water (used for flushing, washing and rinsing of medical devices), Critical Water (used for final rinse or steam generation), and Steam (used for sterilization of medical devices). Requirements increase as water gets closer to patient contact.

Frequently Asked Questions

How will regulatory bodies like CMS and The Joint Commission evaluate our facility?

Surveyors expect a structured, well-documented water quality management program, including defined limits, routine monitoring, data trending, testing and corrective actions. While CMS may not cite ST108 directly, its expectations are reflected in Conditions of Participation related to safety, quality and infection prevention.

What practical steps should our facility take to achieve compliance?

Facilities must move beyond equipment to structured governance and measurable control by defining water types, setting limits, monitoring and trending data, validating system performance, formalizing a Water Quality Management Plan and documenting all activities. Taking timely corrective action is required when limits are exceeded.

Who needs to be involved in our Water Quality Management Program?

ST108 requires cross-functional accountability. Sterile Processing monitors daily performance, Facilities maintains system infrastructure, Infection Prevention provides risk oversight and Clinical/ Quality teams support integration and compliance.

How do we conduct a risk assessment to identify contamination points?

Start by mapping the system from source to point of use. Identify risks such as stagnation, dead legs and biofilm formation in storage tanks and distribution loops. This process should involve multidisciplinary collaboration, with Infection Prevention leading risk assessment and oversight.

Discover how Apex can help your health care facility achieve water safety and compliance. Connect with our team to learn more:
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