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**Introduction to ANSI/AAMI ST108**

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- 2. Conflict of interest:** Employee of STERIS.
- 3. Commercial company support:** Fees are underwritten by education funding provided by STERIS.
- 4. Non-commercial company support:** None.
- 5. Alternative/Complementary therapy:** None.

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- This program is approved for:
  - **0** hour(s) of GI Specific content credit by **ABCGN** (American Board of Certification for Gastroenterology Nurses),
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  - **1** contact hour(s) of continuing education credit
    - **CBRN** (California Board of Registered Nursing);
    - **CBSPD** (Certified Board for Sterile Processing and Distribution); and
    - **HSPA** (Healthcare Sterile Processing Association).

**Continuing Education**




Through a partnership with CCI®, it also meets CNOR® and CSSM® recertification requirements for perioperative nurses.

**Learning Objectives**

- Describe the scope of the ANSI/AAMI ST108 standard, Water for the processing of medical devices
- Describe the focus of each section within the standard

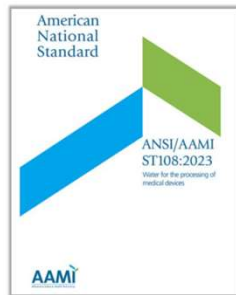
**Insufficient Water Quality = Poor Outcomes**



- Medical Device Damage
- Processing Equipment Damage
- Processing inefficiencies
- Negative Patient Outcomes

### Scope:

- Healthcare
- Water quality requirements for processing medical devices
- Maintenance and quality assurance



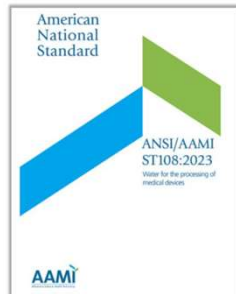
### 5 Subject Areas

- Roles and Responsibilities
- Water Quality and Use
- Water Treatment Systems
- Quality Control
- Special Considerations



### Exclusions:

- Hemodialysis
- Laboratory water
- Steam quality specifications
- Water within medical equipment
- Municipal water quality
- Post use water testing



### Key Definitions - POU

#### Point-of-use treatment (POU)

*Device treatment immediately following use that may include rinsing, flushing, and preparation for transport.*

#### Point-of-water use (POU)

*Closest point in the distribution loop where water is exposed to a medical device during processing.*

#### Point-of-water use system (POU system)

*A water treatment system in which purification takes place just before a single water supply outlet.*

(ANSI/AAMI ST108, 2023)

### Key Definitions – Water Management Program

*A multistep process to identify hazardous conditions and take steps to minimize the growth and transmission of waterborne pathogens in building water systems; the program requires continuous review and documentation of the plan's implementation, operation, and mitigation strategies as appropriate.*

(ANSI/AAMI ST108, 2023)

### Key Definitions – Water Treatment System

*Collection of water purification devices and associated piping, pumps, valves and gauges that together produce treated water of a specified quality and deliver it to the point-of-water-use.*

(ANSI/AAMI ST108, 2023)

# 1 Roles and Responsibilities



- ## Roles And Responsibilities
- Section 4 and 5
- Multidisciplinary team identification
  - Roles and responsibilities
  - Water risk analysis
- Annex B: Risk analysis
- Annex I: Typical presentation of water quality issues during processing of medical devices

## Multidisciplinary Team Responsibilities

- Water Management Program
- Establishes training and competencies
- Obtains necessary resources
- Reporting

## Multidisciplinary Team

Team Member	Responsibilities
Executive Sponsorship	Resource allocation and support
Facility engineering	Installation, validation, and qualification
Clinical engineering	Risk management, equipment selection, construction, etc.
Water treatment specialist	Water treatment
Surgical suite / procedure room	Visual device inspection
Device processing	Alert leaders of potential water quality issues
Infection prevention	Surveillance monitoring, risk assessment, escalation

## Risk Analysis

**When**

- Prior to water treatment Implementation
- Periodically

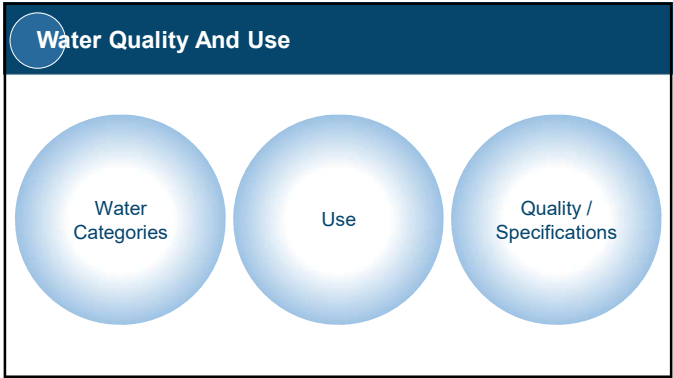
**What**

- Medical Devices
- Processes
- Patient (indirect)

**Help**

- Annex B
- Annex I

# 2 Water Quality And Use

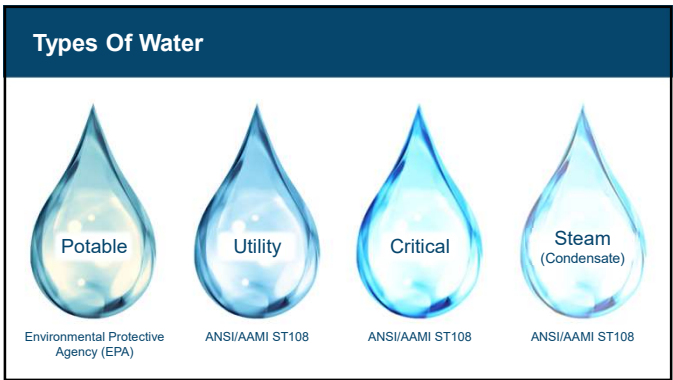


**Water Quality and Use**

Section 6 and 7

- Categories of water
- Water selection and requirements

Annex A: Guidance on the application of the normative requirements  
 Annex C: Automated Endoscope Reprocessor (AER)  
 Annex D: Water used in cleaning and moist heat processes



**Water Quality**

<u>Properties</u>	<u>Impurities</u>
<ul style="list-style-type: none"> <li>• pH</li> <li>• Total Alkalinity</li> <li>• Color &amp; Turbidity</li> <li>• Conductivity</li> </ul>	<ul style="list-style-type: none"> <li>• Bacteria and Endotoxin</li> <li>• Total organic carbon (TOC)</li> <li>• Silicate</li> <li>• Aluminum, copper, iron, manganese, zinc</li> <li>• Chloride, nitrate, phosphate, sulfate</li> </ul>

**Purity Progression**

See Table 2

	Potable	Utility	Critical	Steam (Condensate)
Bacteria (Heterotrophic Plate)	n/a	<500 CFU/ml	<10 CFU/ml	n/a
Copper	≤1.3 mg/L	<0.1 mg/L	<0.1 mg/L	<0.1 mg/L
Total Hardness	No limit	<150 mg CaCO <sub>3</sub> /L	<1 mg CaCO <sub>3</sub> /L	<1 mg CaCO <sub>3</sub> /L

Use

### Manual Cleaning

<ul style="list-style-type: none"> <li>• Utility Water</li> </ul>	<ul style="list-style-type: none"> <li>• Cold water rinse</li> <li>• Cleaning solutions</li> <li>• Intermediate rinse</li> </ul>	<ul style="list-style-type: none"> <li>• Final rinse</li> </ul>
Point-of-Use Treatment	Utility Water	Critical Water

### Washers And Washer Disinfectors

<ul style="list-style-type: none"> <li>• Initial rinse</li> <li>• Wash stage</li> <li>• Post-wash rinse stage</li> <li>• Chemical disinfection stage</li> </ul>	<ul style="list-style-type: none"> <li>• Final rinse</li> <li>• Thermal disinfection</li> </ul>
Utility Water	Critical Water

### Cleaning Chemistry Exception

- Tap water exception
- Formula specific
- Must test water
- Cleaning and intermediate rinse

### Ultrasonic Cleaner

<ul style="list-style-type: none"> <li>• Cold water rinse</li> <li>• Cleaning solutions</li> </ul>	<ul style="list-style-type: none"> <li>• Unless different in the instructions for use</li> <li>• No rinse water recommendations</li> </ul>
Utility Water	

### Manual High-Level Disinfection

<ul style="list-style-type: none"> <li>• Cleaning</li> <li>• Post-wash rinse</li> <li>• Disinfectant Solution</li> </ul>	<ul style="list-style-type: none"> <li>• Post disinfection rinses</li> </ul>
Utility Water	Critical Water

## Mechanical High-Level Disinfection

- Cleaning Solutions
- Intermediate post wash rinses
- HLD Solution (from concentrate)
- Post HLD rinses including final rinse\*

\*Unless different in the instructions for use

Utility Water



## Sterilization

### Liquid Chemical Sterilization

- Follow instructions for use liquid chemical sterilant



### Steam Sterilization

- Steam condensate and ANSI/AAMI ST79 steam quality



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## Water Treatment Systems

## Water Treatment Systems

Design

Qualification  
Testing

Maintenance

## Water Treatment Systems

Section 8, 9, and 12

- Water system design
- Qualification
- Maintenance

Annex E: Water treatment technologies

Annex F: Water treatment system design

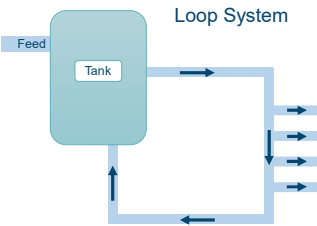
## Types Of Water Treatments

Physical Treatment

Chemical Treatment

## Design Considerations

- Order of treatment equipment
- Delivery system design
- Loop system
- Water sampling access



## Qualification

Installation an Operational Qualifications (IQ/OQ)

- Proper Installation
- Test each treatment step
- Test point-of-water use
- Establish alert and action levels



## Qualification

Performance Qualification

- Water volume and quality
- Seasonal variation
- Confirms alert and action levels



## Maintenance

- Daily checks
- Monthly disinfection
  - Tanks
  - Loop system
- Instructions For Use



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Quality Control

## Quality Control

Routine Testing

Continuous Improvement

## Quality Control

- Section 10 and 11
- Routine Monitoring
- Continuous improvement

Annex G: Routine monitoring of water treatment equipment & produced water

Annex H: Maintaining microbiological quality

## Sampling Locations

### Point-of-Generation

- The point after the last treatment
- Start and end of loop
- Table 5

### Point-of-Water Use

- Varies based on test
- Table 6

## Utility Water

	<u>Point of Generation</u>	<u>Point of Water Use</u>
Daily	• None	• Visual Inspection
Quarterly	• pH • Conductivity • Total Alkalinity • Total Hardness	• Conductivity • Total Alkalinity • Total Hardness

Additional Testing: type of impurities and treatment equipment

## Critical Water

	<u>Point of Generation</u>	<u>Point of Water Use</u>
Daily	• Conductivity	• None
Monthly	• pH • Conductivity • Total Alkalinity • Total Hardness • Bacterial • Endotoxin	• pH • Conductivity • Total Alkalinity • Total Hardness • Bacterial • Endotoxin

Additional Testing: type of impurities and treatment equipment

## Steam Condensate

	<u>Point of Generation</u>	<u>Point of Water Use</u>
Daily	• None	• None
Monthly	• None	• None
Quarterly	• None	• Conductivity • Total Alkalinity • Total Hardness

Additional Steam Quality Requirement in ANSI/AAMI ST79 Section 3.3.3.2

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Special Considerations



## Special Considerations

Extended  
Shutdown

Boil Alert

Repair or  
Modification

## Special Considerations

- Section 13
- Post construction and extended shutdowns
- Extended boil water alerts
- Interruptions in service
- System repair or modification

## Extended Shutdown

- Remove stagnant water
- Reduce bacterial counts
- Remove aerators and flush sink lines
- Qualification



## Boil Alerts

- Change filters and resin tanks
- Disinfect and flush



## System Wide Disinfection Required When:

- Installation of new or replacement equipment
- Major repair
- Expansion
- Non-compliant bacteria levels

## Action Items

- Perform a baseline water quality risk assessment.
- Acquire ANSI/AAMI ST108.
- Plan the next steps.

## References

- Association for the Advancement of Medical Instrumentation (AAMI) (2021) *ANSI/AAMI ST79:2017 with Amendments A1:2020, A2:2020, A3:2020, A4:2020 Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. AAMI
- Association for the Advancement of Medical Instrumentation (AAMI) (2023) *ANSI/AAMI ST108:2023 Water for the processing for medical devices*. AAMI

Questions?



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