Water Management in Sterile Processing:

Evolution at UF Health

UF Health
UNIVERSITY OF FLORIDA HEALTH

phigenics®
Independent Water Management

Presented by:

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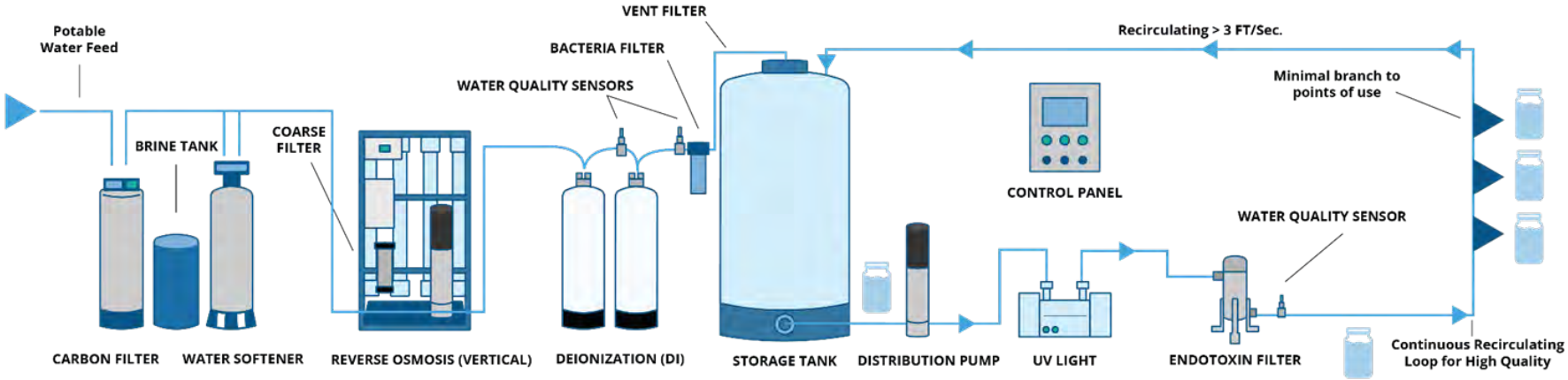
Learning Objectives

1. Components of a water management program in alignment with ANSI/AAMI ST108
2. Industry best practices for alignment with water quality goals
3. Lessons learned from
    - Design
    - System start-up & commissioning
    - Six month check-in
4. Functional roadmap for ongoing operations

Definitions

1. RO = reverse osmosis
2. DI = deionization
3. WMP = water management program
4. MDR = medical device reprocessing

Critical Water System



Critical Water System

Components of a water management program in alignment with ANSI/AAMI ST108

Goals of SP

Objective: To ensure that a device is safe for patient use and does not cause an adverse event in the patient. Adverse events to which inadequate water quality can cause includes:

- ✓ Device malfunction during a patient procedure e.g. breakage in a patient
- ✓ Toxic effects and tissue irritation from residuals
- ✓ Patient infection

Overall goals of water treatment in SP:

- ✓ Prolong the life of medical instrumentation (reduce cost)
- ✓ Ensure effectively functioning instrumentation (increase quality/performance)
- ✓ (More importantly), help minimize the risk of adverse patient outcomes arising from contaminated medical devices
- ✓ Ensure reliability & redundancy of water systems to prevent failure, down time, impact to OR schedules

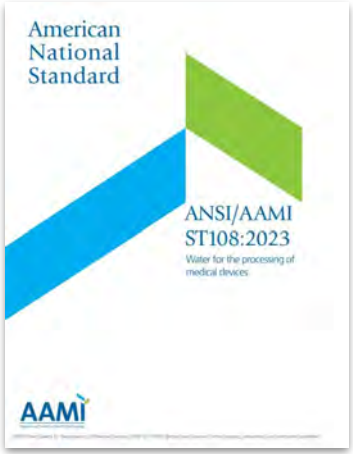
General categories of water in SP

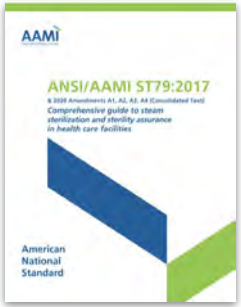
- **Utility Water (defined by AAMI)**
  - Any water that does not have to meet critical water requirements. Can be softened, filtered or simply tap water (as processed by building system)
- **Critical Water (defined by AAMI)**
  - DI or RO water that must meet a high purity requirement. Used for final rinsing of equipment at various MDR stages but probably most importantly, in the cart washers. Can also be used as makeup water to steam generators on sterilizers (clean steam)
- **Steam**
  - DI or RO water supplying steam generation is considered “clean”, while minimally processed water results in “dirty” or “process” steam.

Who determines water quality requirements?

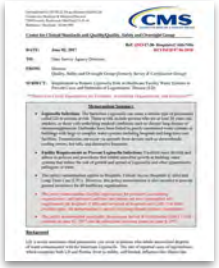
- ✓ City Water Supply
- ✓ Facility water processing prior to MDR
- ✓ Equipment Manufacturers (IFUs)
- ✓ ANSI/AAMI ST108 (Association for the Advancement of Medical Instrumentation)
- ✓ ANSI/AAMI ST79:2017
- ✓ AORN (Association of periOperative Registered Nurses)
- ✓ VHA Directive 1116(2)
- ✓ HSPA (Healthcare Sterile Processing Association)
- ✓ AHJ (i.e. TJC, AHCA, DNV)

Standards for Water in MDR



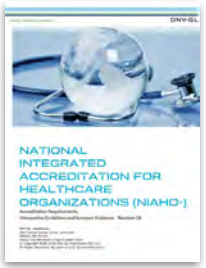


Standards for Water Management

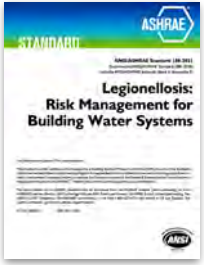


CMS Memo 17-30

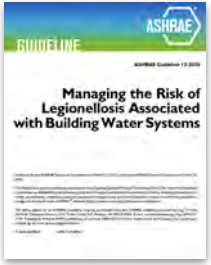
TJC EC.02.05.02



DNV PE.8



ANSI/ASHRAE
Standard 188:2021



ASHRAE Guideline
12:2020

ANSI/ ASHRAE
Standard 514

Recommendations for a Water Management Team

Stakeholders of the water treatment systems:

- ✓ Facility Management
- ✓ Sterile Processing Personnel
- ✓ BioMed
- ✓ 3rd party Contractors
- ✓ Infection Prevention
- ✓ Hospital WMT Chair
- ✓ Nursing / OR Leadership
- ✓ Quality

Water Management Program for Medical Device Reprocessing

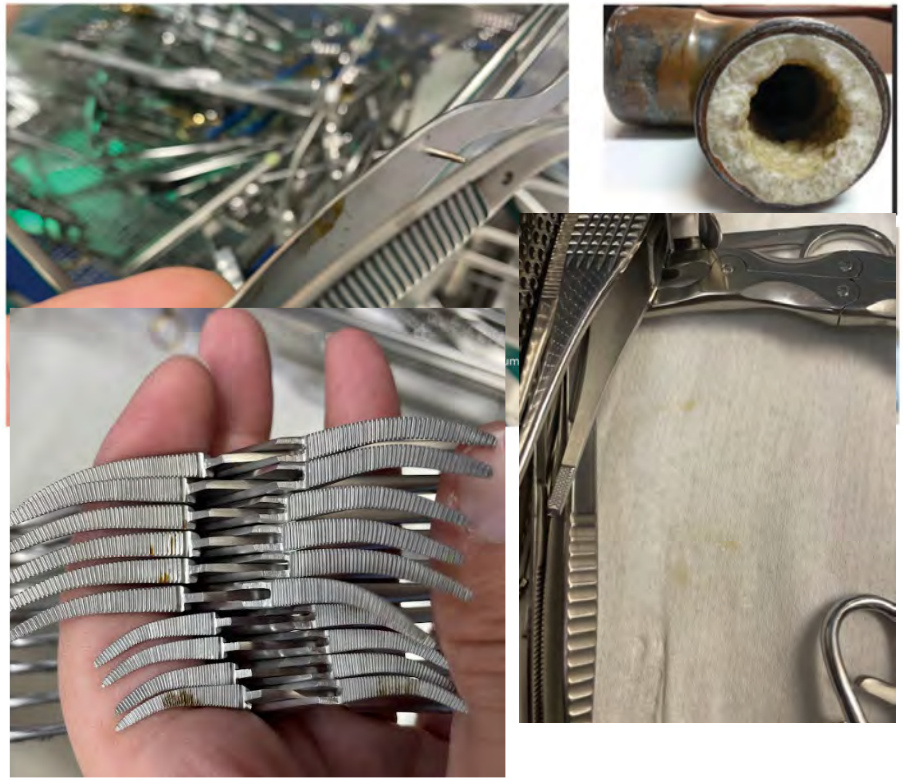
6-Week Design Work Plan

Meeting:	1		2		3
Week:	1		3		6
Attendees:	All	Facilities & Sterile Ops	All	Facilities & Sterile Ops	All
Deliverables:	+ Water Management Team Roster + Executive Summary + Water System Survey(s)	+ Baseline Monitoring: (Data AAMI TIR34 Table 1) • Hardness • Conductivity • pH • Chlorides + Draft Water Sampling Plan	+ Water Use Description + Process Flow Diagrams + System Analysis Summary + Program Control Summary + Verification & Validation Schedule + Validation Criteria Table + Validation Response Guide	+ Baseline Validation: (Data AAMI TIR34 Table 1) • Water Chemistry • Total Organic Carbon • Heterotrophic Plate Count (HPC) • Endotoxin • Endoscopy + Sample Collection Training	+ Verification & Validation + Sampling Plan + Forms and Logs

phigenics Independent Water Management

Water safety / quality can contribute to the following problems:

- ⚠ Disruption to surgical schedule
- ⚠ Increased down time & resources for problem-solving
- ⚠ Unforseen costs
- ⚠ Instrument failure during a patient procedure.
- ⚠ Inadequate cleaning related to poor water quality
- ⚠ Toxic effects and tissue irritation
- ⚠ Poor water quality could cause pyrogenic reactions
- ⚠ Residual salts
- ⚠ A disinfected or sterilized device could transmit an infection
- ⚠ Ineffective cleaning or disinfection
- ⚠ Water with an acidic or alkaline pH
- ⚠ Hard water can cause hard-water deposits



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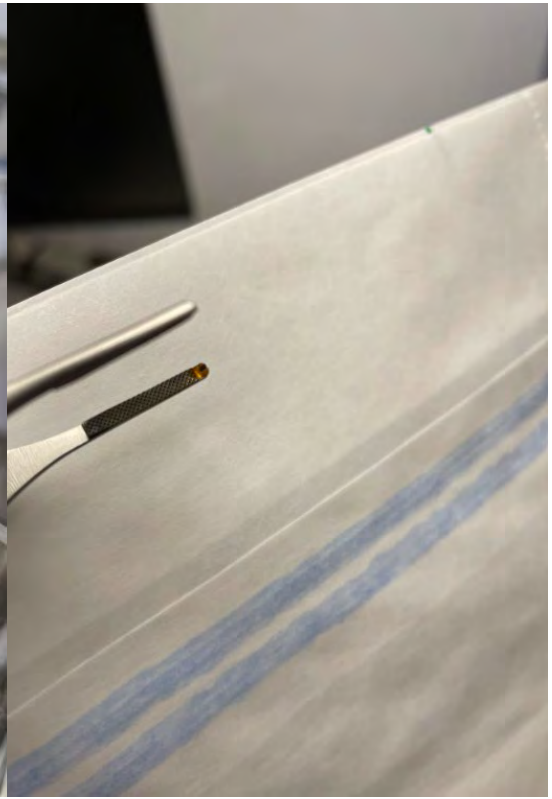
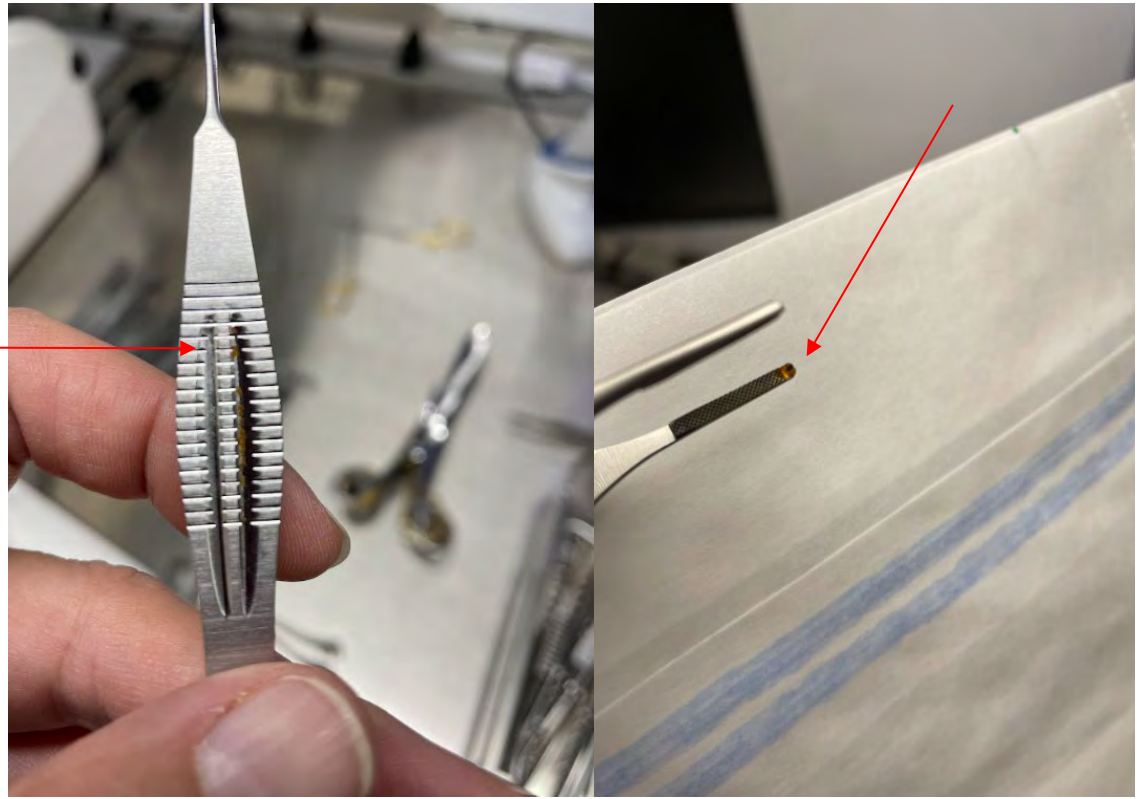


Water safety / quality can contribute to the following problems:

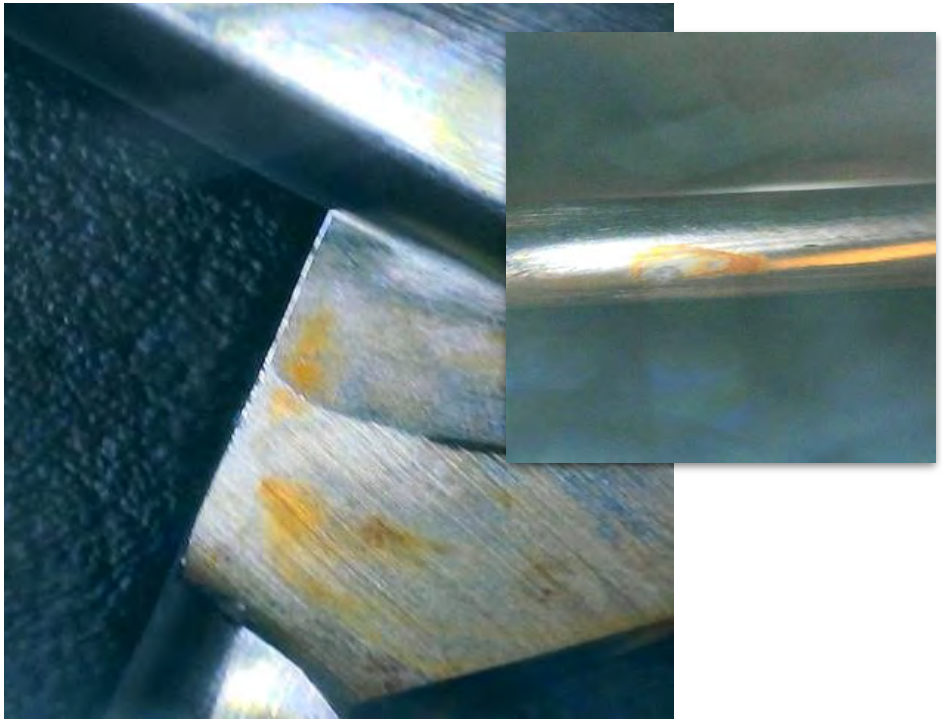
SPD Team needs a trained and detail-oriented eye!



Rust on both instruments.

Water safety / quality can contribute to the following problems:

Clean side of instrument water, instrument right out of wash.



Rejected due to "blood staining" but later identified as rust

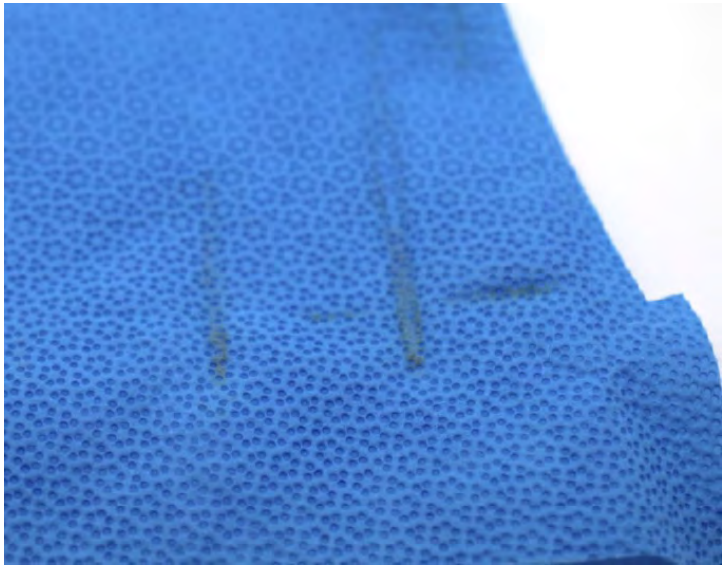
Water safety / quality can contribute to the following problems:

Staining on an eye caliper

Eye scissor with rust build up

Bone clamp with fractures and staining

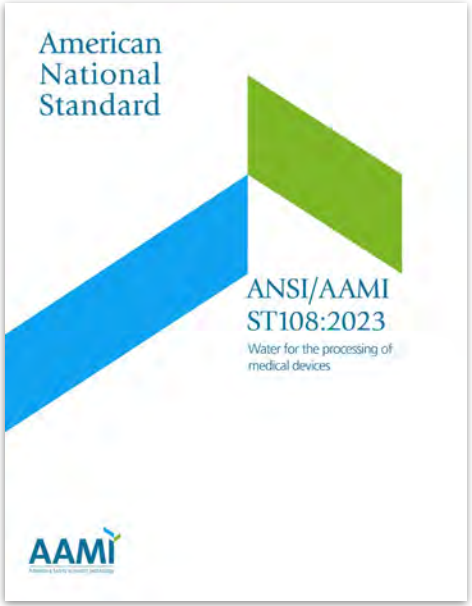
Water safety / quality can contribute to the following problems:



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

Industry best practices for alignment with water quality goals

What is new about ANSI/AAMI ST108?



- **Replaces AAMI TIR34** as the premier industry guidance on water management for sterile processing
- **Updated water quality specifications, which now include steam**
  - *Table 2:* Categories and performance qualification levels of water quality
  - *Table 4:* Water quality monitoring requirements
  - *Table 5:* Water quality monitoring requirements "Generation" or Origin
  - *Table 6:* Water quality monitoring requirements "Point-of-Use"
- **Updated Section 4** requires a **multidisciplinary team** with defined roles and responsibilities
- **Updated Section 5** on risk analysis requires monitoring water quality

What is new about ANSI/AAMI ST108? — Most Critical

Section 4 identifies the multidisciplinary team responsible for water quality, the water management program and specifies the roles each plays in maintaining an acceptable level of water quality:

- ✓ Executive sponsorship
- ✓ Medical Device Reprocessing Personnel
- ✓ Facilities
- ✓ Infection Prevention
- ✓ Clinical Engineering / Biomedical Engineering
- ✓ Surgical Suite Personnel

Section 5 - Risk Analysis:

"As part of the water management program, monitoring water quality is a prospective process meant to confirm that control strategies are functioning as expected. Monitoring is performed in order to detect when control strategies might require review or remedial action….."

Multidisciplinary team roles - Facilities engineering personnel

Section 4.3.2 Facilities engineering personnel are responsible for the water system installation, qualification, validation for the appropriate water quality for device processing and water system maintenance. All of these disciplines may not exist on staff but may be represented by an outside vendor/contractor.

ANSI/AAMI ST108 —Parameters for Testing

Routine:

Tested during normal, ongoing operations

Qualification:

Additional parameters tested during exceptional events such as start-up of new systems, major repairs and shut-downs, or other circumstances that require additional testing, e.g. a boil water notice for a municipality

Frequency:

Will vary based on recommendations from ANSI/AAMI ST108 depending on the type of water (Utility, Critical, Steam). The WMT should also make considerations to frequency based on their unique circumstances, i.e. emerging events

Ranges:

As above, these will vary based on recommendations from AAMI

ANSI/AAMI ST108 —Parameters for Testing

Table 2—Categories and performance qualification levels of water quality for medical device processing

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25 °C:	pH	6.5 – 9.5	5.0 – 7.5	5.0 – 9.2**
Total Alkalinity	mg $CaCO_3$/L	<400	<8	<8
Bacteria	CFU/mL	<500***	<10	N/A
Endotoxin	EU/mL	N/A***	<10	N/A
Total Organic Carbon (TOC)	mg/L (ppm)	N/A	<1.0	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment
Ionic Contaminants				
Aluminum	mg/L	<0.1	<0.1	<0.1
Chloride	mg/L	<250	<1	<1
Conductivity	µS/cm	<500	<10	<10
Copper	mg/L	<0.1	<0.1	<0.1
Iron	mg/L	<0.1	<0.1	<0.1
Manganese	mg/L	<0.1	<0.1	<0.1
Nitrate	mg/L	<10	<1	<1
Phosphate	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Total Hardness	mg $CaCO_3$/L	<150****	<1	<1
Zinc	mg/L	<0.1	<0.1	<0.1

* Steam parameters are for monitoring as steam condensate
**See 6.3 a) for specifics. For local steam generation, the condensate pH should be 5.0 to 7.5. For boiler-treated steam, most boilers should be treated to maintain a condensate pH of 7.5 to 9.2
*** When Utility Water is used after chemical high-level disinfection as a final rinse, the bacteria should be <10 CFU/mL and endotoxin <10 EU/mL
**** If hardness is greater than 150 mg/L a water softener is recommended unless used for washing where the cleaning chemistry is capable of handling higher levels of hardness

Table 4—Water quality monitoring requirements

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25 °C:	pH	6.5 – 9.5	5.0 – 7.5	5.0 – 9.2**
Conductivity	µS/cm	<500	<10	<10
Total Alkalinity	mg $CaCO_3$/L	<400	<8	<8
Total Hardness	mg $CaCO_3$/L	<150	<1	<1
Bacteria	CFU/mL	<500	<10	N/A
Endotoxin	EU/mL	N/A	<10	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment

*NOTE 1 Sampled as Steam condensate

**NOTE 2 The pH range for steam is wider than for Critical Water as some steam may not be generated locally but from a centralized/facility system. The need to add chemicals to the boiler and the steam to travel distances over black iron piping may result in higher pH requirements. A pH <7.5 in these systems should be avoided.

ANSI/AAMI ST108 —Parameters for Testing

Table 5—Frequency for water quality monitoring at water generation system

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

*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 When using these tests, the user should carefully follow the manufacturer's written IFU for accurate results. When measuring Critical Water levels, the water sample must be filled to the brim for these test kits, sealed and, if the sample is hot, allowed to cool to room temperature before testing. Testing within 15 minutes of sample collection prevents carbon dioxide absorption that can result in an inaccurate pH.

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.

Lessons learned from:

-design

-system start-up & commissioning

-six month check-in

Design

1. plan for redundancy
2. independent access
3. challenge the design
4. this is all new
5. diversity
6. stainless steel piping
7. flow of building
8. floor colors
9. access for equipment repair & routine maintenance
10. air locks
11. controlling air
12. mechanical room environmental controls

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System start-up & Commissioning

1. **Systems must be managed prior to contractor hand over**
2. Do not hesitate to bring in outside help
3. Use your installation contractors to train you on the new types of equipment
4. If you find yourself in a difficult position, what do you do?

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Six month check-in

1. validation
2. verification
3. evaluate processes for relevance
4. opportunity to automate processes
5. energy & resource utilization
6. team collaboration
7. associate training & rotation
8. mechanical equipment reliability
9. leaks after system down-time

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Customer Name: UF Health-UF Shands Hospital
Customer Code: UNIV0021
PO: 2421128162
Work Order: WO-2024-007264
Contact Name: Griffin Hilgenfeldt
Contact Email: ghilgenfeldt@phigenics.com

Performance Qualification Levels for Medical Device Processing	
Water Quality Measurement	Recommended Maximum Limit
	Steam
pH	5.0-9.2
Total Alkalinity (mg $CaCO_3$/L)	<8
Conductivity (µSiemens/cm)	<10
Total Hardness (mg $CaCO_3$/L)	<1

72703

ation Test Report Summary

team Water Chemistry Panel

Location Identification	pH	Alkalinity, Total	Conductivity	Hardness, Total
		mg/L	µS/cm	mg/L
) R03 Steam Condensate Blue CEP Valve	6.11	8	9.7	2.56
R03 Steam Condensate Orange CEP Valve	7.82	20	24.8	9

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3B. CONDITIONING - Softening (Stand Alone System)	Preventative Maintenance and Inspection	06/10/2024	Griffin Hilgenfeldt	06/10/2024	03/28/2024 - 06/10/2024	Griffin Hilgenfeldt	Verified 6/10/2024.
4B/6C. HEATING/DISTRIBUTION - Clean Steam	Preventative Maintenance & Inspection of Steam Trap System	06/10/2024	Griffin Hilgenfeldt	06/10/2024	03/28/2024 - 06/10/2024	Griffin Hilgenfeldt	Dean to follow up & confirm.
6A/6B. DISTRIBUTION - Utility Cold/Hot Water (Unsoftened/Softened)	Temperature	06/10/2024	Griffin Hilgenfeldt	06/10/2024	03/28/2024 - 06/10/2024	Griffin Hilgenfeldt	Verified 6/10/2024.

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Name	Title	Functional Area	Team Role	Member Type	Email Address	Action
Bobby Baird	Facilities	Facilities	Chair	Voting Member	bairdr@shands.ufl.edu	
Matt Hartley	Construction/Project Manager	Construction/Project	Member	Voting Member	mhartley@parrish-mccall.com	
Rich Nutt	Special Equipment Repair Technician-Amsco	Tech	Member	Voting Member	nuttrw@shands.ufl.edu	
Sara Vinson	Sterile Processing	Sterile Processing	Member	Voting Member	svin0002@shands.ufl.edu	
Scott Brown	Director of Infection Prevention	Infection Prevention	Voting Memeber	Voting Member	brosco@shands.ufl.edu	
Steven Hansen	Special Equipment Repair Technician-Amsco	Tech	Member	Voting Member	hanss@shands.ufl.edu	

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2. verification
3. evaluate processes for relevance
4. opportunity to automate processes
5. energy & resource utilization
6. team collaboration
7. associate training & rotation
8. **mechanical equipment reliability**
9. leaks after system down-time

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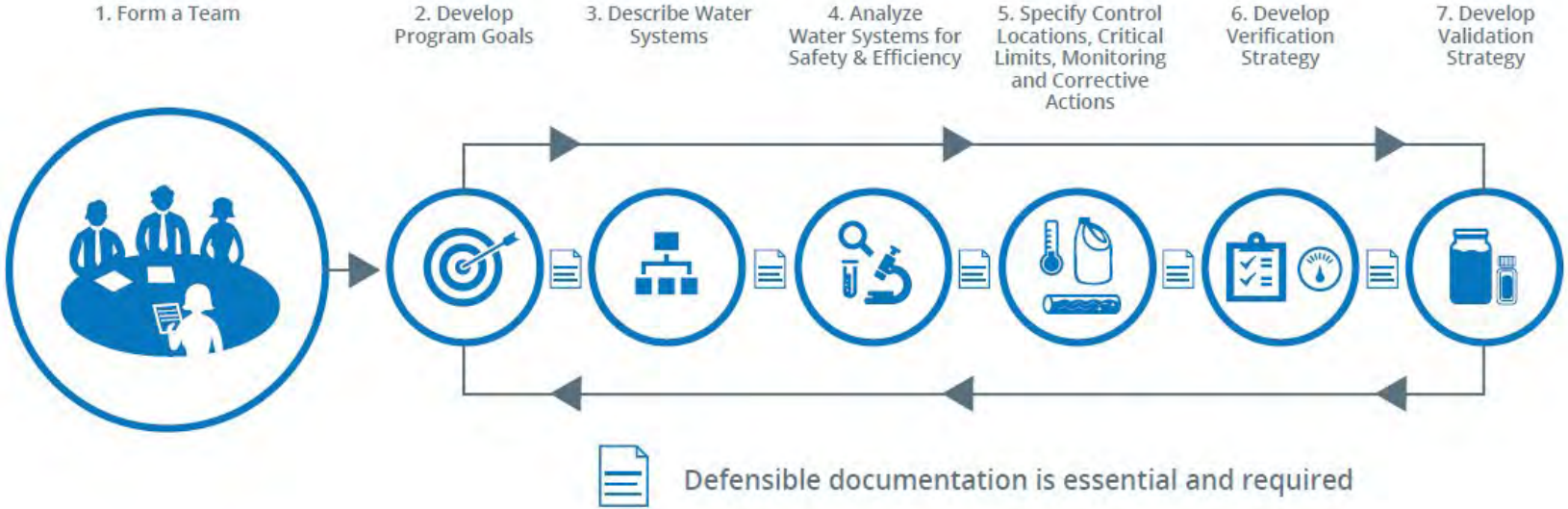
Functional roadmap for ongoing operations

Functional Roadmap



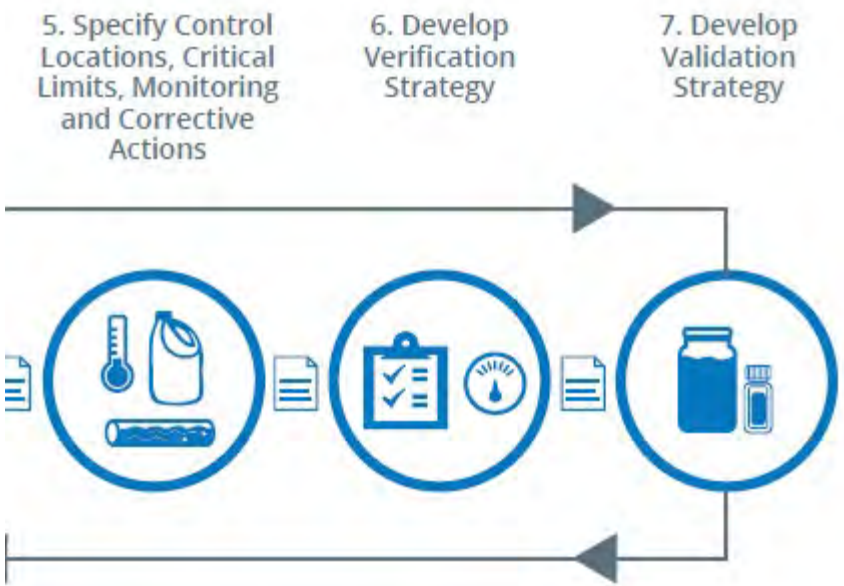
7 STEPS OF THE SUSTAINABLE COMPREHENSIVE WATER MANAGEMENT PROGRAM

Ongoing Operations

5. Are we collecting too much data? Too frequently? Does it make sense?

6. How do we manage data? Work order, logs, vendor service reports, other system?

7. Should we be testing less or more? How do we know if we are making the right decisions?



CAUTION

You do not have to test everything & upgrade equipment because of ST108!

The focus is on water quality performance, not system design. Additionally, the risk process can support a Team in customizing the expectations to your system set-up & need for data!

Let data from your WMP drive decisions.

CAUTION

THINK

You do not have to test everything & upgrade equipment because of ST08!

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Let data from your WMP drive decisions.

Ready for a photo reel?

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Learning Objectives

1. Components of a water management program in alignment with ANSI/AAMI ST108
2. Industry best practices for alignment with water quality goals
3. Lessons learned from
    - Design
    - System start-up & commissioning
    - Six month check-in
4. Functional roadmap for ongoing operations

Q&A

Bobby Baird

"That Facility Guy"
"If you don't schedule time for maintenance,
Your equipment will schedule it for you."

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