



 PROGRESSIVE
SURGICAL SOLUTIONS
A DIVISION OF VMG HEALTH

ST108 IN ASCs


A CLEAR GUIDE FOR UNDERSTANDING AND IMPLEMENTATION

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1

Objectives

- Describe the roles and responsibilities of the Water Management Program multidisciplinary team.
- Conduct the Water Quality for the Processing of Medical Devices risk assessment.
- Define and describe the three different categories of water used in each stage of instrument processing, their performance qualifications, and minimum frequency of testing.
- Identify the observed problems associated with poor water quality, possible causes, and troubleshooting recommendations.



2

WHAT IS IT?

American National Standards Institute (ANSI)
Association for the Advancement of Medical
Instrumentation (AAMI)

ST108:2023

Water for the processing of medical devices standard

- Establishes minimum requirements for the water quality used in instrument processing
- Includes point-of-use, cleaning, rinsing, disinfection, and sterilization of instruments

ADDRESSES THE FOLLOWING:

- Responsibility for the water management program
- Adverse effects of water impurities
- Categories and requirements of water quality
- Selection of water of the appropriate quality
- Purity requirements of water used to generate steam
- Considerations for ongoing ITM and quality improvement of the water treatment system
- Troubleshooting water quality issues

3

- ✓ Appointed by the Governing Body
- ✓ Can be the QAPI Committee

Roles & Responsibilities

- Responsible for overall water quality for the facility
- Contract with water specialist and/or water treatment system vendor/contractor
- Install system, conduct ITM per MIFU and ANSI/AAMI guidelines
- Testing occurs at system and at point-of-water-use
- Report back to QAPI and then to Governing Body
 - *Water testing results = quality indicator*

Water Management Program

Multidisciplinary Team

Policy & Procedure sample available
on eSupport: Infection Control >
Water Quality > Policy | Water
Quality

4

Available to eSupport Members

Compliance & Operations > Infection Control > Water Quality

Policy | Water Quality

WATER QUALITY

POLICY:

It is the policy of **Facility Name** to comply with the 'ANSI/AAMI ST108 2023: Water for the processing of medical devices' standard which was developed with the objective of setting the quality requirements for the different categories of water used in processing of medical devices and providing guidance as to when and where to use water of each category. In addition, this standard provides information on how to verify that the water continues to meet those minimum requirements. This standard also provides valuable information for the performance qualification of a water.

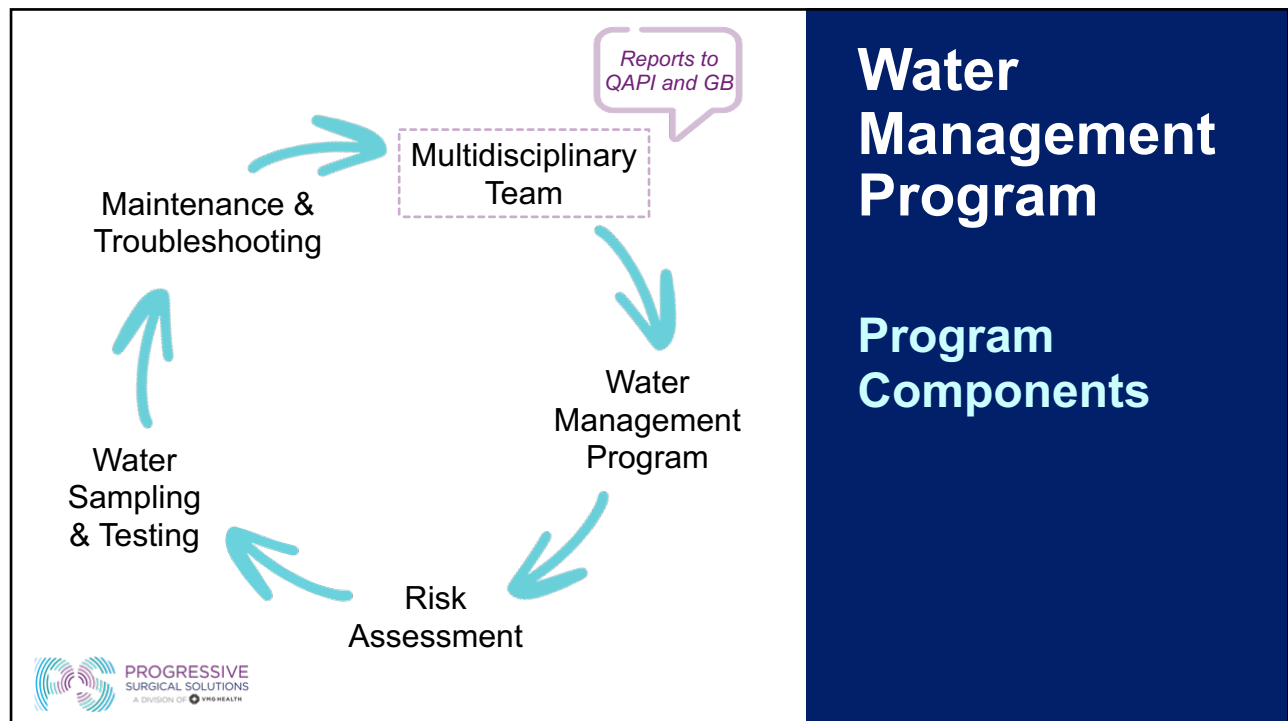
The color and turbidity of the water in **Facility Name** will be colorless, clear, and without sediment upon visual inspection.

PROCEDURE:

- The Governing Body will appoint the members of the multidisciplinary team responsible for the Water Management Program and allocate resources accordingly. This team may consist of the Clinical Director **and/or Administrator, Facilities Manager and/or** water system maintenance vendor/contractor, the **Infection Control Coordinator**, Instrument/ SPD technician, OR/procedure room personnel, and the water treatment specialist.
- Collectively, the team will be responsible for the:
 - general assessment of water quality, per manufacturer guidelines routinely sample water and determine if values are within specified ranges per management plan
 - determination of appropriate method / equipment required for the facility's



5



6

Risk Assessment

Consideration of adverse effects

Medical devices
Process
Patients
Personnel

Characteristics to be considered

- Physical appearance of the water (color, clarity and absence of particulates/sediment)
- Microbial level in water;
- Inorganic and organic contaminants of water
- pH of the water
- Conductivity of the water
- Water temperature

- ✓ **Complete** prior to water system installation
- ✓ **Review** "periodically"

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Compliance & Operations > Risk Assessments

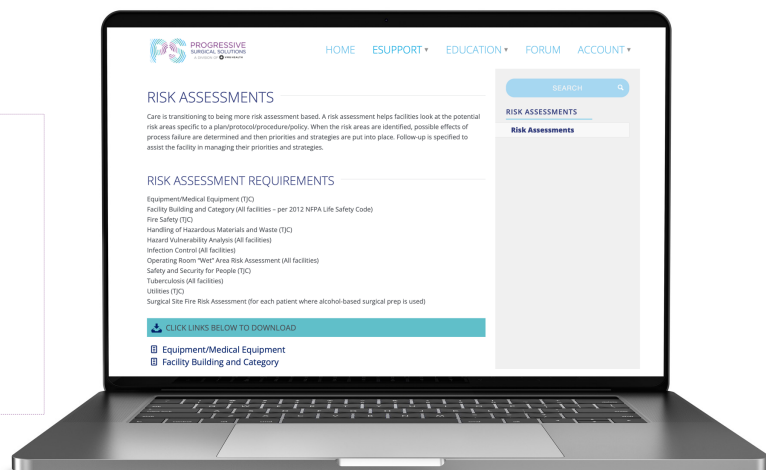
Water Quality Processing Medical Devices

RISK ASSESSMENT: WATER QUALITY FOR THE PROCESSING OF MEDICAL DEVICES Page 1 of 2

Perform the risk assessment in collaboration with the multidisciplinary team related to water quality impacting the processing of instruments and devices. **The risk assessment is to be performed by each facility based on its unique situation and operating conditions.**

Potential risk areas specific to water quality issues

- Patient safety
 - Water of the correct quality for each stage of the chain of events in processing, point-of-use treatment, manual, ultrasonic, automated cleaning, final rinse, and steam generation
- Sterilizer water supply
 - Utility water supply, old piping, piping with dead legs, and water main breaks
- Critical water supply
 - Treatment system maintenance, incorrect plumbing material (anything but stainless steel or plastic piping), system design does not provide sample ports or points for disinfection, and ineffective disinfection
- Bacterial or endotoxin loading
- Risks to personnel
 - Water pressure, cleaning agents/disinfectants, water temperature



Categories of Water

Utility Water

Water as it comes from the tap that can require further treatment

- Mainly used for flushing, washing, and rinsing
- All facilities that process instruments should consider the need to treat incoming tap water

Critical Water

Water that meets the water quality measurement values

- Typically requires extensive treatment by a multi-step process
- Mainly used for the final rinse after high-level disinfection, for the final rinse for critical devices prior to sterilization and feedwater for process steam production
- Not always necessary in every step of instrument processing

Steam

Vaporized water that is produced by a centralized boiler or a generator/heat exchanger near the sterilizer

- Steam is tested as a condensate

9

Performance Qualifications

Testing is conducted in two major locations*

1

Water treatment system

Utility water
Critical water

2

Point-of-water-use

Utility water
Critical water
Steam

Testing Equipment

- pH and conductivity meters
- Dipsticks (alkalinity and hardness)
- Plate counts (bacteria)
- Lumulus Amebocyte Lysate (LAL) test (endotoxin)
- Visual inspections

*Sampling sites vary

10

Testing Frequencies

Frequency	Water Category	Testing Location
Daily (visual inspection)	Utility Critical Steam	Point-of-water-use
Monthly	Critical	Water treatment system Point-of-water-use
Quarterly	Utility	Water treatment system (<i>excluding bacteria and endotoxin</i>) Point-of-water-use (<i>excluding endotoxin</i>)
	Steam	Point-of-water-use (<i>excluding bacteria and endotoxin</i>)



11

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Compliance & Operations > Infection Control > Water Quality

Water Quality Monitoring Guide

WATER QUALITY MONITORING GUIDE

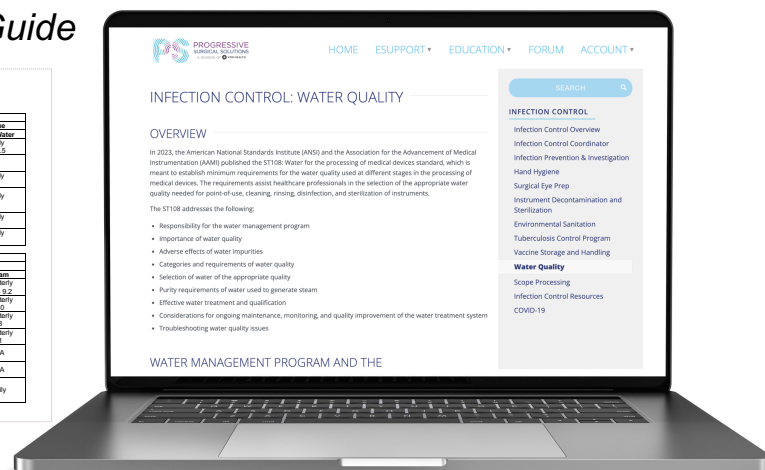
Frequency for water quality monitoring at water treatment system			
Measurement / Unit	Testing Type	Sampling Site	Minimum Frequency / Value
pH	pH meter or Colorimetric dipsticks (sample tested within 15 minutes)	After the last treatment step	Utility Water: Quarterly Critical Water: Monthly
Conductivity (µmhos/cm)	Conductivity meter (on line or by measurement of a collected sample)	After the last treatment step. Storage tanks if used	Utility Water: Quarterly Critical Water: Monthly
Total Alkalinity (mg CaCO ₃ /L)	Colorimetric dipsticks Alkalinity test kit	After the last treatment step. Storage tanks if used	Quarterly Monthly
Total Hardness (mg CaCO ₃ /L)	Determination of ppm as CaCO ₃ by Colorimetric dipsticks, Titration kit, or Handheld meter	After the last treatment step	Quarterly Monthly
Bacteria (CFUs)	Heat-stable plate count (see Annex H)	Loop out and loop return points	N/A
Endotoxin (EU/mL)	LAL test (see Annex H)	Loop out and loop return points	N/A

Frequency for water quality monitoring at point-of-water-use			
Measurement	Testing Type	Sampling Site	Minimum Frequency / Value
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	Utility Water: Quarterly Critical Water: Monthly Steam: Quarterly
Conductivity (µmhos/cm)	Conductivity meter (on line or by measurement of a collected sample)	At the point the distribution loop enters the processing area or first POU on the distribution loop	Utility Water: Quarterly Critical Water: Monthly Steam: Quarterly
Total Alkalinity (mg CaCO ₃ /L)	Colorimetric dipsticks Alkalinity test kit	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly Monthly
Total Hardness (mg CaCO ₃ /L)	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
Bacteria (CFUs)	Heat-stable plate count (see Annex H)	Each location of points of-use in department	Quarterly Monthly
Endotoxin (EU/mL)	LAL test (see Annex H)	Each location of points of-use in department	N/A
Visual Inspection	Visual inspection of inside of equipment - Look for residue, staining, scaling, and discoloration (Annex I)	Spray Arms/Inlets Chamber Wall/Inlets Interior of Machine	Daily

Adapted from the AAMI/ASHE ST108: 2013 Water for the Processing of Medical Devices



12



Water Quality Monitoring Guide

WATER QUALITY MONITORING GUIDE

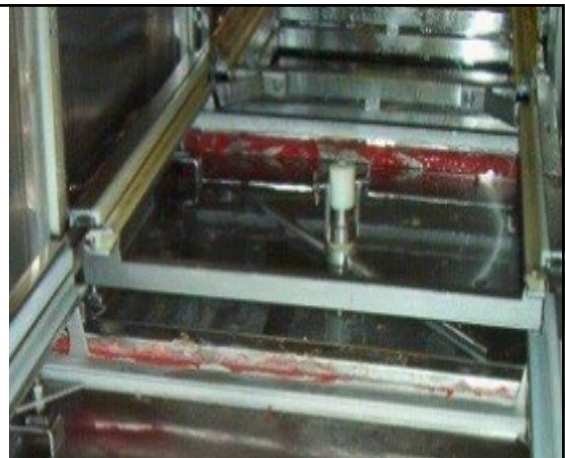
Frequency for water quality monitoring at water treatment system				
Measurement / Unit	Testing Type	Sampling Site	Minimum Frequency / Value	
			Utility Water	Critical Water
pH (pH)	pH meter or Colorimetric dipsticks (sample tested within 15 minutes)	After the last treatment step	Quarterly 6.5 – 9.5	Monthly 5.0 – 7.5
Conductivity (µS/cm)	Conductivity meter (in line or by measurement of a collected sample)	After the last treatment step, Storage tanks (if used)	Quarterly <500	Daily <10
Total Alkalinity (mg CaCO3/L)	Colorimetric dipsticks Alkalinity test kit	After the last treatment step, storage tanks (if used)	Quarterly <400	Monthly <8
Total Hardness (mg CaCO3/L)	Determination of ppm as CaCO3 by Colorimetric dipsticks, Titration kit, or Handheld meter	After the last treatment step	Quarterly <150	Monthly <1
Bacteria (CFU/mL)	Heterotrophic plate count (see Annex H)	Loop out and loop return points	N/A	Monthly <10
Endotoxin (EU/mL)	LAL test (see Annex H)	Loop out and loop return points	N/A	Monthly <10

Frequency for water quality monitoring at point-of-water-use					
Measurement	Testing Type	Sampling Site	Minimum Frequency / Value		
			Utility Water	Critical Water	Steam
pH (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 6.5 – 9.5	Monthly 5.0 – 7.5	Quarterly 5.0 – 9.2
Conductivity (µS/cm)	Conductivity meter (in line or by measurement of a collected sample)		Quarterly <500	Monthly <10	Quarterly <10
Total Alkalinity (mg CaCO3/L)	Colorimetric dipsticks Alkalinity test kit		Quarterly <150	Monthly <1	Quarterly <8
Total Hardness (mg CaCO3/L)	Determination of ppm as CaCO3 by Colorimetric dipsticks, Titration kit, or Handheld meter		Quarterly <150	Monthly <1	Quarterly <1
Bacteria (CFU/mL)	Heterotrophic plate count (see Annex H)	Each location of point-of-use in department	Quarterly <500	Monthly <10	N/A
Endotoxin (EU/mL)	LAL test (see Annex H)		N/A	Monthly <10	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

Adapted from the ANSI/AAMI ST108: 2023 Water for the processing of medical devices

Poor Water Quality

- Ineffective cleaning or residual soil
- Surface damage:
 - Corrosion
 - Pitting
 - Rusting
 - Stress cracking
- Black or purple staining
- White, chalky spotting or deposits
- Loss of color or discoloration (gold/orange-brown or rainbow)
- Biofilm or “slime”
- Obstructions in water lines or valves





15

Troubleshooting

Annex I

Typical presentation of water quality issues during the processing of medical devices.

- Examine instruments and devices for signs of poor water quality
- Review all steps of instrument processing
- Conduct water analyses
- Water control processes and ongoing monitoring
- *Remove instruments from circulation and replace!*



16

Regulatory Standards

CMS Conditions for Coverage



§416.51(a) Standard: Sanitary Environment

The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to **professionally acceptable standards of practice**.

- Ventilation and **water quality control issues**, including measures taken to maintain a safe environment during internal or external construction/renovation

§416.51(b) Standard: Infection Control Program

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has **considered, selected, and implemented nationally recognized infection control guidelines**.

- Addressing aseptic technique practices used in surgery, including **sterilization** or high-level disinfection of instruments, as appropriate

Enforcement

Potential for enforcement at the local or state level

	TJC	AAAHC
QUESTION	Will TJC be enforcing ANSI AAMI ST108 requirements in the ASC?	Will AAAHC be enforcing ANSI AAMI ST108 in the ASC?
ANSWER	Please understand that full compliance with the intent of the standards may only be assessed during an onsite survey.	In response to your specific question, if your organization adheres to AAMI Standards then AAAHC surveyors will survey your organization to ensure compliance with those Standards as evidenced by your organization's policies and practices.



Key Takeaways

- No “one size fits all” solution, facility specific
- Applies **only** to water that touches your instruments
 - Does *not* apply to bottled water
- MIFUs, state regulations, best practices, and other guidelines still apply!
- Establish the committee and program (QAPI)
- Testing may be expensive with slow turnaround times
- Water treatment systems are expensive
- Work with a water quality / treatment system specialist

Available to Members on eSupport

Compliance & Operations > Infection Control

> Water Quality

- Overview
- Policy and Procedure sample
- Water Quality Monitoring Guide



INFECTION CONTROL: WATER QUALITY

OVERVIEW

In 2023, the American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) published the ST108: Water for the processing of medical devices standard, which is meant to establish minimum requirements for the water quality used at different stages in the processing of medical devices. The requirements assist healthcare professionals in the selection of the appropriate water quality needed for point-of-use, cleaning, rinsing, disinfection, and sterilization of instruments.

The ST108 addresses the following:

- Responsibility for the water management program
- Importance of water quality
- Adverse effects of water impurities
- Categories and requirements of water quality
- Selection of water of the appropriate quality
- Purity requirements of water used to generate steam
- Effective water treatment and qualification
- Considerations for ongoing maintenance, monitoring, and quality improvement of the water treatment system
- Troubleshooting water quality issues

WATER MANAGEMENT PROGRAM AND THE

SEARCH

INFECTION CONTROL

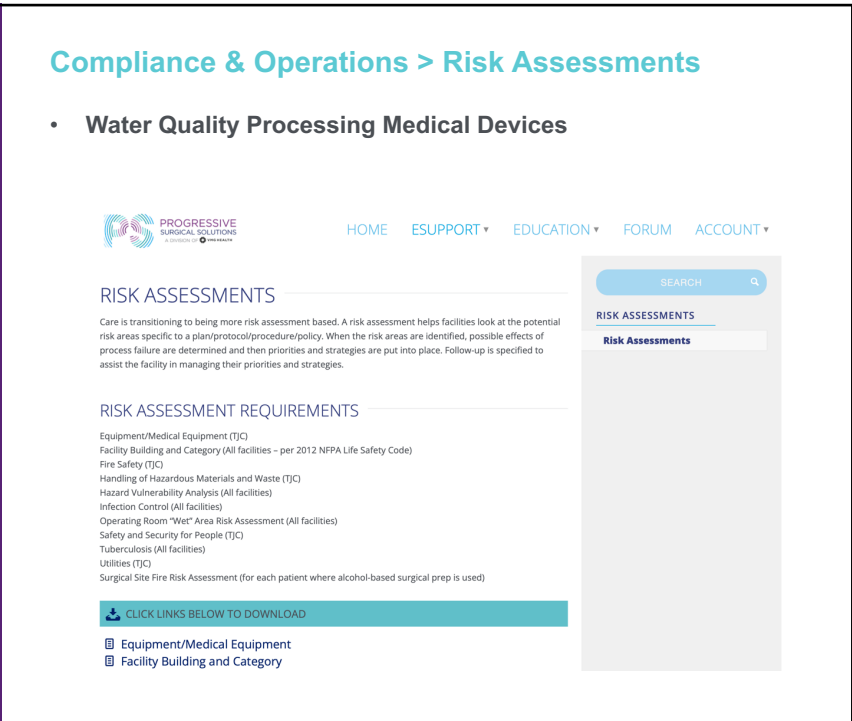
- [Infection Control Overview](#)
- [Infection Control Coordinator](#)
- [Infection Prevention & Investigation](#)
- [Hand Hygiene](#)
- [Surgical Eye Prep](#)
- [Instrument Decontamination and Sterilization](#)
- [Environmental Sanitation](#)
- [Tuberculosis Control Program](#)
- [Vaccine Storage and Handling](#)
- Water Quality**
- [Scope Processing](#)
- [Infection Control Resources](#)
- [COVID-19](#)

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Compliance & Operations > Risk Assessments

- Water Quality Processing Medical Devices**



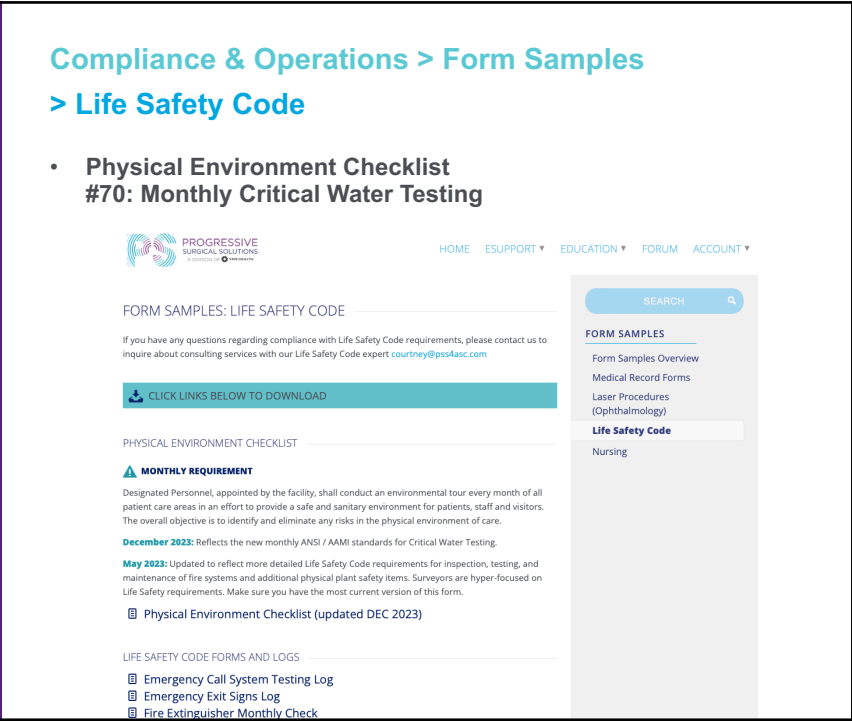
21

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Compliance & Operations > Form Samples > Life Safety Code

- Physical Environment Checklist
#70: Monthly Critical Water Testing**



22

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PROGRESSIVE SURGICAL SOLUTIONS
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Compliance & Operations > Contracts > Documentation

- **Contracted Services Assessment Tool
Water Quality and/or Treatment System Specialist**



CONTRACTS: DOCUMENTATION

CLICK LINKS BELOW TO DOWNLOAD

- ASC Contract Documentation Recommendations
- Table of Contents for Facility Contracts (Sample)
- Contracted Services Assessment Tool (UPDATED) with Quality Indicators

OFFICE OF INSPECTOR GENERAL (OIG) QUERY

Every contracted service vendor should be searched on the OIG exclusion database. Use link below to run each contractor **annually**.

OIG Query Website


VENDOR CREDENTIALING

Vendor Credentialing is a growing trend in the healthcare industry. This is simply the process of ensuring that the individuals and entities that sell goods and services meet the standards and requirements of the purchasing healthcare providers. While this is required in most hospitals, it is not yet a requirement for ASCs. If this is something that your facility is interested in implementing, here are some resources:

Reprax is a company that has been recommended by some of our clients.

23

Thank You






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24



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We are the **leading** online membership for ASC nurse leaders who want to run a compliant, efficient, and profitable ASC **with confidence.**



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RUNNING AN ASC CAN BE OVERWHELMING
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25



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A place to **connect, support,** and **network** with other ASC managers all over the country.



26



ASC NURSE LEADERSHIP CONFERENCE
 APRIL 25-26 2024 DALLAS, TX
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27

Upcoming Webinars

DATE	🕒	CE	WEBINAR TOPIC	SPEAKER
APR 25 - 26			ASC NURSE LEADERSHIP CONFERENCE <i>No Webinar</i>	
MAY 20	20		Building Your Financial Acumen: ASC Fee Schedule	Nancy Stephens
JUN 28	60	RN, CASC	How to Deliver Excellent Customer Service in Your ASC	Elizabeth Monroe
JUL 29	20		Harmonizing Success: Unlocking RCM Fundamentals for ASC Excellence	JR Thompson
AUG 26	60	RN, CASC	A Culture of Security: Preventing DEA Scheduled Medication Diversion in the ASC	Gregory Tertes
SEP 30	20		Before It's Mandatory: Understanding OAS CAHPS	Vanessa Sindell
OCT 25	60	RN, CASC CAIP	A Comprehensive Review of the ASC QAPI Program	Debra Stinchcomb
NOV 25	20		Annual Survey Watch Report 2024	Vanessa Sindell
DEC 13	60	RN, CASC CAIP	Infection Control Risk Assessment: A Guided Review	Crissy Benze

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28