ANSI/AAMI ST108

# Compliance Self-Audit Checklist

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Apex Water + Process

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## Overview and Disclaimer

*This self-audit checklist has been developed by Apex as a complimentary professional resource to assist Sterile Processing personnel, Water Management Specialists, and facility leadership in assessing current readiness for ANSI/AAMI ST108:2023 compliance.*

*This tool is provided for informational and educational purposes only. It is not intended to constitute legal, regulatory, accreditation, engineering, or clinical advice, nor does it replace a formal compliance review, independent validation, or professional consultation.*

*The checklist is provided "as-is" without any representations or warranties, express or implied, including but not limited to warranties of completeness, accuracy, fitness for a particular purpose, or regulatory sufficiency.*

*Apex shall not be liable for any direct, indirect, incidental, consequential, regulatory, financial, operational, or patient-care-related damages arising from the use of, reliance upon, or inability to use this tool, including but not limited to audit deficiencies, survey findings, non-compliance citations, infection control events, or system failures.*

*Final responsibility for regulatory compliance, documentation accuracy, water system performance, and patient safety remains solely with the facility and its designated Multidisciplinary Team.*

*Facilities are encouraged to conduct independent validation and seek qualified professional consultation where appropriate.*

## Instructions for Use

- ***Status:*** *Record the current state as* ***C*** *(Compliant),* ***P*** *(Partial), or* ***NC*** *(Non-Compliant).*
- ***Audit Verification Task / Evidence:*** *Document specific evidence reviewed (e.g., Physical inspection of RO skid).*
- ***Action Items/Notes:*** *Document specific gaps, required remediation, and target completion dates.*

## Section 1: Leadership and Administrative Readiness

| Audit Verification Task | Status (C/P/NC) | Evidence and Action Items |
|---|---|---|
| **Verify formal appointment of a Multidisciplinary Team (MDT)** including Senior Leadership, Facilities, Infection Prevention, SPD, Clinical Engineering, and a Water Specialist. | | |
| **Confirm MDT has a designated Executive Sponsor** with documented authority to allocate financial resources and approve command decisions. | | |
| **Examine the written Water Management Program (WMP)** for hazardous condition identification and specific clinical protocols to minimize waterborne pathogens. | | |
| **Review the formal Risk Analysis documentation** to confirm it was completed prior to system installation and shows evidence of periodic review by the MDT. | | |
| **Inspect training and competency records** to verify device processing personnel have documented education regarding water quality standards and patient safety risks. | | |

**Auditor Name & Title:** _____ **Date:** _____

## Section 2: System Design and Physical Infrastructure

| Audit Verification Task | Status (C/P/NC) | Evidence and Action Items |
|---|---|---|
| **Determine the water type(s)** (cold & hot utility and critical water and steam) currently being supplied to your devices (sinks, washers, ultra sonics, cart washers, sterilizers, scope reprocessors, etc.) | | |
| **Verify the Critical Water system** is configured as a fully recirculating loop to maintain continuous movement and prevent stagnation. | | |
| **Confirm loop return velocity** (3 to 5 FPS) by reviewing flow transmitter (FT) data. | | |
| **Inspect piping materials** for compatibility (Schedule 80 PVC, polypropylene, or HDPE). | | |
| **Audit for Dead-Legs:** Review "As-Built" PI&D and physically inspect to ensure no stagnant piping segments exceed 3–5 times the internal pipe diameter. | | |
| **Verify storage tank design** features a conical or bowl-shaped base that facilitates drainage from the absolute lowest point. | | |
| **Inspect storage tank venting** for a hydrophobic 0.2 µm air filter on the vent line. | | |
| **Confirm all major components** are labeled and a current "As-Built" PFD or PI&D is permanently posted in the treatment room. | | |

**Auditor Name & Title:** _____ **Date:** _____

## Section 3: Treatment Equipment and Monitoring Tools

| Audit Verification Task | Status (C/P/NC) | Evidence and Action Items |
|---|---|---|
| **Confirm standard treatment configuration**: Carbon filter/chemical destruct, water softener, RO, and DI/EDI modules as required. | | |
| **Examine final loop filtration** for absolute rated filters at ≤0.2 microns (Review CoC or validation data). | | |
| **Verify RO safety features** including "divert to drain and flush" functionality and trigger setpoints for poor quality water. | | |
| **Inspect sample port placement** at the beginning of the loop (loop out) and at the return point before the storage tank. | | |
| **Verify monitoring hardware installation**: Calibrated pressure gauges (PI), flow transmitters (FT), and conductivity transmitters (CT). | | |
| **Test system alarms**: Verify audible and visual alarms activate for conductivity limits or maintenance requirements. | | |

**Auditor Name & Title:** _____ **Date:** _____

## Section 4: Water Quality Compliance (Ongoing Monitoring)

| Requirement / Frequency | Status (C/P/NC) | Action Items/Notes |
|---|---|---|
| **DAILY:** Visual Equipment Inspection (SPD logs for washers and sterilizers for residue, staining, or scaling). | | |
| **DAILY:** Critical Water Monitoring (Conductivity levels and visual inspection). | | |
| **MONTHLY:** Critical Water Monitoring (Lab results for pH, total alkalinity, total hardness, bacteria (HPC), and endotoxins). | | |
| **QUARTERLY:** Utility Water Monitoring (pH, alkalinity, bacteria, and hardness). | | |
| **QUARTERLY:** Steam Condensate Monitoring (pH, conductivity, alkalinity, and hardness). | | |
| **ANNUALLY:** Critical Water Monitoring (TOC and 11 ionic contaminants). | | |

**Auditor Name & Title:** _____ **Date:** _____

## Section 5: Maintenance and Quality Improvement

| Audit Verification Task | Status (C/P/NC) | Evidence and Action Items |
|---|---|---|
| **Verify disinfection frequency**: distribution loop and storage tank disinfected at least **MONTHLY**. | | |
| **Confirm data management**: Verify monitoring results are recorded, trended, and subjected to **REGULAR REVIEW** by the MDT. | | |
| **Review Alert and Action levels**: Verify the MDT has defined specific values for early warning and immediate intervention. | | |
| **Inspect written contingency plans** for service interruptions, construction, and recovery from "Boil Water" alerts. | | |

**Auditor Name & Title:** _____ **Date:** _____

# ST108 Compliance Self-Audit Summary Report

## Facility Information

| | | | |
|---|---|---|---|
| **Facility Name** | | | |
| **Facility Address** | | | |
| **Contact Person** | | **Phone #** | |

## Executive Summary Statement

*Provide a concise 5–7 sentence overview, such as overall compliance posture, whether risks are isolated or systemic, any immediate patient safety concerns, survey readiness status, and urgency level.*

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## Critical Findings Summary

| Critical Findings | Risk Level (H,M,L) | Recommended Actions | Owner |
|---|---|---|---|
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## Immediate Action Items

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**Auditor Name & Title:** _____ **Date:** _____

**Executive Sponsor Approval:** _____ **Date:** _____

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