Initial Assessment for Sterile Processing & ST108 Compliance

This form is designed to help hospital water management teams assess the current state of their sterile processing unit per ANSI/AAMI ST108:2023. Your responses will be collected into a spreadsheet and sent to the email address you provide below.

RECOMMENDATION_Use the answers as a baseline to determine your next steps. Place initial focus on any acquiring the data questions you don't have answers for right now - filling in those gaps first will allow you to more effectively plan a phased implementation of solutions.

* Indicates required question

1. Email *

_____

Sterile Processing Department (SPD) Overview

2. Do you have a distribution loop or direct feed system for your SPD water? *

Check all that apply.

- [ ] Distribution Loop
- [ ] Direct Feed
- [ ] Not Sure

3. Have all water entry points, treatment systems, and distribution paths been mapped? *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Other: _____

4. What water-quality challenges does the facility currently face? *

Check all that apply.

- [ ] Scale (hardness)
- [ ] Dissolved Salts
- [ ] Sediment
- [ ] Organic pollutants
- [ ] Bacteria
- [ ] Endotoxins
- [ ] Ionic Molecules (chlorine, iron, copper, etc)
- [ ] pH
- [ ] Alkalinity
- [ ] TOC
- [ ] Color and Turbidity
- [ ] Other: _____

5. Are devices pre-cleaned at the point-of-use before transport to SPD? (EX: operating room) *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Other: _____

6. If yes, is water quality at point-of-use controlled or validated?

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Other: _____

Water Treatment Evaluation [within SPD]

7. In the sterile processing department, which water treatment systems are in place? *

Check all that apply.

- [ ] Chemical treatment
- [ ] Green Sand Depth Filter
- [ ] Sediment Filters
- [ ] Softeners
- [ ] Carbon Filtration
- [ ] Carbon Adsorption Tanks
- [ ] pH Adjustment
- [ ] Bisulfite Injection
- [ ] Distillation
- [ ] Reverse Osmosis (RO) Systems
- [ ] Deionizer (DI) Systems / Exchange Resin
- [ ] UV Light
- [ ] Ultrafilters
- [ ] Ozone
- [ ] Steam
- [ ] Other: _____

8. If a Reverse Osmosis (RO) system is in place, is free chlorine / chloramine pre-treatment verified and monitored upstream? (If yes, document date of last test and method)

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Other: _____

9. What point-of-use equipment is in place within sterile processing? *

Check all that apply.

- [ ] Initial Rinse Sinks
- [ ] Washers/Decontaminators
- [ ] Automated Endoscope Reprocessors (AERs)
- [ ] Sterilizers
- [ ] Storage Tanks
- [ ] Final Rinse Sinks
- [ ] Other: _____

10. Which points-of-use currently use Utility Water? *

Check all that apply.

- [ ] Initial Rinse Sinks
- [ ] Washers/Decontaminators
- [ ] Automated Endoscope Reprocessors (AERs)
- [ ] Sterilizers
- [ ] Storage Tanks
- [ ] Final Rinse Sinks
- [ ] Other: _____

11. Which points-of-use currently use Critical Water? *

Check all that apply.

- [ ] Initial Rinse Sinks
- [ ] Washers/Decontaminators
- [ ] Automated Endoscope Reprocessors (AERs)
- [ ] Sterilizers
- [ ] Storage Tanks
- [ ] Final Rinse Sinks
- [ ] We don't have Critical Water - everything uses Utility Water
- [ ] Other: _____

12. Which points-of-use have commercial filtration? *

Check all that apply.

- [ ] N/A
- [ ] Initial Rinse Sinks
- [ ] Washers/Decontaminators
- [ ] Automated Endoscope Reprocessors (AERs)
- [ ] Sterilizers
- [ ] Storage Tanks
- [ ] Final Rinse Sinks
- [ ] Other: _____

13. Which points-of-use have microbiological filtration? *

Check all that apply.

- [ ] N/A
- [ ] Initial Rinse Sinks
- [ ] Washers/Decontaminators
- [ ] Automated Endoscope Reprocessors (AERs)
- [ ] Sterilizers
- [ ] Storage Tanks
- [ ] Final Rinse Sinks
- [ ] Other: _____

14. If microbiological filtration is in place, what is the current pore size and where is it placed? (ie, is it installed on fixtures or directly to water lines?) Enter N/A if appropriate *

_____

_____

_____

_____

_____

15. Which points-of-use require, or may require, source water changes? (ie, utility vs critical water) *

Check all that apply.

- [ ] N/A
- [ ] Initial Rinse Sinks
- [ ] Washers/Decontaminators
- [ ] Automated Endoscope Reprocessors (AERs)
- [ ] Sterilizers
- [ ] Storage Tanks
- [ ] Final Rinse Sinks
- [ ] Other: _____

Maintenance Evaluation

16. Which points-of-use are being maintained in accordance with manufacturer's IFU? * Maintenance includes disinfection if appropriate

Check all that apply.

- [ ] N/A
- [ ] Initial Rinse Sinks
- [ ] Washers/Decontaminators
- [ ] Automated Endoscope Reprocessors (AERs)
- [ ] Sterilizers
- [ ] Storage Tanks
- [ ] Final Rinse Sinks
- [ ] Other: _____

17. Which points-of-use are require disinfection? *

Check all that apply.

- [ ] N/A
- [ ] Initial Rinse Sinks
- [ ] Washers/Decontaminators
- [ ] Automated Endoscope Reprocessors (AERs)
- [ ] Sterilizers
- [ ] Storage Tanks
- [ ] Final Rinse Sinks
- [ ] Other: _____

18. Regarding disinfection throughout SPD, list each type of disinfectant used along with amounts and frequency of use *

_____

_____

_____

_____

_____

19. How frequently are sediment filters monitored for clogging? *

Check all that apply.

- [ ] Daily
- [ ] Weekly
- [ ] Monthly
- [ ] Quarterly
- [ ] Other: _____

20. Current status of carbon adsorption tank chlorine levels: (enter current chlorine levels or N/A if not in use) *

_____

Current Water Quality Values

21. Is the pH level within the specified range for each water type? (Utility 6.5 - 9.5, Critical 5.0 - 7.5, Steam 5.0 - 9.2) *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] For Utility only
- [ ] For Critical only
- [ ] For Steam only

22. Enter the most recent pH level readings for Utility and Critical Water, and Steam *

_____

23. Enter Total Alkalinity Levels (mg CaCO3/L) for Utility, Critical Water, and Steam: (ensure Utility <400 mg CaCO3/L, Critical <8 mg CaCO3/L, Steam <8 mg CaCO3/L) *

_____

24. Enter current Bacteria level (CFU/mL) for both Utility and Critical Water: (ensure Utility <500 CFU/mL, Critical <10 CFU/mL) *

_____

25. Enter Endotoxin level (EU/mL) for Critical Water: (ensure <10 EU/mL) *

_____

26. Enter Total Organic Contaminants (TOC) level for Critical Water: (ensure ≤1.0 mg/L (ppm)) *

_____

27. Enter Color and Turbidity description for Utility, Critical Water, and Steam: (ensure colorless & clear w/out sediment for all) *

_____

28. Enter Conductivity levels for Utility, Critical Water, and Steam: (measure with calibrated, temperature-compensated conductivity meter; specify the values in μS/cm) *

NOTE: Conductivity equals total amount of electrically charged impurities (ions); see pg 19 in ST108)

_____

29. Enter Water Hardness levels (CaCO3/L) for Utility, Critical Water, and Steam: (ensure Utility <400 mg CaCO3/L, Critical <8 mg CaCO3/L, Steam <8 mg CaCO3/L) *

_____

Documentation

30. Is maintenance scheduled for all equipment in line with ANSI/AAMI ST108? *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Other: _____

31. When was the last disinfection of the distribution loop?

_____

Example: January 7, 2019

32. Are logs up-to-date for each maintenance and monitoring activity? *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Other: _____

33. Are all test results and corrective actions documented in accordance with hospital protocol? *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Other: _____

34. Is there a designated individual or team for overseeing water quality management? *

Check all that apply.

- [ ] Facilities Engineering
- [ ] Infection Control
- [ ] Water Treatment Specialist
- [ ] Biomeds
- [ ] Other: _____

Risk Analysis

35. Has a risk assessment been conducted for microbial risks in the sterile processing unit? *

Check all that apply.

- [ ] Yes
- [ ] No
- [ ] Other: _____

36. Having completed the previous questions, have you identified the potential for adverse effect(s) to: *

Check all that apply.

- [ ] Medical device(s)
- [ ] Process
- [ ] Patient
- [ ] Personnel

37. Identify any corrective actions needed based on recent water-quality assessments: (describe any observed issues, such as scaling, biofilm buildup, or other compliance concerns) *

_____

_____

_____

_____

_____

38. Describe any potential patient risks associated with water quality in this area (e.g., infection, equipment damage): *

39. Identify all existing sample ports and whether they are dead legs. (if there are dead legs, are they being flushed routinely? are the sample ports in the appropriate locations? are additional ports needed?) *

40. Do you have a documented plan in place for out-of-range results and emergencies? *