

Sterile Processing Utilities & Water Integration Assessment

For Operational Alignment Across ANSI/AAMI ST108, ST79, and ST91

Healthcare device safety depends on successful execution of reprocessing workflows supported by stable utility systems.

ANSI/AAMI ST79 and ST91 provide guidance and expectations for both sterilization and high-level disinfection processes, while ANSI/AAMI ST108 introduces structured oversight of water quality supporting medical device processing.

This assessment tool helps facilities evaluate where water and utility conditions intersect with sterile processing and endoscope reprocessing practices.

This tool is intended to support multidisciplinary discussion and operational alignment; it does not replace facility policies, manufacturer instructions for use, or formal compliance assessments.

Intended Users

Complete collaboratively with representation from:

- Sterile Processing
- Endoscopy
- Facilities / Engineering
- Infection Prevention
- Water Management Team

How To Complete

For each evaluation point:

- Select the condition that best reflects current practice.
- Then review the associated operational action.

Ratings Scale

A: Assumed

Utilities not evaluated

B: Reactive

Reviewed after problems occur

C: Managed

Documented or periodically reviewed

D: Integrated

Included in routine multidisciplinary oversight

SECTION 1: Steam & Sterilization Utilities

1. Steam source supporting sterilizers is understood by SPD leadership

- A Unknown or assumed acceptable
- B Reviewed only after failures
- C Source documented
- D Reviewed jointly with Facilities on defined cadence

If A–B: Meet with Facilities to review steam generation and feedwater treatment

If C: Define routine review responsibility and cadence

If D: Maintain multidisciplinary oversight and validate during investigations

2. Steam quality considered during sterilization investigations

- A Equipment troubleshooting only
- B Utilities reviewed after repeated issues
- C Utilities occasionally reviewed
- D Standard investigation step

If A: Add utilities review to failure investigation SOP

If B–C: Establish escalation criteria

If D: Continue integrated practice

3. Wet packs evaluated for infrastructure contribution

- A Treated primarily as handling, packaging, or loading error
- B Environmental causes sometimes considered
- C Facilities consulted when recurring
- D Utilities routinely evaluated

If A–B: Expand investigation to include sterilizer function, cycle selection, load configuration, and steam quality indicators

If C: Document escalation pathway

If D: Maintain practice

4. Boiler feedwater treatment understood by reprocessing leadership

- A Unknown
- B Known only to Facilities
- C Communicated informally
- D Included in oversight discussions

If A–B: briefing on feedwater treatment, boiler chemistry program, and known excursions that impact steam quality

If C: Formalize documentation

If D: Maintain communication

SECTION 2: Cleaning & Washer Water

5. Water quality supporting washer-disinfectors is evaluated and managed to support effective cleaning performance

- A Not evaluated
- B Reviewed after equipment issues
- C Documented
- D Included in water management review

If A: and key quality risks for washers, eg hardness, chlorides, conductivity, microbial control approach

If B: Add utilities check to washer troubleshooting and recurring cleaning failures

If C: Assign review cadence and escalation triggers

If D: Maintain governance and include washer performance trend correlation

6. Water used for detergent preparation is evaluated and managed to support effective cleaning performance

- A Unknown
- B Assumed potable water adequate
- C Documented
- D Reviewed with Facilities

If A–B: Document source and confirm it supports detergent efficacy and device protection, then assign ownership

If C: Confirm consistency

If D: Maintain oversight

7. Utility disruptions communicated to SPD and other affected departments

- A No notification process
- B Informal notification
- C Documented notification
- D Integrated into facility water or utilities management program with defined triggers, notifications, and response actions

If A: Establish notification pathway

If B: Formalize process

If C: Integrate into operational response procedures

If D: Maintain coordination and periodically validate effectiveness

SECTION 3: Endoscope Reprocessing Water

8. Post-HLD rinse water source evaluated for risk of device recontamination

- A Potable water assumed acceptable
- B AER filtration assumed adequate
- C Water is managed consistent with critical water quality expectations, with defined verification
- D Included in water oversight program

If A: Identify water used for post-HLD rinsing and assess microbial risk controls and ownership

If B: Confirm AER filtration maintenance responsibilities and change controls, and assess whether filtration alone is being treated as assurance

If C: Document criteria, verification method, cadence, and escalation triggers

If D: Maintain integration and review after any water event or HLD failure investigation

9. AER filtration performance operationally reviewed

- A Not reviewed
- B Reviewed during maintenance only
- C Maintenance, replacement cadence, and change controls are defined and periodically confirmed
- D Integrated into oversight

If A–B: Review maintenance records, replacement intervals, alarms, and ownership

If C: Define review cadence and escalation triggers

If D: Maintain integration within governance and event response

10. Water quality, water source, filtration status, and controls evaluated during contamination investigations

- A Not considered
- B Considered after recurrence
- C Occasionally reviewed
- D Standard investigation step

If A: Add water review to investigation

If B–C: Define triggers

If D: Maintain practice

11. Drying effectiveness is assessed to minimize residual moisture within device channels

- A Not considered
- B Considered after issues
- C Drying steps are standardized and staff competency is reinforced, with periodic review
- D Included in drying protocols

If A–B: Review drying workflow, alcohol flush and forced air use where applicable, storage conditions, and residual moisture failure handling

If C: Document standard workflow and define triggers for review

If D: Maintain integration and include in investigations of contamination or positive cultures

SECTION 4: Monitoring & Investigation

12. Monitoring interpretation includes infrastructure conditions

- A Monitoring results are interpreted without considering utilities conditions or recent disruptions
- B Utilities reviewed after failures
- C Trends occasionally reviewed
- D Utilities routinely considered

If A: Expand investigation scope

If B–C: Establish review criteria

If D: Maintain approach

13. Repeated variability triggers multidisciplinary review

- A Department only
- B Infection Prevention added
- C Facilities added when needed
- D Multidisciplinary review standard

If A–B: Define escalation pathway

If C: Formalize triggers

If D: Maintain collaboration

14. Equipment performance distinguished from system performance

- A Not differentiated
- B Recognized informally
- C Documentation distinguishes equipment malfunction from utilities or system-level conditions during investigations
- D Included in investigations

If A: Introduce systems review concept

If B–C: Formalize documentation

If D: Maintain practice

SECTION 5: Ownership & Communication

15. Facilities and other relevant departments (eg, IP) participate in reprocessing performance discussions

- A Never
- B After major events
- C Periodically
- D Routine participation in defined forums with documented actions and follow-up

If A–B: Invite multi-disciplinary representation

If C: Establish routine review

If D: Maintain collaboration

16. Shared responsibility for utilities supporting reprocessing is defined

- A Undefined
- B Informal ownership
- C Documented responsibility
- D Managed through multidisciplinary governance with defined triggers and accountability

If A: Define ownership roles

If B: Document responsibilities

If C: Implement governance

If D: Maintain governance

Interpretation

Mostly A–B > Outcome-focused troubleshooting, utilities risks may be missed

Mostly C > Utilities inputs are managed, integration is developing

Mostly D > System-based sterility assurance aligned with ST108 intent