

ANSI/AAMI ST108:2023 – Water Quality for Medical Device Processing (Cheat Sheet)

Water Quality Categories & Uses

Utility Water (Tap Water): Potable water (from municipal supply) used for washing, flushing, and intermediate rinsing of devices (not for final rinse or direct patient contact). May require pre-treatment to meet quality specs.

Example: tap water in the decontamination sink for initial cleaning.

Critical Water: High-purity water used for critical steps like the final rinse of disinfected/sterilized instruments or as feed water for steam sterilizers. Produced by multi-step treatment (e.g. filtration, softening, reverse osmosis, deionization, UV) to remove virtually all contaminants.

Example: final rinse water in an instrument washer or endoscope reprocessor.

Steam (Condensate): Vaporized water used to produce steam for sterilization (from a hospital boiler or on-site generator). Evaluated by testing the condensate (steam distilled water) after the sterilizer to ensure steam purity.

Example: condensate from autoclave steam lines, checked for purity.



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Quality Requirements & Limits by Category

Utility Water – Minimum Quality Standards (Initial Cleaning Water)

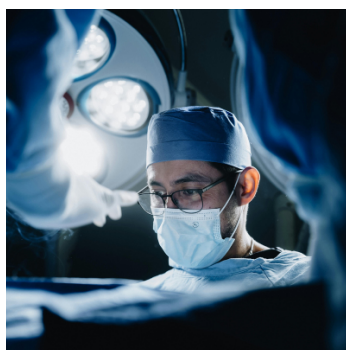
Microbial Limit: Heterotrophic bacteria count < 500 CFU/mL (colony-forming units per mL) at point of-use. This aligns with EPA's potable water guideline for microbial content.

Endotoxins: **No specific limit** for endotoxin in utility water (endotoxin testing is not required on potable water). Note: If utility water is used as a final rinse after high-level disinfection, it must meet critical water levels (<10CFU/ml and <10EU/ml endotoxin).

Chemical & Physical Limits:

- **pH:** 5.0 – 7.5 (neutral to slightly acidic)
- **Alkalinity:** < 8 mg/L as CaCO_3
- **Hardness:** < 1 mg/L as CaCO_3 (virtually zero hardness)
- **Conductivity:** < 10 $\mu\text{S}/\text{cm}$ (very low dissolved solids, ~equivalent to ≤ 5 ppm TDS). Often achieved with deionization or RO polishing.
- **Total Organic Carbon (TOC):** < 1.0 mg/L to ensure minimal organic residues.
- **Inorganic contaminants:** Most ionic impurities are limited to ≤ 1 mg/L or less. For example, Chloride < 1 mg/L, Sulfate < 1 mg/L, Nitrate < 1 mg/L, Phosphate < 1 mg/L, Silicate < 1 mg/L.
- **Heavy metals** (Fe, Mn, Cu, Zn, Al) each < 0.1 mg/L. This high purity prevents spotting, corrosion, or residue on instruments.

Appearance: Clear, colorless, no sediment (essentially ultra-filtered water)



Quality Requirements & Limits by Category

Steam Condensate – Steam Purity Requirements (Sterilization Steam Water)

Usage: Steam for sterilization should be generated from at least critical-quality water. Steam purity is verified by testing the condensate (condensed steam) post-sterilizer.

Microbial/Endotoxin: Not applicable in condensate – steam at sterilization temperatures is sterile and endotoxin-free if feed water is pure (no routine CFU or endotoxin testing required on condensate).

Chemical & Physical Limits: Steam condensate must meet high purity standards similar to critical water:

pH: 5.0 – 9.2 range in condensate (Note: For on-site steam generators, condensate pH ~5.0–7.5 is expected; boiler-treated steam typically yields condensate ~7.5–9.2 due to amine additives).

Alkalinity: < 8 mg/L CaCO₃.

Conductivity: < 10 µS/cm in condensate (indicates very low dissolved solids in steam).

Inorganic limits: Same tight limits as critical water – e.g. <1mg/L for chloride, sulfate, etc., <0.1mg/L for heavy metals in condensate. Any excessive carryover of impurities could indicate boiler water issues.

Appearance: Condensate should be clear, colorless, with no sediment. (No rust, scale, or particulate from steam lines.)

Steam quality: (Per AAMI ST79) Steam should be dry and free of excessive non-condensable gases, but ST108 focuses on chemical purity of the condensate.

Monitoring & Testing Guidelines

Water Management Program: Establish a **multidisciplinary water management team** (e.g. sterile processing staff, facilities/engineering, infection control, and water treatment experts) to oversee water quality. This team is responsible for **risk assessments**, protocol development, and upkeep of the water quality program. They must perform a risk analysis identifying potential issues with utility and critical water and steam systems (considering factors like microbial growth, endotoxin, scaling, corrosivity, etc.).

Routine Monitoring: Perform regular water quality testing at defined intervals to ensure ongoing compliance. **Minimum testing frequencies** are specified for each parameter and water type (at water treatment system output and at points of use) – for example: **pH, conductivity, and hardness** may be checked monthly, **microbial counts** weekly or monthly depending on the water type, and **endotoxin** monthly. (ST108 reduced some daily tests from prior guidance; many checks are now monthly or quarterly, easing daily workload.) **Steam condensate** is typically tested quarterly under the new standard.

Action and Alert Levels: Define alert and action levels for each water quality parameter. An **“action level”** is the threshold that, if exceeded (e.g. a test result outside the acceptable limit), requires immediate corrective action (e.g. investigate cause, take remedial measures). **“Alert levels”** are set more conservatively – they serve as early warnings so you can intervene before a full excursion occurs. For example, if the action limit for bacteria is 10 CFU/mL, an alert might be set at 5 CFU/mL to trigger cleaning or system disinfection proactively. Trending of results is emphasized – if values trend upward toward limits, act before they exceed the specs.

Documentation: Keep thorough records of all water quality tests, maintenance, and corrective actions. Document dates, sample points, results, and any response taken. This supports **trend analysis** and compliance verification. ST108 also recommends documenting system qualifications (installation, operation, performance qualification of water treatment systems) and any changes or repairs.

Monitoring & Testing Guidelines

System Maintenance: Adhere to **maintenance schedules** for the water treatment system to maintain water quality. This includes regular filter replacement (e.g. final 0.2 µm filters for critical water), softener regeneration, RO membrane cleaning/replacement, UV lamp replacement, and periodic system disinfection/flushing to control biofilm. Proper maintenance is critical since even a high-end treatment system can grow bacteria or leach contaminants if not serviced.

Bacterial Control: Implement measures to **prevent microbial growth** in the water system. ST108 provides strategies such as: avoiding stagnant “dead-legs” in piping, using UV sterilizers or ozone for storage tanks, routine hot-water flush or chemical disinfection of distribution lines, and ensuring sample ports/faucets are sanitary (since faucets can harbor bacteria). Maintaining continuous circulation of critical water and using final filters with **0.2 µm (absolute)** ratings (endotoxin-retentive filters) are recommended to keep bacteria and endotoxin levels within spec.

Contingency Plans: ST108 addresses **emergency situations** like water supply interruptions or contamination events. Facilities should have plans for **boil-water advisories, line breaks, or contamination incidents** – e.g. switching to bottled sterile water for final rinses, or postponing processing, until water quality is restored.

After such events, **re-qualification of the water system** and testing (for microbial, endotoxin, etc.) is advised before resuming normal instrument processing.

By following ANSI/AAMI ST108:2023's requirements for water quality – controlling **microbial counts, endotoxins, and chemical/physical parameters** – sterile processing departments can greatly reduce the risk of instrument damage, cleaning failures, or patient infections caused by water impurities. This cheat sheet highlights the core limits and practices; always refer to the full standard for comprehensive guidance on implementation and compliance monitoring.

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