

# UNDERSTANDING AAMI ST108:2023: ESSENTIAL GUIDE TO NEW WATER QUALITY STANDARDS IN HEALTHCARE



Water is essential in healthcare settings, not just for basic hygiene but also for complex medical procedures and device processing. Recognizing its critical role, the Association for the Advancement of Medical Instrumentation (AAMI) has introduced ST108. This standard evolves from its predecessor, AAMI TIR34. This new standard marks a significant advancement in defining water quality parameters, underscoring the integral link between water quality and patient safety.

ANSI/AAMI ST108:2023 is more than just a set of recommendations; it is a beacon that guides healthcare facilities toward achieving the highest standards in water quality.



***"It's about building a culture of excellence where water quality is consistently managed to the highest standards, ensuring patient safety and care quality.."***

The implications of this standard are profound, affecting various types of water in healthcare, from tap water to critical water used in sterilizing, cleaning, rinsing, and disinfecting medical instruments. As we plunge into this comprehensive guide, we will explore the nuances of AAMI ST108, shedding light on its importance and impact on healthcare practices.

## Overview of AAMI ST108

AAMI ST108, a successor to AAMI TIR34, stands as a cornerstone in healthcare, especially in water quality for medical device processing. This standard is a blueprint for ensuring the highest patient care and safety standards. It focuses on selecting and maintaining adequate water quality, pivotal in preventing healthcare-associated infections (HAIs) and ensuring the functionality and longevity of medical equipment.

The scope of AAMI ST108 is comprehensive. It covers parameters for selecting the water quality necessary for processing various categories of medical devices. This includes considerations for water treatment equipment, distribution and storage, quality control procedures, strategies for bacterial control, and the impact on the environment and personnel. Each element is meticulously detailed, ensuring that healthcare facilities can implement practical and effective water quality management systems.

The importance of water quality in the context of medical device processing cannot be overstated. Water is integral to many processes, from cleaning and disinfection to sterilization. The standard ensures that the water used in these processes meets stringent quality criteria, thus minimizing the risk of HAIs and ensuring that medical devices function as intended.

AAMI ST108 represents a critical step forward in healthcare. By adopting this standard, healthcare facilities comply with industry standards and demonstrate a commitment to the highest level of patient care and safety.

### Critical Aspects of Water Quality Management

Water quality plays a pivotal role in the intricate medical device processing world. AAMI ST108 delineates specific categories of water quality, each tailored to meet the unique requirements of various medical device processing stages. Understanding these categories and their respective criteria is essential for healthcare facilities committed to maintaining the highest standards of care and safety.

#### Categories of Water Quality:

1. **Utility Water:** This is the most basic form of water used in healthcare settings. While not intended for direct patient contact or for use in direct sterilization processes, utility water must still meet specific quality standards to ensure it doesn't adversely affect the medical environment.
2. **Critical Water:** This category includes water used in the final rinsing of sterilized medical devices. The highest quality standards apply here, as this water comes into direct contact with critical devices used for patients.
3. **Steam:** This category includes steam produced by a central steam boiler system or a steam generator located near sterilization equipment. Steam should be tested as condensate water.

**General Requirements for Water Quality Selection:** The selection of water quality in healthcare is governed by a set of general requirements as outlined in AAMI ST108. These include:

- **Purity Levels:** The standard specifies the required levels of chemical and microbial purity for each category of water, ensuring that it is suitable for its intended use.
- **Treatment and Monitoring:** Adequate water treatment and regular monitoring are essential. This includes routine checks for contaminants and the effectiveness of purification systems.
- **Regulatory Compliance:** Water quality in healthcare must comply with local, state and federal regulations, ensuring both patient safety and legal adherence.

The application of these recommendations is not merely about meeting regulatory standards; it's about safeguarding patient health. By meticulously managing water quality, healthcare facilities can prevent infection, enhance the effectiveness of medical devices, and ultimately contribute to better patient outcomes.

### Roles and Responsibilities in Water Quality Management

Effective water quality management in healthcare is a collaborative effort, necessitating the involvement and commitment of a diverse team. AAMI ST108 emphasizes the importance of a multidisciplinary approach, assigning specific roles and responsibilities to various team members. This collective action is critical to ensuring that water used in medical device processing meets the highest standards.

#### Key Roles in Water Quality Management:

- **Facility Managers:** They oversee the implementation and maintenance of water quality standards, ensuring that the infrastructure and resources are in place to meet AAMI ST108 requirements.
- **Medical Device Processing Personnel:** This group, including nurses and technicians, is crucial in monitoring water quality during medical device processing procedures. They are the front-line defenders in ensuring the water used meets the necessary standards.

- **Infection Control Specialists:** These professionals are tasked with developing and enforcing policies and procedures related to water quality. Their expertise is crucial in identifying potential risks and implementing preventive measures.
- **Clinical Engineering Personnel:** They are responsible for the design, implementation, and maintenance of water treatment systems. Their technical expertise ensures that these systems function effectively and comply with the standards set by AAMI ST108.
- **Water Treatment Consultants:** Tasked with selecting equipment, regular monitoring and validating water quality parameters, these teams ensure continuous compliance with water quality standards.

The collaborative effort of these diverse roles ensures a holistic approach to water quality management. Each member contributes their expertise, ensuring that every aspect of water use in healthcare is safe, effective, and compliant with AAMI ST108. This multidisciplinary approach not only enhances patient safety but also fosters a culture of excellence in healthcare settings.

### Water Treatment Systems and Monitoring

Effective water quality management in healthcare facilities hinges on properly installing, operating and monitoring water treatment systems, as emphasized in AAMI ST108. These systems play a crucial role in ensuring that water used in medical device processing meets the stringent purity standards for patient safety.

- **Installation and Operation of Water Treatment Systems:** The installation of water treatment systems must be meticulously planned and executed. This involves selecting systems appropriate for the specific needs of the healthcare facility and ensuring qualified professionals install them. Once operational, these systems require a performance qualification plan, to ensure these systems make the appropriate quality water and to ensure they function as intended.
- **Performance Qualification:** Performance qualification is a critical component of water treatment systems. It involves rigorous testing to verify that the system consistently produces water of the required quality. This testing should be conducted per the procedures set out in AAMI ST108, ensuring that the systems meet all necessary standards for medical device processing.
- **Routine Monitoring Requirements:** Routine monitoring is vital to maintaining the integrity of water treatment systems. This includes regular checks for contaminants, system functionality, and adherence to the prescribed water quality standards. Table 4 in AAMI ST108 provides a comprehensive guideline for monitoring requirements, outlining the specific parameters that need to be regularly evaluated. Adhering to these guiding principles ensures that water treatment systems remain effective and compliant, thus safeguarding patient health.

### Implementing AAMI ST108 in Healthcare

The adoption of AAMI ST108 in healthcare settings is a critical step towards enhancing patient safety and the efficacy of medical device processing. Implementing this standard involves a comprehensive approach, starting with a thorough review of current water quality management practices. Healthcare facilities need to audit and assess their existing systems and procedures against the water quality parameters set forth in ST108 to identify areas for improvement.

Critical steps in adopting AAMI ST108 include:

- **Audit Water Treatment Systems:** Laboratory testing should confirm whether existing equipment can meet the water quality standards. Audits can be performed with a water treatment consultant, who understands all aspects of water treatment equipment.
- **Educating Staff:** All relevant personnel must be informed about the new standards and understand their roles in maintaining water quality.

- **Updating Policies and Procedures:** Existing Water Management Plans should be revised to align with ST108, ensuring that all water treatment and monitoring practices meet the new requirements.
- **Investing in Infrastructure:** This may involve upgrading or installing new water treatment systems to comply with the enhanced standards of ST108. This could include investing in ST108 compliant reverse osmosis units and determining if Electro Dionizer units can replace traditional DI exchange tanks.
- **Regular Audits and Monitoring:** Continuous monitoring and periodic audits are essential to ensure ongoing compliance and identify further improvement areas.

Embracing AAMI ST108 is an ongoing process of quality improvement. It's about building a culture of excellence where water quality is consistently managed to the highest standards, ensuring patient safety and care quality.

AAMI ST108 sets a new benchmark in healthcare, elevating water quality standards for medical device processing. This article has outlined the critical aspects of the standard, underscoring its importance in patient care. Healthcare facilities are encouraged to review and update their water quality management practices by ST108. By doing so, they commit to a higher standard of patient safety and play a pivotal role in advancing healthcare quality.