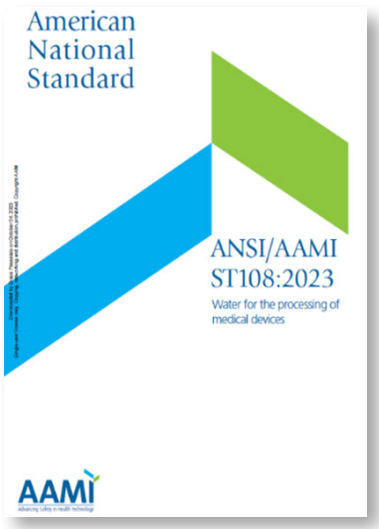
ANSI/AAMI ST108 SUMMARY

Water for the processing of medical devices

Introduction

ANSI/AAMI ST108 Water for the processing of medical devices was approved on August 16, 2023. This standard replaced the Technical Information Report 34. Unlike the Technical Information Report, the updated standard provides clear requirements for every stage of medical device processing. ANSI/AAMI ST108 establishes minimum requirements for water quality and steam purity for processing medical devices intended for patient use. Proper implementation of this standard improves the effectiveness and lifespan of equipment, such as ultrasonic sterilizers, endoscope reprocessors, autoclaves, and local steam generators. Implementing this standard involves a comprehensive process, starting with an assessment of current water quality management practices.



Standard Applicability

The applicability of ANSI/AAMI ST108 applies to facilities that have medical device processing equipment (cleaning, rinsing, disinfection, and sterilization). Criteria includes the considerations listed below.

1. Water is categorized into three different types based on the disinfection characteristics or sterilization process type.
   a. **Utility water** is tap water that is used for rinsing, flushing, and intermediate rinsing (rinsing between cleaning and disinfection). This water may require treatment.
   b. **Critical water** is final rinse water that has been processed by high-level disinfection. To meet the water quality requirements, critical water requires an extensive multi-step treatment process. This process can include pretreatment, storage, distribution, and final treatment.
   c. **Steam** is considered vaporized water produced by a centralized boiler near the sterilizer(s). Steam is tested as condensate, following the sterilizer.
2. A multidisciplinary team must be established and should have knowledge of the water systems and associated processes in use. Team members should include facilities engineering staff, infection prevention, medical device processing personnel, clinical engineering staff, and water treatment specialists.
3. A risk analysis should be performed to evaluate and identify risks associated with utility water, critical water, and steam. The following water characteristics should be considered: physical appearance, microbial concentrations, inorganic/organic contaminants, pH, conductivity, and temperature.
4. Routine monitoring and performance qualification testing is essential to maintaining the integrity of the water treatment systems. The updated standard provides detailed guidance on water quality testing standards, testing frequency, and system functionality. Monitoring is performed by the multidisciplinary team. The team reviews the water quality results and implements the necessary corrective actions if the results are out of range. The standard includes reference tables that specify testing parameters and frequencies.
5. The new standard provides guidance on water treatment system installation, operation qualification, and design of water treatment systems. It also provides recommendations on service interruptions, system shutdowns, and construction related activities.

The standard serves as a framework for facilities to create an impact on water quality and patient safety. Proper implementation of this standard can help prevent issues such as, medical device and processing equipment damage, processing inefficiencies, and negative patient outcomes from surgical site infections.

To access the standard, go to: https://www.aami.org

Reference: ANSI/AAMI ST108:2023 Water for the processing of medical devices