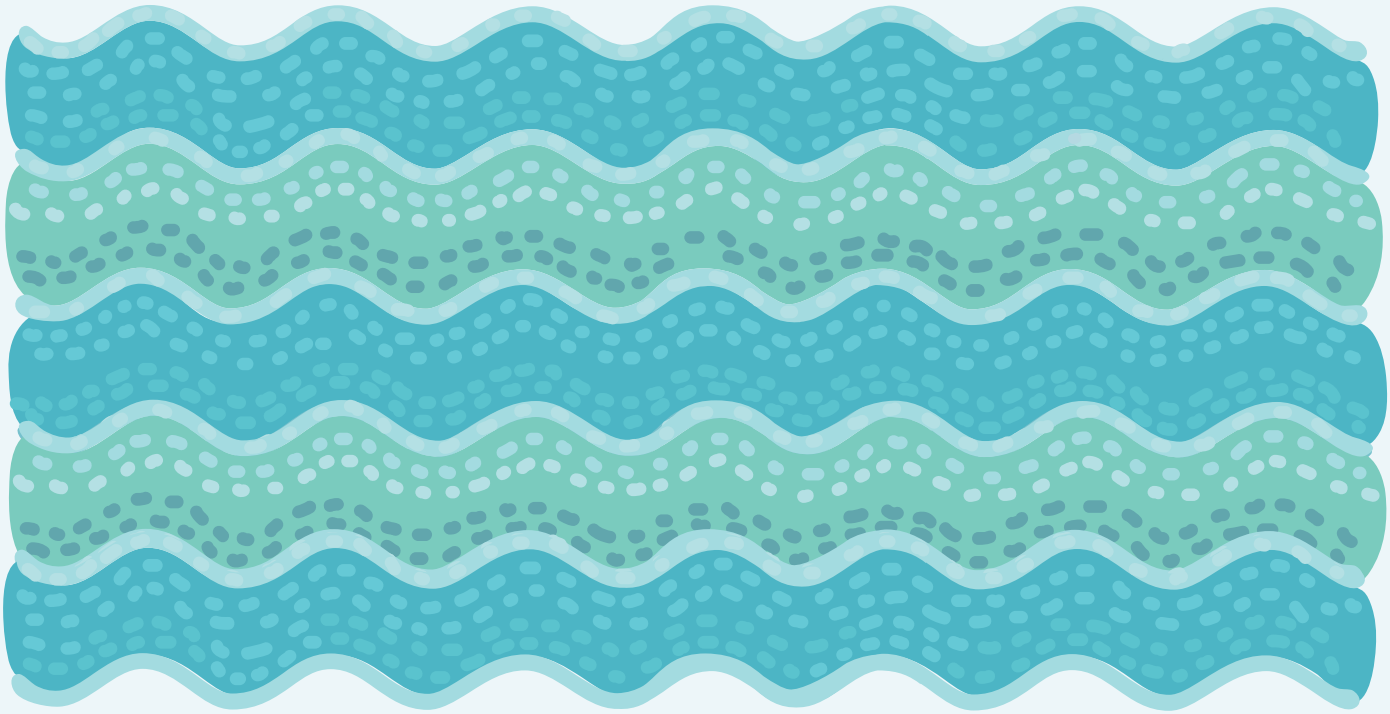

Water Quality and Its Critical Importance in Sterile Processing

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LEARNING OBJECTIVES

1. Explain the different types of water and the requirements of each
2. Discuss the roles of healthcare personnel pertaining to water quality management
3. Examine water quality monitoring requirements for Sterile Processing

The purpose of medical device processing is to prepare medical devices and equipment for the delivery of safe patient care. At the time of use, reprocessed items must function as they were designed, without any debris or processing residues remaining. Water quality has a major impact on this objective because water is used for cleaning, rinsing and steam sterilization.

Water is the largest part of the cleaning solution and is used to rinse all debris and chemicals after the device has been cleaned. Of course, water is also transformed into steam. The newly released standard, ANSI/AAMI ST108:2023 *Water for the processing of medical devices*, provides healthcare Sterile Processing departments (SPDs) with guidance on the selection of water and the management of water-quality to help ensure safe, effective medical device processing. The standard establishes minimum requirements for the water quality used for different stages of device processing. Specifically, ST108 provides recommendations for water selection for processing and addresses water treatment equipment, water distribution and storage, quality-control procedures for monitoring water quality, strategies for bacterial control, and environmental and personnel considerations.

This lesson plan addresses the importance of maintaining water quality and includes specific recommendations from ST108 that affect Sterile Processing (SP) functions and operations.

Objective 1: Explain the different types of water and the requirements of each

Every SPD requires different types of water, and the type needed is dependent upon the processing stage. The terminology used to describe the water types is based on the water-treatment process used—and its associated requirements—not on the location of use. For example, the term "tap water" may be used to refer to water originating from the sink tap; however, the water quality may be considered "utility water"

RO water system


DI water system


Instrument that underwent a final rinse with utility water (note the water residue)

(ST108 provides the detailed chemical requirements for this type of water).

Three types of water are used in an SPD: utility, critical and steam. Utility and critical water are both used for cleaning, rinsing and disinfecting, and the third type is steam for steam sterilization. More specifically, utility water is used as the initial water for cleaning, flushing and intermediate rinsing and is largely used for cleaning, except for the final rinse. Utility water comes directly into the healthcare facility, is monitored and, depending upon its water quality measurements, may require treatment to achieve the water quality recommendations stated in ST108. If utility water is used as a final rinse, there are specific requirements for endotoxin and bacteria levels; this is identified in Table 2 of the standard.

Critical water is used for the final rinse of critical devices. This occurs prior to sterilization or as the final rinse after high-level disinfection (HLD) to remove endotoxins and reduce the risk of pyrogens and other adverse patient reactions. *Note: It is not necessary to use critical water for all processing stages as it is expensive and can damage the water system or processing equipment.* Critical water is extensively treated by a multi-step process to remove the microorganisms and the inorganic and organic materials to achieve the water quality measurement values outlined in ST108. The primary treatment methods—reverse osmosis (RO) and/or deionization (DI)—must be used.

RO utilizes a mechanical process where a semi-permeable membrane is used for the separation process for purifying water. This creates a molecular sieving and ionic rejection process, effectively removing the dissolved organic contaminants and metals from the water system. DI is a chemical process that performs the purification process through ion-exchange resins to produce high-purity water. After the primary treatment is completed, proper storage and distribution best practices must be followed.

Understanding your distribution system is critical in determining how to manage water use in your operations. The distribution system may be recirculated or not recirculated, have a storage vessel, or additional treatment equipment to remove safety hazards from the water (ultraviolet lighting and endotoxin filtration would be examples of this). Fully understanding the distribution system is as important as the equipment that produces the purification process. All these components combined create the critical water system, and understanding how it is maintained is important. For example, water storage tanks should be monitored for endotoxin and bacteria levels. The test results can often identify when cleaning the tank is necessary. Your water management program will identify the individuals responsible for monitoring water conditions, when maintenance work is necessary, and who will perform the work.

Steam is vaporized water produced by a centralized boiler or a generator/heat exchanger near the sterilizer. Routine testing of steam should be conducted on steam that has been condensed back into a liquid and referred to as steam condensate. This testing and the subsequent results should meet the specified criteria as defined in ST108.

There are two methods of steam generation that healthcare facilities use to deliver steam to a steam sterilizer, the most common of which is derived from a centralized system used for other purposes throughout the facility. This is known as "plant" or "house" steam. The SPD might be located a lengthy distance from the central steam supply, resulting in the steam passing through an extensive distribution system before being delivered to the sterilizer. The other method involves steam being generated near the sterilizer. This steam can be produced with a high-purity water source and can be either "process" steam or "clean/pure" steam. Process steam uses critical water; clean/pure steam uses a pure steam generator fed with water for injection.

All stages of water processing should be monitored, and its performance should be compared to the water quality levels outlined in ST108. The standard provides specific categories and performance qualification levels of water quality for medical device processing for each category of water quality. The components being monitored include ionic contaminants, such as iron and

chloride, total alkalinity, endotoxins, bacteria, color and turbidity, and total organic carbon. The identification of the roles and responsibilities of the work being performed will be critical. Your water management program and the team that is involved with its development will identify all individuals involved with routine maintenance and testing. The water management team may identify that a third-party vendor or contractor is responsible for some of the work that is necessary for proper operations.

Objective 2: Discuss the roles of healthcare personnel pertaining to water quality management

Quality systems function best when there are clearly defined roles for the stakeholders such as each member of the water quality management team. Most healthcare facilities already have a water management system in place that monitors water quality. The Joint Commission (TJC) requires hospitals to have a water management committee. This multidisciplinary team will ideally include representatives from Sterile Processing, Facilities Engineering, Infection Prevention and Control (IPC), Surgery, Clinical Engineering, and a water treatment specialist. ST108 also recommends acquiring sponsorship from facility executives who are authorized to allocate resources *(ST108 refers to SP professionals as medical device processing personnel and applies to all areas that process medical devices*). Members of the multidisciplinary team should have demonstrated competency to perform their water management tasks and the resources to address any challenges with or changes to the program. The team is responsible for developing water quality policies, procedures and protocols for medical device processing as part of a quality assurance program that meets current regulatory and accreditation requirements, standards and guidelines and accreditation requirements. *Note: Members of the water quality management team can be either internal or external to the healthcare organization.*

Medical device processing personnel (SP technicians) should receive the appropriate education, training, and competency verification about the importance of water quality, patient risks associated with improper water system characteristics, and the appropriate water quality monitoring that should be performed in all processing areas. Additionally, they should monitor the processing equipment and medical devices for issues that may indicate water quality issues, such as discoloration and damage, and have adequate time and resources to complete these essential activities.

Personnel in the Operating Room and other procedural areas are responsible for visually inspecting medical devices for any signs of water-quality issues, such as corrosion or discoloration, before their use.

IPC personnel play a vital role in the water management process. They review the water monitoring results and, if needed, make recommendations to correct problem areas, bring concerns to the water management team and discuss issues of concern with the healthcare organization's leadership. Infection preventionists routinely perform patient surveillance, which includes patients who were potentially exposed to waterborne pathogens carried by a medical device (this can include endoscopes, implants and surgical instruments that may have been processed with questionable water quality).

Objective 3: Examine water quality monitoring requirements for Sterile Processing

Water monitoring is necessary to promote safety and quality. Water that is not monitored can become contaminated by metals, microorganisms and other contaminates, resulting in instrument corrosion and malfunction, decreased effectiveness of cleaning agents, staining and increased microbial levels after processing.

It is not uncommon to identify that a healthcare facility's water systems are monitored by the Facilities Engineering department, and the results should be disseminated and reviewed by designated personnel throughout the facility. If water-quality parameters are outside of acceptable limits, appropriate corrective actions should be taken, and water maintenance personnel should inform SP professionals in all areas where processing occurs if the water quality is outside of acceptable range. Water should be monitored by facilities engineering since the water treatment system could become heavily contaminated with metals, microorganisms or other contaminants and could contribute to corrosion and staining. If the monitoring shows the water quality measurements are not within the acceptable range recommended in ST108, they should inform the SP staff so they are aware of it as they resolve the problem. If the SP technicians observe the water is cloudy or discolored, they should immediately notify Facilities Engineering and IPC. ST108 provides acceptable water

performance qualification levels for utility water, critical water and steam.

Water quality can vary throughout a healthcare facility, from season to season and during construction. Water line repairs or interruptions can also affect water quality. Remember, utility water used for SP processes is typically produced at a centralized facility and then travels through the water distribution network to the SPD and other areas where medical device processing occurs. Through this distribution network, the system can become contaminated. For that reason, monitoring the water used in Sterile Processing at the point of use is necessary. Point-of-use monitoring is performed by collecting water directly from the water taps and placing it in a sterile, endotoxin-free container. *Note: Contact Facilities Engineering or the testing lab for specific instructions before performing this test.*

The following identifies water quality monitoring steps to perform at the point of water use:

For medical device processing equipment, point-of-use water monitoring should be performed daily. Inspect the processing equipment's interior chamber walls and spray arms for residues, staining and discoloration that may have been caused by poor water quality. When inspecting processed medical devices, monitor each for damage and discoloration that may have been caused by poor water quality.

Water from a tap should be visually inspected before each use to ensure it is clear and odorless. If it is not, it should be reported and unused until the problem is resolved. Water temperature is also essential because it has a major impact on cleaning effectiveness. Its associated recommendations vary with the stage of medical device processing and the cleaning agent used [cleaning agent instructions for use (IFU) will state the appropriate water temperature].

Water sample testing should be performed quarterly for utility water at the point of use and processing equipment. This is due to bacteria, which can survive and multiply in water systems, posing a significant infection risk. Regarding critical water use and processing equipment, it is important to understand that water treatments to produce critical water may affect the chemical attributes of water, such as its pH, conductivity, total alkalinity and total hardness. This can cause microbial levels to increase biofilm development and endotoxin. For that reason, bacteria and endotoxins testing should be performed monthly by providing a water sample from the point of use (as previously stated, water should be collected directly from the tap and placed in a sterile, endotoxin-free container. Before performing this test, contact Facilities Engineering or the testing lab for specific instructions).

ST108 recommends a systematic and ongoing process to ensure compliance with water management and quality-testing procedures. Routinely performed audits can enhance quality processes. Findings from these activities should be summarized, documented and shared with stakeholders, as needed. Process and practice consistency are essential for delivering safe, high-quality patient care. Therefore, healthcare organizations should prepare for the unexpected and any unusual incidents that can affect the water supply. This new standard provides recommendations for monitoring and corrective actions to take in the event of such occurrences. Even though these actions are primarily undertaken by the Facilities Engineering department, SP technicians and others within the department should be aware of the events and their causes, the existing and anticipated outcomes (i.e., service interruptions and extended shutdowns, extended-time water boiling, steps to take after alerts are lifted, and modification and routine maintenance of critical water production).

Conclusion

Water is an essential component of medical device processing, and its quality is vital to safe and positive patient outcomes. The new water quality standard, ST108, guides managing the quality of the three types of water used in areas where medical devices are processed. Additional information and more in-depth explanations about the standard are included in ST108's nine annexes.

Water quality management is a team responsibility that requires input and expertise from Facilities Engineering, Clinical Engineering, IPC and medical device processing personnel (and others, as deemed appropriate by each facility). SP professionals should review and keep on file the new standard so they can help develop and comply with a comprehensive plan for managing water quality consistently across all SP areas. P