How Water Quality and ST108 Affect Endoscope Processing Departments

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LEARNING OBJECTIVES

1. Identify issues associated with using poor-quality water in endoscope processing
2. Understand how ANSI/AAMI ST108: 2023 applies to endoscope processing
3. Review recommendations for water-testing methods, requirements and frequencies

Water is simple, right? It is potable (drinkable), or it isn't. That may be true when considering water that comes into our homes, but water for processing endoscopes and other medical devices is far more complicated. Water for device processing can affect patient outcomes, damage processing equipment, cause cleaning chemicals to perform poorly, and damage endoscopes. It is in every facility's best interest to pay particular attention to the type and quality of water used for endoscope processing.

Like many aspects of processing, requirements change as the industry becomes aware of practices that cause harm or prevent it. Water is no exception. Water categories for device processing are broken into two groups: critical and utility. That is where simplicity ends.

With several methods available to generate critical water—and the need to understand the multiple characteristics and requirements that utility water should meet—it is essential that endoscope reprocessors and their facilities carefully consider all options and ensure water quality is prioritized.

Until recently, guidance from the Association for the Advancement of Medical Instrumentation (AAMI) on water quality was in the form of a technical information report (TIR), which was expressed as statements of expert opinion. In other words, it provided helpful information but was more applicable to Facilities Maintenance engineers. Now that the TIR has become a full standard, the question many are asking is, "How much of the guidance has changed and how does it apply to endoscope processing areas?" This lesson highlights some of those primary changes and recommendations and how endoscope and other medical device processors can become involved in their facilities' water management activities.

Objective 1: Identify issues associated with using poor-quality water in endoscope processing

Water plays a critical role in processing. For endoscopes, it begins with point-of-use treatment and continues through the final stages of processing. At each point, water can impact the process in multiple ways. Consider the following:

Endoscopes – Poor-quality water can leave deposits or buildup on and inside the endoscope, damaging the device, increasing repair and replacement costs, and make cleaning more difficult, which puts patients at risk.

Processing Equipment – Components may become damaged by poor-quality water, and the overall function of the machine can be affected, causing malfunction and increasing repair costs. Items processed in poorly functioning equipment also poses a patient-safety risks (see **Figure 1**)

Efficacy of chemicals – Chemicals used to process endoscopes have very specific parameters for use. Chemicals will perform effectively when water quality is good and the dilutions, temperature and exposure times are followed.

Patient safety – A damaged or improperly processed endoscope can pose a danger to the patient. Soil can harbor bacteria, and damage can cause the endoscope to malfunction.

To reduce the risk of any of these issues occurring, SP professionals must implement measures to determine water quality issues. That begins at the water's point of use. Point of use for water is defined as the closest point in the distribution loop where water is exposed to a medical device during processing. Consequently, if there is no water quality testing being performed at the point of use (i.e., the sink where processing occurs), there is a danger that the point-of-use water may not be of sufficient quality.

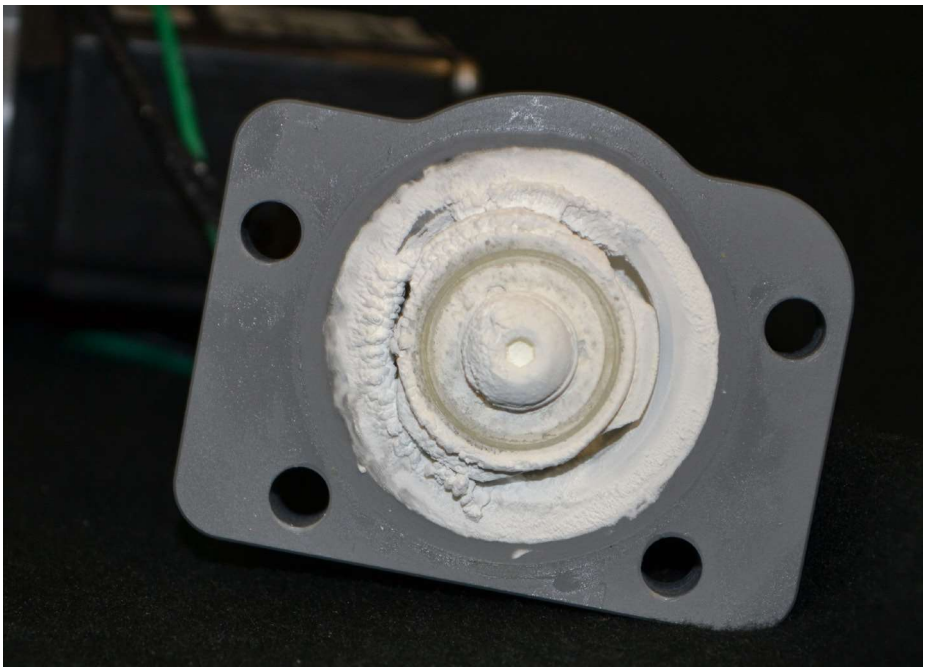

Figure 1: AER component damaged by poor-quality water

Objective 2: Understand how ANSI/AAMI ST108: 2023 applies to endoscope processing

ANSI/AAMI ST108:2023 *Water for the processing of medical devices* provides recommendations for measuring water quality for medical device processing. Water quality influences an institution's water practices from point of entry until it exits the drains at the point of use. To comply with ST108:2023, each facility should first establish or revise an existing, multidisciplinary, cross-functional management team. A collaborative, group effort is required to ensure an effective water management program.

ST108 covers all critical aspects of water quality and steam purity; therefore, it is little wonder that the standard recommends collaboration between Facility Engineering, Infection Prevention & Control, Clinical Engineering and Sterile Processing. This internal, multidisciplinary water management team should be responsible for evaluating and understanding the facility's water needs. Additionally, they should know the steps and equipment involved in providing the required water treatment. *Note: This does not mean that all team members need to be water experts; however, they must be aware of the institution's water needs, by stage, and which steps are in place to ensure those needs are met.* A facility's water management team does not have to be solely comprised of internal individuals, either. Third-party water testing companies and equipment manufacturers may also be involved in the testing and maintenance of the water systems.

It is likely that many facilities are already performing some water testing, but is it enough? Studies have proven that waterborne pathogens pose a risk to patients. Simply testing the water as it enters the facility or leaves the

generation system does not give the complete picture of an institution's water quality; therefore, a risk assessment of the facility's current water management systems should be performed to identify gaps and develop a plan to address them. The risk assessment will need to address many questions, some of which will be dependent on or specific to location and infrastructure, for example. Still, these two questions are relevant to all facilities and provide an excellent starting point for the water management team's initial assessment:

1. Have there been recently identified water-quality issues or adverse events? These could be in the form of patient infections, water treatment system failures, poor physical appearance of the water (i.e., dark, cloudy, containing particles), or staining, scaling, spotting or pitting of instruments and equipment.
2. Are the current policies and procedures regarding water management adequate and being followed? Be sure to answer the following: What is being tested in our water currently? Where is the testing being performed? How often should testing be performed?

By analyzing these two questions, the team will begin to get a clearer picture of what is happening with the water flowing through its pipes. How much the SPD will be directly affected depends on the answer to the second question.

Endoscope processing staff must be trained on the importance of water quality and the risk to patients if water quality is not verified and maintained. The development and implementation of a dedicated water-quality training and competency program will need to be established.

Objective 3: Review recommendations for water-testing methods, requirements and frequencies

Ease of compliance with the testing recommendations in ST108 will depend significantly on the current location and frequency of water testing. For example, if the SPD followed the guidance in TIR34 then the department is likely performing much of the recommended testing already. New to the standard, however, is a distinct separation of water-testing sites. Understanding water point of use should be clear to all involved in the water management process, especially those performing testing.

Point of use for utility water is described as the delivery point to the washer or the sink. Hence, the testing for utility water should occur directly inside the washer or from the tap. If this is impossible, it can be retrieved from nearby contiguous plumbing. The point of use for critical water is described as close to the point where the water can represent the water that touched the device. Again, this indicates directly from the tap whenever possible, but it can be at another point, as long as it is not too far away. This is an important consideration. If the source of deionized or reverse osmosis water is in another building, the water can pick up contaminants along the way. Finding a location near where the water is used is essential.

Recommended categories and performance qualification levels of water at both the generation system and point of use are listed here and should be part of every facility's testing program:

- pH
- Total alkalinity
- Bacteria content
- Endotoxins
- Total organic carbon
- Physical appearance
- Ionic contaminants that affect conductivity

These seven measurements should be tested in the facility's utility water, critical water and steam supply systems. When not properly maintained, any of these measures can adversely affect patients, equipment, endoscopes and their accessories—or, potentially, all three. Regular testing, at minimum specified intervals, is the only way to ensure a facility's water remains at a level appropriate for device processing. The testing frequency will depend on the characteristics being tested, the location where the testing is performed, and the type of water being tested. For example, the minimum recommended frequency for testing pH is the same at the generation system and point of use: quarterly for utility water and monthly for critical water. A measure like conductivity, however, has the same frequency for utility water—quarterly at the generation system and point of use—but has vastly different recommendations for critical water, which is daily at the generation system and monthly at the point of use.

The multidisciplinary team should be familiar with and refer to Tables 5 and 6 of ST108, while also understanding that testing frequencies of daily, monthly, and quarterly are recommended depending on the characteristics being tested, the location where the testing is performed, and the type of water being tested.

Understanding how all this directly affects the endoscope processing department requires a closer look at the water point of use. Again, this is defined as the closest point in the distribution loop where water is exposed

to a medical device during processing. Consequently, if no water quality testing is being performed at the point of use (i.e., the sink where processing occurs) in the SPD, the new standard will have an effect.

When a facility implements point-of-use water testing, the processing department will likely be part of the process. The reason is that water-quality measurements for total alkalinity, hardness, pH and physical appearance are simple to obtain and document. Colorimetric dipsticks and observation are often all that is required to measure these values. Training staff members on how to perform the testing and reviewing logs to ensure testing is continued at the specified frequency is relatively simple to implement for most processing departments. Processing professionals are already monitoring the temperature (another critical function described in detail in ST108) and hopefully the appearance of water in every sink used to clean endoscopes. Adding a quick, easy-to-interpret dipstick test to this process should cause little disruption to employees' workflow.

Bacteria, endotoxins and conductivity require specific testing equipment and processes. Consideration should be given to whether it is best for the facility to obtain this equipment and teach processing staff how to use it and perform these tests. Alternatively, the facility could outsource the testing to an internal or external water quality specialist. Once these decisions and any others identified in the risk assessment are addressed by the water management team, an educational program can be developed and required training can begin.

Another question endoscope processing departments should consider is point-of-use water testing in automated processing equipment. Automated endoscope reprocessors (AERs) manufacturers, for example, often require particular water-quality levels and state that highly filtered water should be used for the final rinse phase. This level of water quality is attained through a series of filters that remove smaller and smaller particles. The filters should be on a strict replacement schedule to ensure they provide the water quality required by the AER manufacturer.

Does this mean water quality testing is not required for point-of-use water? For that topic, ST108 defers to guidance from the endoscope processing recommendations in ANSI/AAMI ST91:2021. Currently, ST91 only recommends testing AER water quality when a problem is identified. Although processing staff may not need to do any specific testing in their AERs, providing technicians with information about the water produced by AERs and the filter replacement schedule should be included in their education and competency activities.

When addressing water testing needs, one final section of ST108, Annex I, *Typical presentation of water quality issues during the processing of medical devices*, is an excellent place to turn for information on building a water education program. The annex provides several examples, with pictures, to demonstrate how poor water quality affects devices being processed. The annex also gives possible causes and recommended actions to take when these issues are found.

Conclusion

As with any updates or changes, there is a learning curve associated with understanding and complying with standards. ST108 seeks to address water and quality recommendations for device processing in a way that underscores its critical importance to device processing and outcomes.

Many endoscope processing technicians do not consider themselves to be more than just a user of water, but their role in that aspect is more significant. Water quality has such a big impact on endoscope and other medical device processing that it must be prioritized appropriately across the various stages of device processing. Although monitoring water quality will primarily be the responsibility of the facility's engineers or water maintenance personnel, ST108 highlights the need for reprocessing departments to be part of the water multidisciplinary team. It is vital that all processing professionals are trained in the important role water quality plays in their responsibilities to elevate employees' understanding about how quality water affects patient outcomes. P

RESOURCES

AAMI TIR34:2014/(R)2021 *Water for the reprocessing of medical devices.*
ANSI/AAMI ST91:2022 *Flexible and semi-rigid endoscope processing in health care facilities.*
ANSI/AAMI ST108:2023 *Water for the processing of medical devices.*