The Importance of Water in the Production of Steam for Sterilization

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LEARNING OBJECTIVES

1. Describe the impact of water quality on steam quality
2. Compare the types of steam available for medical device sterilization
3. Understand how to prepare for clean steam

Many assume that steam delivered to the sterilizer is pure steam vapor. In reality, steam is a combination of water vapor, water condensate, boiler chemical carry over, and materials picked up along the way to the sterilizer. Once steam enters the chamber, it has direct contact with reusable devices, exposing them to its assortment of contaminants. Still, most facilities do not have specifications for their steam, and even fewer test the vapor quality of the steam entering the steam chambers. Times are changing, however, because water quality standards are on the horizon—and the impact to Sterile Processing departments (SPDs) could be significant. Preparing for the future begins with a basic understanding about the most important sterilant in sterile processing: steam.

Objective 1: Describe the impact of water quality on steam quality

Steam sterilization relies on temperature and steam's ability to heat instrumentation to sterilization temperatures quickly through the process of condensation. To do this, steam used to sterilize must be relatively dry but not superheated (superheated steam is produced when steam is heated beyond its saturation temperature); this is referred to as saturated steam. Steam quality refers to the amount of liquid water mixed with steam vapor. The more liquid the water, the wetter the steam is, and the less effective it becomes. Steam used for sterilization should be saturated steam and consist of at least 97% steam vapor or less than 3% liquid water by volume. This is referred to as a steam quality of 97%.

Sterilization relies on the condensation of steam into liquid water to transfer heat quickly to instrumentation. As steam vapor condenses to liquid, the heat energy that was in the steam quickly transfers to the item that the steam touches, turning the vapor into liquid. If steam cannot condense, the heat energy becomes trapped within the vapor and unable to quickly transfer to items being sterilized.

Superheated steam should not be used for sterilization. Superheated steam has reduced capability of condensing; therefore, sterilization is affected.

SPDs typically use house steam. House steam is often called plant steam. This type of steam is generated at a central steam generator or boiler and then dispensed throughout the facility using insulated piping. During the trip to the sterilizer, steam vapor condenses, becoming liquid water. This changes the ratio between vapor and liquid, making steam wetter (more saturated). The longer the trip, the more liquid is produced, and the steam quality is reduced. Keeping steam dry is important. Insulating steam lines and utilizing steam traps to remove condensation from steam lines can help, as can using high efficiency boilers and right sizing the system to the facility's needs. Another way to maintain dry steam is to shorten the distance between steam generation and the sterilizer chamber. Integral or dedicated local steam generators shorten that distance significantly, reducing the potential for wet steam.

The quality of steam and efficiency of the steam generator or boiler are also dependent upon incoming water. Tap or utility water is the primary source of water used to create steam for sterilization. Prior to becoming steam, tap water is treated to remove hard water minerals of calcium and magnesium. The softened water prevents scale buildup in the boiler or generator, keeping heating efficient.

Tap water also contains dissolved gases like air. Dissolved gases in tap water mix with the steam during steam generation. These non-condensable gases are unable to heat instrumentation in the same way as steam. Excessive non-condensable gas can compete with the steam, preventing sterilization of items within the load. Dissolved gases are removed from the water prior to injection into the boiler or generator. Water that has been softened is placed in a conditioning tank. The tank heats the water to between 90°C and 100°C. As the water is heated, dissolved gases vaporize and leave the water. Water and steam can be corrosive to many metals, including those used in the boiler and steam piping. Chemicals are added to the boiler's water to help protect the boiler and steam lines from corrosion. These same additives can be carried with the steam into the sterilizer chamber.

Although plant steam uses softened and conditioned water, it contains more than water. Water is known as the universal solvent, allowing many minerals and compounds to dissolve within it. Tap water may have naturally occurring minerals, metal ions, and organic compounds, depending upon the tap water's source, and those dissolved components can be carried with the steam. Many assume that water softening and conditioning removes all dissolved chemicals. This is not the case. Water softening removes only calcium and magnesium, leaving behind the other dissolved components.

The presence of excessive dissolved metals, minerals and organic compounds manifests in many ways. Metal ions can stain instrumentation and chamber walls. Copper can color paper sterilization pouches green and react with some metals. Iron can discolor chamber walls and instrumentation, creating rouge and corrosion. Excessive calcium and magnesium create water stains and scale and mineral deposits within chambers, on instrumentation and in container systems. Carbonate, hydroxide and bicarbonate can change the water and steam pH, which can lead to pitting, staining and corrosion of instrumentation. Some protected soft metals can lose their protective layer (anodized aluminum can blacken, for example).

Water components do more than stain and damage instrumentation. Some components have also caused toxic anterior segment syndrome (TASS), an inflammatory response caused by exposure of the anterior segment to non-infectious substances that induce a toxic effect. This response can result in blindness. Steam contaminants transferred to eye instrumentation used for cataract surgery have been linked to several incidents of TASS.

The ability to sterilize relies on steam quality (saturated steam) and condensability, but the interactions from the steam contaminants have a significant impact on the instrumentation and, ultimately, patient safety.

Objective 2: Compare the types of steam available for medical device sterilization

Facilities must determine how clean steam should be to provide a safe and effective sterilization process. A cross-functional team that includes Infection Prevention, Sterile Processing, Operating Room, and Facilities Maintenance personnel should evaluate the current status to determine the facility's needs. The evaluation should include (but not be limited to):

- Steam and water quality test results
- Reports of water staining, pitting or corrosion
- Reports of instrument damage or malfunction
- Steam sterilizer manufacturer recommendations
- National standards and guidance documents such as AAMI TIR34
- Potential risks to patient safely from water contaminants

Three types of steam are available to healthcare facilities. The first is plant steam. As discussed, plant steam relies on softened and conditioned water. Many facilities use this type of steam without risk; however, facilities experiencing staining, discoloration and other problems associated with steam contaminants may consider using the next (higher) grade of steam.

Clean steam is generated with water that has undergone deionization or reverse osmosis (RO) to remove dissolved contaminants in the water. Deionization removes charged minerals, including chlorine, iron, copper, sodium and many more. RO applies specialized filters to screen out large ions, heavy-metal ions, bacteria, viruses, cysts, some organic molecules, and undissolved solids. Deionized (DI) and RO water generate steam that is free of impurities that could affect instrumentation.

Pure steam requires further treatment of the steam itself. Pure steam starts as clean steam prior to treatment. Treatment removes liquid water and other low-level contaminants. Importantly, the condensed steam following treatment must meet the requirements for sterile water used for injection. Pure steam is not used in healthcare facilities for sterilization of medical instrumentation. It is primarily used for the sterilization of certain pharmaceutical products. This type of steam is also the costliest. It includes costs associated with clean steam but also requires steam filtration units for further processing.

Plant steam is the most economical type. Since it serves many departments and needs, the cost of boiler operation is spread throughout the facility. However, it does have disadvantages for Sterile Processing applications. Changes in facility steam demand can drastically change pressure throughout the day, causing fluctuations within the SPD. Often, steam used for sterilization comprises only 3–5% of all steam supplied to the facility.

Clean steam is more costly to produce because it requires additional water filtration units to remove impurities. Removing ions from water makes water seek more ions. The solvent nature of the treated water leeches metal ions from copper pipes and tanks, causing corrosion. For this reason, all surfaces that touch either the treated water or clean steam generated must be corrosion resistant.

Stainless steel must be used instead of copper, which increase the cost of boilers, generators and transport piping. Steam generators integral to the sterilizer or a smaller steam generator located in or near the SPD help control costs by limiting filtration costs and stainless-steel piping and generator costs. It is important to remember that older sterilizers designed for plant steam may need to be replaced because they often have copper components that would contact clean steam and corrode during operation.

Objective 3: Understand how to prepare for clean steam

ANSI/AAMI ST79 describes two aspects of steam: steam quality and steam purity. Steam quality refers to the specifications required for successful steam sterilization, including:

- 97–100% dryness
- < 3.5% volume/volume condensate
- Superheat of <25°/77°F above saturation point

Steam purity refers to dissolved chemicals and suspended particles within the steam. Steam purity is not the same as pure steam. Regarding purity, ANSI/AAMI ST79 states that contaminants should be minimized and monitored. The facility must decide which levels are appropriate for the various chemicals and particulates that can be found in their steam.

Clean steam is currently not required for SPD reprocessing; however, clean steam requirements are coming. How far into the future and which specifications will be identified is a matter of current debate. ANSI/AAMI TIR34 guides healthcare facilities in the selection of water quality specifications and purity requirements within SPDs. TIR 34 recommends the use of critical water for steam generation, which it defines as DI or RO water. TIR 34 is not a standard; therefore, healthcare facilities are not required to follow it today. Still, this technical document is being reviewed and revised to become a national standard, ANSI/AAMI ST108. The document has been issued for public review and is currently in its final stages to becoming a standard. Although the final document will differ from TIR 34, the requirement for DI or RO water has remains and was included in the final draft ST108 that was issued for public review. Healthcare facilities should consider the possible implications of using DI or RO water:

- What is the number of sterilizers that is incompatible with clean steam? Monitor the replacement schedule and ensure that new sterilizers are compatible with both plant steam and clean steam.
- Will facility steam be upgraded? The cost of upgrading facility steam and all its steam lines for clean steam is cost prohibitive for most, if not all, facilities. Instead, plans should be considered to use local or integral steam generators. Determine if this can be incorporated in the current space or if additional space and remodeling would be required. Always review any remodeling or new-build planning

with the potential for conversion from plant steam to clean steam.

- Develop a water and steam testing program. Steam quality and purity testing is already a requirement in ST79. The frequency is decided by the facility; managers should work with facility maintenance personnel to determine the best frequency. Consider incorporating testing identified in TIR 34. Many steam sterilizer and steam generator manufacturers can provide resources and recommendations for testing.

Conclusion

Steam quality and purity are critical components for effective and safe steam sterilization. As standards change, adoption of testing and preparation for improving the steam purity will become a focus for many healthcare facilities.

RESOURCES

1. Hellinger, W, Hasan, S, et al. "Outbreak of Toxic Anterior Segment Syndrome Following Cataract Surgery Associated With Impurities in Autoclave Steam Moisture." *Infection Control & Hospital Epidemiology*, 27(3), 294-298. 2016. doi:10.1086/501540
2. ANSI/AAMI ST79:2017 & 2020 Amendments A1, A2, A3, A4 (Consolidated Text) *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Available for purchase at www.aami.org.
3. AAMI TIR34:2014/®2017 *Water for reprocessing of medical devices*. Available for purchase at www.aami.org.