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SELF-STUDY SERIES

Steam requirements for sterile processing

*An overview of revisions to the ANSI/AAMI ST79 Standard**

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August 2020

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LEARNING OBJECTIVES

1. *Identify and understand implementation of the AAMI TIR34 2014, Water for the reprocessing of medical devices guideline*
2. *Identify the different stages of rinsing and when they should occur during the process*
3. *Distinguish different water quality types and treated water rinses and when/how each one should be used*

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Sterile Processing is often regarded as the front line for fighting infections. Following proper protocols and standards is critical if we are to win that fight. This article will discuss the ANSI/AAMI ST79 Standard* for steam sterilization, while also explaining why the ST79 recommendations are important for Facilities and Design engineers to be aware of if they are to successfully support the sterile processing department (SPD). Content for this article has been derived from multiple sources, including the Association for the Advancement of Medical Instrumentation (AAMI).

The Standard* is an all-encompassing standard, covering everything from steam conditions, airflow, temperatures, and water quality through the SPD. It offers guidelines and recommendations that "should" be followed. "Should'" indicates the most suitable option among several possibilities. It may also suggest that a certain course of action is preferred, but not necessarily required. Additionally, it may highlight when a certain possibility or course of action should be avoided, but is not prohibited.

What makes sterilization steam so special?

It's important to remember that the last thing to touch an instrument or textile before it's used on a patient is steam. The Standard* says there are two common sources for steam used in sterile processing: hospital steam boiler systems and self-contained electric boilers. In both cases, a treated water supply is necessary to remove total dissolved solids (TDS). Each system should be designed, monitored, and maintained to ensure that the quality, quantity, and purity of the steam provided are appropriate for effective sterile processing. With that standard in mind, reach out to your Engineering staff and ask for a walkthrough of the boiler room, making sure they show you the solids measurement and controls.

What are the parameters of steam quality?

The Standard* describes steam quality as having three parameters: dryness, non-condensible ratio, and superheat. It offers acceptable levels for those three parameters and stresses the importance of assessing and documenting upon installation or relocation of the sterilizer and after any change to the steam distribution lines or boiler supply water.

What is dryness?

Steam dryness is a measure of how much liquid water is present in the flowing steam. It is expressed as a "dryness fraction," which is a percentage by weight. The standard says steam dryness should be between 97% and 100%. This dryness fraction is measured at the inlet to the sterilizer. Most boiler plants do sampling of the steam near the boiler header to detect any boiler carryover. You may want to request that Engineering take samples from behind the sterilizers. (See figures 1 and 2.)

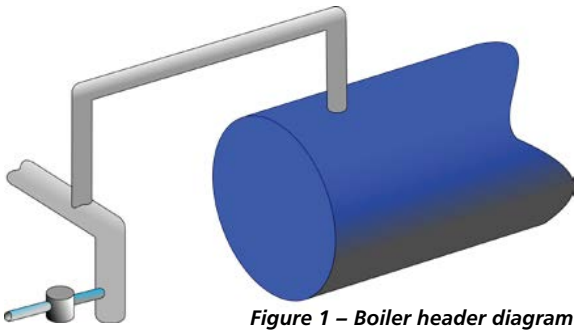

Figure 1 – Boiler header diagram

Figure 2 – Boiler header in a healthcare facility

Figure 4 Deaerator (DA) tank in boiler room

A sample cooler in the boiler plant typically condenses some steam from the header or main to measure solids and pH. If liquid is being discharged (carry-over) by the boiler, it shows up as a high-solids concentration. The same measurement can also be used at the sterilizer. Liquid water at the sterilizer might be boiler carry-over, but can also be condensate. Condensate is the equivalent of distilled water and will not have a high-solids concentration.

What if dryness is too low?

If too much liquid water flows into the sterilizer chamber, a '*wet load*' may result. Any liquid water present on or in the sterilized container can breed bacteria, becoming a threat to patient safety. If that happens, it must be reprocessed - an expensive, three-hour procedure. Unfortunately, the problem is sometimes not discovered until containers are opened in the surgical suite. Then, reprocessing becomes an emergency and all other items processed with the wet load are recalled.

Unlike most other hospital processes (except humidification) the steam is injected directly into the sterilizer. This makes SPD one of the first to know if there is a steam system upset.

The sterilizer is designed to deal with soaking wet instruments. The steam is intended to condense on the instruments, creating the "time and temperature" required to achieve sterilization. The drying cycle is programmed to pull a vacuum, causing the condensation to return to steam. When there is too much "extra liquid" carried with the steam, the dry cycle can't handle it and a wet load results. (See figure 3.)

What are non-condensable gases (NCGs)?

NCGs are defined as gases that cannot be liquefied by compression under the conditions of temperature and pressure used during the sterilization process. These gases are more commonly known as air, CO2, and O2.

"*Air*" means the atmospheric air that is introduced into the sterilizer chamber when the door is opened, or into the steam piping when the system is opened for maintenance. The steam system normally loses water over time due to leaks, humidification, and boiler blowdown (flushing the boiler). The system needs some fresh water to make up for these losses. Air is introduced into the system with this fresh water, as well as carbonates. Carbonates are the primary source of NCGs. When heated in the boiler, the carbonates (CO_3) break down, producing oxygen (O_2) and carbon dioxide (CO_2). These two gases can cause problems with corrosion. Boiler treatment adds chemicals to the system to head off the negative corrosive impacts of $CO_2$and O_2. The boiler water pre-heater, or Deaerator (DA) tank are designed to remove dissolved air and NCGs from the boiler feedwater. (See figure 4.)

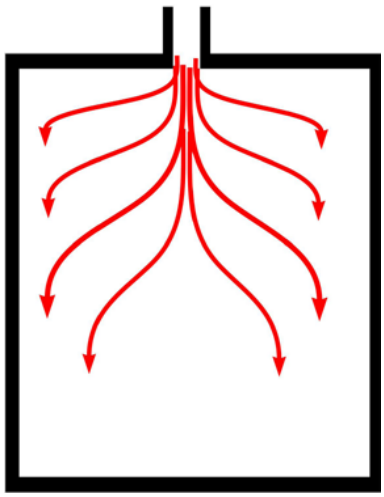

Figure 3 Steam Flow in the sterilizer

It's crucial to note the importance of daily testing to determine if there are problems with the DA tank. The Bowie-Dick test, which measures air removal, combined with the strategic placement of biological indicators (BI's) to confirm steam penetration, will help identify failure in the steam system or the presence of NCGs. As a result of this continuous testing, SPD is one of the first areas to be aware of a steam system upset.

According to the Standard*, the level of NCGs, should be at a level (less than 3.5% v/v condensate) that will not impair steam penetration into sterilization loads.

What if the NCGs level is too high?

Air and NCGs cause problems with the sterilization process in two ways. First, they lower steam temperature. Second, they occupy space - insulating the instruments we are trying to heat and sterilize. The more air is present, the harder it becomes to reach the 270°F temp required by the sterilization cycle. During a sterilization cycle, steam flows towards the instruments, collapsing and condensing as it transfers heat to the instrument. The steam flow also pushes air and NCGs towards the instruments – much like wind pushing balloons (NCGs) towards the surface of the instrument. Since they don't condense, they can collect at the instrument surface, creating a heat transfer barrier. (See figure 5.)

What is superheat?

Superheat is steam that is hotter than saturation conditions, which prevents condensation. Superheat can be found in large campus systems or district (city) steam-by-design. It can also be the result of a large reduction in pressure through a pressure-reducing station. It is unlikely to be of significance under normal circumstances that you encounter in hospital steam distribution systems, but superheating might occur if the main steam supply pressure is unusually high (usually 250 PSI

Self-Study Test Answers: 1. A, 2. A, 3. a, 4. A, 5. B, 6. B, 7. A, 8. A, 9. A, 10. B

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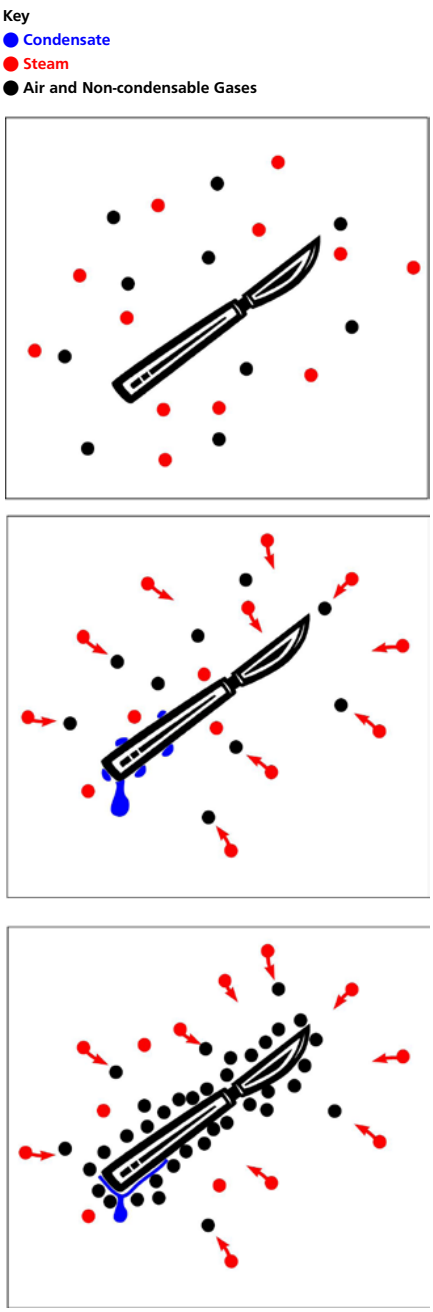

Figure 5 – Steam pushes NCGs toward the instrument surface

or above). Superheated steam is an unsuitable medium for steam sterilization. The standard calls for measurement of superheat of steam, expressed as a temperature in degrees above saturation point. This value should be less than 25°C (77°F).

What if superheat is too high?

Superheated steam can cause sterilization failure, scorching of textiles and paper, and rapid deterioration of rubber. Once again, the sterilizing cycle creates wetness and superheat prevents wetness. The sterilizer chamber is usually jacketed with 30 PSI steam, so having dry steam in the chamber is more like cooking pizza in an oven, as opposed to the desirable, wet conditions needed to prevent sterilization failure.

What is dynamic pressure?

Sterilizer manufacturers specify a minimum pressure needed to operate and sterilize effectively. This is measured as steam pressure during peak steam flow. Total steam demand, and the corresponding capacity necessary to support that, should be determined so that the steam supply system can be designed and built to meet peak demands of the facility. You must be able to ensure that constant steam pressure is available, at all times and under all conditions of steam demand, to properly operate sterilizers.

What if dynamic pressure is too low?

In our experience, there are two symptoms of low steam quantity. First, the sterilizer will go into alarms, especially door-seal alarms found on newer sterilizers. Secondly, wet steam issues can happen sporadically, without rhyme or reason. High-pressure drops are proportional to high velocity, causing condensate to flow past trap stations. Sudden pressure drops can impact trap performance and responsiveness. Consider asking that high-quality gages be installed on the sterilizer steam supply, as well as a transducer, to constantly monitor steam pressure.

What about treatment chemicals, especially amines?

Caution is advised when using amines for conditioning steam lines as the injection of amines directly into the sterile steam supply can create a staining issue, as well as high pH if the pump were to over-dose the line. To avoid this, ask to see the amine injection point and request it not be directly in the SPD steam supply.

Monitoring and alarms

Procedures should be in place for the preventive maintenance, repair, and monitoring of boilers and steam distribution lines that provide steam for sterile processing and for the documentation of corrective actions. This means that a pressure monitor is a good idea, and that traps and insulation on the sterile steam supply should be "hyper-managed." Most facilities check traps to find the energy loss created by leaking valves. For this reason, temperature monitoring of traps on the sterile steam supply is a good idea. A good best practice is to ask that preventive maintenance be done monthly on the traps between the boilers and SPD. This maintenance can be as simple as regular surveying with an infrared thermometer gun.

In addition to testing the boiler water conductivity or TDS, the monitoring and testing program for boilers should generally include determination of:

a. Incoming water hardness, pH, iron content, and alkalinity;
b. Boiler water alkalinity and pH; and
c. Condensate return alkalinity, conductivity, sulfites, and pH.

In the battle against infections, the SPD can arm itself with the revised Standard*, which suggests ways to ensure that the quality, quantity, and purity of the steam provided are appropriate for effective sterile processing. Key take-aways include:

1. *Conduct a steam quality validation whenever a sterilizer is relocated, steam piping changes are made to the sterile steam supply, or boiler water supply systems change. Values to be tested are dryness fraction, NCG level, and superheat.*
2. *Monitor steam pressures, trap operation on the sterile steam lines, and water chemistry (incoming, boiler, and condensate return) on a continuous basis.*
3. *Consider implementing a proactive communication strategy, so that it's the boiler plant calling SPD to notify them of a steam system upset, rather than the other way around. The revised Standard* will be in most SPDs, and it prepares them to effectively question these aspects of the steam supply.*

For reference:

Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2017. Arlington, VA. 2010

For recommendation:

Facilities and Design Engineers should review Section 3, Annex L (Steam Quality) and Annex O (Moisture Assessment)

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