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Steam sterilization standards for perioperative practice

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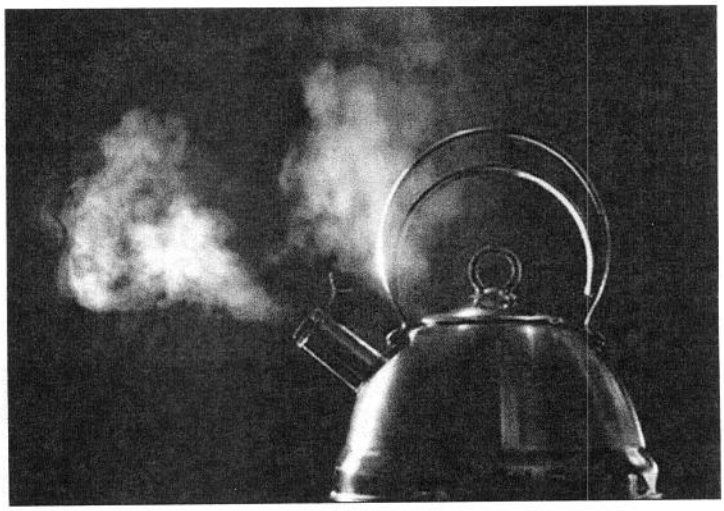

Steam sterilization is the mainstay of reprocessing surgical instruments and equipment due to its fast, reliable, and cost-effective qualities. Recommended standards guide perioperative nursing practice in all aspects of the surgical environment. The basis of care, handling, and sterilization of medical devices rests on the standards and recommended practices of the Association for the Advancement of Medical Instrumentation (AAMI).

Established in 1967, the AAMI creates and updates sterilization standards; however, the new steam standard is under continuous maintenance procedures. As of this writing, the organization was in the process of creating additions to the current standards and we will report on them once they are announced. The AAMI's members consist of a multidisciplinary group that includes biomedical and clinical engineers, materials/purchasing/supply specialists, physicians, nurses, quality assurance professionals, and representatives from manufacturers, hospitals, the FDA, and others.[1]

The American National Standards Institute (ANSI) oversees the creation and use of guidelines and standards, assuring the safety and health of consumers and the protection of the environment. Membership includes government agencies, organizations, companies, and academic and international bodies.[2]

The ANSI and AAMI's publication ST79: *A Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, Amendment 1*[3] has become a must-have resource. The following tables feature some of the updates and where they can be found in the guide (see *ANSI/AAMI steam sterilization updates*). The latest edition of the steam sterilization guide has a wealth of information that should be incorporated into every healthcare setting that involves the processing of instrumentation for use in surgical procedures. **OR**

REFERENCES

1. Association for the Advancement of Medical Instrumentation. http://www.aami.org/membership/index.html.

2. American National Standards Institute. http://www.ansi.org/about_ansi/overview/overview.aspx?menuid=1.

3. ANSI, AAMI. ST 79:2006/A1:2008 -Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Amendment 1. Arlington, VA: AAMI; 2008:1-185.

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ANSI/AAMI steam sterilization updates[3]

Topic	Recommended standards	Rationale
Decontamination sink for manual cleaning Section 3.3.7.1 (page 28)	• There should be at least one, three-section sink in the decontamination area. • The sink should be 36 inches from the floor and 8-10 inches deep, and should allow a tray of instruments to be placed flat inside. • Ports at the sink should allow for lumens to be flushed with water or forced air. • The final rinse should be done with deionized, distilled, or reverse osmosis water.	• The three sink sections allow simultaneous soaking, washing, and rinsing. • Sinks need to be deep enough for instruments to be cleaned beneath the surface of the water to prevent aerosolization, and at an appropriate height to decrease the risk of back injuries.
Quality controls for decontamination and cleaning processes Section 10.2 (page 79) Section 7.5.5 (pages 46-47) Section 7.5.3.2 (pages 45-48)	• Monitor, verify, and document that all cycles for mechanical decontamination and cleaning processes have been completed. • Monitor water quality. • Decontaminate reusable brushes and cleaning implements daily.	• Microbial debris and biofilms must be properly removed for sterilization processes to be effective. • Verification of the decontamination process should be documented via test devices and cycle printouts. • Aspects of water quality such as hardness, pH, alkalinity, and temperature can alter the effectiveness of enzymatic cleaners and detergents if not optimally maintained.
CI Section 10.5.2.1 (page 84)	• Every load should be run with a chemical indicator (CI) and the results recorded. A Class 5 integrating indicator offers the highest level of sterility assurance and can be used inside each set to satisfy the requirement for an internal CI. They can also be used to monitor routine loads that don't contain implants, and provide enough information to release the load for use when used inside a process challenge device.	• Class 5 integrating indicators mimic the response of a biological indicator (BI) in a load but don't replace the BI. Integrators are designed to react to all critical parameters over a specified range of sterilization cycles. • For loads containing implants, the integrating indicator again provides additional information along with the use of a BI, but load release will hinge on the results of the BI whenever possible. • Integrating indicators don't replace a BI as the basis for releasing implants within a load.
Peel pouches	• Peel pouches shouldn't be used inside wrapped sets or containerized instrument sets.	• The issue isn't whether the items inside the peel pouch are sterilized, but whether the items surrounding the peel pouch in the set are sterilized.
Instrument set assembly	• Instruments must be carefully inspected for cleanliness and proper functioning prior to packaging for sterilization.	• Instruments containing bioburden must be returned to the decontamination area to be recleaned.

(continued...)

ANSI/AAMI steam sterilization updates[3] *(continued...)*

Topic	Recommended standards	Rationale
Section 8.4.4 (pages 63-64)	• When assembling instrument sets, lumens must be moistened with distilled or demineralized water. • Hinged instruments should be held in an open position in the set.	• Cleaning only occurs in the decontamination area. • Moist lumens allow the steam to penetrate and contact all inner surfaces and help to more easily displace the air inside. • Open positions allow the steam sterilant to contact all surfaces of the instruments.
Instrument sets and weights Section 8.4.2 (page 62)	• The maximum weight of containerized or wrapped trays is 25 pounds.	• When instrument sets are too heavy, sterilization time and drying time can be compromised, yielding unsterile and wet sets. • The National Institute for Occupational Safety and Health has ergonomic calculations that recommend weight limits to protect workers from injuries related to manual lifting.
Instrument sets and sterilization Section 8.5.6 (page 67)	• Rigid sterilization containers need to be put on sterilizer carts below absorbent items. • Containers should be stacked depending on the manufacturer's recommendations from written sterilization verification testing results, and not just "made to fit" on the sterilizer cart. • Containers from various manufacturers shouldn't be stacked on each other when sterilized.	• This prevents condensate from dripping onto the absorbent items. • Stacking various manufacturers' containers on top of each other and not following recommendations can cause the sets to be unsterile due to inadequate air removal, steam contact, and drying.
Extended cycles Section 8.6.3 (page 70)	• The manufacturer's recommendations should be consulted for base settings for sterilizing wrapped, unwrapped, porous, and nonporous items. • Specialty medical devices such as certain implant systems may require special cycles with parameters extended beyond the "standard" cycle recommended by the sterilizer manufacturer.	• Cycle parameters for "standard cycles" can vary widely. The instructions for extended cycles from medical device original equipment manufacturers should be followed and reconciled with the instructions of the sterilizer vendor to ensure sterility. • The specialty device manufacturer is best qualified to identify the sterilization parameters required by its device to render it sterile and safe to use. • When using extended cycles, contact the BI manufacturer to ensure that the BIs will still function.
Instrument sets and sterile storage Section 8.9.2 (page 73)	• In the sterile storage area, the rigid sterilization containers are designed to be stacked if they're firmly seated on each other and can be moved easily.	• Written policies should be developed concerning the storage of rigid sterilization containers. • Midlevel shelving placement should help prevent back injuries.

(continued...)

ANSI/AAMI steam sterilization updates[3] *(continued...)*

Topic	Recommended standards	Rationale
	• Heavy trays shouldn't be stacked, and should be placed on midlevel shelving. • Wrapped packaging should never be stacked. • Sterile items should be stored 8-10 inches from the floor, at least 18 inches below sprinkler heads on the ceilings, and 2 inches from outside walls. • Sterile items shouldn't be stored under sinks, on the floor, or near doors and windows.	• Stacking crushes or compresses the wrappers, compromising sterility. • The National Fire Protection Association has fire codes that specify the distances from sprinkler systems so they'll work well in case of a fire. • Space is needed all around sterile sets to prevent contamination. • Sterile sets that get wet are considered unsterile.
Relative humidity values for sterile processing Section 3.3.6.6 (page 25)	• Relative humidity in all areas should fall between 30% and 70%.	• Relative humidities that are too high can promote microbial growth and increase bioburden. Relative humidities that are too low can adversely dry materials and interfere with steam penetration, and the functioning of CIs and BIs.
Temperature values for sterile processing Section 3.3.6.5 (page 25)	• Decontamination area temperatures should fall between 60° F and 65° F. • General work area temperatures should fall between 68° F and 73° F. • Sterilization area temperatures should fall between 75° F and 85° F. • Sterile storage area temperatures can go up to 75° F.	• The temperature in the decontamination area is the lowest of all areas because the personal protective equipment is worn for long periods of time, making staff hot and uncomfortable. • Bacteria dislike cooler temperatures and this may aid in decreasing bioburden.
Ventilation values for sterile processing Section 3.3.6.4 (pages 23-24)	• Ventilation in the decontamination area should be negative, with a minimum of 10 air exchanges/hour with air exhausted directly to the outdoors. • Ventilation in the prep and pack area should be positive with a minimum of 10 air exchanges/hour. • Ventilation in the sterilization area should be positive with a minimum of 10 air exchanges/hour with air exhausted directly to the outdoors. • Ventilation in sterile storage should be positive with four air exchanges/hour.	• The airflow patterns should be designed so that contaminants can't enter clean areas via air travel.