Q&A

The Power of Clean

AAMI regulations for the cleaning and sterilization of dental instruments

Marie T. Fluent, DDS

Marie T. Fluent, DDS (MTF): My daughter recently purchased an older home with a kitchen that bears the scars of having been well used over the years. My countertops display variance in color and texture, making it difficult for the eye to tell if they need cleaning. She can scrub and polish her kitchen endlessly, and it still appears worn and soiled. But mine can be covered in the sticky remains of recent meals, yet still appear fresh and clean to the naked eye. If appearances can be this deceiving and misleading, what principles and policies should guide and inform our approach to "cleanliness" in the dental office setting? Moreover, who should provide recommendations and regulations to guide these important efforts that are so critical to the safety and well-being of our patients and dental team? This is where AAMI (pronounced "Amy") comes into play.

Infection Control/Prevention Coordinator (ICC): Who's AAMI, and what does she have to do with cleanliness and sterilization?

MTF: AAMI is not a person, but an organization—The Association for the Advancement of Medical Instrumentation. AAMI's purpose is to advance the development and safe and effective use of medical technology. One of AAMI's principle documents, ST79, is the go-to reference for steam sterilization in all healthcare facilities—including dental offices. This document sets standards that help guarantee safety at every step in the processing of medical and dental devices, ensure proper sterilization practices, and support the delivery of properly processed medical devices.

ICC: I've heard of the US Centers for Disease Control and Prevention's (CDC) guidelines, and I am aware of the Occupational Safety and Health Administration's (OSHA) regulations, but must I also be in compliance with AAMI?

MTF: Yes, you must—but only indirectly. Dental personnel who clean and sterilize instruments in private practice settings are likely to have never heard of AAMI. However, those who process instruments in institutional or hospital settings are most likely very familiar with this organization. In dentistry, I like to think of AAMI as working "behind the scenes" because its publications are read mostly by the manufacturers. Because dental devices, supplies, and equipment used for instrument processing are manufactured and distributed, corporations must be in compliance with AAMI standards and they must provide readable and understandable instructions for use.

ICC: So, if I understand correctly, team members who process dental instruments according to the manufacturer's instructions (and follow CDC guidelines and OHSA regulations) should automatically be in compliance with AAMI's standards.

MTF: That is correct, and it means that dental personnel who process instruments must have access to the manufacturer's instructions and follow them carefully. This includes the reprocessing instructions for the specific instrument as well as the instructions for all of the equipment and supplies used for instrument processing. CDC recommends having these instructions readily available in the area where the device is used. For example, consider posting the instructions or keeping them all together in a binder in the sterilization area.

Highlight any critical components and review the instructions with your dental team. If an area within the instructions is unclear, call the manufacturer and ask for written clarification.

ICC: Am I correct in assuming that I will not need to purchase my own copy of AAMI ST79?

MTF: For processing instruments in a private dental practice, it is not necessary to purchase a copy of ST79. Dental facilities should have a written office-specific infection control manual as well as access to CDC's guidelines, OSHA's required regulatory documents, and all other required documentation. Dental facilities in institutional organizations may require additional regulatory documents, including AAMI standards.

ICC: If compliance with AAMI is already incorporated into our existing regulatory and compliance documents, then why do I need to know about the organization?

MTF: That is a great question. First, I want to stress to you the importance of following all instructions for use and instructions for reprocessing. If reprocessing instructions are not available, the device you are using may require disposal after a single use. Dental instruments in this category that frequently cause confusion include burs and endodontic files. Read the manufacturer's instructions thoroughly to clarify whether a device can be reprocessed. Second, AAMI ST79 was recently updated in 2017, and you should be familiar with some of these updates because they will eventually affect your dental practice.

ICC: What parts of the document were recently updated?

MTF: Most of the updates pertain to cleaning and sterilization. If debris has been left on an instrument, the sterilant may not reach all of the surfaces, and the instrument may not be fully sterilized.

Gross soil must be removed prior to instrument cleaning in automated cleaning equipment (ie, ultrasonic cleaner or instrument washer). This can be achieved by presoaking the instruments or using an enzymatic spray. Because dental personnel who process instruments may not have time to process them immediately after patient care, a presoak or pre-cleaning solution may be used. These solutions keep the instruments moist so that debris does not dry and crust on to them. In addition, the use of enzymatic solutions begins to break down bioburden. Whichever solutions are used, AAMI standards indicate that these presoaking and pre-cleaning chemicals must be rinsed prior to automated cleaning.

ICC: I will instruct my dental team to utilize more pre-cleaning agents and ensure that all of these solutions are fully rinsed off of all instruments prior to placement in the ultrasonic cleaner or instrument washer.

MTF: There are also additional recommendations for the most effective use of automated cleaning equipment. AAMI specifies that hinged instruments must be opened to allow the cleaning agent to reach all of the surfaces. In addition, when using an ultrasonic cleaner, instruments should be placed in an open weave or perforated metal basket below the water level. When using an instrument washer, a hold-down screen should be employed. Fortunately, most ultrasonic cleaners in dentistry have perforated metal baskets, and the use of cassettes as an instrument management system will further satisfy these AAMI requirements.

Similar to AAMI's requirement that instruments must be rinsed after pre-cleaning, any residual chemicals from instrument washing must be removed prior to sterilization. An instrument washer has a rinse and dry cycle at the end, but instruments placed in an ultrasonic cleaner must be manually rinsed. Remember to wear heavy-duty, puncture-resistant utility gloves and prevent contact with contaminated water. In addition, AAMI requires that ultrasonic equipment be cleaned daily per the manufacturer's instructions.

ICC: Going back to your kitchen metaphor, how clean is clean? How do you know if your instruments are clean?

MTF: Well, verification of cleaning is another new component of AAMI ST79. First, it is important to visually inspect instruments after cleaning. Consider using an illuminated magnifying lens to help in this process. In addition, it is important to know whether or not your cleaning process is effective. There are new verification testing strips that can be placed in your ultrasonic cleaner or instrument washer. These strips have colored ink printed on them. The instructions for use indicate where these strips should be placed during the cleaning and/or washing cycle. If by the end of the cycle, the strip is free of all "debris," you can be confident that your cleaning process has been effective.

ICC: Is this test required? Do I need to record results and maintain these records?

MTF: Some institutional facilities and larger practices do require verification of cleaning and maintenance of records. However, at this time, there are no regulations that mandate this in private practice. Having said that, if the manufacturer of your ultrasonic cleaner or instrument washer states that this test must be performed in its instructions for use, then it is definitely a requirement. But most importantly, wouldn't you want to know that your cleaning process is effective?

ICC: Are there any new recommendations for unloading the autoclave?

MTF: It is important to inspect the packages. Look for holes or perforations in the packaging, check package identification, and be sure that the external indicator has changed color. Also look for evidence of moisture. Moist instrument packages should not be handled because the packaging can act like a wick and absorb contaminants from hands. If this occurs, the instruments should be unwrapped and reprocessed entirely.

ICC: This is a lot of great information to help keep us up to date.

MTF: When it comes to infection control, it is critical that dental personnel make a firm commitment to consistency and compliance. Through such efforts, instruments will not merely "appear clean," they will "be clean" and ready to proceed in the reprocessing cycle. After sterilization, the dental team can open up the final instrument set in front of the patient, confident that the instruments are ready for the delivery of safe care.

ABOUT THE AUTHOR

Marie T. Fluent, DDS, is an educational consultant for the Organization for Safety, Asepsis and Prevention. With over 30 years in practice, she has written numerous articles and lectured extensively on infection control topics in dentistry.