

Sterilization & Infection Control

AAMI updates 'bible' on steam sterilization

The Association for the Advancement of Medical Instrumentation (AAMI) has updated its "bible" of recommendations for steam sterilization, formerly ST46. Also, for the first time, AAMI has gathered all of its major steam sterilization documents into one collection, titled *AAMI/ANSI ST79: Comprehensive guide to steam sterilization in health care facilities*.

In addition to steam sterilization, the collection covers guidelines for decontamination and packaging. Also included are guidelines for steam sterilization for wrapped loads, flash sterilization, and table-top sterilizers.

AAMI says the guide is intended to cover all steam sterilization activities in hospitals, ambulatory surgery centers, and physician and dental offices. The guide is available in a single PDF document as well as a hard copy in a binder to permit easy updates.

A consensus document

AAMI recommendations are considered consensus documents because they represent the collective expertise of health care and industry professionals who served on the working group that developed them. Among those on the working group for this guide are the Association of periOperative Registered Nurses, the Association for Professionals in Infection Control and Epidemiology (APIC), both sterile processing professional organizations (ASHCSP and IAHCMM), as well as independent hospital representatives. The majority of working group members, however, are from industry.

This article highlights a few of the important principles and changes in the AAMI document. Major areas the document addresses are:

- selection and use of rigid containers: how to evaluate them and biologically test them in your facility
- use of flash sterilization containers, including how to perform biological testing
- biological testing of steam sterilizers, including recommendations for routine monitoring, implantable devices, and testing after major repairs and installation or relocation of sterilizers
- classification, selection, and use of chemical indicators and integrators
- steam quality and purity
- prevention of wet packs
- selection of packaging materials, including proper set configuration and wrapping techniques
- correct loading and unloading of steam sterilizers
- product testing.

Quality control for sterilization

Managers will want to take time to digest the quality control section, which runs 30 pages and covers, among other things, product identification and traceability, monitoring of steam sterilization cycles, and sterilizer efficacy monitoring.

AAMI has added 2 helpful charts:

- a summary of sterilization process monitoring recommendations (Table 7)
- types and applications for use of sterilization monitoring devices (Table 8).

There is an extensive discussion of “process challenge devices” (PCDs), a term that may be new to some. These are test packs used to challenge sterilizer performance that are either assembled by the user or purchased. If PCDs are purchased, AAMI advises using only those cleared by the Food and Drug Administration. The document advises how to select PCDs and how to use them for release of loads with and without implants as well as for sterilizer monitoring.

The section also includes criteria for routine release for loads with and without implants.

More on release of implants

AAMI continues to strongly recommend quarantining loads with implants until the BI results are available. BIs, which consist of spores, are the only direct measure of the lethality of the sterilization process. Conventional BIs must be incubated for the specified amount of time (usually 48 hours for wrapped items and 24 hours for flash sterilization cycles) until it is determined whether the microorganisms grew or failed to grow. For the rapid-result BI, AAMI permits release of the implant with the 3-hour reading (for wrapped items) and the 1-hour reading (for flash sterilization cycles). (AAMI continues to state that implants should not be flash sterilized, however.)

AAMI says that when “documented medical exceptions dictate,” and an implant needs to be released before the BI results are known (eg, the need for trauma-related orthopedic screw-plate sets that may still be in quarantine), the early release of the implant should be documented. When the final BI result is obtained later, that should also be documented.

“It is critical that this documentation be fully traceable to the patient,” AAMI states. “Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.” AAMI further recommends that emergencies be defined and reviewed periodically to see if there are consistent patterns causing emergency release that should be corrected. (The guide has a sample form for documenting and tracking emergency release in Annex L.)

Biological testing for steam sterilizers

If rigid containers are used, AAMI advises performing biological testing prior to purchase of the containers and on an ongoing basis (at least annually). This recommendation was in the previous container standard, but many users were not aware of it. Biological testing of flash sterilization containers is also recommended.

Biological testing of steam sterilizers is recommended weekly, preferably daily, and with all loads containing implantable devices.

Steam sterilizers should also be tested after major repair (defined in the document), relocation, or new installation. This is referred to as “qualification testing.”

There is one major difference in the new standard. Routine testing of dynamic air-removed (DAR, or prevacuum) sterilizers includes performing the DAR test first, followed by a biological test in the first cycle (for wrapped cycles, the first wrapped load). For qualification testing, the process is reversed, and each test is performed 3 times. Therefore, on a DAR sterilizer:

- 3 biological tests using a process challenge device containing a BI would be performed (for each type of cycle available)
- followed by 3 DAR tests.

Many sterilizer operators are not aware that each type of cycle must be tested. Because prevacuum steam sterilizers can be operated as gravity displacement sterilizers, the gravity displacement cycle should also be tested.

Product testing

For quality control, AAMI advises periodic testing of routinely sterilized items. In addition, AAMI says product testing should “always be performed when major changes are made in packaging, wraps, or load configurations (eg, dimensional changes, weight changes, or changes in the type or material of packaging or wrapper).” This should include biological and chemical testing (with indicators located throughout the inside of the packs or containers) and poststerilization assessment of moisture content (eg, “wet packs”).

Guidance on CJD

The guide has a new appendix with general guidance for reprocessing devices exposed to patients with diagnosed or suspected Creutzfeldt-Jakob disease (CJD) (prion contamination). The guidance is based on the scientific literature and advice from health care authorities. AAMI notes that these recommendations may change and urges readers to check with agencies such as the Centers for Disease Control and Prevention for the latest recommendations.

As managers, we have a responsibility to ensure the safety of the devices we process for our patients. The AAMI document, which is a national standard, will provide the information managers need to develop and implement effective steam sterilization protocols to ensure the safety and efficacy of devices sterilized. ❖

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AAMI/ANSI ST79 can be ordered by phone at 877-249-8226 or at www.aami.org. Price is \$100 for AAMI members and \$200 for nonmembers.