Examining the New AAMI Standard…

Containment Devices for Reusable Medical Device Sterilization

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Metal and plastic reusable rigid sterilization containers for surgical instruments have been in use in the United States for nearly three decades. In more recent years, metal and plastic organizing trays and instrument cases and cassettes have become a staple in central service departments. With their ability to provide cost-effective, reusable, rigid packaging for sterilization processing, storage, transportation, and presentation of surgical instruments and other medical devices, these containers are true workhorses at any hospital. Thus, containment devices are a very important part of the patient safety and cost-control equations.

With such widespread use comes a concern over their ability to perform as needed. A new AAMI standard, Containment devices for reusable medical device sterilization (ANSI/AAMI ST77:2006), is the first U.S. performance standard for rigid sterilization container systems and other containment devices. The standard provides requirements to help ensure that containment devices allow sterilization and sterility maintenance of their contents, as well as (where applicable) adequate drying and sterilant removal.

“ST77 is a long-awaited and sorely needed document,” says Nancy Chobin, RN, SCPDM, of St. Barnabas Health Care System in West Orange, NJ, and a member of AAMI’s Reusable Sterilization Container Working Group. “Previously, there was no regulation or guidance on the manufacture, cleaning, or sterilization of rigid containers or organizing cases. Construction of the containers and organizing cases was a major issue. Both the materials and the construction of the containers and organizing cases has an impact on sterility maintenance because the design often would cause damage to the packaging system being used. For healthcare personnel this was a serious issue.”

ST77 addresses these important concerns about materials of construction by setting requirements for a number of key parameters, including:

- Durability—materials shall not deteriorate (crack, flake, peel, fracture, become brittle, or deform) within the manufacturer’s recommended useful life at the maximum conditions of use.

- Compatibility with the sterilization process—materials shall not inhibit or interfere with the sterilization and drying process for which the containment device is recommended.

- Biocompatibility—materials shall not adversely affect the biocompatibility of the devices being processed.

Sections on performance, labeling, and testing are offered to provide manufacturers with guidance in these areas.

ST77 addresses many important aspects of device performance, but one particular requirement will be particularly welcome by healthcare workers: the standard sets a 25-pound limit on the weight of the containment device, the instruments, and any accessories or wrappers when the device load is configured according to the manufacturer’s instructions. This weight requirement addresses three major concerns: it is intended to help ensure that the contents of a containment device can be reliably sterilized and, just as importantly, reliably dried. “It also address ergonomic aspects for the benefit of healthcare workers,” says Chobin, “by protecting them from potential back injuries and other lifting-related injuries that are an occupational hazard in central service departments. As the orthopedic and neurosurgery loaner instrument sets
Containment Devices for Reusable Medical Device Sterilization became more sophisticated, the sets became larger and heavier. This presented ergonomic challenges for healthcare personnel in the sterile processing department and the operating room who had to lift the numerous trays used in a procedure, which can be as many as 20."

Another significant element of the standard is the recommendation that containment devices be validated for use in sterilization methods and cycles commonly available in healthcare facilities. These methods include gravity-displacement steam sterilization, dynamic-air-removal steam sterilization, EO sterilization, dry heat sterilization, hydrogen peroxide plasma sterilization, and ozone sterilization. The standard includes helpful tables (derived from sterilizer manufacturers’ instructions) detailing cycle parameters based on nature of the item(s) to be sterilized, exposure time/temperature, and drying time that are commonly available in the United States.

Other AAMI documents (e.g., ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance for health care facilities) provide guidelines for the use of containment devices. For more information, visit www.aami.org.

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