American National Standard

ANSI/AAMI ST77:2013/(R)2018

Containment devices for reusable medical device sterilization

AAMI
Advancing Safety in Health Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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American National Standard

ANSI/AAMI ST77:2013/(R)2018
(Revision of ANSI/AAMI ST77:2006)

Containment devices for reusable medical device sterilization

Developed by
AAMI

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American National Standards Institute Inc.

Abstract: This standard covers minimum labeling and performance requirements for rigid sterilization container systems and for instrument organizers.

Keywords: containment devices, reusable rigid sterilization containers, instrument organizers.

AAMI Standard

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International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Reusable Sterilization Container Working Group

This standard was developed by the AAMI Reusable Sterilization Container Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval. At the time this standard was published, the **AAMI Reusable Sterilization Container Working Group** had the following members:

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NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

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Foreword

This standard was developed by the AAMI Reusable Sterilization Container Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this standard is to provide minimum labeling, safety, performance, and testing requirements to help ensure a reasonable level of safety and efficacy in rigid sterilization containers and instrument organizers, which are referred to in this standard as containment devices for reusable medical device sterilization.

This standard is the second edition of *Containment devices for reusable medical device sterilization*, which was first published as an American National Standard in 2006 as ANSI/AAMI ST77:2006. In comparison to the first edition, this new edition includes an informative annex on integrating medical devices with rigid sterilization container systems.

Compliance with this standard is voluntary. The existence of the standard does not preclude anyone from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed in order to conform to the standard; “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; “may” is used to indicate that a course of action is permissible within the limits of the standard; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

This standard should be considered flexible and dynamic. As technology advances and as new data are brought forward, the standard will be reviewed and, if necessary, revised. Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the American National Standard *Containment devices for reusable medical device sterilization* (ANSI/AAMI ST77:2013), but it does provide important information about the development and intended use of the document.

Containment devices for reusable medical device sterilization

Introduction

Containment devices for reusable medical device sterilization comprise a number of different types of systems, including reusable rigid sterilization containers and instrument organizers. Containment devices are intended to serve as packaging for instruments and other medical devices before, during, and after sterilization of the instruments and devices. Furthermore, such systems can be designed as an aid to the efficiency of the surgical procedure. Instrument organizers with lid and base serve to secure and organize instrument sets and other medical devices within a sealed reusable rigid sterilization container or within a legally marketed sterilization wrap. Reusable rigid sterilization containers require a barrier system (e.g., filters or valves) to maintain the integrity of the package. Reusable rigid sterilization containers and instrument organizers vary in their design, the mechanics of operation, and the materials of construction.

Although AAMI has published recommended practices (ANSI/AAMI ST79 and ANSI/AAMI ST41[1]) that contain guidance for users of reusable rigid sterilization container systems, ANSI/AAMI ST79 and ANSI/AAMI ST41 are not device standards. These recommended practices do outline in a broad format the information that the manufacturer should supply the user to demonstrate that a reusable rigid sterilization container system has been qualified in commonly available hospital cycles. However, they do not establish performance requirements for reusable rigid sterilization container systems or other containment devices such as instrument organizers. Therefore, a design and performance standard for containment devices, ANSI/AAMI ST77, was developed to provide manufacturer requirements. These requirements entail labeling, sterilization effectiveness (e.g., sterilant penetration, air removal), sterilant compatibility, sterility maintenance (barrier properties), compatibility with the intended use (e.g., containment for sterilization of endoscopes, implants, and other devices), maximum size, maximum load, and validation of performance (including accessories) in specific sterilization cycles.

There are two primary categories of containment devices: (a) self-contained reusable rigid sterilization containers that require a barrier system (e.g., filters or valves), and (b) containment devices that require a sterilization wrap or pouch to maintain sterile integrity once the containment device and its contents are sterilized. Containment device and packaging manufacturers bear the ultimate responsibility for validating that their products are compatible with a specified sterilization method. Health care personnel bear the ultimate responsibility for using the containment device or packaging material in the recommended sterilization method and for performing tests to ensure that items to be packaged can be sterilized by the specific sterilizers and sterilization methods used within the health care facility.

1 Scope

1.1 General

This standard applies to containment devices intended for use in sterilizing reusable medical devices in health care facilities.

NOTE—For purposes of this standard, “health care facilities” means hospitals, nursing homes, extended-care facilities, free-standing surgical centers, clinics, and medical and dental offices. For convenience, the term “hospital” is sometimes used in this recommended practice; in all instances, this term should be taken to encompass all other health care facilities.

[1] Guidance for the use of reusable rigid sterilization container systems was originally provided in ANSI/AAMI ST33, *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities.* The provisions of this document pertaining to sterilization container systems intended for use in steam sterilization were updated and incorporated into ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. The provisions of ANSI/AAMI ST33 pertaining to sterilization container systems intended for use in ethylene oxide sterilization were updated and incorporated into the latest edition of ANSI/AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.*

