American National Standard

ANSI/AAMI ST77:2006/(R)2010

Containment devices for reusable medical device sterilization

Association for the Advancement of Medical Instrumentation

The 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 health care 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:

1. 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 need 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.

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Containment devices for reusable medical device sterilization

Developed by
Association for the Advancement of Medical Instrumentation

Approved 2 November 2006 and reaffirmed 6 December 2010 by
American National Standards Institute Inc.

Abstract: This standard covers minimum labeling and performance requirements for rigid sterilization container systems and for instrument cases, cassettes, and organizing trays.

Keywords: containment devices, reusable rigid sterilization containers, instrument cases, cassettes, organizing trays

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

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Contents

Annexes

Tables

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated text)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical

International designation	U.S. designation	Equivalency
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO/TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2006	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

[1]In production
[2]Final approval pending

As of 1/8/2007.

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 standard 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, cassettes, cases, and organizing trays, which are referred to in this standard as containment devices for reusable medical device sterilization.

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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201–4795.

NOTE—This foreword does not contain provisions of the American National Standard *Containment devices for reusable medical device sterilization* (ANSI/AAMI ST77:2006), 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 cases, cassettes, and organizing trays. 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. Sterilization cases, cassettes, and organizing trays 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 wrapper. 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 cassettes, cases, and organizing trays vary in their design, the mechanics of operation, and the materials of construction.

Metal and plastic reusable rigid sterilization containers for surgical instruments have been in use in the United States for more than 25 years. In more recent years, metal and plastic organizing trays and instrument cases and cassettes have been made available. Such products can provide cost-effective, reusable, rigid packaging for sterilization processing, storage, transportation, and presentation of surgical instruments and other medical devices. Moreover, surgical instruments and other medical devices have become more complex, minimally invasive, and composed of temperature-sensitive materials; consequently, new performance criteria are needed and old practices should be reviewed and analyzed based on current needs and recommended practices.

While AAMI has published a recommended practice (ANSI/AAMI ST33[1]) for users of reusable rigid sterilization container systems, ANSI/AAMI ST33 is not a device standard. ANSI/AAMI ST33 does 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, ANSI/AAMI ST33 does not establish performance requirements for reusable rigid sterilization container systems, nor does it cover other containment devices such as instrument cases, cassettes, or organizing trays. 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] Subsequent to the completion of this standard, ST33 was superseded by ANSI/AAMI ST79:2006, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. The provisions of ST33 pertaining to sterilization container systems intended for use in steam sterilization were updated and incorporated into ST79. The provisions of ST33 pertaining to sterilization container systems intended for use in ethylene oxide sterilization are being updated and incorporated into a new edition of ANSI/AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.*

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.

1.2 Inclusions

This standard covers the design, performance, and labeling criteria for reusable rigid sterilization containers and instrument cases, cassettes, and organizing trays intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization. Definitions of terms, normative references, and informative annexes are also included, as well as the rationale and relevant test methods for the provisions of the standard.

1.3 Exclusions

This standard does not cover the selection and use of containment devices by health care personnel.

NOTE—Guidelines for the selection and use of reusable rigid sterilization container systems in health care facilities are provided in ANSI/AAMI ST79.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this TIR. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this TIR are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. AAMI maintains a register of currently valid AAMI technical documents.

2.1 Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological indicators—Part 1: General requirements.* ANSI/AAMI/ISO 11138-1:2006. Arlington (VA): AAMI, 2006. American National Standard.

2.2 Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Part 1: General requirements.* ANSI/AAMI/ISO 11140-1:2005. Arlington (VA): AAMI, 2005. American National Standard.

2.3 Association for the Advancement of Medical Instrumentation. *Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices.* ANSI/AAMI ST81:2004. Arlington (VA): AAMI, 2004. American National Standard.

2.4 Association for the Advancement of Medical Instrumentation. *Biological evaluation of medical devices—Part 1: Evaluation and testing.* ANSI/AAMI/ISO 10993-1:2003. Arlington (VA): AAMI, 2003. American National Standard.

2.5 Association for the Advancement of Medical Instrumentation. *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals.* ANSI/AAMI/ISO 10993-7:2001. Arlington (VA): AAMI, 2001. American National Standard.

2.6 United States Pharmacopeial Convention. *The United States Pharmacopeia and National Formulary.* (Current edition.) Rockville (MD): United States Pharmacopeial Convention Inc. Sterility tests.

3 Definitions and abbreviations

For the purpose of this standard, the following definitions apply.

3.1 aseptic presentation: Maintaining the sterility of the contents as a sterilized package is opened and the contents are removed.

3.2 biological indicator (BI): Test system containing viable microorganisms providing a defined resistance to the specified sterilization process.

3.3 chemical indicator (CI): Test system that reveals change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process. (See ANSI/AAMI/ISO 11140-1.)