American National Standard

ANSI/AAMI/ST8:2013/(R)2018

Hospital steam sterilizers

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 ST8:2013/(R)2018
(Revision of ANSI/AAMI ST8:2008)

Hospital steam sterilizers

Developed by
Association for the Advancement of Medical Instrumentation

Approved 25 April 2013 and reaffirmed 17 August 2018 by
American National Standards Institute Inc.

Abstract: This standard covers minimum construction and performance requirements for hospital sterilizers that use saturated steam as the sterilizing agent and have a volume greater than 56.63 liters (2 cubic feet).

Keywords: moist heat sterilization, saturated steam, steam quality, steam sterilization

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

Hospital Steam Sterilizer Working Group

This standard was developed by the AAMI Hospital Steam Sterilizer 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.

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Foreword

This standard was developed by the AAMI Hospital Steam Sterilizer 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 steam sterilizers that are intended for use in health care facilities and that have a volume greater than 56.63 liters (2 cubic feet).

This standard is the sixth edition of *Hospital steam sterilizers,* which was first published as an American National Standard in February 1983 as "ANSI/AAMI ST8—1982." AAMI procedures require that standards be reviewed and, if necessary, revised at least once every five years. Accordingly, *Hospital steam sterilizers* was updated and published in revised editions in 1988, 1994, 2001, and 2008. The present (sixth) edition (a) requires moisture retention tests to be conducted separately from the biological performance tests and to utilize full sterilization cycles rather than half-cycles, (b) excludes drying time from being used during the biological performance testing, (c) incorporates the term "immediate-use steam sterilization" (IUSS) in place of the term "flash sterilization," (d) allows for electronic recording devices to be provided instead of a printer with a printout, and (e) adds a requirement that the instructions for use (IFU) specify a process for cleaning the chamber and loading equipment.

Compliance with this standard does not guarantee that sterilization will be achieved, but it does help ensure that the steam sterilizer will be capable of providing the conditions necessary to achieve product sterility when operated according to appropriate procedures.

This voluntary standard is intended primarily for use by equipment manufacturers in the performance and design qualification of steam sterilizers intended for use in health care facilities. The criteria defined in this standard might be useful to health care personnel and purchasing authorities in the acquisition process. However, the standard is not intended to provide guidelines for hospital receiving inspection testing or for steam sterilization procedures in health care facilities. In addition, any problems with existing equipment should not be judged solely in terms of its conformance to this 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 recommended practice are invited. Comments and suggested revisions should be sent to: Standards Department, AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of ANSI/AAMI ST8:2013, *Hospital steam sterilizers*, but it does provide important information about the development and intended use of the document.

Hospital steam sterilizers

1 Scope

1.1 General

This standard applies to steam sterilizers that are intended for use in hospitals and other health care facilities and that have a volume greater than 56.63 liters (L) (2 cubic feet [ft^3]).

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

1.2 Inclusions

This standard covers minimum labeling, safety, performance, and testing requirements for steam sterilizers that have a volume greater than 56.63 L (2 ft^3), have automatic controls, generally use an external steam source (but might also have an integral electric boiler), and provide a means for automatically recording time and temperature. Definitions of terms and normative references are also included, as well as an annex explaining the rationale for the provisions of the standard and other informative annexes.

NOTE—This standard is intended primarily for use by manufacturers in the performance and design qualification of steam sterilizers intended for use in health care facilities. The criteria defined in this standard might be useful to health care personnel and purchasing authorities in the acquisition process. However, the standard is not intended to provide guidelines for hospital receiving inspection testing or for steam sterilization procedures in health care facilities.

1.3 Exclusions

Sterilizers that generate steam inside the sterilizing chamber, washer-sterilizers, and all other sterilizers not covered in 1.2 are excluded from this standard. Likewise, this standard does not cover installation acceptance testing, sterilization procedures, machine-operator requirements, or sterility assurance testing in health care facilities.

NOTE—Minimum labeling and performance requirements for small steam sterilizers (those that are 56.63 L [2 ft^3] or less in volume) are covered in ANSI/AAMI ST55; guidelines for the use of such sterilizers are provided in ANSI/AAMI ST79. ANSI/AAMI ST79 also covers inhospital steam sterilization procedures and quality control, as well as the selection and use of containment devices intended for use in steam sterilization.

2 Normative references

The following documents contain provisions that, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this standard 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 reference referred to applies. AAMI maintains registers of currently valid AAMI technical documents.

2.1 American Society of Mechanical Engineers. *Boiler and pressure vessel code* (with current amendments). New York: ASME.

2.2 Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes.* ANSI/AAMI/ISO 11138-3:2006/(R)2010. Arlington (VA): AAMI, 2006. American National Standard.

2.3 Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs.* ANSI/AAMI/ISO 11140-5:2007/(R)2012. Arlington (VA): AAMI, 2007. American National Standard.

2.4 Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.* ANSI/AAMI/ISO 17665-1:2006. Arlington (VA): 2006.