American National Standard

ANSI/AAMI ST24:1999/(R)2018

Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities

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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Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

American National Standard

ANSI/AAMI ST24:1999/(R)2018
(Revision of ANSI/AAMI ST24:1992)

Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities

Developed by
AAMI

Approved 27 May 1999 and reaffirmed 26 November 2013 and 6 September 2018 by
American National Standards Institute, Inc.

Abstract: This standard covers minimum labeling, safety, performance, and testing requirements for ethylene oxide sterilizers that are intended for general-purpose use in health care facilities and that have automatic controls. It also covers labeling, product composition, and container requirements for ethylene oxide sterilant sources, as well as labeling, performance, safety, and installation requirements for ethylene oxide emission control systems.

Keywords: ethylene oxide sterilization, ethylene oxide emission control

AAMI Standard

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Committee representation

Association for the Advancement of Medical Instrumentation

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This standard was developed by the AAMI Hospital EO Sterilizer Working Group under the auspices of the AAMI Sterilization Standards Committee. Committee approval of the standard does not necessarily mean that all committee and working group members voted for its approval.

The **AAMI Sterilization Standards Committee** has 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.

Acknowledgment

The AAMI Hospital EO Sterilizer Working Group gratefully acknowledges the significant contributions of Janet K. Schultz, RN, who ably cochaired the Working Group from 1988 to 1998.

Foreword

This standard was developed by the AAMI Hospital EO 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 of automatic, general-purpose EO sterilizers and EO sterilant sources intended for use in health care facilities.

This standard is the third edition of *Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources Intended for use in health care facilities,* which was first approved as an American National Standard in 1987. The provisions of the second edition of the standard were substantially the same as the original standard, but the document was reorganized for clarity. This third edition of the standard has been revised for consistency with the International Electrotechnical Commission (IEC) standard, *Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes,* which was approved in 1996. In addition, it has been revised to take into account new diluents now being used in EO sterilant formulations, and it has been amplified to address EO emission control systems.

Compliance with this standard does not guarantee that sterilization will be achieved, but it will provide assurance that the EO sterilizer and sterilant source will be capable of providing the conditions necessary to achieve product sterility when they are used according to appropriate procedures.

This standard is intended primarily for use in the performance qualification of automatic, general-purpose EO sterilizers and sterilant sources by manufacturers. Although the criteria defined in the standard may be useful to health care personnel in the selection and evaluation of sterilizers and sterilant sources for purchase, the standard is not intended to provide guidelines for acceptance testing or for EO sterilization procedures used in health care facilities.

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, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword does not contain provisions of the American National Standard, *Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities* (ANSI/AAMI ST24:1999), but it does provide important information about the development and intended use of the document.

Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities

1 Scope

1.1 General

This standard applies to automatic, general-purpose ethylene oxide (EO) sterilizers and EO sterilant sources that are intended for use in hospitals and other health care facilities.

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 recommended practice; 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 EO sterilizers that are intended for general-purpose use in health care facilities and that have automatic controls. For purposes of this standard, a "general-purpose" EO sterilizer is defined as a chamber-type sterilization system that injects water vapor to adjust humidity during the cycle, generally employs excursions in pressure from atmospheric levels, and is intended to sterilize a wide range of medical items. This standard also covers labeling, product composition, and container requirements for EO sterilant sources. Referee test methods and definitions of terms are also included, as well as an annex explaining the rationale for the provisions of the standard, annexes containing supplemental technical information, and a bibliography.

1.3 Exclusions

This standard does not apply to EO sterilizers that release EO inside the package containing the wrapped items to be sterilized. Also excluded from the scope of this standard are the performance and use of industrial EO sterilizers, the performance and use of EO aerators and other ventilation systems, and inhospital sterilization procedures and routine sterility assurance. The provisions of this standard do not obviate the need for careful attention in the hospital environment to the control of occupational exposure to EO, including area and environmental monitoring.

NOTE—For detailed recommendations concerning safe and effective EO sterilization in health care facilities, see AAMI (1999). Recommendations concerning industrial EO sterilization are provided in AAMI (1994).

2 Normative references

The following documents contain provisions that, through reference in the text, constitute provisions of this standard. At the time of publication, the editions indicated were valid.

2.1 AMERICAN SOCIETY OF MECHANICAL ENGINEERS. *Boiler and pressure vessel code.* New York: ASME, 1986.

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Ethylene oxide sterilization in health care facilities: safety and effectiveness.* 3rd ed. ANSI/AAMI ST41:1999. Arlington (Vir.): AAMI, 1999. American National Standard.

2.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Sterilization of health care products—Biological indicators for EO sterilization processes in health care facilities*. ANSI/AAMI ST21:1986 (reaffirmed 1994). Arlington (Vir.): AAMI, 1986. American National Standard.

2.4 CALIFORNIA AIR RESOURCES BOARD. Determination of ethylene oxide emissions from stationary sources. Test Method 431. California: ARB, 27 July 1997.