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

HISTORICAL

AAMI
Advancing Safety in Health Technology

American National Standard

ANSI/AAMI ST24:1999/(R)2018 [HISTORICAL]
(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

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Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

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.

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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 this 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.

American National Standard ANSI/AAMI ST24:1999/(R)2018 [HISTORICAL]

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.