American National Standard

ANSI/AAMI ST24:2024

General-purpose ethylene oxide sterilizers with automated process control and ethylene oxide sterilant sources intended for use in health care facilities

AAMI
Advancing Safety in Health Technology

American National Standard

ANSI/AAMI ST24:2024
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General-purpose ethylene oxide sterilizers with automated process control and ethylene oxide sterilant sources intended for use in health care facilities

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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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Association for the Advancement of Medical Instrumentation

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- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall".

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

Introduction

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 general-purpose EO sterilizers with automated process control, and EO sterilant sources intended for use in health care facilities.

This standard is the fourth edition of *General-purpose ethylene oxide sterilizers with automated process control 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. The third edition of the standard was 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* (since withdrawn; content covered by IEC 61010-2-40, *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*) and to address EO emission control systems. It has been over twenty years since the third edition of ANSI/AAMI ST24 was published. During this period, the use of ethylene oxide in health care facilities has changed significantly. This fourth edition of ANSI/AAMI ST24 has been revised to include EO sterilization systems that have been cleared by the FDA since the last edition was published and were not adequately described in the previous edition of the standard. This edition also deemphasizes the large EO tank and mixture-based systems, which were the standard for healthcare EO sterilization in 1999 but are no longer in use. This fourth edition better reflects current practice of EO healthcare sterilization.

Conformance 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 general-purpose EO sterilizers with automated process control 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.

General-purpose ethylene oxide sterilizers with automated process control and ethylene oxide sterilant sources intended for use in health care facilities

1 Scope

1.1 General

This standard applies to general-purpose ethylene oxide (EO) sterilizers with automated process control, and EO sterilant sources that are intended for use in 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.

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. For purposes of this standard, a “general-purpose” EO sterilizer is intended to sterilize a wide range of medical items. This standard also covers labeling, product composition, and container requirements for EO sterilant sources. Reference 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

Excluded from the scope of this standard are the performance and use of industrial EO sterilizers, the performance and use of ventilation systems, and health care facility sterilization procedures and routine sterility assurance. The provisions of this standard do not obviate the need for careful attention in the health care facility 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 ANSI/AAMI ST58. Recommendations concerning industrial EO sterilization are provided in ANSI/AAMI/ISO 11135.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASME *Boiler and pressure vessel code*

ANSI/AAMI/ISO 11138-2, *Sterilization of health care products—Biological indicators—Part 2: Biological indicators for ethylene oxide*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use*

IEC 61010-2-40, *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

NFPA 70, *National electrical code*

