List of Titles

American National Standard

ANSI/AAMI ST:24:1999

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

AAMI Association for the Advancement of Medical Instrumentation

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American National Standard

ANSI/AAMI ST24:1999
(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
Association for the Advancement of Medical Instrumentation

Approved 27 May 1999 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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AAMI Standard

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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.

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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.

American National Standard **ANSI/AAMI ST24:1999**

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.

2.5 U.S. DEPARTMENT OF COMMERCE. Scales. In *National Bureau of Standards Handbook 44/195.* Washington (D.C.): U.S. Department of Commerce, National Bureau of Standards, November 1984. (U.S. Government Printing Office Stock #003-003-02625-5)

2.6 U.S. DEPARTMENT OF TRANSPORTATION. Hazardous materials table*. Code of Federal Regulations,* Title 49, Part 172.101.

2.7 U.S. ENVIRONMENTAL PROTECTION AGENCY. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 7 U.S.C 135 et seq. (1972).

2.8 U.S. FOOD AND DRUG ADMINISTRATION. Quality System Regulation. *Code of Federal Regulations,* Title 21, Part 820.

2.9 GENERAL SERVICES ADMINISTRATION. *Sterilizer, EO gas, for heat- and moisture-labile surgical instruments and supplies (nonportable).* Federal Specification GG-S-1344A. Washington (D.C.): General Services Administration, 1981.

2.10 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Safety requirements for electrical equipment for measurement, control and laboratory use.* IEC 1010-1. Geneva: IEC, 1996. International Standard.[1]

2.11 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *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.* IEC 1010-2-042. Geneva: IEC, 1996. International Standard.

2.12 NATIONAL FIRE PROTECTION ASSOCIATION. *National electrical code.* ANSI/NFPA 70, 1996. Quincy (Mass.): NFPA, 1996. American National Standard.

3 Definitions, symbols, and abbreviations

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

3.1 exposure time: Period of time during a sterilization process in which items are exposed to the sterilant at the specified sterilization parameters.

NOTE—In an EO sterilization process, exposure time is the period during which items are exposed to EO at the specified concentration, pressure, humidity, and temperature.

3.2 general-purpose EO sterilizer: Sterilizing apparatus that utilizes EO as the sterilant, under defined conditions of gas concentration, temperature, and percent relative humidity. This chamber-type sterilization system provides a source of water vapor to adjust humidity during the cycle and generally employs changes in pressure below and/or above atmospheric levels.

3.3 performance qualification: As the term is used in relationship to hospital sterilization processing, testing performed by the sterilizer manufacturer as part of the overall program for establishing that a given sterilizer design and sterilization cycle meet a standard level of performance under simulated, worst-case, in-use conditions. The results of this test enable hospital personnel to assess, during inhospital installation testing, the performance of individual sterilizers against the standard of performance claimed by the manufacturer.

3.4 sterilization validation: Documented procedure for obtaining, recording, and interpreting the results needed to show that a process will consistently yield a product complying with predetermined specifications.

3.5 sterilizer, EO: Apparatus using EO as the sterilizing agent to render a load free from viable microorganisms to a specified extent.

[1] Underwriters Laboratories has developed UL 3101, *Electrical Equipment for Laboratory Use—Part 1: General Requirements,* which utilizes the existing IEC 1010, but with deviations for the U.S. (e.g., wire markings and colors, references to the *National Electrical Code* and various UL standards).

4 Requirements

4.1 Requirements for EO sterilizers

4.1.1 Labeling

4.1.1.1 Device markings

Each sterilizer shall have one or more permanently fastened information plates, which are either visible from the exterior or visible after a cover is removed or a door is opened without the aid of a tool, and which provide the following minimum information:

a) the manufacturer's name;

b) the manufacturer's type and model designation;

c) the serial number;

d) the electrical supply requirements;

e) the ASME *Boiler and pressure vessel code* stamp, if applicable; and

f) warnings that advise the operator of precautions to be taken for the avoidance of harm and that are visible when the equipment is ready for normal use.

4.1.1.2 Information manual

At the time of installation, the manufacturer or the manufacturer's agent shall furnish the purchaser with a manual containing the following minimum information:

a) the name and address of the manufacturer;

b) the manufacturer's type and model designation;

c) instructions for the installation of the sterilizer, complete and comprehensive enough to ensure the safe and effective operation of the equipment, including such information as the required building system utilities and the type of materials to be used for installation;

d) instructions for the safe and effective operation of the sterilizer, including normal safety precautions to be taken during routine use as well as recommended sterilizer settings, safety precautions for terminating a cycle in progress, and a comprehensive explanation of how leaks in the sterilizing system can be detected;

e) an explanation of the type of EO sterilant source to be used and procedures for its installation, storage, and use;

f) technical information about the chamber temperature and chamber pressure ranges acceptable during operation and the minimum allowable gross weight of a full unit-dose container, or the method by which EO concentration in the chamber can be calculated from chamber temperature and pressure;

g) a statement that the manufacturer will make available upon request a description of the validation procedures and results used to establish that the recommended cycle parameters provide a 10^{-6} sterility assurance level;

h) instructions for the preparation of items prior to sterilization, including statements concerning (1) the types of items for which EO sterilization is appropriate, (2) the need for thorough cleaning and drying of items, (3) the selection of appropriate packaging materials, and (4) the need for environmental humidity control;

NOTE—Users should be instructed to ask the device manufacturer for details about the care, handling, packaging, sterilization, and aeration of specific devices.

i) recommendations to assist the health care facility in complying with current standards for maximum permissible occupational exposure to EO (29 CFR 1910.1047);

j) instructions for inspection and routine maintenance, including a schedule for implementing inspection and routine maintenance procedures, a caution that these procedures should be carried out by trained personnel, directions for maintaining critical components such as filters, recorders, valves, and safety valves, and the name and address of the nearest authorized service agent or representative.

NOTE—Information concerning the nearest service agent or representative need not be a permanent part of the information manual but may be provided in the form of a label or an insert affixed to the manual.

4.1.1.3 Service manual

The manufacturer shall make available for purchase a complete service manual, comprehensive enough to ensure that the safety and effectiveness of the device can be maintained. At a minimum, information about parts availability should be supplied. For worker safety and because of the complexity of the equipment, only trained personnel should service EO sterilizers.

4.1.1.4 User training program

The sterilizer manufacturer shall provide a user training program demonstrating the correct and safe operation of the sterilizer.

4.1.2 Sterilizer construction, components, and accessories

4.1.2.1 Pressure requirements

All sterilizers that can be operated at pressures above atmospheric pressure, under normal or fault conditions, shall have a pressure-relief device. The design and materials of construction of sterilizers intended to be operated at an internal pressure of 15 pounds per square inch gauge (psig) or more shall conform to the requirements of section VIII, division 1, of the ASME *Boiler and pressure vessel code* (2.1). The chamber manufacturer shall furnish proof of such conformance. Sterilizers intended to be operated at a pressure below 15 psig shall be designed and tested to withstand a pressure of at least 2.25 times the pressure-relief setting.

NOTE—Pressure-relief devices should be vented in accordance with AAMI (1999) to reduce human exposure to EO.

4.1.2.2 Electrical components

The sterilizer electrical system shall be designed, manufactured, and tested in accordance with IEC 1010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use* (see 2.10), and IEC 1010-2-042, *Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes* (see 2.11). The sterilizer electrical system shall be designed for installation in conformance to the *National electrical code* (see 2.12).

4.1.2.3 Corrosion resistance

The inside surfaces of the sterilizer, the chamber side of the door, and the loading shelves, carts, carriages, and other loading accessories supplied by the manufacturer shall be constructed of materials having corrosion-resistant properties equal to or better than the materials listed in section II of the ASME *Boiler and pressure vessel code* (see 2.1).

4.1.2.4 Air filters

A bacteria-retentive filter, having a minimum filtration efficiency of 99.97% for 0.3-micron particles or complying with Federal Specification GG-S-1344A (see 2.9), shall be installed in each chamber vacuum-relief line. Filters shall be readily accessible for routine maintenance.

4.1.3 Sterilizer safety

4.1.3.1 Prevention of worker exposure to EO

The sterilizer shall comply with IEC 1010-2-042 (see 2.11), part 13.

4.1.3.2 Prevention of thermal hazards

The temperature of all handwheels, handles, or similar devices that will be used by the operator during normal operation of the sterilizer shall comply with table 3 of IEC 1010-1 (see 2.10).

4.1.3.3 Sterilizer controls for aborting cycles

A means for safely aborting or terminating a cycle in progress shall be readily accessible to the operator and shall be clearly labeled.

4.1.4 Process monitoring devices

4.1.4.1 Temperature measurement

The sterilizer shall be equipped with a means of indicating and recording chamber temperature. The temperature monitor shall be accurate to within ± 1° C (± 2° F) at the recommended exposure temperature.

4.1.4.2 Pressure measurement

All sterilizers that can be operated at pressures above atmospheric pressure shall be equipped with a means of indicating and recording the pressure within the chamber if pressure is a critical parameter of the efficacy of the sterilization cycle. In sterilizers in which the gas concentration is controlled by a pressure monitor, the monitor or gauge shall be accurate to within ± 5 millimeters of mercury (mmHg).

4.1.4.3 Exposure time

The sterilizer shall be equipped with a means of indicating and recording exposure time. Timers shall be accurate to within ± 2% of the recommended exposure time.

4.1.5 Physical performance of sterilizers

4.1.5.1 Temperature sensors

After exposure pressure has been reached and exposure timing has begun, the chamber temperature shall stabilize within the first 10% of the selected exposure time, after which the variation of temperature within the chamber shall not exceed ± 3° C (± 5.5° F) of the set temperature throughout the remaining exposure phase of the cycle.

4.1.5.2 Control of exposure time

The duration of the exposure phase of the cycle shall be within ± 2% of the recommended time.

4.1.5.3 Control of relative humidity

The chamber relative humidity shall be at least 30% during the gas exposure phase.

NOTE—This provision does not obviate the need for adequate temperature/humidity equilibration of packaged items or the need for appropriate temperature and relative humidity in the preparation and sterilization areas of the health care facility. (A temperature range of 20° C to 23° C [68° F to 73° F] and a relative humidity range of 30% to 60% [70% maximum] are usually recommended [AIA 1996].)

4.1.5.4 Control of EO delivery

Sterilizers that control pressure within the chamber shall incorporate a means of controlling the delivery of sterilant gas so that the chamber pressure is within ± 10% of the set pressure value throughout the exposure phase of the cycle.

NOTE—This requirement does not apply to unit-dose sterilizer systems.

4.1.6 Biological performance of sterilizers

When tested according to 5.1.6, the manufacturer's recommended cycle or cycles shall be sufficient to reduce a biological-indicator population to a 10^{-6} probability of a surviving organism.

4.1.7 Certification and recordkeeping

The sterilizer manufacturer shall certify each EO sterilizer type, size, and model by documenting satisfactory conformance to this standard. Equipment design and performance shall be recertified every 24 months, using production sterilizers of the design originally qualified. Recertification shall also be performed when there is any change in design that might affect the safety and efficacy of the sterilizer. Reports of tests performed shall be kept on file by the manufacturer for a period of time equal to the design life and the expected life of the device but in no case less than 2 years.

4.2 Requirements for EO sterilant sources

4.2.1 Registration

All EO gas sterilants must be registered with the Environmental Protection Agency (EPA) as pesticides, and all producers of gas sterilants must be registered with EPA (see 2.7).

4.2.2 Labeling

All EO sterilant containers must be labeled in accordance with U.S. Department of Transportation (DOT) and EPA regulations (see 2.6 and 2.7, respectively).

4.2.3 Container safety

All EO sterilant containers shall comply with DOT requirements for compressed gas containers (see 2.6). In addition, EO sterilant containers (and any sterilant container valves) shall be of suitable design for containing hazardous materials.

4.2.4 Product composition

The composition of EO sterilants shall conform to the specifications of the EO sterilant manufacturer. Variations in the net contents of EO sterilant containers shall comply with the requirements of the National Institute of Standards and Technology (see 2.5).[2] Ethylene oxide sterilants shall not foul gas supply lines (e.g., by plugging supply-line filters with particulates) when used in accordance with the recommendations for storage and handling provided by the EO sterilant manufacturer and, if applicable, the EO sterilizer manufacturer.

4.2.5 Shipping

Ethylene oxide sterilant manufacturers and suppliers shall ship the sterilant containers in accordance with DOT and EPA regulations (see 2.6 and 2.7, respectively).

4.3 Requirements for EO emission control systems

NOTE—Emission control of EO can be achieved by any of several means, including catalytic oxidation, acid scrubbing, and compression condensation. The recommendations of the sterilizer manufacturer should be considered when selecting an emission control system.

4.3.1 System approvals

Emission control systems shall meet all current local, state, and federal requirements.

4.3.2 Labeling

4.3.2.1 Device markings

Emission control equipment shall be labeled with pertinent system information, such as serial number, voltage requirements, and the manufacturer's name and address.

4.3.2.2 Information/service manuals

The manufacturer shall provide comprehensive information and service manuals to the using facility before the equipment is installed and operated. The information manual shall contain at least

a) instructions for the safe operation of the emission control system;

b) the minimum efficiencies for initial gas removal and aeration control;

c) instructions for the disposal of spent materials and/or byproducts requiring special handling (e.g., catalytic materials, acid baths, compressed EO).

The service manual shall contain at least

a) the recommended service interval;

b) a description of any required periodic testing and the frequency with which such testing should be conducted.

4.3.2.3 User training program

The emission control system manufacturer shall provide a user training program demonstrating the correct and safe operation of the emission control system.

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[2] Additional state regulations could apply; information can be obtained from the Department of Commerce, Bureau of Weights and Measures, in the particular state.

4.3.3 Performance requirements

The minimum efficiency of the emission control system shall meet current local and state regulations.

4.3.4 Safety requirements

The emission control system shall be designed to respond safely to failure-mode conditions.

4.3.5 Installation requirements

The emission control system shall be installed in a location acceptable to both the using facility and the manufacturer. The installation shall be in accordance with current local, state, and federal regulations.

5 Tests

This section provides referee test methods and procedures by which compliance with the requirements of section 4 can be verified. These tests are not intended for routine quality assurance testing. The paragraph numbers below correspond to those of section 4 except for the first digit (e.g., compliance with the requirement of 4.2.3 can be determined by the test method of 5.2.3).

Test apparatus and instruments. Apparatus and instruments used for testing sterilizers must be calibrated for accuracy. The quality assurance program establishing the frequency and method of calibration must be documented. The calibration of all test instruments must be traceable to primary standards, as specified in federal Quality System regulations (see 2.8).

Installation and operation of sterilizers. The sterilizers used in testing compliance with the requirements of section 4 must be identical to and installed and operated in the same way as those that will be provided by the manufacturer to health care facilities.

5.1 Methods of verifying compliance with the requirements for EO sterilizers

5.1.1 Labeling

Compliance with the requirements of 4.1.1.1, 4.1.1.2, and 4.1.1.3 can be verified by inspection. The requirement of 4.1.1.4 for a user training program can be satisfied by such means as videotaped demonstrations, training classes, lectures, and/or CD-ROM or other self-directed learning activities.

5.1.2 Sterilizer construction, components, and accessories

5.1.2.1 Pressure requirements

Methods by which compliance with 4.1.2.1 can be verified are provided in 2.1.

5.1.2.2 Electrical components

Methods by which compliance with the electrical safety requirements of 4.1.2.2 can be verified are provided in 2.10, 2.11, and 2.12.

5.1.2.3 Corrosion resistance

See 2.1.

5.1.2.4 Air filters

Inspection can verify that a bacteria-retentive filter is installed in each chamber vacuum-relief line and that it is readily accessible for routine maintenance. The required performance of the filter can be verified by the test procedures of 2.9.

5.1.3 Sterilizer safety

5.1.3.1 Prevention of worker exposure to EO

See 2.11.

5.1.3.2 Prevention of thermal hazards

Temperature-measuring devices are attached to the handwheels, handles, or similar devices used by the operator during normal sterilizer operation. The sterilizer is tested in a room where the ambient temperature is maintained

between 20° C and 23° C (68° F and 73° F). A normal sterilization cycle is run, and the temperatures monitored for compliance with 4.1.3.2.

5.1.3.3 Sterilizer controls for aborting cycles

Compliance with 4.1.3.3 can be verified by inspection.

5.1.4 Process monitoring devices

Compliance can be verified by testing the temperature monitor, pressure monitor, and timers against certified laboratory standards.

5.1.5 Physical performance of sterilizers

5.1.5.1 Temperature control

Five temperature-measuring devices providing continuous temperature readout are placed in the empty chamber of the sterilizer. Temperatures are measured, during a normal sterilization cycle, in the lower front, upper front, center, lower rear, and upper rear of the cart or basket containing the load in the chamber.

5.1.5.2 Control of exposure time

Testing is accomplished by comparing results with precision measurement equipment, usually traceable to a National Institute of Standards and Technology reference. The testing is performed in an empty chamber.

5.1.5.3 Control of relative humidity

Relative humidity within the chamber, which is empty for purposes of this test, can either be measured directly by a humidity sensor or, if steam is injected, derived indirectly from the pressure rise. In the first method, the sterilizer is equipped with a humidity sensor accurate to within ± 10% of the measured value; a normal sterilization cycle is started, and the relative humidity is monitored. In the second method, the sterilizer is equipped with a pressure sensor accurate to within ± 5 mmHg; a normal sterilization cycle is started, the pressure resulting from the partial pressure of water is measured, and the relative humidity is calculated (see annex B).

5.1.5.4 Control of EO delivery

A normal sterilization cycle is run in an empty chamber. When the sterilizer is in the sterilization phase, the minimum EO gas concentration within the sterilizer is determined by measuring the chamber pressure that results from sterilant gas addition (after the water vapor pressure is corrected for) and then calculating the concentration (see annex C).

5.1.6 Biological performance of sterilizers

Compliance with 4.1.6 can be verified through the use of fractional EO exposure times to determine the degree of lethality as a function of process conditions.

Test pack composition and use. The test pack used for biological qualification shall be the challenge test pack recommended in AAMI (1999) (see 2.2), and the test packs shall be assembled according to AAMI (1999). Table 1 specifies the number and positioning of test packs for empty-chamber testing. For simulated-load testing, enough test packs shall be uniformly distributed within the sterilizer so that the total volume of test packs is equal to at least 10% of the sterilizer chamber volume. (The volume of one test pack is approximately 0.13 cubic feet.) Table 2 provides examples of the numbers of test packs necessary to achieve 10% fill of sterilizer chambers of various volumes. The test packs shall be placed in wire baskets, metal sterilizer carts, or other carriers that do not absorb EO.

Biological indicators. The biological indicators used in testing shall contain *Bacillus subtilis* spores and shall comply with the requirements of AAMI (1994) (see 2.3). The culturing and incubation conditions shall be in accordance with the instructions supplied by the manufacturer of the biological indicator.

Degree of lethality. The manufacturer shall demonstrate that the recommended cycle has a sterility assurance level of at least 10^{-6} when the challenge test pack and simulated-load procedures described here are used under the minimum allowable sterilization parameters (i.e. lowest allowable temperature, relative humidity, and EO concentration). The degree of lethality can be determined by developing a death-rate curve (D values) or by an end-point analysis using fraction-negative data. An example of one approach is to demonstrate a 6-log spore reduction at one-half the recommended sterilization exposure time. At least three exposures at each time increment shall be performed to establish the degree of lethality.

Table 1—Test pack number and location for empty-chamber testing

Sterilizer chamber volume (cubic feet)	Number of test packs	Location in chamber
< 16	1	Front bottom
16 to 39	2	Rear top Front bottom
40 to 79	3	Rear top Center Front bottom

Table 2—Number of test packs for simulated-load testing

Sterilizer chamber dimensions (inches)	Sterilizer chamber volume (cubic feet)	Number of test packs
20 x 20 x 38	8.8	7
24 x 36 x 48	24	19
24 x 36 x 60	30	23
26 x 62 x 42	39	30
26 x 62 x 76	71	55

Final qualification. A series of three consecutive cycles shall be run, with the test packs placed in an otherwise empty chamber, according to the manufacturer's cycle recommendations. A second series of three consecutive cycles shall be run under simulated-load conditions. Test pack sterility shall be demonstrated by the killing of all spores on the biological indicators. Final qualification is complete upon three successful consecutive cycles under empty-load conditions and three successful consecutive cycles under simulated-load conditions.

5.1.7 Certification and recordkeeping

Compliance with 4.1.7 can be verified by inspection.

5.2 Methods of verifying compliance with the requirements for EO sterilant sources

5.2.1 Registration

Compliance with 4.2.1 can be verified by inspecting the labeling.

5.2.2 Labeling

Compliance with 4.2.2 can be verified by inspection.

5.2.3 Container safety

See 2.6.

5.2.4 Product composition

Certification by the manufacturer will suffice to verify compliance with 4.2.4. It is not recommended that compliance be verified by sampling and analysis of the sterilant gas because of the risks of excessive exposure to EO and because of the technical difficulties of such analyses.

5.2.5 Shipping

See 2.6 and 2.7.

5.3 Methods of verifying compliance with the requirements for EO emission control systems

5.3.1 System approvals

See applicable current local, state, and federal regulations.

5.3.2 Labeling

5.3.2.1 Device markings

Compliance with 4.3.2.1 can be verified by inspection.

5.3.2.2 Information/service manuals

Compliance with 4.3.2.2 can be verified by inspection.

5.3.2.3 User training program

The requirement of 4.3.2.3 for a user training program can be satisfied by such means as videotaped demonstrations, training classes, lectures, and/or self-directed learning activities such as CD-ROMs.

5.3.3 Performance requirements

See 2.4.

5.3.4 Safety requirements

See 2.11.

5.3.5 Installation requirements

See applicable current local, state, and federal regulations.

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Introduction

This annex discusses the need for developing a standard to guide sterilizer manufacturers and EO gas producers by defining minimum labeling, safety, performance, and testing requirements for EO sterilizers and EO sterilant sources intended for use in health care facilities. The rationale for each of the provisions of the standard is also provided.

A.1.1 Historical background and scope of the standard

Health care facilities have been using EO gas for many years. Its use as a sterilant can be traced back to 1936, when Schrader and Bossert recognized EO's bactericidal properties, and to 1937, when the Gross and Dixon patent, "Method of Sterilization," was issued. Between 1940 and 1943, Griffith and Hall were issued a series of patents involving EO. Phillips and Kaye encouraged industrial and hospital use of EO sterilization in the late 1940s and early 1950s (Kaye 1949; Kaye & Phillips 1949; Kaye *et al.* 1952; Phillips 1949, 1952, 1954; Phillips & Kaye 1949). Now, nearly every hospital in the United States uses at least one EO sterilizer.

One of EO's most important characteristics is its ability to sterilize materials that are sensitive to heat or high concentrations of moisture. As a result, EO is commonly used to sterilize medical devices that cannot withstand the rigors of steam sterilization.

In 1974, the AAMI Sterilization Standards Committee established an Ethylene Oxide Sterilization Subcommittee to develop performance standards for industrial and hospital EO sterilizers and to develop guidelines for inhospital EO sterilization processing. This subcommittee, in turn, appointed a Hospital EO Sterilizer Working Group charged with the responsibility of developing the needed performance standards for sterilizers intended for use in health care facilities.

Since the government phaseout of chlorofluorocarbon-12 (CFC-12) as an EO diluent, alternative hydrochlorofluorocarbon (HCFC) diluents have been developed and are available to hospital EO users in nonflammable EO sterilant blends. These EO/HCFC blends are included in the scope of this standard.

A.1.2 Need for the standard

Ethylene oxide sterilizers are intended to render products and materials sterile. Because many of the materials processed with EO in health care facilities are intended for use in surgical procedures, failure or inadequate performance of the sterilizer could result in serious, even life-threatening, infections. In addition, EO sterilizers and sterilant sources present potential risks to the safety of sterilizer operators and other health care personnel, particularly in regard to potential inhalation exposure to EO.

At the outset of the standards-development effort, three areas of concern were identified: the need to ensure the safety of sterilizer operators and other health care workers; the need to ensure adequate sterilization parameter measurement and control by the sterilizer; and the need for adequate validation of sterilizer performance and cycle parameters. The committee judged that the best way to address these needs was to define safety and performance criteria that could be used by manufacturers in qualifying equipment design. Recognizing that the characteristics of EO sterilant sources also have a bearing on worker safety and sterilizer efficacy, the committee decided to include EO sterilant sources within the scope of a safety and performance standard for EO sterilizers.

The need for a performance standard for EO sterilizers was subsequently supported by the Food and Drug Administration's classification of these devices as class II (performance standards). Based on the recommendations of its advisory panels, FDA deemed a performance standard necessary for reasonable assurance of device safety and effectiveness (FDA 1980).

In summary, the purpose of this standard is to help ensure that EO sterilizers intended for use in health care facilities control the parameters of EO sterilization in order to adequately sterilize medical products and materials and that EO sterilizers and sterilant sources can be used safely by health care personnel.

A.2 Normative references

No additional guidance is provided for section 2 of this standard.

A.3 Definitions, symbols, and abbreviations.

No additional guidance is provided for section 3 of this standard.

A.4 Rationale for the specific provisions of the standard

A.4.1 Requirements for EO sterilizers

A.4.1.1 Labeling

The requirements of 4.1.1 are intended to help ensure that users of EO sterilizers will be given sufficient information by the manufacturer to enable them to correctly install, safely and effectively operate, and adequately maintain the equipment. With respect to 4.1.1.4, proper education of users is essential to the safe and efficient operation of sterilization equipment.

A.4.1.2 Sterilizer construction, components, and accessories

A.4.1.2.1 Pressure requirements

This standard incorporates by reference the requirements of the ASME *Boiler and pressure vessel code* to help ensure that the sterilizer will be able to withstand ordinary chamber pressures with a generous safety margin built in to protect the operator.

A.4.1.2.2 Electrical components

Compliance with the *National electrical code*, IEC 1010-1, and IEC 1010-2-042 helps protect sterilizer operators from electrical hazards.

A.4.1.2.3 Corrosion resistance

The interior surfaces of EO sterilizers are routinely subjected to moisture, because humidification is one element of effective sterilization cycles. The surfaces must therefore be corrosion-resistant to prolong the useful life of the equipment and to prevent loads from being contaminated. It is also the intent of 4.1.2.3 to help ensure that the materials used will present a clean appearance that can be easily maintained over time.

A.4.1.2.4 Air filters

Air-line filters help prevent recontamination of products and materials before they are removed from the sterilizer.

A.4.1.3 Sterilizer safety

A.4.1.3.1 Prevention of worker exposure to EO

Ethylene oxide is a toxic chemical that poses risks to the health of exposed workers. The sterilizer manufacturer is responsible for ensuring that means are incorporated into the sterilizer control system to address foreseeable potential failure modes that could compromise worker safety. However, these requirements do not relieve health care personnel of the obligation to maintain the sterilizer properly, to observe safe work practices, and to conduct regular leak testing (AAMI 1999).

A.4.1.3.2 Prevention of thermal hazards

The requirements of 4.1.3.2 are intended to ensure that surfaces that the operator touches during normal sterilizer operation cannot exceed a safe temperature.

A.4.1.3.3 Sterilizer controls for aborting cycles

In the event of an emergency, such as failure of a gas supply or exhaust line, evacuation of the premises, and/or other unforeseen event, it could be necessary to abort or terminate a cycle in progress.

A.4.1.4 Process monitoring devices

Temperature, gas concentration as indicated by pressure (see annex C), and exposure time are critical EO sterilization processing parameters and should be monitored accurately to ensure effective cycles. The particular accuracies specified can be reasonably obtained with today's technology, and experience in the field has shown that these accuracies are sufficient to achieve proper control of the process.

A.4.1.5 Physical performance of sterilizers

A.4.1.5.1 Temperature control

The time required to achieve a desired level of sporicidal activity is highly dependent upon temperature. In the range of 30° C to 60° C, the D_o value approximately halves with each 10° C increase in temperature. (Put another way, a reduction in temperature will necessitate a longer exposure time.) As sterilizing gas is introduced to the chamber of an EO sterilizer, the chamber temperature can be expected to vary from the selected exposure temperature. The specified temperature-stabilizing time and variability are based on manufacturers' experience with the dynamics of the equipment and controls and the effectiveness of cycles operating within these limits.

A.4.1.5.2 Control of exposure time

As one of the primary factors in achieving sterilization, exposure time must be accurately controlled to ensure a proper combination of the four major parameters.

A.4.1.5.3 Control of relative humidity

All EO sterilization processes depend on the presence of adequate moisture. Severely dried (desiccated) materials resist EO sterilization, because some moisture is necessary to permit EO entry into and action on microorganisms. Therefore, if the relative humidity in the chamber is too low, a sterilization failure could occur. It should be noted that extremely high chamber humidity can also cause problems, such as wet packs at the end of the sterilization cycle and adverse effects on the performance of chemical indicators.

A.4.1.5.4 Control of EO delivery

As one of the primary factors in achieving sterilization, gas concentration must be accurately controlled. Ethylene oxide and its carrier behave as near-ideal gases under normal sterilizing conditions, making direct pressure and temperature readings a valid means of calculating chamber concentration.

A.4.1.6 Biological performance of sterilizers

All of the critical parameters needed for sterilization are not directly monitored during the cycle nor recorded on physical monitoring devices on EO sterilizers designed for use in health care facilities. Therefore, EO sterilizers must be biologically challenged to ensure the efficacy of the equipment and the lethality of the recommended processing parameters. In the test method of 5.1.6, both empty-chamber and simulated-load qualification testing are specified in order to provide reasonable assurance that the sterilizer will perform adequately in actual use. Empty-chamber testing by the manufacturer provides data that can be used by health care personnel to verify sterilizer performance during inhospital installation testing (see 2.2). Lethality determinations are to be made under simulated-load conditions, because a loaded chamber in an EO sterilizer (unlike a steam sterilizer) is a greater challenge than is an empty chamber.

Only a portion of a sterilizer chamber (35% to 40%) is available as usable volume for sterilizing items because of the space occupied by loading equipment and the need for adequate EO circulation. For the simulated-load testing, the specified fractional volume (10%) is less than the fractional volume occupied by hospital loads, because the challenge test pack presents more of a biological challenge than does a typical pack, and the intent is to approximate the challenge of a full load. The specified load is not intended, however, to be "typical" of hospital loads, but to generally simulate in-use conditions. For the rationale for the composition of the test pack, see 2.2.

Unless the equipment used for testing sterilizers is properly calibrated for accuracy and yields consistent data, the results of the tests performed could be misleading, and incorrect conclusions about the efficacy of the sterilizers could be drawn.

If the sterilizers to be tested are installed and operated in a manner different from that recommended to the final user, the results might not be a valid representation of how the equipment will perform in actual use.

A.4.1.7 Certification and recordkeeping

Section 4.1.7 specifies that a sterilizer manufacturer must document conformance to this standard as part of the original design qualification, every 24 months for production sterilizers of the originally qualified design, and upon any change in design. Certification is essential to help demonstrate that the sterilizer, as originally designed and qualified, is safe and efficacious. Recertification helps ensure that the safety and efficacy of production sterilizers do not deviate from the originally qualified design and that any changes made in that design do not affect safety or efficacy.

The sterilizer manufacturer must keep thorough test reports as proof and documentation that the sterilizer conforms to this standard. It is the purchaser's right to receive, upon request, a copy of these test reports from the manufacturer.

A.4.2 Requirements for EO sterilant sources

A.4.2.1 Registration

Gas sterilants containing EO are classified by law as pesticides and are regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act. Producers of gas sterilants must be EPA registrants; the gases that they sell must be registered products carrying EPA-approved labeling.

A.4.2.2 Labeling

All sterilant gas containers are required by law to carry EPA-approved labeling. The user should check the labels of containers prior to use. If there is no label on the container or if the label is not legible, the product should not be used but returned to the sterilant gas supplier. Certain labeling is also required by DOT. (See also A.4.2.1, 2.6, and 2.7.)

A.4.2.3 Container safety

Pressurized containers and toxic substances present hazards during transportation. Consequently, federal regulations have been developed for safe transportation of materials.

A.4.2.4 Product composition

The EO concentration in the sterilant gas must, by law, be clearly stated and must conform to 4.2.4. Because of the possibility of excessive personnel exposure to EO, it is not recommended that the user attempt to verify the concentration analytically or by sampling the sterilant gas.

A.4.2.5 Shipping

Sterilant gas manufacturers, suppliers, and users should ship both full and empty containers in accordance with DOT and EPA regulations (see 2.6 and 2.7, respectively). Empty nondisposable cylinders contain a residual amount of sterilant gas by virtue of their construction, and they should be transported under DOT shipping regulations as if they were full. The cylinder valve should be closed, and the outlet plugged after use. The cylinder should be leak-tested and returned to the sterilant manufacturer. The return bill of lading should read: “Empty cylinders last contained _____” (repeat DOT classification used on bill of lading delivering the full cylinders).

A.4.3 Requirements for EO emission control systems

Legislative requirements for EO emission control have been put in place by several state and local air quality boards. The emission of both EO and diluents may necessitate control. Facilities should consult current state and local requirements when preparing to install and operate sterilization systems.

A.4.3.1 System approvals

Many local and state agencies require specific equipment certifications for issuance of permits to install and operate emission control equipment.

A.4.3.2 Labeling

Proper labeling of emission control equipment is necessary so that pertinent operating utilities and manufacturing information can be identified. Operator and service manuals are needed for emission control systems to be operated in a safe and efficient state. Proper education of users is essential to the safe and efficient operation of emission control equipment.

A.4.3.3 Performance requirements

Emission control systems need to meet all requirements legislated by the installation location and must perform to the manufacturer’s claims. Compliance with regulations and laws at the installation location is mandatory. These may include both air quality and safety requirements.

A.4.3.4 Safety requirements

Without such provisions in the design, loss of electrical power or other system failure could adversely affect the safe operation of an emission control system, resulting in danger to workers and/or the general public.

A.4.3.5 Installation requirements

Installation should be performed in accordance with the manufacturer’s instructions. Failure to follow installation instructions could result in unsafe operation of the equipment and cancellation of the warranty.

Annex B
(informative)

Calculating chamber relative humidity

B.1 Calculations

From the partial pressure due to water vapor and the chamber temperature, the relative humidity (RH) within an EO chamber can be calculated:

$$\%RH = 100 \times P_v/P_g$$

where:

P_v = the partial pressure due to water vapor

P_g = the saturation pressure of water vapor at the sterilizing temperature

The saturation pressure of water vapor at various sterilization temperatures is shown in table B.1.

Table B.1—Temperature versus saturation pressure of water vapor

° F	P_g
100	0.9492
110	1.2748
120	1.6924
130	2.2225

Therefore, at a sterilization temperature of 130° F and a partial pressure of 1.5 pounds per square inch atmosphere (psia) (P_v), the relative humidity in the chamber is

$$\%RH = 100 \times 1.5/2.2225 = 67.5\%$$

B.2 Graphic representation of relative humidity versus pressure

For the two common sterilization temperatures, 100° F and 130° F, and partial pressures due to water vapor ranging from 0 to 3.0 psia, relative humidity can be read from figure B.1.

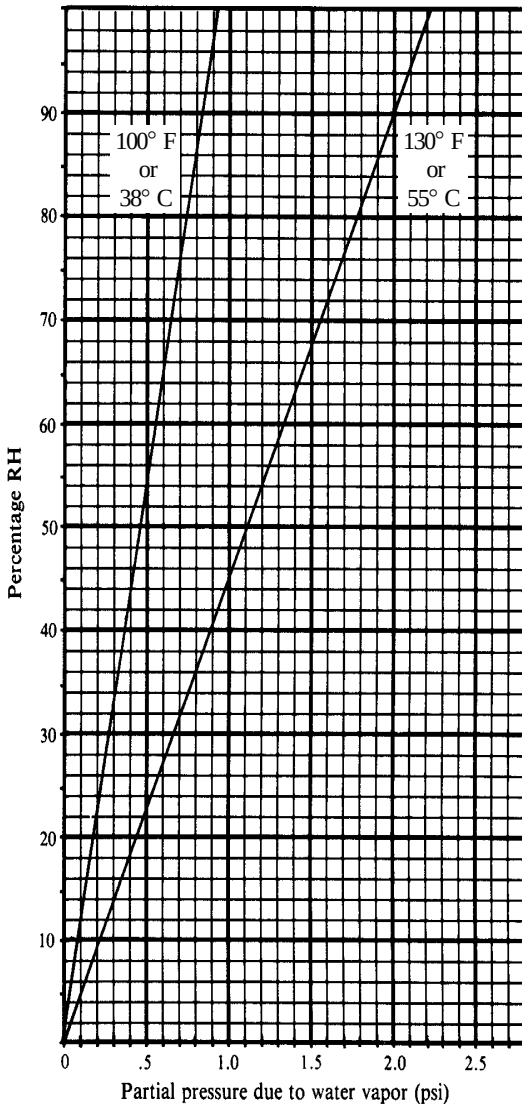

Figure B.1–Relative humidity versus partial pressure for two common sterilization temperatures

Annex C
(informative)

Calculating chamber ethylene oxide concentration

C.1 Introduction

The theoretical calculation of the concentration of EO in a sterilizer, after the initial charge of gas and at temperature equilibrium, is based on the Ideal Gas Law (PV = nRT). The following assumptions are made:

a) The mixture of EO, water vapor, and air (and the diluent gas when used) behaves as an ideal gas.

b) There is no selective loss of a component of the mixture (e.g., by absorption or adsorption). Component concentrations are at their nominal concentrations.

c) The label information on the cylinders containing the gas is accurate, and the percentage of weight of the mixture of gas remains constant as it is introduced to the sterilizer chamber.

d) Pressure is stated in absolute terms of differences in gauge readings, rather than as gauge pressure (difference from atmospheric).

e) The temperature is constant and uniform throughout.

f) The chamber is free of leaks.

g) The diluent gas is stable over the temperature and pressure ranges used.

C.2 Calculations

Using this simplified model, the EO concentration is calculated on the basis of the difference in total pressure resulting from the addition of EO plus carrier or diluent gas, and the sterilizer chamber temperature. The difference in total pressure due to the addition of EO can be expressed as

$$P = (n/V) \times R \times T = P_{EO} + P_{DG} = [(n/V)_{EO} + (n/V)_{DG}] \times R \times T \quad (1)$$

Rearranging the Ideal Gas Law expression (1) permits calculation of EO concentration, regardless of the EO/diluents gas mixture, using the following equation:

$$C = (K \times P)/(R \times T)$$

$$= [(4.4 \times 10^4 \times M \times E)/(M \times E + 44 \times \{100 - E\})] \times P/(R \times T) \quad (2)$$

where:

C = EO concentration (mg/L)

K = constant for a given diluent

P = difference in total pressure due to EO and diluent

R = gas constant

T = absolute temperature of EO/diluent gas mixture giving pressure P

M = molecular weight of diluent gas

E = weight percentage of EO in diluent mixture

Table C.1 lists the constants and molecular weights of some common EO/diluent combinations for use in equation 2. Table C.2 gives gas constants for various pressure and volume units.

Table C.1—EO/diluent constants and molecular weights

EO/diluent	K (mg/gm mole)*	K (lb/lb mole)**
8.6% EO/91.4% HCFC blend	9.942×10^3	9.942
10% EO/90% HCFC blend	9.989×10^3	9.989
8.5% EO/91.5% CO_2	3.74×10^3	3.74
100% EO	4.40×10^4	4.40×10^1
Molecular weights		
Ethylene oxide		44.0
HCFC diluent for 8.6% EO blend		136.5
HCFC diluent for 10% EO blend		116.3
Carbon dioxide (CO_2)		44.0

* Use when calculating mg/L.

** Use when calculating lb/ft^3.

Table C.2—Gas constants (R = PV/nt)*

Pressure**	Volume***	Moles	Temperature****	Gas Constant (R)
atm	cc	Gm	^{o}K	82.057
atm	liters	Gm	^{o}K	0.08205
atm	cubic feet	Lb	^{o}K	1.3140
bar	liters	Gm	^{o}K	0.08314
kg/m^2	liters	Gm	^{o}K	847.80
kg/cm^2	liters	Gm	^{o}K	0.08478
mmHg	liters	Gm	^{o}K	62.361
mmHg	cubic feet	Lb	^{o}K	998.90
inHg	liters	Gm	^{o}K	2.4549
lb/in^2	cubic feet	Lb	^{o}R	10.73

*It is important to maintain the proper units when using equation (2) and the gas constants.

**1 atm = 760 mmHg = 29.92 inHg = 14.70 psia = 1.013 bar = 1.033 kg/cm^2 = 101.3 kPa (kN/m^2)

***1 liter = 1000 cc = 0.03532 ft^3

****^{o}K = ^{o}C + 273; ^{o}R = ^{o}F + 460

C.3 Example calculations

C.3.1 Determining EO concentration in pounds per cubic foot (lbs/ft^3)

Assume a process that uses an 8.6% EO/91.4% HCFC blend. After gas injection, the increase in pressure was 20 pounds per square inch (psi).

NOTE—This increase in pressure does not include the pressure increase due to moisture preconditioning.

If the temperature at the end of gas injection was 134° F, then

P = 20 psi

T = 590° R

R = 10.73 (psi-ft^3/lb mole ° R)

K = 9.942 lb/lb mole

Using equation (2), the EO concentration is

$$C = (K \times P)/(R \times T) = (9.942)(20)/(10.73)(590) = 0.0314 \text{ lb/ft}^3$$

As another example, assume a process that uses a 10.0% EO/90.0% HCFC blend. After gas injection, the increase in pressure was 20 psi.

NOTE—This increase in pressure does not include the pressure increase due to moisture preconditioning.

If the temperature at the end of gas injection was 134° F, then

P = 20 psi

T = 590° R

R = 10.73 (psi-ft^3/lb mole ° R)

K = 9.989 lb/lb mole

Using equation (2), the EO concentration is

$$C = (K \times P)/(R \times T) = (9.989)(20)/(10.73)(590) = 0.0316 \text{ lb/ft}^3$$

C.3.2 Determining EO concentration in milligrams/liter (mg/L)

Assume a process that uses a 10% EO/90% HCFC blend. After gas injection, the increase in pressure was 48.8 inches of mercury (inHg). If the temperature at the end of gas injection was 55° C, then

P = 48.8 inHg

T = 55° C = 328° K

R = 2.4549 (inHg 1/gm moles ° K) (see table C.2 for gas constants)

K = 9.989 x 10^3 mg/gm mole

Using equation (2), the EO concentration is

$$C = (K \times P)/(R \times T) = [(9.989 \times 10^3) \times (48.8)]/(2.4549 \times 328) = 605.4 \text{ mg/L}$$

C.4 Derivation of equation (2)

Because in most operations the pressure change during EO gas injection is recorded, equation (2) was derived to allow the calculation of EO concentration in a simplified manner from the pressure increase due to EO gas injection with or without a diluent gas such as carbon dioxide or a hydrochlorofluorocarbon (HCFC). The purpose of the equation is to provide a simple and rapid method of calculating EO concentration for production as well as experimental facilities.

The pressure increase can be expressed as the sum of the partial pressures of the EO and diluent gas, as in equation (1):

$$P = P_{EO} + P_{DG} = (n/V)_{EO}RT + (n/V)_{DG}RT = [(n/V)_{EO} + (n/V)_{DG}]RT$$

The preceding formula can be expressed in ml/L:

$$(n/V)_{EO} = gm/M_{EO}1 = 10^{-3}/44\ (mg/L)_{EO}$$

$$(n/V)_{DG} = gm/M_{DG}1 = 10^{-3}/M_{DG}\ (mg/L)_{DG} = 10^{-3}/M(mg/L)_{DG}$$

where:

M_{EO} = molecular weight of ethylene oxide = 44.0

M_{DG} = molecular weight of diluent gas = M

Then, the pressure increase can be rewritten as follows:

$$P = [10^{-3}/44\ (mg/L)_{EO} + 10^{-3}/M\ (mg/L)_{DG}]RT \quad (3)$$

Because the weight % EO is usually known, and the sterilizer volume remains constant, the expression derived above can be rewritten as follows:

$$Wt\%\ EO = 100 \times (mg/L)_{EO}/[(mg/L)_{EO} + (mg/L)_{DG}]$$

Solving for $(mg/L)_{DG}$:

$$(mg/L)_{DG} = [(mg/L)_{EO}100 – (mg/L)_{EO}\ Wt\%\ EO]/Wt\%\ EO$$

$$= (mg/L)_{EO}[(100 – Wt\%\ EO)/Wt\%\ EO]$$

Substituting the above for $(mg/L)_{DG}$, equation (3) becomes:

$$P = 10^{-3}/44(mg/L)_{EO} + 10^{-3}/M(mg/L)_{EO} \times [(100 – Wt\%\ EO)/Wt\%\ EO]RT \quad (4)$$

Solving for $(mg/L)_{EO}$ in equation (4):

$$P = RT[(10^{-3}/44) + (10^{-3}/M)(100 – Wt\%\ EO)/Wt\%\ EO](mg/L)_{EO}$$

Let Wt% EO = E, and rewrite:

$$P = RT[(10^{-3}/44) + (10^{-3}/M)(100 – E)/E](mg/L)_{EO}$$

Then rewrite:

$$P = 10^{-3}RT[1/44 + (100 – E)ME](mg/L)_{EO}$$

$$= 10^{-3}RT[(ME – 44(100- E)/44\ ME]\ (mg/L)_{EO}$$

Then:

$$(mg/L)_{EO} = 10^{3}P/RT[44ME]/[ME + 44(100 - E)]$$

or:

$$C = P/RT[4.4 \times 10^{4}ME]/[ME + 44(100 – E)]$$

Annex D
(Informative)

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