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American National Standard



Advancing Safety in Health Technology

ANSI/AAMI ST41:2008/ (R)2018

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Ethylene oxide sterilization
in health care facilities:
Safety and effectiveness

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*.

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(Revision of ANSI/AAMI ST41:1999/(R)2005)

Corrected 31 March 2010: Includes change to subclause 10.7.6.1



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Approved 31 July 2008 and reaffirmed 29 November 2012 and 16 January 2018 by **American National Standards Institute Inc.**

Abstract: This recommended practice covers the safe and effective use of ethylene oxide as a sterilant in health care facilities. The provisions of this document are intended to promote sterility assurance, help minimize occupational exposure to ethylene oxide, and guide health care personnel in the proper use of processing equipment.

Keywords: chemical sterilization, gas sterilization, ethylene oxide emission control, ethylene oxide monitoring

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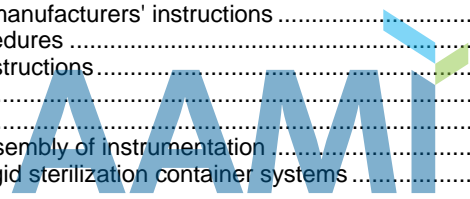
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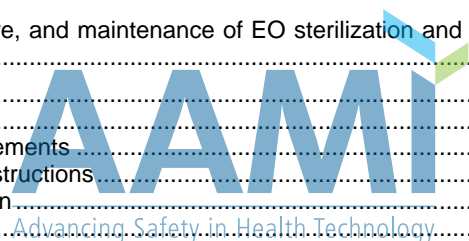
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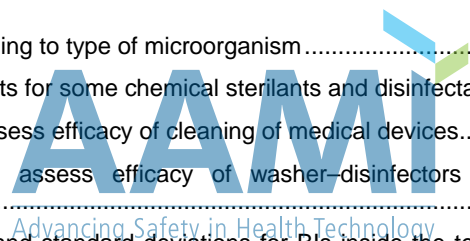
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International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI I136:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI I151:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations

International designation	U.S. designation	Equivalency
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
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ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical

Committee representation

Association for the Advancement of Medical Instrumentation AAMI Ethylene Oxide Sterilization Hospital Practices Working Group

This recommended practice was developed by the Ethylene Oxide Sterilization Hospital Practices Working Group, under the auspices of the AAMI Sterilization Standards Committee. Approval of the recommended practice does not necessarily mean that all working group members voted for its approval. At the time this document was published, the AAMI Ethylene Oxide Sterilization Hospital Practices Working Group had the following members:

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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

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Foreword

This recommended practice was developed by the Ethylene Oxide Sterilization Hospital Practices Working Group of the AAMI Sterilization Standards Committee. The guidelines in this document are intended to help assure achievement of sterilization with hospital ethylene oxide (EO) sterilizers, maintenance of sterility of processed items until the point of use, and reduction of occupational exposure to EO.

ANSI/AAMI ST41:1999 combined two previously published recommended practices: the second edition of *Good hospital practice: Ethylene oxide sterilization and sterility assurance* (ANSI/AAMI ST41:1992) and the third edition of *Good hospital practice: Ethylene oxide gas—Ventilation recommendations and safe use* (ANSI/AAMI ST43:1993). Combining these two recommended practices placed all of AAMI's recommendations concerning EO sterilization in health care facilities into a single document for ease of reference. The provisions of the previously published recommended practices were updated to reflect new regulatory and technological developments, especially with respect to EO monitoring, EO emission control, and new diluents that had come into use as substitutes for chlorofluorocarbon-12 (CFC-12). The current edition of this document, ANSI/AAMI ST41:2008, provides revised recommendations concerning qualification testing of EO sterilizers and incorporates extensive information from ANSI/AAMI ST79 (*Comprehensive guide to steam sterilization and sterility assurance in health care facilities*) regarding attire, handling and transport of contaminated items, cleaning and decontamination processes, user verification of cleaning processes, selection and use of chemical disinfectants, thermal disinfection, and devices returned to the manufacturer.

In today's cost-conscious health care environment, it is important not to lose sight of the need for economy. However, cost-effectiveness in EO sterilization processing is not just a matter of the purchase price of instrumentation or the direct cost of quality assurance procedures. The effectiveness of risk management, the level of performance and longevity of equipment, and other factors should be integrated into the overall system for optimum assurance of safety, effectiveness, and true economy.

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with manufacturers of EO sterilization and aeration equipment, to develop recommendations for optimum performance levels in the processing of reusable medical devices to be sterilized by EO and for optimum control of occupational exposure to EO in health care facilities. It is not intended that these recommendations be construed as universally applicable in all circumstances. It is also recognized that in many cases these recommendations might not be immediately achievable. Therefore, the document should be used to guide personnel toward desirable performance objectives, and all of its provisions should be considered and applied in the light of professional judgment and experience.

As used within the context of this document, "shall" indicates requirements strictly to be followed in order to conform to the recommended practice; "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 recommended practice; and "can" is used as a statement of possibility and capability. "Must" is used to describe only "unavoidable" situations, including those mandated by government regulation.

Departmental managers should review the provisions of this recommended practice and adapt the provisions to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with appropriate hospital committees (e.g., safety, hazardous materials, risk management, infection control).

The concepts incorporated in this recommended practice should be considered flexible and dynamic. The recommendations set forth in this document are reviewed and updated periodically to assimilate progressive technological developments. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every 5 years.

This standard is expected for continuous maintenance procedures. If the standard is continuously maintained, AAMI will create a notification registry that will send e-mail announcements when any maintenance activity occurs to the recommended practice. To register, visit www.aami.org/standards/st41.registry.html. Suggestions for improving this recommended practice are invited. Comments or proposals for revisions to any part of the standard may be submitted to AAMI at any time. Written comments should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Comments may also be e-mailed to standards@aami.org.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness* (ANSI/AAMI ST41:2008), but it does provide important information about the development and intended use of the document.

Ethylene oxide sterilization in health care facilities: Safety and effectiveness

Introduction: Need for the recommended practice

Ethylene oxide (EO) gas and its mixtures are effective sterilants that are primarily used for heat- and moisture-sensitive medical devices that cannot be steam sterilized. Despite the many recent advances in medical and surgical care, health care-associated (nosocomial) infections continue to be a significant drain on human and economic resources, producing human suffering and higher health care costs. One way to prevent these health care-associated infections in health care facilities is effectively reprocessing and sterilizing medical devices by EO.

The delivery of sterile products for use in patient care depends not only on the efficacy of the sterilization process itself but also on efficient facility design, good infection prevention and control practices, effective quality control, and other aspects of device processing before, during, and after sterilization.

Ethylene oxide gas must be used with care because of its toxicity and (when used in its pure form) its flammability and explosiveness. For these reasons, EO should be used to sterilize only those items that cannot undergo the steam sterilization process. The currently available sterilant mixtures of EO and hydrochlorofluorocarbons (HCFCs) and of EO and carbon dioxide (CO₂) were developed to reduce the potential flammability of EO and to replace previously used mixtures of EO and chlorofluorocarbon-12 (CFC-12).

The Occupational Safety and Health Administration (OSHA) has established a permissible exposure limit (PEL) of 1 part per million (ppm) airborne EO in the workplace, expressed as a time-weighted average (TWA) for an 8-hour work shift in a 40-hour work week. OSHA also has defined an "action level" of 0.5 ppm, expressed as an 8-hour TWA, and an excursion limit (EL) of 5 ppm, expressed as a 15-minute TWA. (See Annex A.) As a result of the Clean Air Act (CAA) and Clean Water Act (CWA), which are enforced by regulations of the Environmental Protection Agency (EPA), some states have implemented emission control requirements that affect health care facilities. In addition, the EPA recently promulgated national emission standards for hospital EO sterilizers (40 CFR 63). Health care facilities must comply with the OSHA standard and with applicable EPA regulations.

It is essential that health care personnel keep current with applicable federal, state, and local regulations and with voluntary guidelines, because additional requirements might be adopted as a result of ongoing research on the health effects of EO or as a result of experience with the OSHA standard and the emission control regulations. Information on current OSHA regulations (see Annex A) can be obtained from either state OSHA offices or the federal office (Occupational Safety and Health Administration, Office of Information Services, 200 Constitution Avenue, NW, Washington, DC 20210; <http://www.osha.gov>). Information on current EPA regulations can be obtained from either state EPA offices or the federal office (Environmental Protection Agency, Office of Pollution Prevention and Toxics Substances [TAIS #7408], 1200 Pennsylvania Avenue, NW, Washington, DC 20480; <http://www.epa.gov>). Information on the current Food and Drug Administration (FDA) regulatory status of sterilants and sterilizing agents can be obtained by contacting the Chief of the Infection Control Devices Branch (HFZ-480), Office of Device Evaluation, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850, 240-276-3747), or by checking <http://www.fda.gov/cdrh>.

Health care facilities differ in their physical design and equipment and in the training level of personnel with regard to sterilization processing. This recommended practice sets forth guidelines for facility design and work practices to assist health care personnel in developing procedures to achieve and maintain the sterility assurance level (SAL) of devices sterilized by EO. This recommended practice also provides guidelines for EO ventilation, the use of EO sterilization and aeration equipment, and personnel work practices to assist health care personnel in complying with the OSHA standard and in otherwise minimizing occupational exposure to EO. The provisions of this recommended practice should be reviewed by departmental managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with appropriate hospital committees (e.g., safety, hazardous materials, risk management, and infection prevention and control).