

American
National
Standard

ANSI/AAMI
ST41:2008/
(R)2018

Ethylene oxide sterilization
in health care facilities:
Safety and effectiveness

HISTORICAL

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ANSI/AAMI ST41:2008/(R)2018 [HISTORICAL]
(Revision of ANSI/AAMI ST41:1999/(R)2005)

Corrected 31 March 2010: Includes change to subclause 10.7.6.1

Ethylene oxide sterilization in health care facilities: Safety and effectiveness

Developed by
AAMI

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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Published by

AAMI
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

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Printed in the United States of America

ISBN 978-1-57020-316-9

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Contents

	Page
Glossary of equivalent standards	ix
Committee representation	xi
Acknowledgments	xiii
Foreword	xiv
Introduction: Need for the recommended practice	1
1 Scope	2
1.1 General	2
1.2 Inclusions	2
1.3 Exclusions	2
2 Definitions, symbols, and abbreviations	3
3 Design considerations	11
3.1 General rationale	11
3.2 Centralization	11
3.3 Containment areas	11
3.4 Routing of traffic	12
3.5 Sterilizer access area	12
3.6 Storage of supplies	13
3.7 Temperature	13
3.8 Relative humidity	13
3.9 Ventilation recommendations for areas housing EO sterilization and aeration equipment	13
3.9.1 General considerations	13
3.9.2 Local exhaust ventilation	14
3.9.3 General room ventilation	15
3.10 Emergency eyewash and shower equipment	16
3.11 Environmental discharge controls	17
3.11.1 Ethylene oxide	17
3.11.2 Ethylene glycol	17
3.11.3 Hydrochlorofluorocarbons	17
4 Personnel considerations	19
4.1 General rationale	19
4.2 Qualifications	19
4.2.1 Supervisory personnel	19
4.2.2 Sterilizer and aerator operators	20
4.3 Training and continuing education	20
4.3.1 Sterile processing personnel	20
4.3.2 Other personnel	21
4.4 Personnel health	21
4.4.1 General considerations	21
4.4.2 Information concerning the potential hazards of exposure to EO	22
4.4.3 Medical surveillance and treatment	22
4.4.4 First aid	23
4.5 Air	23
4.5.1 General considerations	23
4.5.2 Decontamination area	24
4.5.3 Service personnel	24
4.5.4 Prevention of occupational exposure to EO	25
5 Receiving	27
5.1 General rationale	27
5.2 Receiving of purchased or loaner items	27
5.2.1 General considerations	27

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5.2.2	Newly purchased reusable items and repaired reusable items	27
5.2.3	Rigid sterilization container systems	27
5.2.4	Disposable items	28
5.3	Disposition of sterile items (issued but not used)	28
6	Handling, collection, and transport of contaminated items	29
6.1	General rationale	29
6.2	Separation of waste and reusable items at point of use	29
6.3	Care and handling of contaminated reusable items at point of use	29
6.4	Containment	30
6.5	Transport	31
6.5.1	Transportation scheduling and routes	31
6.5.2	Transportation equipment	31
6.5.3	Hand transport	31
6.5.4	Dedicated lifts	31
6.5.5	Transport between buildings	31
6.5.6	Off-site transportation	32
7	Cleaning and other decontamination processes	33
7.1	General rationale	33
7.2	Policies, procedures, and manufacturers' instructions	33
7.2.1	Policies and procedures	33
7.2.2	Manufacturers' instructions	33
7.3	Presoaking	34
7.4	Disassembly	34
7.4.1	Sorting and disassembly of instrumentation	34
7.4.2	Disassembly of rigid sterilization container systems	34
7.5	Cleaning	35
7.5.1	General considerations	35
7.5.2	Cleaning agents	35
7.5.3	Methods of cleaning	36
7.5.4	Rinsing	37
7.5.5	Verification of the cleaning process	38
7.5.6	Cleaning of instruments	38
7.5.7	Utensils	39
7.5.8	Reusable textiles	39
7.5.9	Rigid sterilization container system	39
7.6	Microbicidal processes	40
7.6.1	General considerations	40
7.6.2	Processes to decontaminate devices for safe handling	41
7.6.3	Terminal sterilization processes to prepare devices for the next patient use	43
7.7	Servicing and repair of devices in the health care facility	44
7.7.1	General consideration	44
7.7.2	Potential for exposure	44
7.7.3	Protective measures for service personnel	45
7.7.4	Postexposure program	45
7.7.5	Devices that cannot be repaired in-house	45
8	Packaging, preparation, and sterilization	47
8.1	General rationale	47
8.2	Items suitable for EO sterilization	47
8.3	Preconditioning (humidification)	47
8.4	Packaging	47
8.4.1	Selection of packaging materials	47
8.4.2	Packaging configurations and preparation	48
8.5	Loading the sterilizer	49
8.5.1	Load composition	49
8.5.2	Load configuration	49
8.6	Sterilization parameters	49
8.6.1	General considerations	49
8.6.2	Sterilizer manufacturer's instructions	49
8.6.3	Device and packaging manufacturers' instructions	50
8.6.4	Monitoring	50

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8.7	Unloading the sterilizer	50
8.7.1	General considerations.....	50
8.7.2	Sterilizers without purge cycles.....	50
8.7.3	Sterilizers with purge cycles.....	50
8.7.4	Sterilizers with integral aeration.....	50
8.7.5	Sterilizers with "detoxification".....	51
8.7.6	Handling of EO-sterilized items before aeration	51
8.8	Aeration recommendations.....	51
8.8.1	General considerations.....	51
8.8.2	Metal and glass items.....	51
8.8.3	Aeration capacity.....	52
8.8.4	Aeration times.....	52
8.9	Sterile storage.....	52
8.9.1	Handling and inspection	52
8.9.2	Sterility maintenance covers.....	53
8.9.3	Storage facilities	53
8.9.4	Shelf life.....	54
8.10	Distribution	54
8.10.1	Handling and inspection	54
8.10.2	Distribution containers	54
9	Installation, venting, routine care, and maintenance of EO sterilization and aeration equipment and EO gas sources	55
9.1	General rationale	55
9.2	Installation.....	55
9.2.1	Regulatory requirements	55
9.2.2	Manufacturer's instructions.....	55
9.2.3	Equipment location	55
9.3	Installation testing	55
9.3.1	Sterilizers.....	55
9.3.2	Emission control and ventilation systems	55
9.4	Venting of EO sterilizers	56
9.4.1	General considerations.....	56
9.4.2	Sterilizers venting to the outside atmosphere.....	56
9.4.3	Sterilizers venting to a sanitary floor drain.....	57
9.4.4	Sterilizers without exhaust to the outside atmosphere or a sanitary floor drain	57
9.4.5	Ventilation of EO gas cylinders.....	58
9.5	Venting of EO aeration cabinets	58
9.5.1	Vent lines.....	58
9.5.2	Equipment modification	58
9.6	Ventilation system alarms	58
9.7	Maintenance of EO sterilizers, aerators, emission control systems, and ventilation systems	58
9.7.1	Manufacturer's instructions	58
9.7.2	Routine care of sterilizers and aerators	59
9.7.3	Preventive maintenance	59
9.8	Storage and handling of EO gas sources	60
9.8.1	Unit-dose containers of 100 % EO	60
9.8.2	Storage and handling of EO gas cylinders (tanks) and supply line filters.....	61
9.9	EO leaks and spills.....	62
9.9.1	General considerations.....	62
9.9.2	Emergency team	62
9.9.3	Emergency plan.....	62
9.9.4	First aid.....	63
9.10	Personal protective equipment.....	64
10	Quality control	65
10.1	General rationale.....	65
10.2	Monitoring of mechanical cleaning equipment.....	65
10.3	Product identification and traceability	65
10.3.1	Lot control numbers	65
10.3.2	Sterilizer records.....	65
10.3.3	Expiration dating	66

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10.4	Overview of sterilization process monitoring	66
10.5	Sterilization process monitoring devices	68
10.5.1	Physical monitors	68
10.5.2	Chemical indicators	68
10.5.3	Biological indicators	70
10.5.4	Process challenge devices	71
10.6	Routine load release	71
10.6.1	Process monitoring devices	71
10.6.2	Release criteria for nonimplants	71
10.6.3	Release criteria for implants	72
10.6.4	Sterilization process failures	72
10.7	Routine sterilizer efficacy monitoring	73
10.7.1	General considerations	73
10.7.2	Composition of the PCD (routine BI test pack)	73
10.7.3	Placement of the PCD (routine BI test pack)	74
10.7.4	Test procedure	75
10.7.5	Acceptance criteria	75
10.7.6	Positive BI results	75
10.8	Qualification testing	76
10.8.1	General considerations	76
10.8.2	Composition of the PCD (challenge BI test pack)	77
10.8.3	Placement of the PCDs (challenge BI test packs)	79
10.8.4	Test procedure	80
10.8.5	Acceptance criteria	80
10.8.6	Positive BIs	80
10.9	Periodic product quality assurance testing of routinely processed items	82
10.10	Periodic product quality assurance testing of rigid sterilization container systems	82
10.10.1	General considerations	82
10.10.2	Responsibilities of the manufacturer	82
10.10.3	User responsibilities	84
10.11	Aeration of PCDs	86
10.12	Product recalls	86
10.12.1	General considerations	86
10.12.2	Recall procedure	86
10.12.3	Recall order	86
10.12.4	Recall report	87
10.13	Quality process improvement	87
10.13.1	General rationale	87
10.13.2	Quality process	87
11	Environmental and employee monitoring	89
11.1	General rationale	89
11.2	Instrumentation	89
11.2.1	Selection of monitoring methods	89
11.2.2	Reliability and use of instrumentation	89
11.3	Procedures	89
11.3.1	Monitoring sites	89
11.3.2	Frequency of monitoring	90
11.3.3	Sterilizer system leak checks	90
11.3.4	Ventilation system monitoring	90
11.3.5	Short-term exposures	91
11.4	Calculations and interpretation of data	91
11.5	Record keeping	92
Appendix		
A	Occupational exposure to ethylene oxide, final standard (29 CFR 1910.1047)	95
	Ethylene oxide and hydrochlorofluorocarbon emission control technologies	125
C	Processing CJD-contaminated patient care equipment and environmental surfaces	126
D	Selection and use of chemical disinfectants	127

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E	User verification of cleaning processes.....	133
F	Thermal disinfection.....	138
G	Devices returned to the manufacturer.....	139
H	Round-robin study of the PCD (routine BI test pack).....	145
I	Development of a prepurchase evaluation protocol for rigid sterilization container systems.....	147
J	Selecting equipment or services for monitoring airborne ethylene oxide at an EO sterilization facility.....	153
K	Bibliography and cited references.....	163

Tables

1	Packaging for EO sterilization.....	48
2	Sterilization process monitoring recommendations.....	67
3	Simulated loads.....	79
D.1	Levels of disinfection according to type of microorganism.....	129
D.2	Occupational exposure limits for some chemical sterilants and disinfectants.....	132
E.1	In-use tests available to assess efficacy of cleaning of medical devices.....	136
E.2	In-use tests available to assess efficacy of washer–disinfectors used for medical device reprocessing.....	137
H.1	Mean kill times (minutes) and standard deviations for BIs inside the test pack vs. outside the test pack.....	146

Figures

1	Example of an EO sterilization containment area.....	12
2	Microbicidal processes and use of PPE.....	41
3	Preparation of the PCD (routine BI test pack, drawing not to scale).....	74
4	Placement of BI in syringe.....	78
5	Some components of the PCD (challenge BI test pack).....	78
6	Placement of components in PCD (challenge BI test pack).....	79
7	Placement of PCDs (challenge BI test packs).....	81
8	Example of placement of BIs and CIs in test rigid sterilization container system.....	85

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IEC 60601-1-2:2005	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

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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
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
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

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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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Acknowledgments

The AAMI Ethylene Oxide Sterilization Hospital Practices Working Group gratefully acknowledges the important contributions of Anne Cofield, CRCST, FAC, International Association of Healthcare Central Service Materiel Management. Ms. Cofield participated in numerous AAMI standards development activities over many years and most recently served as cochair of the Ethylene Oxide Sterilization Hospital Practices Working Group. The expertise and hard work that she contributed to the development of AAMI standards and recommended practices pertaining to the sterilization of medical devices are very much appreciated.

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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).