

American National Standard



ANSI/AAMI ST41:2008/ (R)2018

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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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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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

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
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

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).

1 Scope

1.1 General

This recommended practice provides guidelines for EO sterilization processing in hospitals and other health care facilities. These guidelines are intended to promote sterility assurance and to assist health care personnel in the proper use of processing equipment. These guidelines also are intended to help ensure the safe use of EO by defining equipment and procedures, including ventilation recommendations and (if applicable) emission controls, to minimize personnel exposure to EO or its residuals.

NOTE—For purposes of this recommended practice, “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 recommended practice specifically addresses

- a) design considerations for EO sterilization processing facilities, including traffic control; location of work areas; general and local exhaust ventilation systems; and storage of equipment, supplies, and EO gas sources;
- b) staff qualifications, supervision, training, health, and other personnel considerations;
- c) processing recommendations;
- d) installation, operation, care, and maintenance of EO sterilizers, EO sterilizer-aerators, and aeration cabinets;
- e) quality control; and
- f) environmental and employee health monitoring.

Definitions of terms, a bibliography, and informative annexes also are provided in this recommended practice.

1.3 Exclusions

This recommended practice does not cover

- a) specific construction and performance criteria for EO sterilizers (see ANSI/AAMI ST24),
- b) detailed design criteria for central service departments (see ANSI/AAMI ST79),
- c) guidelines for the use of EO sterilizers that release EO or an EO blend inside the package containing the wrapped items to be sterilized, or
- d) the reprocessing of devices labeled for single use only.

NOTE—For more information on the subjects excluded from the scope of this recommended practice and for additional background information on the inclusions, refer to the references listed in Annex K.

2 Definitions, symbols, and abbreviations

For the purpose of this recommended practice, the following definitions apply.

- 2.1 absorb:** To take up or receive in a vapor or gas by chemical or molecular action.
- 2.2 absorbent surgical towel:** Typically, a low-lint, 100 % cotton, surgical towel woven with a plain weave (1:1).
- 2.3 action level:** 1) For certain chemicals, the airborne concentration of an air contaminant, calculated as an 8-hour time-weighted average (TWA), above which particular monitoring, medical surveillance, or other stated OSHA requirements apply. 2) Concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels. See also **excursion limit** and **permissible exposure limit**.
- NOTE—The action level for EO is currently set by OSHA at 0.5 ppm, calculated as an 8-hour TWA.
- 2.4 adsorb:** To collect a gas, liquid, or dissolved substance in condensed form on a surface.
- 2.5 aerator, ethylene oxide:** Machine designed to speed up the removal of EO residuals from sterilized items by subjecting them to warm, flowing air.
- 2.6 AIA:** American Institute of Architects.
- 2.7 air flow:** Air movement as measured in volume of air per unit time (e.g., cubic feet per minute or liters per second).
- 2.8 air gap:** Space left between the sterilizer vent termination and the drain pipe.

NOTE—Plumbing codes require that sterilizers venting to sanitary floor drains cannot be hard plumbed into the sewer system.

- 2.9 air velocity:** Air-flow rate as measured by the average distance that air travels per unit time (e.g., feet per second).
- 2.10 asepsis:** Prevention of contact with microorganisms.
- 2.11 best available control technology:** Control measures designed to reduce emissions to the lowest level achievable, not as a specific technology but rather as a level of control based on considerations of risk, control device applicability, demonstrated control efficiency, availability of control equipment, and cost.
- 2.12 bioburden (bioload or microbial load):** Population of viable microorganisms on or in a product and/or a sterile barrier system.

NOTE—When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.

- 2.13 biofilms:** An accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily (Donlan, 2002).

NOTE—Some microscopic organisms have the ability, when growing in water or aqueous solutions or *in vivo* (e.g., the bloodstream), to adhere to a surface and then exude over themselves a polysaccharide matrix. The matrix contains cells, living and dead, as well as polysaccharide (sometimes referred to as “glycocalyx”) and prevents antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells.

- 2.14 biological indicator (BI):** Test system containing viable microorganisms and providing a defined resistance to a specified sterilization process.

NOTE—Biological indicators are intended to demonstrate whether conditions were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

- 2.15 calibration:** Set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

- 2.16 ceiling limit:** According to OSHA, “the employee’s exposure [to an air contaminant] which shall not be exceeded during any part of the work day. If instantaneous monitoring is not feasible, then the ceiling shall be assessed as a 15-minute time weighted average exposure which shall not be exceeded at any time over a working day” (29 CFR 1910.1000). See also **threshold limit value (TLV®)**.

- 2.17 central service department:** Department within a health care facility that processes, issues, and controls medical supplies, devices, and equipment, both sterile and nonsterile, for some or all patient care areas of the facility. Also known as **sterile processing department**.

2.18 CFR: Code of Federal Regulations

2.19 challenge test pack: Test pack used by the manufacturer or other service provider, in cooperation with the health care facility, for qualification testing after installation, relocation, major redesign, malfunctions, or major repairs of the sterilizer. See also **process challenge device**.

2.20 chemical indicator (CI): Test system that reveals change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process.

NOTE—Chemical indicators are intended to detect potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The “pass” response of a CI does not prove that the item accompanied by the indicator is sterile.

ANSI/AAMI/ISO 11140-1, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines six classes of CIs and specifies performance requirements for them:

Class 1 (process indicators): chemical indicators intended for use with individual units (e.g., packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units.

Class 2 (indicators for use in specific tests): chemical indicators intended for use in specific test procedures (e.g., the Bowie-Dick test) as defined in relevant sterilizer/sterilization standards.

Class 3 (single-variable indicators): chemical indicators designed to react to one of the critical variables and intended to indicate exposure to a sterilization process at a stated value of the chosen variable.

Class 4 (multi-variable indicators): chemical indicators designed to react to two or more of the critical variables and intended to indicate exposure to a sterilization process at stated values of the chosen variables.

Class 5 (integrating indicators): chemical indicators designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs.

Class 6 (emulating indicators): cycle verification indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specified sterilization process.

NOTE—This edition of ANSI/AAMI ST41 does not cover the use and application of Class 6 emulating indicators.

See also 10.5.2.

2.21 contaminated: State of having been actually or potentially in contact with microorganisms.

NOTE—As used in health care, the term generally refers to microorganisms that could be capable of producing disease or infection.

2.22 culture: 1) Growth of microorganisms in or on a nutrient medium that supports their multiplication. 2) to grow microorganisms in or on such a medium.

2.23 culture medium: Substance or preparation used to grow and cultivate microorganisms.

2.24 cycle, sterilization: Defined sequence of operational steps that are designed to achieve sterilization and are carried out in a sealed chamber. See also **cycle time**.

2.25 cycle time: Total elapsed time of a sterilization cycle from the time the sterilizer door is closed and the process is initiated until the cycle is completed and the door is opened.

NOTE—Cycle time includes prevacuum time, humidification time, exposure time, and postvacuum time and may include airwash and/or aeration time if those steps are performed in the sterilizer chamber.

2.26 decontamination: According to OSHA, “the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal” (29 CFR 1910.1030).

NOTE—The term is generally used in health care facilities with reference to all pathogenic organisms, not just those transmitted by blood.

2.27 decontamination area: Area of a health care facility designated for collection, retention, and cleaning of soiled or contaminated items.

2.28 dedicated exhaust line: Ductwork or tubing that leads from an interior building site to the exhaust termination or exhaust source and that is used solely to provide an exhaust path for the subject source.

2.29 dedicated local exhaust ventilation system: Exhaust ventilation system comprising hoods, ductwork, and an exhaust fan that removes air and air contaminants from a localized area; this area may be a single room or a single piece of equipment. The system is used solely to provide a means of exhaust ventilation for the subject sites.

2.30 diffusion restricter: Device or material that by its composition or geometry impedes the movement of gases (e.g., ethylene oxide, air).

2.31 distilled water: Water that has been heated to the boiling point, vaporized to remove nonvolatile impurities, cooled, condensed into a liquid condensate, and collected and stored so that no impurities are reintroduced.

2.32 door capture zone: Position of the door defined by the manufacturer to be within the influence of the gas-scavenging door hood vented to the dedicated exhaust system.

2.33 dust cover: Protective plastic bag used to maintain the sterility of an item by protecting it from environmental contamination such as moisture, dust, and lint; also known as a **sterility maintenance cover**.

2.34 EBZ: Employee breathing zone. See 2.36.

2.35 EL: Excursion limit. See 2.40.

2.36 employee breathing zone (EBZ): According to the OSHA *Industrial Hygiene Technical Manual* (OSHA 1984), sphere approximately 2 feet in diameter surrounding the head.

NOTE—The term is commonly used by industrial hygienists and safety professionals to refer to the air around a worker's nose. Air samples collected from the shoulder or lapel are assumed to assess a worker's breathing zone exposure to air contaminants.

2.37 engineering controls: Physical, mechanical, or electrical systems (e.g., proper ventilation, materials, equipment) that reduce the potential for worker exposure to EO.

NOTE—OSHA defines three elements of "engineering control measures": enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials (29 CFR 1910, 1915, 1926).

2.38 EO: Ethylene oxide.

2.39 EPA: Environmental Protection Agency.

2.40 excursion limit (EL): Maximum concentration of a chemical to which workers can be exposed over a short time period.

NOTE 1—The OSHA-mandated EL for ethylene oxide is currently 5 ppm as a 15-minute TWA.

NOTE 2—Setting a short-term exposure limit (TLV®–STEL) requires the correlation of human mortality with exposure to a toxic chemical. Because no such correlation has been established for EO, use of the term "STEL" is inappropriate in relation to EO.

2.41 exhaust duct: Pipe, tubing, or duct leading from the area of generation of airborne pollutants and eventually discharging the pollutants to the outdoors. The air is moved through the exhaust duct by the exhaust source.

2.42 exhaust source: Motor and fan, or other means of providing air movement, placed so as to cause all the sources of airborne pollutants to be expelled from the building. The exhaust source creates negative pressure, thereby drawing contaminated air into ducts or hoods and propelling it outdoors.

2.43 expiration date: Date that is calculated by adding a specific period of time to the date of manufacture or sterilization of a medical device or component and that defines its estimated useful life.

2.44 expiration statement: Statement, also known as a day-to-day expiration date, indicating that the contents of a package are sterile indefinitely unless the integrity of the package is compromised.

2.45 exposure time: Period for which the process parameters are maintained within their specified tolerances.

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.

2.46 FDA: Food and Drug Administration.

2.47 flame ionization detector: Sensing device that uses a flame to ionize a substance and that detects the resulting electrical charge.

2.48 gram-negative bacteria: Bacteria that are decolorized when stained by Gram's method but take on the color of the counterstain.

2.49 gram-positive bacteria: Bacteria that are not decolorized by Gram's method but retain the original violet color.

2.50 Gram's method of staining: Method of differential staining used in microbiological identification. See also Stanier, Adelberg, and Ingraham (1976).

2.51 HAI: health care–associated infection. See 2.53.

2.52 HCFC: Hydrochlorofluorocarbon. See 2.56.

2.53 health care–associated infections (HAIs): Infections that patients acquire during the course of receiving treatment for other conditions or that health care workers acquire while performing their duties within a health care setting. (See <http://www.cdc.gov/ncidod/dhqp/index.html>.)

2.54 heat sink: Heat-absorbent material; a mass that readily absorbs heat.

2.55 huck towel: All-cotton surgical towel with a honeycomb-effect weave.

NOTE—Both warp and fill yarns are tightly twisted.

2.56 hydrochlorofluorocarbon (HCFC): Compound consisting of hydrogen, chlorine, fluorine, and carbon.

NOTE—HCFCs differ from chlorofluorocarbons (CFCs) in that only some, rather than all, of the hydrogen in the parent hydrocarbon has been replaced by chlorine or fluorine. The most familiar example is known as HCFC-22, which is used as a refrigerant and in many home air conditioners. The hydrogen atom makes the molecule susceptible to attack by the hydroxyl (OH) radical, so a large fraction of HCFCs are destroyed before they reach the stratosphere. Molecule for molecule, then, HCFCs destroy much less ozone than CFCs, and they were suggested as CFC substitutes as long ago as 1976. HCFCs are currently used in some nonflammable EO blends.

2.57 industrial hygienist: Professional trained to anticipate, recognize, measure, evaluate, and control health hazards in the workplace.

2.58 infrared energy: Electromagnetic radiation of wavelength greater than that of the visible, red end of the spectrum.

2.59 installation test: Test conducted by health care personnel to confirm the standard of performance of an EO sterilizer under hospital conditions and to verify proper installation of the equipment.

2.60 ionization: Process of producing an electrical charge on a neutral atom or molecule by adding or removing electrons to produce ions.

2.61 labeling: Any legend, work, or mark attached to, included in, belonging to, or accompanying any medical device or product.

NOTE—According to the U.S. Food and Drug Administration, labeling includes any literature provided with a device as well as all advertising claims published by the manufacturer (including those on the Internet).

2.62 local exhaust hood: System designed to capture contaminated air and conduct it into an exhaust duct system. Also termed **venting hood**.

2.63 lot control number (load control number): Numbers, letters, or a combination of both by which a particular group of products can be traced to a particular manufacturing or sterilization operation.

2.64 material safety data sheet (MSDS): Document specifying the properties of a material, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the material safely.

2.65 medium: See **culture medium**.

- 2.66 microorganism:** Entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses.
- 2.67 MSDS:** Material safety data sheet. See 2.64.
- 2.68 muslin:** Broad term describing a wide variety of plain-weave cotton or cotton-polyester fabrics having approximately 140 threads per square inch.
- 2.69 NFPA:** National Fire Protection Association.
- 2.70 NIOSH:** National Institute for Occupational Safety and Health.
- 2.71 OSHA:** Occupational Safety and Health Administration.
- 2.72 parametric release:** Declaration that product is sterile, based on records demonstrating that the process parameters were delivered within specified tolerances.

NOTE—Parametric release is generally restricted to sterilization processes that have gone through a complete validation process (installation qualification, operational qualification, and performance qualification, with appropriate documentation and review).

- 2.73 PCD:** Process challenge device. See 2.80.
- 2.74 PEL:** Permissible exposure limit. See 2.75.
- 2.75 permissible exposure limit (PEL):** According to OSHA, “limits developed by OSHA to indicate the maximum airborne concentration of a contaminant to which an employee may be exposed over the duration specified by the type of PEL assigned to that contaminant” (29 CFR 1910.1000). See also **threshold limit value**.

NOTE—The PEL for EO is currently 1 ppm (8-hour TWA).

- 2.76 personal protective equipment (PPE):** According to OSHA, “specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment” (29 CFR 1910.1030).
- 2.77 photoionization detector:** Sensing device that uses ultraviolet radiation to ionize certain components of a sample and measures the resulting ion current between two electrodes.
- 2.78 PPE:** Personal protective equipment. See 2.76.
- 2.79 ppm:** Parts per million.

NOTE—Concentrations of trace contaminant gases in the air are commonly measured in parts per million by volume; 1 ppm equals 1 volume of contaminated gas per 1,000,000 volumes of contaminated air (e.g., 5 ppm EO = 5 cubic feet of EO gas per 1,000,000 cubic feet of air). Parts per million is also a measure of the amount of EO residue in absorbent materials after sterilization; 1 ppm EO residue is 1 weight of EO per 1,000,000 weights of solid absorbent (e.g., 5 ppm EO residue = 5 grams of EO per 1,000,000 grams of solid).

- 2.80 process challenge device (PCD):** Item designed to constitute a defined challenge to the sterilization process and used to assess performance of the process.
- 2.81 processing area:** Area of a health care facility in which decontaminated, clean materials, instruments, and other medical devices are inspected, assembled into sets and trays, and wrapped, packaged, or placed into container systems for subsequent sterilization. This area is commonly referred to as the “preparation and packaging area” of the central service department.
- 2.82 pyrogen:** Fever-producing substance.
- NOTE—Debris (usually consisting of cell wall material) from killed microorganisms can be pyrogenic; limiting the bioburden before sterilization minimizes this debris.
- 2.83 qualification test:** As used in this document, a challenge test of the sterilizer performed by the sterilizer manufacturer or other service provider, in cooperation with health care personnel, after (a) installation, relocation, and any major redesign of the sterilizer, and (b) sterilizer malfunctions and major repairs.
- 2.84 quality assurance test:** Periodic test conducted by qualified health care personnel as part of an ongoing quality assurance program and designed to provide a substantial challenge to the sterilizer under actual use conditions.

2.85 restricted access area: Area designed and designated to house equipment that is accessible only to authorized personnel.

2.86 routine test: Simplified quality assurance test that is conducted for each sterilization cycle and that is designed to detect gross malfunctions of the EO sterilizer or improper EO sterilization procedures.

2.87 SAL: Sterility assurance level. See 2.96.

2.88 shelf life: When the term is used with respect to a sterilized medical device, the period of time during which the item is considered safe to use.

2.89 short-term exposure: Brief exposure to an air contaminant during a work day.

2.90 short-term exposure limit (STEL): According to OSHA, “the employee’s 15-minute time weighted average exposure which shall not be exceeded at any time during a work day unless another time period is specified [by OSHA]. If another time period is specified, the time weighted average exposure over that time period shall not be exceeded at any time during the working day” (29 CFR 1910.1000). See also **threshold limit value**.

NOTE—Exposures at the STEL should not be longer than 15 minutes and should not be repeated more than four times per day. There should be at least 60 minutes between successive exposures at the STEL (ACGIH®, 2007a).

2.91 spectrophotometry: Process of identifying and quantifying chemical compounds by measuring the extent to which they absorb electromagnetic energy of various frequencies.

2.92 spore strip: Paper strip that is impregnated with a known population of microorganisms and that meets the definition of **biological indicator**.

2.93 STEL: Short-term exposure limit. See 2.90.

2.94 sterile: State of being free from viable microorganisms.

NOTE—In practice, no such absolute statement regarding the absence of microorganisms can be proven. See **sterilization**.

2.95 sterile storage area: Area of a health care facility designed to store clean and sterile items and protect them from contamination.

2.96 sterility assurance level (SAL): Probability of a single viable microorganism occurring on an item after sterilization.

NOTE 1—SAL is normally expressed as 10^{-n} .

NOTE 2—A SAL of 10^{-6} means that there is less than or equal to one chance in a million (1 in 10^6) that a single viable microorganism is present on a sterilized item. It is generally accepted that a SAL of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers). The sterilizer manufacturer is responsible for ensuring that the sterilizer is capable of achieving the desired SAL. The user is responsible for monitoring the performance of the sterilizer to ensure that it is operating in conformance to the manufacturer’s recommendations.

2.97 sterilization: Validated process used to render product free from viable microorganisms.

NOTE—In a sterilization process, the nature of microbial inactivation is exponential; thus, the survival of a microorganism on an individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

2.98 sterilization area: Area of a health care facility designated to house sterilization equipment, usually steam sterilizers, EO sterilizers, or both.

2.99 sterilizer, ethylene oxide: Sterilizing apparatus that uses EO as the sterilant under defined conditions of gas concentration, temperature, and relative humidity.

NOTE—This recommended practice covers the use of chamber-type EO sterilization systems that provide a source of water vapor to adjust humidity during the cycle and that generally employ changes in pressure both below and above atmospheric levels.

2.100 threshold limit value (TLV®): According to ACGIH®, “Threshold Limit Values (TLVs®) refer to airborne concentrations of substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects” (ACGIH®, 2007a). Three categories of TLVs® are specified by ACGIH®: TLV®–TWA, TLV®–STEL, and TLV®–ceiling (TLV–C).

TLV®–TWA: According to ACGIH®, “the time-weighted average concentration for a normal 8-hour workday and a 40-hour workweek, to which nearly all workers may be repeatedly exposed, day after day, without adverse effect.”

TLV®–STEL: According to ACGIH®, “a 15-minute TWA exposure which should not be exceeded at any time during a workday even if the 8-hour TWA is within the TLV®–TWA. Exposure above the TLV®–TWA up to the STEL should not be longer than 15 minutes and should not occur more than four times per day. There should be at least 60 minutes between successive exposures in this range.”

TLV®–C: According to ACGIH®, “the concentration that should not be exceeded during any part of the working exposure. In conventional industrial hygiene practice if instantaneous monitoring is not feasible, then the TLV®–C can be assessed by sampling over a 15-minute period except for those substances that may cause immediate irritation when exposures are short.”

2.101 time-weighted average (TWA): According to OSHA, “the employee’s average airborne exposure in any 8-hour work shift of a 40-hour work week which shall not be exceeded” (29 CFR 1910.1000). See also **threshold limit value**.

NOTE—The permissible exposure limit for EO is 1 ppm as an 8-hour TWA. Exposures above the 1-ppm limit are permitted if they are compensated for by equal or longer exposures below the limit during the 8-hour work day.

2.102 TLV: Threshold limit value. See 2.100.

2.103 TWA: time-weighted average. See 2.101.

2.104 validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

2.105 venting: Collecting or capturing EO in order to discharge it through a pipe or duct to an area where human exposure can be minimized.

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3 Design considerations

3.1 General rationale

Proper design of EO sterilization areas will help minimize occupational exposure to EO as well as promote efficient work flow. This section describes design criteria specific to EO sterilization processing, including ventilation recommendations. The release of EO within health care facilities is a potentially serious problem. Centralization of EO sterilization processing, containment of EO sterilization areas, adequate ventilation and environmental discharge controls, proper storage of supplies, proper use of alarms, and traffic control can prevent unnecessary or inadvertent exposure of hospital personnel, visitors, and patients to EO.

NOTE—Detailed guidance on the design of central service departments is provided in ANSI/AAMI ST79.

3.2 Centralization

Centralized EO processing, sterilization, and aeration in health care facilities is strongly encouraged. Consistent policies and procedures should be maintained throughout the health care system, with special emphasis on necessary engineering controls, safe work practices, and quality assurance.

Rationale: Ethylene oxide sterilization is a complex and potentially hazardous process requiring sophisticated equipment, adequate space, trained personnel, and ongoing exposure monitoring. Compliance with recent state and local Clean Air regulations restricting the emission of EO into the environment (and compliance with federal regulations that might be enacted in the future) could be prohibitively expensive if EO processing is decentralized. Thus, both safety and cost-effectiveness considerations dictate centralization of EO processing equipment and functions rather than replication in several areas of the health care facility. See also 3.3, Samuels (1978a), Samuels and Eastin (1980), Hancock (1993), Schneider (1997), and Danielson (1998).

3.3 Containment areas

All EO sterilizers and aerators should be located in a containment area that is physically separate from all other work areas. The containment area should be large enough to ensure adequate EO dilution and to accommodate the loading, unloading, and maintenance of sterilizers and aerators. It should be actively ventilated to ensure that under normal conditions, the EO concentration does not exceed the permissible exposure limit (PEL).

Adequate space to allow service access to the equipment must be provided (see also 9.2.3). Figure 1 provides an example of a layout for an EO sterilization area. Outside the EO containment area but in a readily accessible locker or cabinet, respirators and other protective equipment must be stored for use in emergencies. Employee work stations, pack preparation areas, desks, washing areas, lounge areas, and other personnel support areas must be located so as to minimize EO exposure. The acceptability of these locations can be determined through environmental monitoring (see Section 11 and Annex J).

Signs demarcating regulated areas and entrances to regulated areas must be posted and maintained. Such signs must be legible and must bear the following legend:

DANGER
ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED
TO BE WORN IN THIS AREA

Precautionary labels must be affixed to all containers of EO whose contents are capable of causing employee exposure at or above the action level or whose contents may be reasonably foreseen to cause employee exposure above the excursion limit. These labels must remain affixed when the EO containers leave the workplace. The labels must comply with the requirements of 29 CFR 1910.1200(f) of OSHA's Hazard Communication Standard, must include a warning statement against breathing airborne EO, and must bear the following legend:

DANGER
CONTAINS ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD

NOTE—Reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers.

Rationale: Physical containment of the EO sterilization area can significantly reduce incidental personnel exposure to EO. Adequate dilution ventilation can reduce residual EO in the room that is not readily captured by local dedicated exhaust systems or that is released from minor sources. Personal protective equipment designated for use in

emergencies must be readily available but not stored in an area likely to be affected by an EO spill or other emergency. Otherwise, personnel could be exposed to high levels of EO when attempting to retrieve the equipment. The committee considered defining specific minimum distances between EO sterilization-aeration equipment and employee work areas but ultimately concluded that such a detailed specification was not feasible. “Safe” locations for employee work stations and other personnel support areas will depend largely on the specific characteristics of the ventilation system and thus can be determined only by environmental monitoring, as outlined in Section 11 and Annex J. See also 3.2.

The signs and labeling described herein are required by OSHA's Hazard Communication Standard (19 CFR 1910.1200) and Ethylene Oxide Standard (19 CFR 1910.1047).

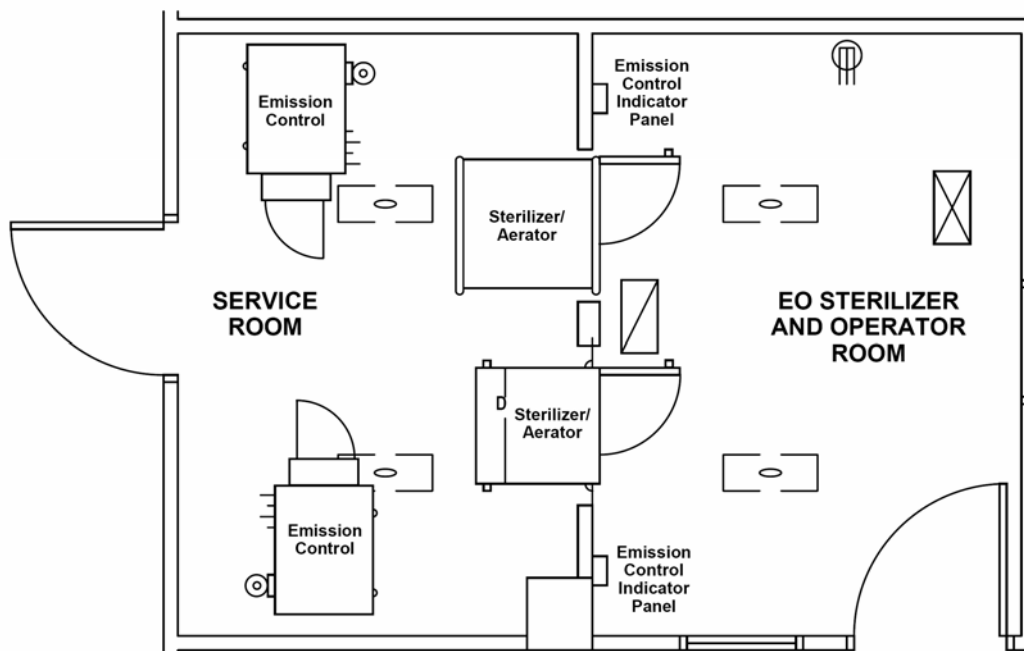


Figure 1—Example of an EO sterilization containment area

3.4 Routing of traffic

Personnel not involved in sterilization processing should be routed around or away from all sterilization and aeration equipment. Such routing can be accomplished by signs and posters, floor paint or tape lines around the equipment area, or temporary or permanent partitions.

Rationale: Traffic control around EO sterilization equipment is an important aspect of infection prevention and control and occupational health and safety. Aseptic practice demands that sterilizers and aerators be operated, and sterile items handled, only by trained personnel directly responsible for sterilization. This principle is equally important for personnel safety, because under normal circumstances only those persons directly involved with EO sterilization will be familiar with safe handling techniques and potential hazards. Demarcating areas where the PEL for EO could be exceeded and limiting access to those areas should significantly reduce incidental personnel exposure to EO. Tape lines will serve as visual reminders to personnel.

3.5 Sterilizer access area

Sterilizer access areas must have restricted personnel access in accordance with the “regulated area” provisions of the OSHA standard. No one should be permitted in a sterilizer access area when the sterilizer is exhausting. At those times, the area should be monitored to ensure the safety of sterile processing and maintenance personnel.

Rationale: See 19 CFR 1910.1047, provided in Annex A.

3.6 Storage of supplies

As part of traffic control, supplies should not be stored in the immediate vicinity of sterilization and aeration equipment. Nothing other than EO gas sources in use should be kept in the sterilizer equipment access area behind wall-mounted sterilizers or aerators.

Rationale: A report issued by the National Institute of Occupational Safety and Health (Glaser, 1977) indicated concern about the storage of general stock near the sterilizer, where passive personnel exposure to EO could occur during the removal of such supplies. Items stored in the sterilizer equipment access area could also absorb residual EO from the sterilizer exhaust.

3.7 Temperature

General work areas should have a temperature controlled between 20 °C and 23 °C (68 °F and 73 °F). The decontamination area should have a temperature controlled between 16 °C and 18 °C (60 °F and 65 °F). The temperature in sterilization equipment access rooms should be controlled between 24 °C and 29 °C (75 °F and 85 °F) or as recommended by the equipment manufacturer. The temperature in sterile storage and personnel support areas (e.g., toilets, showers, locker rooms) may be as high as 24 °C (75 °F). Independent monitors should be located in each of the areas where temperature should be controlled; temperature should be recorded daily. Processing personnel in each work area are responsible for monitoring and recording the temperature to ensure that the correct temperature is being achieved.

Rationale: Work areas should be comfortable for properly attired personnel. Comfort is a particular consideration in the decontamination area, where PPE is worn for long periods of time and where temperatures suitable for general work areas may be uncomfortably hot. Because bacteria thrive at high temperatures, cool temperatures in the decontamination area may help minimize bioburden. Although AIA (2006) allows the temperature in clean work areas to be as high as 24 °C (75 °F), the consensus of the AAMI committee was to recommend consistent temperature ranges for all general work areas. Controlling the temperature in sterilization equipment access rooms promotes repeatable operation of the equipment contained within the enclosures. For additional information on temperature control, see AIA (2006).

3.8 Relative humidity

Relative humidity should be controlled between 30 % and 60 % in all work areas except the sterile storage area, where the relative humidity should not exceed 70 %.

NOTE—Ideal relative humidity in the preparation and packaging area is 50 % and should not be less than 35 % for best results in achieving sterilization. In the decontamination area, the recommended range of relative humidity should be maintained to the extent possible, but temporary elevations may occur because of the type and quantity of cleaning and decontamination equipment.

Humidifiers may be installed to maintain the recommended humidity level seasonally (e.g., during the winter months, when the heating system is functioning). If duct humidifiers are located upstream of the final filters, they should be placed at least 4.57 meters (15 feet) upstream of the final filters. For ductwork with duct-mounted humidifiers, there should be a means of water removal. An adjustable high-limit humidistat should be located downstream of the humidifier to reduce the potential for condensation inside the duct. All duct takeoffs should be sufficiently downstream of the humidifier to ensure complete moisture absorption. Steam humidifiers should be used. Reservoir-type water spray or evaporative pan humidifiers should not be used.

Rationale: Relative humidities higher than those recommended can promote microbial growth and thus increase bioburden. A relative humidity lower than 30 % will permit absorbent materials to become excessively dry, which can adversely affect certain sterilization parameters (such as EO penetration) and the performance of some products (such as BIs and CIs). Thus, for best results, the committee recommends an ideal relative humidity level of 50 % and a minimum level of 35 %. The recommended range for relative humidity was largely based on AIA (2006).

3.9 Ventilation recommendations for areas housing EO sterilization and aeration equipment

3.9.1 General considerations

Engineering controls, in the form of general room ventilation and local exhaust ventilation, play an important role in controlling personnel exposure to EO. Variables that should be considered in evaluating the overall effectiveness of the ventilation system include

- a) the total exhaust volumetric flow rate (i.e., cubic feet per minute) with respect to room size;
- b) the ratio of makeup air to total exhaust volumetric flow rate;
- c) the concentration of EO in the supply air; and

- d) EO concentrations for an appropriate period of time in selected areas, which will indicate the potential for exposure.

The recommendations in the following paragraphs address ventilation needs for areas housing EO sterilization and aeration equipment, but adequate space for personnel to work and service equipment should also be provided.

3.9.2 Local exhaust ventilation

3.9.2.1 Local exhaust ventilation systems

Local exhaust ventilation (LEV) systems, including the exhaust hood, associated ductwork, and exhaust fan, capture or control contaminants at their source before they can escape into the general work environment. The contaminant is collected in a suitable hood and is exhausted to the outside atmosphere through a fan and duct system. LEV is an accepted, effective industrial hygiene method of controlling the workplace hazards of airborne chemicals.

Rationale: Many studies have demonstrated the effectiveness of LEV systems in reducing EO diffusion and, hence, active and passive EO exposure (e.g., Samuels and Eastin, 1980; Roy, 1981).

3.9.2.2 Local exhaust ventilation parameters

Variables that can affect the efficacy of LEV in reducing EO exposure in the workplace include

- a) dimensions of the LEV hood in relation to the sources to be controlled,
- b) hood design and location,
- c) air-flow patterns between the hood and the sources to be controlled,
- d) hood flow rate and velocity,
- e) capture velocity and ambient air velocity around the sources to be controlled, and
- f) system design specifications.

3.9.2.3 Sites for local exhaust ventilation

The following areas benefit from LEV:

- a) the area immediately in front of the sterilizer door opening;
- b) the area near the EO sterilizer chamber pressure-relief valve, if applicable;
- c) the area immediately above the drain line for sterilizers that discharge to a sanitary floor drain;
- d) the EO gas cylinder connection areas; and
- e) the area near the aerator vent.

See also 9.4.2.2, 9.4.2.3, 9.4.3, 9.4.4, 9.4.5, and 9.5.

Rationale: These sites are the most common areas where high contaminant EO concentrations could occur.

3.9.2.4 Location of exhaust hoods

For sterilizers not factory equipped with integral capture devices, a local exhaust hood should be installed as close to the source of EO as possible. (For some sterilizers, it will be necessary to position the hood above the door; for others, below or alongside the door. The manufacturer should be consulted for recommendations.) The face velocity of air entering the exhaust hood (i.e., the capture velocity) should be high enough to ensure the capture of most of the EO being released. The sterilizer manufacturer, the exhaust hood manufacturer, or a qualified industrial hygienist or engineer with expertise in EO ventilation should be consulted for specific recommendations.

Rationale: The closer the exhaust hood is to the EO source, the smaller the amount of EO that will escape to the workplace environment. Proper placement of the exhaust hood depends on the sterilizer design and on the air-flow patterns. Sterilizer manufacturers are best able to recommend the hood placement that will be most effective for their equipment.

3.9.2.5 Exhaust source

The health care facility should establish that the exhaust capacity of the system (expressed as cubic feet of air per minute) is sufficient to handle the output from all sterilizers, aerators, and exhaust hoods connected to the dedicated exhaust system, while maintaining system operation at or above its nominal flow rate. If a flammable mixture of EO is

being used, the exhaust source (e.g., fan) should be of a nonsparking type, and the local exhaust hood should be electrically grounded to the sterilizer. For flammable EO mixtures, it might also be necessary that electrical equipment meet ANSI/NFPA 70. Exhaust sources near sterilizer doors must be connected to a nonrecirculating or dedicated ventilation system or one that exhausts gases to a well-ventilated equipment room or other room where workers are not normally present.

Rationale: The importance of adequate air movement is described in 3.9.3.5. The provisions concerning nonsparking exhaust sources and electrical grounding are designed to reduce fire hazard. See also Glaser (1977) and 19 CFR 1910.1047.

3.9.2.6 Exhaust ducts

A separate exhaust duct to the outside is required. The exhaust duct should terminate away from areas where people walk or work. The duct should be located at least 7.6 meters (25 feet) away from the building air intake source and must be engineered according to existing codes. A longer distance might be needed in some situations, depending on the direction of prevailing winds and the location of buildings.

NOTE—State or local EO emissions regulations might also dictate a longer distance or prohibit altogether the discharge of EO into the environment. The manufacturer of the sterilizer or aerator should be consulted before a local exhaust system is installed. See also 9.4.2.

Rationale: See ACGIH® (2007b) for further construction details for exhaust ducts, and refer to earlier discussions of the importance of consulting with the manufacturer.

3.9.2.7 Vent system alarms

Consideration should be given to the installation of an alarm or other means (determined in consultation with the health care facility engineer) by which failure or malfunction of the exhaust ventilation system can be detected. It is recommended that the exhaust ventilation system be connected to the emergency power distribution system of the health care facility.

Rationale: Ventilation system malfunctions can cause elevated ambient EO concentrations, and prompt corrective action will be required. Connecting to the health care facility emergency power source will aid in reducing unnecessary exposure to EO in case of a power failure.

3.9.3 General room ventilation

3.9.3.1 Ventilation parameters

Variables that can affect the efficacy of general room ventilation in reducing EO levels include

- a) the size and layout of the department,
- b) the location of supply air inlets and exhaust outlets,
- c) the air-flow rate at each inlet and outlet,
- d) air-flow patterns within the room, and
- e) system design specifications.

3.9.3.2 Ventilation systems

A positive differential air pressure with respect to areas outside the clean area of the department should be maintained. If the EO equipment is flush mounted into a wall, the mechanical access area behind the wall should be under negative pressure.

Rationale: Positive differential pressure protects clean-area supplies from outside contamination. Negative pressure in mechanical access areas protects personnel from EO exposure.

3.9.3.3 Minimum room size

The room in which the sterilizer and aerator are located should be large enough to ensure adequate EO dilution and to accommodate the loading, unloading, and maintenance of the sterilizer. See also 3.3.

Rationale: Dilution ventilation can reduce residual EO in the room that is not captured by local exhaust systems or that is released from minor sources. The committee decided that room size should be addressed here to discourage

the use of closets as EO sterilization facilities, a practice that was revealed in the NIOSH study (Glaser, 1977) and other studies.

3.9.3.4 Air flow

Locating sterilization equipment in proper relationship to room air intakes and exhausts helps ensure adequate ventilation of the area housing the sterilizer. The rate and direction of exhaust air flow in the immediate vicinity of sterilizers and aerators should be measured to verify that there is adequate air flow away from sterilizer operators and other personnel in the sterilization area and that air flows into the mechanical access area.

Rationale: See 3.9.3.2 and 3.9.3.3.

3.9.3.5 Air exchanges

A minimum of 10 total air exchanges per hour is recommended for areas housing EO sterilizers and aerators.

Rationale: The recommended number of air exchanges per hour was selected on the basis of the consensus of the committee regarding the minimum air exchange rate necessary to effectively reduce environmental microbial contamination by air dilution. A well-ventilated EO sterilization area can also help reduce passive exposure to EO. General ventilation, however, should never be relied on as the only means of reducing EO concentrations to safe levels. Local exhaust ventilation and proper operating practices, in addition to the proper venting of EO sterilizers and aerators to the outside, are the most important methods of reducing EO concentrations, and thus EO exposure, in the workplace. See also Glaser (1977) and AIA (2006).

3.9.3.6 Ventilation monitoring

Because general ventilation is essential for EO sterilization areas, ventilation rates should be monitored and documented at least annually by the health care facility engineer, other qualified in-house personnel, or an outside contractor. One measure of general ventilation performance is the ratio of the total volumetric flow rate exhausted from the room to the room volume. Assessing general ventilation should take into account such factors as the floor plan; the dimensions of the EO sterilization area; supply air inlet and exhaust air outlet locations and volumetric flow rates; and the air flow between and around possible EO release points, work stations, and ventilation openings. If possible, the system design specifications for duct sizing, fan ratings, and makeup air or recirculation parameters should be obtained. The monitoring results should be compared to the system design specifications to determine if the system is functioning as designed.

Rationale: Monitoring is necessary to verify ongoing compliance with the recommendations of 3.9.3.4 and 3.9.3.5.

3.10 Emergency eyewash and shower equipment

Suitable eyewash and shower equipment must be available, with unobstructed access, for immediate emergency use in all locations where EO and other chemicals are used. The eyewash and shower station must not be located within the EO containment area. Eyewash and shower equipment, other safety gear, and EO monitoring controls must be located in an area deemed to be near and safe.

The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units and shower equipment (ANSI Z358.1). ANSI Z358.1 requires that eyewash units provide a minimum of 0.4 gallons per minute continuously for at least 15 minutes, that they be designed to flush both eyes simultaneously, and that they have a "hands free, stay open" feature once activated. Under the ANSI standard, drench hoses or eyewash bottles are not acceptable emergency eyewash units. Emergency eyewash units should be located within 10 seconds' travel time of all chemical usage locations; for a strong acid or strong caustic, the eyewash unit should be immediately adjacent to the hazard. The eyewash facilities should be identified with a highly visible sign, should be maintained in accordance with the manufacturer's instructions, and should be tested routinely to ensure proper operation. Before attempting to implement the ANSI standard, health care personnel should consult the standard itself to familiarize themselves with all of its provisions.

Rationale: Emergency eyewash and shower equipment should be readily accessible to provide first aid to employees exposed to injurious chemicals and materials. However, it must not be located within an EO containment area, because employees will have to immediately vacate the area in the event of an EO leak or spill. OSHA requires the availability of eyewash units for immediate emergency use. Proper maintenance of eyewash units is necessary to ensure adequate performance and to prevent contamination. See also OSHA's Eye and Face Protection Standard (29 CFR 1910.133), OSHA's Medical and First Aid Standard (29 CFR 1910.151), OSHA's Ethylene Oxide Standard (21 CFR 1910.1047), and ANSI Z358.1.

3.11 Environmental discharge controls

3.11.1 Ethylene oxide

Many local jurisdictions require engineering controls to reduce airborne emissions of toxic substances, such as EO, through the application of best available control technology.

Several emission control technologies are available for use in health care facilities. All are based on the assumption that reducing toxic gas to an acceptable level will be accomplished before the sterilized materials are released from the system. That system removes the EO and diluent gas (if used) while the materials are enclosed in the sterilizing chamber. The concentration of EO in the exhaust stream strongly influences the applicability and efficiency of the various control technologies that are available. Sterilization-phase exhaust is typically a high-concentration, low-volume stream, whereas aeration-phase exhaust is typically a low-concentration, high-volume stream. Some control systems direct both high-concentration, sterilization-phase exhaust and low-concentration, aeration-phase exhaust to the same emission control device. Others separate the two, diverting the flow to an emission control device appropriate to the flow conditions and concentration. Ventilation ducting around the sterilizer is used to capture EO emissions in the event of equipment failure or to capture EO emissions from sterilizers that emit sterilant into the work environment when the sterilizer door is opened. These ventilation ducts are usually routed to the aeration-phase emission control device.

Some states and local authorities also prohibit the discharge of EO and its byproducts into the wastewater stream. Such regulations might dictate the use of a recirculating vacuum pump system with the sterilizer.

Rationale: See Annex B.

3.11.2 Ethylene glycol

Ethylene glycol, a low-hazard substance, is generated in low concentration as a byproduct of EO reacting with water. Several options are available for disposal of ethylene glycol: disposal through a commercial waste disposal company, reclamation for recycling, and neutralization under local permit for discharge to the sewer system. The volume of ethylene glycol produced in hospital sterilizer operations is typically very small.

Rationale: See Annex B.

3.11.3 Hydrochlorofluorocarbons

Until recently, many health care facilities used “12/88” EO mixtures (i.e., mixtures of 12 % EO and 88 % chlorofluorocarbon-12 [CFC-12]) as the sterilizing agent. Chlorofluorocarbon-12 is an ozone-depleting hydrocarbon, and its production and use have been severely restricted. HCFC substitutes for CFC-12 have been developed for use as EO diluents. These substitutes are also ozone depleting, although to a much lesser extent than CFC-12, and might be subject to emission control requirements. Health care personnel are advised to keep abreast of state and local regulations regarding HCFCs.

Rationale: See Annex B.

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4 Personnel considerations

4.1 General rationale

This section provides guidelines for personnel qualifications, training, and education, as well as minimum criteria for personnel health, personal hygiene, and attire. For worker safety and for reliable assurance of the sterility of processed items, it is important that all aspects of EO sterilization processing be performed and supervised by qualified, knowledgeable personnel with demonstrated competency. The other personnel considerations covered in this section are key elements in minimizing bioburden and containing environmental contamination, which are essential for effective sterilization.

4.2 Qualifications

4.2.1 Supervisory personnel

All preparation and sterilization activities, including decontamination, inspection, preparation, packaging, sterilization, storage, and distribution, should be supervised by competent, qualified personnel. Personnel assigned to supervisory functions should be prepared for this responsibility by education, training, and experience. Minimum recommended qualifications include

- a) successful completion of a central service management certification examination;

NOTE—Information concerning certification of central service processing managers and technicians can be obtained from the Certification Board for Sterile Processing and Distribution (2 Industrial Park Road, Suite 3, Alpha, NJ 08865; 800-555-9765; <http://www.sterileprocessing.org>); the International Association of Healthcare Central Service Materiel Management (213 Institute Place, Suite 307, Chicago, IL 60610; 312-440-0078; <http://www.iahcsmm.org>); or the National Health Information Center (P.O. Box 1133, Washington, DC 20013; <http://www.health.gov/nhic>).

- b) demonstration of current knowledge and adequate relevant experience in health care or hospital-related work;
- c) participation in continuing education programs and courses, including programs on federal and local regulations; personnel and material management programs; programs on financial management and leadership skills; and courses directly related to the management position, with special emphasis on the following: personnel safety; health risks of exposure to EO; safe use of EO, including current regulations; and decontamination, sterilization, and storage and distribution of sterile medical devices;
- d) demonstration of comprehensive knowledge of pertinent state and federal regulations, particularly OSHA regulations related to occupational exposure to bloodborne pathogens (29 CFR 1910.1030) and EO (20 CFR 1910.1047), including specified methods of compliance, such as an exposure control plan, use of standard and transmission-based precautions, and engineering and work practice controls; and
- e) familiarity with the current literature on EO sterilization.

Supervisory personnel should maintain competency throughout their tenure. In addition to participating in continuing education programs and courses, personnel should

- a) participate in facility and departmental in-service and training programs and
- b) demonstrate and improve their expertise through participation (as a member or resource person) in committees within the health care facility (e.g., risk management, hazardous materials, quality improvement, infection prevention and control, safety, standardization, product evaluation, policy and procedures) and in quality improvement activities.

Rationale: Ethylene oxide sterilization and aeration are complex and potentially hazardous processes that should be supervised by qualified, knowledgeable personnel with demonstrated competency and extensive experience, especially in sterilization processing and infection prevention and control. For both effective processing and their own safety to be ensured, it is important that these personnel be thoroughly familiar with the potential hazards of EO and with techniques to reduce human exposure to EO. Compliance with OSHA regulations will lower the incidence of occupational exposure to bloodborne pathogens and ethylene oxide. Participation of personnel in the product evaluation committee can help prevent the purchase of items that cannot be reprocessed by equipment currently available in the sterile processing department. Certification is a recognized method of initially determining competency.

4.2.2 Sterilizer and aerator operators

The responsibility for EO sterilization and aeration should be assigned to qualified individuals who have demonstrated competence in all aspects of sterile processing: decontamination, preparation, packaging, sterilization, sterile storage, and distribution of sterile medical devices. Qualifications include

- a) demonstrated knowledge of and documented competence in all aspects of decontamination, including sorting, disassembly, reassembly, manual and mechanical cleaning methods, microbicidal processes, equipment operation, standard and transmission-based precautions, and engineering and work practice controls;
- b) demonstrated knowledge of and documented competence in the operation of the specific EO sterilizing system used by the health care facility (a variety of systems are in general use);
- c) demonstrated knowledge of and documented competence in principles of sterilization and infectious disease transmission; infection prevention and control; and all aspects of EO sterilization (including decontamination, inspection, and packaging of items to be sterilized; sterilizing procedures; equipment operation; safety precautions; and aeration requirements); and
- d) demonstrated knowledge of and documented competence in worker safety as it relates to medical device processing and sterilization.

It is recommended that all personnel performing sterile processing activities be certified as a condition of employment. At a minimum, all such personnel should successfully complete a central service certification examination within 2 years of employment and should maintain that certification throughout their employment. See also 4.2.1(a).

Rationale: Sterilizer operators are responsible for final packaging inspection and for the critical step of loading the sterilizer. If aeration inside the sterilizer is not available, operators are also responsible for transferring sterilized items to the aerator on completion of the cycle—the point at which personnel are most likely to be exposed to EO and items are most vulnerable to contamination—and they remain responsible for the items until the items are released for sterile storage or distribution. Ethylene oxide sterilizers present potential health hazards to personnel. Safe handling and operational practices are among the most important means of reducing occupational EO exposure to a safe level. For all these reasons, it is important that sterilizer and aerator operators have special training to ensure effective processing, their own safety, and the safety of others. Documentation of competence provides verification of qualifications and workplace training, as required by regulatory and accrediting agencies.

4.3 Training and continuing education

4.3.1 Sterile processing personnel

4.3.1.1 General considerations

Personnel engaged in sterile processing must receive both an initial orientation and on-the-job training designed to lead to competency-based knowledge and skills in all tasks performed in the sterile processing department. Training should also include orientation in facility and department policies and procedures regarding infection prevention and control, safety, attire, personal hygiene, and compliance with state and federal regulations. For EO sterilizer and aerator operators, this training should specifically include instruction on EO sterilizer operation, loading and unloading procedures, aerator operation, parameters of EO sterilization, safety precautions, and potential hazards. Ethylene oxide evacuation drills should be conducted at least annually. In addition, continuing education should be provided at regular intervals to review and update knowledge and skills of workers and to maintain their competency and certification. Education and training materials and information are available from sterile processing vendors, associations, and journals; in addition, OSHA has education materials available for loan. Personnel should receive in-service training for all new instrumentation, devices, and equipment. All orientation, on-the-job, and in-service training should be documented.

A training manual should document all aspects of training related to the on-site approved protocols. This manual should include checklists to document that training was performed and when competency was achieved. This training manual may reference guidance documents and training modules, but it should be based on the facility's policies and procedures, accepted standards of practice, and manufacturers' recommendations.

Rationale: Orientation training and on-the-job training establish the worker's base of knowledge, while continuing education increases knowledge and skills. Education and training decrease the possibility of operator error during preparation and EO sterilization processing and help ensure that personnel are conversant with the latest data and techniques. Education and training are the most important aspects of any program intended to protect employees from a potential safety hazard. Knowledge of the health risks of exposure to EO will help ensure that sterilizer

operators, aerator operators, and other potentially exposed personnel will adhere to established procedures. Such training is required by OSHA (29 CFR 1910.1047). Hospital policies and procedures are a necessary part of any education and training program, and all personnel should be familiar with and adhere to these policies and procedures. Documentation of training and continuing education is required by the Joint Commission (Joint Commission, 2008), the Healthcare Facilities Accreditation Program (HFAP, 2005), and other organizations recognized by the U.S. Centers for Medicare and Medicaid Services (CMS) as deemed accrediting organizations.

4.3.1.2 In-service training

In-service programs on EO sterilization processing must be regularly scheduled (at least annually) by the health care facility and must be held frequently enough to ensure that all operators, maintenance personnel, and other potentially exposed workers are kept abreast of current technical knowledge and regulatory requirements.

Before a sterilizer, aerator, or sterilizer–aerator is put into service, an in-service training program on its operation and maintenance must be conducted by the equipment manufacturer.

4.3.1.3 Manufacturers' instructions

Operators of EO sterilizers, aerators, and sterilizer–aerators should follow the manufacturers' written instructions.

4.3.1.4 Record keeping

Records, including the names of employees in attendance, must be maintained for the orientation, in-service, and training programs conducted.

4.3.2 Other personnel

Personnel who are not assigned to the sterilization department but who have responsibility for maintaining EO sterilizers, aerators, ventilation systems, or emission control systems or for changing EO supply sources should be trained in safe work practices and engineering controls and should demonstrate competence. Personnel training and continuing education must be documented.

Rationale: Maintenance personnel are especially at risk of exposure to high concentrations of EO and also could be at risk of exposure to toxic chemical agents (e.g., catalysts, acids, bases) used in emission control systems. Consequently, it is particularly important that they be well versed in the work practices and engineering controls that will ensure their safety. Such training is required by OSHA (29 CFR 1910.1047) and by the Joint Commission (Joint Commission, 2008), the Healthcare Facilities Accreditation Program (HFAP, 2005), and other organizations recognized by the U.S. Centers for Medicare and Medicaid Services as deemed accrediting organizations.

4.4 Personnel health

4.4.1 General considerations

Written policies on personal hygiene should be developed and communicated to employees. Such policies should be approved by the infection prevention and control department, the office safety manager, or the designated person in charge of employee health. Hand hygiene procedures should be specified. Hair, body, and nails should be clean at all times. Neither nail polish nor artificial nails should be worn. Fingernails should be kept short and clean and should not extend beyond the fingertips (CDC, 2002; AORN, 2008c). Uniforms or other garments that become soiled or wet during wear should be changed immediately. In collaboration with the health care facility's infection prevention and control committee or the facility's designated infection prevention and control authority, the department should establish a written policy on the reporting, treatment, and disposition of employees who are at risk of acquiring or transmitting infections. Exposures to bloodborne diseases should be handled in accordance with OSHA regulations and current Centers for Disease Control and Prevention (CDC) recommendations.¹ Personnel who can potentially come into contact with items contaminated with blood or other potentially infectious material (occupational exposure) should be encouraged to accept hepatitis B immunization. Any employee who declines immunization should sign the hepatitis B vaccine declination statement required by OSHA.

Rationale: Careful attention to employee health, safety, and personal hygiene will minimize the potential that employees will acquire or transmit disease. Nail polish can flake off, and the flakes can get into items being prepared; artificial nails can promote the growth of fungus under the nails (Baumgardner, et al., 1993; CDC, 2002; Jeanes and Green, 2001; Porteous, 2002; Saiman, et al., 2002). Vaccinations provide backup protection when there has been a failure in work practices or when an unexpected event occurs. Vaccination against hepatitis B will protect personnel from this serious disease, and OSHA requires that hepatitis B vaccination be offered free of charge to personnel who

¹ Information on CDC recommendations regarding exposures to bloodborne diseases can be obtained by checking the CDC web site at <http://www.cdc.gov/ncidod/hip/guide/phssep.htm> or by calling the CDC at 1-800-311-3435.

could come into contact with blood or other potentially infectious material in performing their jobs (29 CFR 1910.1030). Other immunization could become appropriate or mandatory in the future.

4.4.2 Information concerning the potential hazards of exposure to EO

4.4.2.1 General considerations

Upon assignment to the EO sterilization department and at least annually thereafter, each worker must be informed of the possible health effects of exposure to EO. This information must include an explanation of OSHA requirements (29 CFR 1910.1047) and must identify the areas and tasks in which there is potential exposure to EO. Workers must also be notified if they have been exposed to EO at levels above the PEL.

NOTE—Persons with occasional potential exposure to EO, such as maintenance personnel and cylinder handlers, should receive the same information.

Rationale: Potential health hazards are associated with the use of EO. The OSHA standard mandates the dissemination of information on health risks to employees.

4.4.2.2 Health effects of short-term exposure to EO

Exposure to EO can cause acute reactions such as skin, eye, or mucous membrane irritation. Exposure to EO in liquid form can cause chemical burns or severe irritation of the skin if contact with EO is prolonged; frostbite-like symptoms can also occur, because of the rapid evaporation of EO from the skin surface. Liquid EO can also cause eye irritation and injury to the cornea. Ingesting EO can cause stomach irritation and liver damage. Acute effects of inhaling EO vapors include respiratory tract irritation and lung damage, headache, nausea, vomiting, diarrhea, shortness of breath, cyanosis, and even death.

4.4.2.3 Health effects of long-term exposure to EO

With respect to chronic, long-term exposure, there are concerns that EO could be mutagenic or carcinogenic or that it could adversely affect the reproductive system.

NOTE—See Steenland et al. (1991) and the OSHA standard (29 CFR 1910.1047) for a more detailed summary of known potential health effects in humans of long-term exposure to EO.

4.4.2.4 Health effects of exposure to EO residuals

Excessive levels of residual EO or EO byproducts (ethylene glycol, ethylene chlorohydrin) on medical devices can be harmful. Anyone exposed to items such as prosthetic devices, instruments, or catheters that have been improperly aerated can experience serious chemical burns or tissue irritation.

4.4.3 Medical surveillance and treatment

4.4.3.1 Routine medical examinations

Employees who are exposed to EO at or above the action level (0.5 ppm) for at least 30 days per year, even if an approved respirator is used, must have medical examinations at least annually. All examinations and procedures must be performed or supervised by a licensed physician at a reasonable time and place and at no cost to the employee. Although broad latitude in prescribing specific tests to be included in the medical surveillance program is extended to the examining physician, OSHA requires that the following elements be included in the routine examination:

- a) medical and work histories, with special emphasis on symptoms related to the respiratory, blood, nervous, and reproductive systems and the eyes and skin;
- b) physical examination, with particular emphasis on the respiratory, blood, nervous, and reproductive systems and the eyes and skin;
- c) complete blood count, including at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin measurement; and
- d) any laboratory or other test that the examining physician deems necessary on the basis of sound medical practice.

At the employee's request, the medical examination must include pregnancy testing or a laboratory fertility evaluation as deemed appropriate by the physician.

In certain cases, to provide sound medical advice to the employer and the employee, the physician might find it necessary to evaluate situations not directly related to EO exposure. For example, employees with skin diseases might be unable to tolerate wearing protective clothing. In addition, those with chronic respiratory disease might not tolerate wearing negative-pressure (air-purifying) respirators. Additional tests and procedures that will help the physician determine which employees are medically unable to wear such respirators should include an evaluation of cardiovascular function, a baseline chest x-ray to be repeated every 5 years, and a pulmonary function test to be repeated every 3 years. Medical records are confidential; information discovered during the course of an examination not related to EO concerns must not be disclosed to anyone but the worker.

Rationale: Routine medical examinations of EO workers are necessary to detect adverse health effects and to comply with the OSHA standard.

4.4.3.2 Medical examinations for acute exposures

Accidental excessive exposure to EO by inhalation or skin contact (e.g., as a result of a leaking EO canister, a spill, a malfunctioning ventilation system) must be recorded. Inhalation levels higher than those specified by OSHA set in motion a variety of record-keeping, medical surveillance, and other requirements (29 CFR 1910.1047). In cases of accidental acute exposure, a medical examination is necessary. A physician examining personnel exposed to excessive EO must document the extent and degree of inflammatory changes in involved tissues. Inflammatory changes clear within several hours or within 2 to 3 days, depending on the severity of involvement. In severe instances, anti-inflammatory medications might be useful. See also 9.9.4.

Rationale: Guidelines for medical examinations are provided here for general information in response to requests from reviewers. See the OSHA standard (provided in Annex A) for more detailed information.

4.4.3.3 Record keeping

Medical records and records of employee exposures to EO must be maintained in accordance with local, state, and federal regulations. Health care facilities are required to provide an employee's exposure records to the employee's physician on written request.

Rationale: These record-keeping requirements are based in part on OSHA regulations (29 CFR 1910.20).

4.4.4 First aid

See 9.9.4.

4.5 Attire

4.5.1 General considerations

All personnel entering the decontamination, preparation, sterilization, and sterile storage areas should wear clean uniforms that are provided by and donned at the facility. Attire should be changed daily or more often as needed (i.e., when wet, grossly soiled, or visibly contaminated with blood or body fluids). Reusable uniforms that are visibly contaminated by blood or body fluids must be laundered in the laundry facility or area designated by the health care facility for decontaminating reusable surgical textiles (see ANSI/AAMI ST65).

Shoes worn in the department should be clean, should have non-skid soles, and should be sturdy enough to prevent injury if an item drops on the foot. All head and facial hair (except for eyebrows and eyelashes) should be completely covered with a surgical-type hair covering. Jewelry and wristwatches should not be worn in the decontamination, preparation, or sterilization area. The policy on use of cover apparel when employees leave the department to travel to other areas of the health care facility should be determined by each facility and should comply with state and local regulations. Employees should change into street clothes whenever they leave the health care facility or when traveling between buildings located on separate campuses.

Rationale: Appropriate, clean attire minimizes the introduction of microorganisms and lint from personnel to items being processed and to the environment. Controlled laundering of garments contaminated by blood or body fluids reduces the risk of transferring pathogenic microorganisms from the health care facility to home and family.

Jewelry should not be worn because it is not easily or routinely cleaned daily, it can harbor microorganisms, it can become dislodged and fall into processed items, and it can cause holes in gloves or other barrier protection. Wristwatches and rings, in particular, can catch on equipment or instruments, injuring personnel or damaging the item or packaging.

4.5.2 Decontamination area

The OSHA bloodborne pathogen regulation (29 CFR 1910.1030) requires that each facility have in place an exposure control plan that outlines the potential hazards that personnel may encounter while on the job. The plan must also identify the engineering controls, work practice controls, and preventive and postexposure medical care procedures that will be used to maintain the safety and health of employees. In the decontamination area, these measures will include the use of PPE. In addition to the attire recommended in 4.5.1, personnel working in the decontamination area should wear general-purpose utility gloves and a liquid-resistant covering with sleeves (for example, a backless gown, jumpsuit, or surgical gown). If there is any risk of splash or splatter, PPE should include a fluid-resistant face mask and eye protection. PPE used to protect the eyes from splash could include goggles, full-length face shields, or other devices that prevent exposure to splash from all angles.

Reusable gloves, glove liners, aprons, and eye-protection devices should be decontaminated according to the manufacturer's instructions at least daily and between employees. If the integrity of these materials is compromised, they should be discarded. Torn gloves should be replaced immediately after appropriate hand hygiene. Items worn or used in the decontamination area should be regarded as contaminated. Before leaving the decontamination area, employees should remove all protective attire, being careful not to contaminate the clothing beneath or their skin, and should wash their hands. Employees should also remove and discard hair coverings before leaving the decontamination area. Appropriate areas with the necessary containers should be provided for donning and removing protective attire.

NOTE—Protective attire must be appropriate for the task being performed. In situations that require the highest level of protection (e.g., there is a possibility that attire can become soaked with blood or other potentially infectious material, as when items are being washed by hand), a Level 4 gown (as defined by ANSI/AAMI PB70) should be used.

Rationale: Contaminated instruments and other medical devices are sources of microorganisms to which personnel could be exposed through nicks, cuts, or abrasions in skin or through contact with the mucous membranes of the eyes, nose, or mouth. Appropriate attire will minimize the potential for employee exposure to bloodborne and other disease-producing organisms. PPE and hair coverings might become contaminated in the decontamination area and should be removed when employees leave the area; otherwise, contaminants could be shed onto uniforms or environmental surfaces.

Wearing heavy-duty, waterproof gloves while handling contaminated items greatly decreases the potential for puncture, limits the microbial burden on hands, and decreases the risk of cross-contamination. Gloves do not offer absolute protection, however, because they can develop small leaks because of the stresses of the cleaning process (DeGrott-Kosolcharoen and Jones, 1989); hand hygiene prevents any further contamination of the worker or environment. Personnel should use a style of glove that prevents contact with contaminated water; for example, gloves that are too short or lack cuffs allow water to enter when the arms move up and down. General-purpose utility gloves may be decontaminated and reused, but they should be discarded if there is evidence of deterioration (e.g., punctures, peeling, or cracking). When the integrity of reusable gloves, aprons, or protective eyewear is compromised, they cease to function as a protective barrier. See also FDA's *Guidance for industry and FDA staff—Medical glove guidance manual* (<http://www.fda.gov/cdrh/ocerguidance/1661.html>).

Fluid-resistant face masks protect personnel who are cleaning contaminated items from splash or splatter that contains pathogens. Eye protection reduces the risk of eye contact with microorganisms and eye injury from hazardous chemical agents. Liquid splashes and aerosols can contact the eyes from any direction, including settling out of the air from above. Liquids can act as vehicles for the transfer of microorganisms from soiled materials and from the skin of personnel; therefore, wet surgical attire should be considered contaminated.

Under OSHA regulations, some discretion is provided for the use of masks and eye protection. However, the committee feels that these protective devices should be worn any time biohazardous materials are being handled if exposure is not prevented by engineering controls (such as the use of pneumatic tubes with plastic shielding for sorting soiled laundry). Donning and removing PPE can itself be a source of contamination and thus should be minimized. A face mask is considered contaminated on use; it can promote the spread of microorganisms if it is worn hanging around the neck, stuffed into a pocket, or perched on the forehead.

4.5.3 Service personnel

The health care facility is responsible for providing PPE for all service personnel and for ensuring that used, contaminated PPE is decontaminated, is disposed of properly, or both. Such equipment must comply with OSHA regulations and can include protective gloves, protective attire, face shields, and surgical face masks. PPE should be worn whenever the service person is working on or demonstrating equipment that might be contaminated and whenever the service person is in doubt about the safety of a particular piece of equipment.

Rationale: Personal protective equipment will minimize the possibility of acquiring infectious diseases. The selection and proper use by the worker of the appropriate PPE for the activity being performed are important in protecting service personnel from bloodborne pathogens. Even employees who are adequately protected against hepatitis B by vaccination are at risk of exposure to other infectious diseases.

4.5.4 Prevention of occupational exposure to EO

See 9.10.

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5 Receiving

5.1 General rationale

Sterility assurance “begins at the loading dock”—that is, at the point at which the health care facility assumes responsibility for incoming medical equipment, devices, and supplies. Therefore, sterility assurance measures should be used from the time that items are received into the health care facility until they are used.

5.2 Receiving of purchased or loaner items

5.2.1 General considerations

Policies and procedures for receiving purchased or loaner items should be developed, implemented, and audited. Audits should be scheduled and documented. Clean or sterile items should be handled separately from foodstuffs, waste material, soiled laundry, and other potential sources of contamination. Individual items may be protected by storing bulk items in shipping cartons in the central receiving area. Clean or sterile items to be transported to central processing and storage areas within the facility should be removed from their external shipping containers before they enter the storage areas of the department. Any instructions for use accompanying the items should be kept with the items. When loaner items are delivered to the receiving area, personnel should document that, according to the packing slip, the correct number of packages has been received. Under no circumstances should the packages be opened. The packaged items, along with any instructions for use, should be delivered to the central service area as soon as possible.

Rationale: External shipping containers have been exposed to unknown and potentially high microbial contamination. Shipping cartons, especially those made of corrugated material, serve as generators of and reservoirs for dust.

5.2.2 Newly purchased reusable items and repaired reusable items

Newly purchased or repaired reusable items require decontamination before sterilization. After removing instruments from the external shipping containers, personnel should inspect them to ensure that they meet the required specifications and that instructions for use have been provided and then transport them, together with the instructions for use, directly to the decontamination area. The manufacturer's processing instructions should be followed. Personnel should verify that the processing instructions provided by the manufacturer represent cycle parameters available in current sterilization equipment.

Rationale: Many reusable medical devices are manufactured in an environment in which bioburden is not rigorously controlled, and some are handled extensively during the manufacturing process. Consequently, to ensure that sterility can be achieved, personnel should reduce the bioburden by cleaning the device before packaging it for sterilization. Anticorrosive agents such as oils or greases might have been left on the device by the manufacturer to protect it during shipping, and such agents will interfere with sterilization if they are not removed. External shipping containers should be removed before items are transported to processing areas because the containers have been exposed to unknown and potentially high microbial contamination. In addition, shipping cartons, especially those made of corrugated material, serve as generators of and reservoirs for dust. New or repaired items should be inspected before decontamination so that they can be returned to the vendor in the condition and packaging in which they were received if they do not meet the required specifications.

5.2.3 Rigid sterilization container systems

Each rigid sterilization container system should be thoroughly inspected upon receipt in the central service department:

- a) All gaskets should be free of breaks, cracks, or cuts. Each gasket should be properly secured and should mate evenly at joining surfaces.
- b) All filter material should completely cover the perforated area, and the device holding the filter in place should provide a tight, uniform seal that keeps the filter from dislodging.
- c) The latching mechanism should secure the lid so that it cannot move when locked. A method of demonstrating that the latching mechanism has not been opened after sterilization and before use is preferred.
- d) Rivets and screws should be secure and show no evidence of damage or corrosion.

Rigid sterilization container systems should be cleaned and decontaminated according to the manufacturer's instructions before initial use.

Rationale: Receiving inspection verifies that the rigid sterilization container system has arrived in proper working order.

5.2.4 Disposable items

After they have been removed from their external shipping containers, prepackaged sterile items or prepackaged clean, nonsterile items (e.g., 4" × 4" gauze sponges or packaging materials used for preparing procedure trays) may be received directly into preparation or sterile storage areas without further cleaning.

Rationale: Sterile disposable items received from manufacturers are usually individually packaged for dispensing. Clean, nonsterile disposable items are usually packaged for sterilization, or they have been otherwise protected from contamination during transport. They are generally manufactured in an environment in which the bioburden is controlled, so further cleaning is unnecessary.

5.3 Disposition of sterile items (issued but not used)

Unused items that have previously been packaged, sterilized, and issued to a controlled environment such as the operating room (OR) may be returned to the sterile storage area if the integrity of the packaging has not been compromised and there is no evidence of contamination; such items should be the first to be dispensed when needed. Reusable items that have opened or damaged packaging should be unwrapped and reprocessed appropriately in accordance with departmental policies and procedures. Disposable items that have opened or damaged packaging should be discarded; such items should not be reprocessed unless the manufacturer provides written reprocessing instructions and all FDA requirements for the reprocessing of single-use items are met (<http://www.fda.gov/cdrh/reprocessing/>).

NOTE—Unused items returned from the OR or other areas with controlled environments should be transported on a clean closed or covered cart and should not enter the decontamination area.

Unused disposable items that have previously been packaged, sterilized, and issued to patient care units or other environmentally uncontrolled areas should be discarded unless the packaging is intact and impervious and the previous storage conditions are known and acceptable. The items should be inspected carefully for visible soil, tears or holes, wrinkling, broken seals, or wetness before they are returned to the sterile storage area.

Unused reusable items not meeting the above criteria should be unwrapped and reprocessed through the decontamination area.

Rationale: Many of the packaging materials used today are extremely durable. Unnecessary costs may accrue from indiscriminately discarding expensive, disposable medical supplies that are unused and returned in acceptable condition. The recommendations of 5.3 are based on the assumptions that an appropriate packaging material has protected unused sterile items unless the package has been opened or damaged and that the packaged items have been properly handled. Consequently, retrieving and reissuing unused sterile items are recommended only if the environment is controlled and if personnel are knowledgeable about the proper handling of sterile items. The more frequently sterile items are handled, the greater is the risk of contamination; therefore, reissued items should be used as promptly as possible.

The reprocessing of single-use devices by health care facilities is regulated by FDA, and all premarket and postmarket requirements must be met if a health care facility chooses to reprocess a single-use device. Health care facilities are encouraged to keep themselves informed on FDA regulations because changes might occur (see <http://www.fda.gov/cdrh/reprocessing/>).

6 Handling, collection, and transport of contaminated items

6.1 General rationale

This section provides guidelines for segregating and handling contaminated items at the point of use and for transporting contaminated items from the point of use to the decontamination area. The possibility of items being contaminated with infectious material is greatest at the point of use, where they have been in patient contact. Procedures for safely transporting contaminated items are important, because many people—workers, patients, and visitors—can be exposed to potentially disease-producing microorganisms during transport. In addition, the general environment of a health care facility is not controlled, and persons encountered during transport will not be wearing PPE.

Procedures must be developed, with support from the infection prevention and control and hazardous materials committees, to protect personnel, patients, and the environment from contamination and to comply with OSHA regulations limiting occupational exposure to bloodborne pathogens. Process audits should be performed to ensure that the procedures are being followed. Action plans should be developed to address problems noted during the audit, and a follow-up audit should be scheduled to ensure that the problems have been corrected.

6.2 Separation of waste and reusable items at point of use

Reusable items should be separated from waste at the point of use. Contaminated disposable items should be discarded into an appropriate container; puncture-resistant containers must be used for sharps. All items contaminated with blood, body fluids, and tissue must be placed in a leak-proof container before transport. Contaminated reusable items should be contained in such a way that the contents of the containers are readily identifiable as contaminated by everyone who subsequently handles the items. When the outside of a transport container or cart is visibly soiled, it should be decontaminated before transport with an EPA-registered, intermediate-level disinfectant (see Annex D). Containment should comply with the health care facility's established infection prevention and control and hazardous waste management procedures. Procedures that reduce the potential for contaminating personnel, their clothing, and the environment should be developed and followed. Depending on the nature and amount of waste to be separated and the possibility of contamination, it might be necessary for personnel to wear appropriate PPE, such as gloves, protective eyewear, a surgical face mask, and a protective backless gown, jumpsuit, or surgical gown (see 4.5). Other measures may also be adopted for infection control purposes or as part of hazardous waste management. Contaminated items should be handled as little as possible.

Rationale: Used, soiled, contaminated instruments, devices, and supplies are sources of microorganisms that could cause infections in personnel or patients. The infection hazard to personnel is greatest while handling and segregating soiled, contaminated items at the point of use. All medical devices are considered to be soiled and contaminated after each use and to be potential sources of infection caused by hepatitis C virus (HCV), hepatitis B virus (HBV), human immunodeficiency virus (HIV), and other pathogens. Segregating soiled items and waste into separate streams of dispatch at the point of use will minimize handling and therefore minimize the possibility of subsequent personnel exposure to potentially pathogenic organisms. Separation is best done at the point of use by persons aware of the potential for injury from sharps and the potential infection hazards of the contaminated items. Contaminated reusable items, contaminated disposable items and waste, and tissue specimens are placed into specifically labeled containers to prevent exposure of personnel to potentially infectious materials and to prevent contamination of the environment. The specified characteristics of containers for sharps and other contaminated items are based on OSHA regulations (29 CFR 1910.1030).

6.3 Care and handling of contaminated reusable items at point of use

Contaminated reusable items should be handled as little as possible at the point of use. Soiled items should be immediately contained and transported to the decontamination area or soiled utility area, where cleaning procedures can be accomplished away from patient care. In many health care facilities, however, immediate containment, transportation, and cleaning might not be feasible, so gross soil should be removed at the point of use. When handling contaminated items, personnel should wear appropriate PPE (see 4.5) and use work practice controls and engineering controls, as appropriate, to minimize the risk of injury. Soil should be removed by a method that does not promote cross-contamination; for example, personnel should avoid splashing water and thereby contaminating attire, the area near the sink, and other surfaces in the environment. A disposable sponge moistened with water (not saline) should be used to wipe gross soil from instruments. Gauze sponges and similar items used in the cleaning process are contaminated and should be handled, contained, and discarded according to the health care facility's policy for infectious wastes.

To prevent the formation of biofilm, definitive cleaning should occur as soon as possible. If processing is delayed, attention should be given to minimizing bacterial proliferation, including the use of precleaning disinfectants. Even with this step, extremely long delays in processing, such as might occur over a weekend, can result in the formation of

tenacious and difficult-to-remove biofilm that will shield microorganisms from routine cleaning procedures and possibly interfere with disinfection or sterilization.

Rationale: Contaminated items must always be handled so as to minimize potential exposure of workers to disease-producing organisms and contamination of the environment. Immediate containment and transport to a designated area minimizes the risk of employee contact with contaminants and allows the cleaning process to be performed in a controlled environment by personnel who are protected by PPE.

Gross soil is removed as soon as possible in order to (a) reduce the number of microorganisms on the item, (b) reduce the nutrient material that might support microbial growth, (c) reduce the potential for environmental contamination by aerosolization or spillage, and (d) minimize damage to devices from such substances as blood, saline, iodine, and radiological dyes or from the subsequent vigorous cleaning processes needed to remove encrusted material. Because it cannot be known for certain which patients harbor bloodborne pathogens, the use of PPE is necessary for the protection of the health care worker.

Biofilm consists of an accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed. Biofilm has the effect of protecting microorganisms from attempts to remove them by ordinary cleaning methods used in the sterile processing department. Biofilm can form on many surfaces but is particularly problematic in devices with lumens. Once biofilm forms, direct friction, oxidizing chemicals, or both are needed to remove it. Prompt cleaning reduces or eliminates the population of biofilm-forming microorganisms and thus prevents the formation of biofilm. Precleaning disinfectants are appropriate for use in the event of processing delays; however, some disinfectants (e.g., aldehyde-based products) will act as fixatives for debris and make cleaning more of a problem (Merritt, et al., 2000).

6.4 Containment

Contaminated items should be contained during transport from the point of use to the decontamination area. Containment may be accomplished by any means that adequately prevents personnel contact with the contaminated items during transfer. Containers, devices, or carts must be marked with a biohazard label or other means of identifying contaminated contents; a red bag or container may also be used to denote that the contents are hazardous. Containers should be selected on the basis of the characteristics of the items being transported; in particular, containers should prevent spillage of liquids, if applicable. Puncture-resistant, leak-proof, closable, and labeled containers must be used for devices with edges or points capable of penetrating containers or skin.

Bins with lids, enclosed or covered carts, closed sterilization container systems, and impermeable bags are among the types of containers that may be used alone or in combination to transport contaminated items. Reusable collection containers for holding contaminated supplies should be made of material that can be effectively decontaminated; containers designed for single use should be made of material that can be incinerated or otherwise disposed of following use. Environmental issues and hazardous waste policies should be considered before single-use containers are selected as a containment method.

Body fluids left on medical devices should be prevented from drying during transfer to the decontamination area and prior to the decontamination process. Except for moisture-sensitive items (e.g., those with electrical components), items can be kept moist in the transport container by means of a towel moistened with water (not saline) or a foam, spray, or gel product specifically intended for this use. Transporting contaminated items in liquid should be avoided. If items are soaked in water or an enzymatic solution at the point of use, the liquid should be discarded by properly attired personnel before transport.

If the manufacturer's written instructions permit, rigid sterilization container systems with closed valves or intact, dry filters can be used to contain contaminated items for transport with no further coverings, provided that the external surfaces of the container have not been contaminated by blood or body fluids. Such contamination should be presumed to have occurred if the external surfaces of the container have been touched by persons or items that might have contacted blood or body fluids. Examples include the scrub person in the OR who is still wearing gown and gloves or the circulating nurse assisting with procedure cleanup who might have donned gloves to handle sponges or specimens and has not removed them before touching the container. If such external contamination is present, the reassembled container system should be further enclosed for transport by placing it in a plastic bag, a bin with a lid, or a closed or covered cart.

Rationale: Materials contaminated with blood or body fluids can serve as sources of infection to personnel unless the materials are properly contained. Containment minimizes the possibility of airborne or contact spread of microorganisms. Keeping items moist prevents soil from drying on device surfaces and facilitates the decontamination process. In general, contaminated items should not be transported in liquid because of the risk of spills, the promotion of biofilm formation, and the possibility of employee injury from lifting a heavy container.

Some manufacturers instruct users not to use the same rigid sterilization container system for transport of contaminated items as for sterilization, so it is important to consult the labeling. If the outer surfaces of the container are touched with gloved, soiled hands, then the entire container is considered contaminated.

6.5 Transport

6.5.1 Transportation scheduling and routes

The pickup and transport of soiled items from each area should be scheduled so that the items are transported and cleaned as soon as possible after becoming soiled. Transport routes should be designed to facilitate efficient pickup and delivery to the decontamination area and, whenever possible, should avoid areas of high traffic.

Rationale: The amount of time between use and decontamination should be minimized because the soil on items provides an excellent medium for microbial reproduction. Cleaning items as soon as possible helps prevent the formation of biofilm and the drying of blood, tissue, and mucus on the items, which make cleaning even more difficult to perform.

6.5.2 Transportation equipment

The transport system should be designed to prevent items from falling over or off during transport. Carts should be large enough to maintain the security and package integrity of the items being transported. A covered or closed transport cart is desirable. Carts, reusable covers, and bins and other containers should be decontaminated after each use. The wheels of transport carts should turn easily and should be routinely cleaned.

Rationale: Transportation equipment of appropriate design will help prevent damage to reusable items and avoid contamination of the environment. Decontaminating transportation equipment after each use helps prevent cross-contaminating items transported at a later time. The wheels of a transport cart should turn easily to help prevent items from falling off the cart. Routine cleaning of the wheels removes the string and other debris that can interfere with the wheels' movement.

6.5.3 Hand transport

Containers used to transport contaminated items by hand should be maintained in a position parallel to the floor. The carrier should exercise good body mechanics.

Rationale: Keeping containers parallel to the floor prevents the items within from becoming dislodged or potentially damaged. Good body mechanics promote worker safety.

6.5.4 Dedicated lifts

Dedicated, soiled lifts should always be located in the decontamination area. If containers of contaminated items are transported directly from the point of use to the point of decontamination by means of a dedicated, soiled lift, the lift may be considered equivalent to a closed cart. If the external surfaces of the containers are contaminated, the containers should be placed in plastic bags or bins with lids before being placed in the lift. The lift should be large enough to allow the containers to be placed securely in the appropriate position. Dedicated, soiled lifts should be periodically decontaminated to remove gross contamination that could build up over time and use. Clean or sterile items should not be distributed from a dedicated, soiled lift.

Rationale: Using dedicated lifts and equipment of appropriate design will help prevent damage to reusable items and avoid contamination of the environment. General cleanliness is maintained by periodic and spot cleaning.

6.5.5 Transport between buildings

The transportation system must be enclosed and designed to minimize the risk of personnel exposure to bloodborne and other disease-producing organisms and the possibility of damage to the instruments and other items being transported. Consideration should be given to the containment or packaging of the items, loading procedures, temperature control in transportation vehicles, and other relevant factors. Vehicles used for transporting contaminated items between buildings should provide complete separation of contaminated items from clean and sterile items. Because they might have been contaminated, transportation vehicles should be decontaminated between trips and in the event of spills. Transportation personnel should receive training in basic infection control principles related to their responsibilities. PPE and a biohazardous spill kit should be available in transportation vehicles.

Rationale: Additional factors, such as temperature changes that might enhance microbial growth, should be considered when contaminated items are transported outside the controlled environment of the health care facility. Clean and contaminated items should be separated to prevent cross-contamination during transport. Training is

needed to help reduce the risk that transportation personnel will be exposed to bloodborne and other pathogens. PPE should be available for use in the event of spills of contaminated items or fluids.

6.5.6 Off-site transportation

Vehicles used for transporting contaminated items between health care facilities should provide complete separation of contaminated items from clean and sterile items. Carts housing contaminated items should be secured within the vehicle to prevent damage. Transport vehicles and handling practices should allow for easy loading and unloading.

The design and materials used in the construction of all transport vehicles (motorized or manual) should allow for appropriate decontamination after use. Transport vehicles that are loaded and ready for transport should not be left unattended in unsecured areas. Transport vehicles should be completely enclosed to prevent leaks, and they should be checked periodically to ensure that there are no leaks. Doors should remain closed at all times except during loading and unloading.

The procedures for packaging and transporting contaminated items off-site for processing must comply with applicable Department of Transportation (DOT) and state regulations. See also Annex G.

Rationale: Clean and contaminated items should be separated to prevent cross-contamination during transport. Carts should be secured to prevent damage to contents and to prevent contamination by spills.

Certain contaminated, “nonwaste” products are considered to be “infectious substances” under DOT regulations. DOT defines an infectious substance as a product contaminated with “viable microorganisms ... which cause or may cause disease in humans ...” (49 CFR 173.134 [a][1]). Such products qualify as Class 6, Division 6.2, hazardous materials and thus fall under DOT’s regulations for “Infectious Substances (Etiologic Agents).” Certain states also have regulations that can affect the transport of contaminated items.

7 Cleaning and other decontamination processes

7.1 General rationale

To assist health care personnel in developing appropriate decontamination processes and procedures for the various types of medical devices, this section provides guidelines for selecting and using available cleaning and microbicidal processes.

To be rendered safe to handle, some medical devices require only thorough cleaning; others, because of occupational exposure considerations, must be cleaned and subjected to a microbicidal process. Some devices can be prepared for patient reuse following the decontamination process (e.g., bedpans), while others must be prepared and subjected to terminal sterilization (e.g., EO sterilization of heat-sensitive surgical instruments).

The type of decontamination required for a particular contaminated device depends on the biohazard that the device presents. The cleaning and/or microbicidal process appropriate for a particular device depends on

- a) the device manufacturer's written instructions;
- b) the necessary level of microbial kill (e.g., a higher assurance of lethality is needed for items that have been in contact with body tissues, blood, or body fluids than for items that have only been in contact with unbroken skin);
- c) the design of the device (e.g., items that have been contaminated with blood or body fluids and that have sharp points or edges capable of puncturing or abrading the skin should be subjected to a decontamination process that includes disinfection or sterilization);
- d) other characteristics of the device (e.g., whether the materials from which the device is fabricated can tolerate high temperatures or whether the device is fully immersible); and

NOTE—Health care personnel, including representatives of the central service and infection prevention and control departments, should make a concerted effort to purchase only those devices that can be decontaminated appropriately by a method available in the health care facility. Device manufacturers have the responsibility to provide complete and comprehensive written instructions for decontaminating their products, as well as a summary and interpretation of test results verifying that their products can be safely and effectively decontaminated. See AAMI TIR12 and the FDA document, *Labeling reusable medical devices for reprocessing in health care facilities* (<http://www.fda.gov/cdrh/ode/198.pdf>).

- e) whether the device was exposed to prions, such as the prion that causes Creutzfeldt-Jakob disease (CJD), and thus will require specialized processing steps.

NOTE 1—Because there is no completely effective process for inactivating prions, careful handling, thorough cleaning, and proper disposal of contaminated waste are essential for the safety of patients and personnel.

NOTE 2—For information regarding the decontamination of devices exposed to prions, see Annex C, AORN (2008a), Favero and Bond (2001), Rutala and Weber (2001), Rutala and Weber (2006), World Health Organization (2000), and the recommendations of CDC (<http://www.cdc.gov>) and the International Association of Healthcare Central Service Materiel Management (IAHCSMM) (<http://www.iahcsmm.org>).

7.2 Policies, procedures, and manufacturers' instructions

7.2.1 Policies and procedures

Policies and procedures should be developed for all methods of decontaminating reusable items. Process audits to monitor compliance with the various policies and procedures should be performed on a scheduled basis, with appropriate follow-up addressing problems.

Rationale: Policies and procedures provide guidelines for maintaining control and determining methods of improving processes and products.

7.2.2 Manufacturers' instructions

The written recommendations of the device manufacturer should always be followed. The reusable medical device manufacturer is responsible for ensuring that the device can be effectively cleaned and sterilized. Sterilization qualification of a device requires microbiological, engineering, toxicological, and sometimes clinical evaluations of the device, which are well beyond the abilities of most health care facilities. The device labeling should identify specific methods of cleaning and sterilization that have been validated by the manufacturer. The manufacturer's written

instructions should be kept on file and periodically reviewed for any updates. If there are no specific instructions in the labeling, then the manufacturer should be contacted directly to provide a documented method. See also AAMI TIR12 and the FDA document, *Labeling reusable medical devices for reprocessing in health care facilities* (<http://www.fda.gov/cdrh/ode/198.pdf>).

Rationale: For patient safety to be ensured, a reusable device must be capable of being thoroughly cleaned and sterilized. The manufacturer's written instructions for use are the basis for the department's policies and procedures and must be kept up to date.

7.3 Presoaking

Presoaking with a specialized product (e.g., an enzymatic solution) is generally recommended. When presoaking instruments, personnel should refer to the solution manufacturer's instructions for the correct dilution, temperature, and soak time. Instruments should be thoroughly rinsed after presoaking.

Rationale: Presoaking instruments loosens the soil, thus making the cleaning step easier. Rinsing thoroughly ensures the removal of any potentially harmful residue from the soaking solution (e.g., detergent enzymes, which are proteins, or patient secretions).

7.4 Disassembly

7.4.1 Sorting and disassembly of instrumentation

On arrival in the decontamination area, contaminated items should be removed from their transport containers, sorted, and prepared for cleaning. Surgical instruments and other items composed of more than one part or piece (e.g., metal tracheostomy tubes, procedure needles, dental handpieces, laparoscopic instrumentation, trumpet valves) should be disassembled to expose all surfaces to the cleaning process. The device manufacturer's instructions for disassembling and reassembling all processed items should be included in the procedure manual for the decontamination area. Care should be taken to ensure that all small parts (e.g., screws, nuts, washers) are contained to prevent loss. Noninterchangeable components of assemblies, such as parts of a metal stopcock, should be kept together to ensure correct reassembly. Procedures should be developed to ensure that personnel do not reach by hand into the container to retrieve reusable sharps that may be hazardous and contaminated with blood or other potentially infectious material.

Rationale: Hidden surfaces and crevices can prevent thorough cleaning. Residual organic matter or large numbers of microorganisms can significantly reduce the effectiveness of the subsequent microbicidal process. The recommended procedures for disassembly and reassembly are intended to help ensure that reassembly can be accomplished without loss of time or damage to important equipment. The recommendation concerning reusable sharps is based on OSHA regulations (29 CFR 1910.1030).

7.4.2 Disassembly of rigid sterilization container systems

7.4.2.1 Removable filters

If the rigid sterilization container system is provided with removable filters, the filter protectors or holders (retention plates) should be removed or released to disengage the filter media. If disposable, the entire filter should be disposed of according to the policies and procedures of the health care facility. Removable, reusable filters should be disassembled, cleaned, and replaced according to the manufacturer's instructions.

Rationale: Filters, by their nature, can be reservoirs of contamination, especially when the container system is used to collect or transport used instruments. A disposable filter might not maintain its barrier effectiveness for more than one cycle, and reuse could result in improper sterilization or contamination of the container system's contents.

7.4.2.2 Valves

If the rigid sterilization container system is provided with valve-type closures, the manufacturer's instructions for frequency and method of removal, disassembly, and cleaning should be followed.

Rationale: Improperly maintained valves can interfere with sterilant penetration or allow microbial contamination of container system contents.

7.4.2.3 Interior baskets

The interior basket should always be removed from the rigid sterilization container system for decontamination. Depending on the type of basket and instrument set, the user might need to remove the instruments from the basket before proceeding with cleaning and decontamination. In most cases, the interior basket can be processed with the instruments in the basket according to the health care facility's usual routine.