List of Titles

American National Standard

ANSI/AAMI ST:41:1999

Ethylene oxide sterilization in health care facilities: Safety and effectiveness

AAMI Association for the Advancement of Medical Instrumentation

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American National Standard

ANSI/AAMI ST41:1999
(Revision of ANSI/AAMI ST41:1992 and ANSI/AAMI ST43:1993)

Ethylene oxide sterilization in health care facilities: Safety and effectiveness

Developed by
Association for the Advancement of Medical Instrumentation

Approved 27 May 1999 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 assurance of sterility, 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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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 AAMI Ethylene Oxide Sterilization Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. The guidelines in this document are intended to help assure the achievement of sterilization with inhospital ethylene oxide (EO) sterilizers, the maintenance of sterility of processed items until the point of use, and the reduction of occupational exposure to EO.

This document incorporates 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 provides all of AAMI's recommendations concerning inhospital EO sterilization in a single document for ease of reference. The provisions of the previously published recommended practices have been updated to reflect new regulatory and technological developments, especially with respect to EO monitoring, EO emission control, and new diluents that have come into use as substitutes for chlorofluorocarbon-12 (CFC-12).

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 medical devices to be sterilized by EO and for optimum control of occupational exposure to EO in health care facilities. These recommendations are not intended to be construed as universally applicable in all circumstances. Also, these recommendations might not be immediately achievable in all situations. Therefore, the document should be used to guide personnel towards 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 only to describe "unavoidable" situations, including those mandated by government regulation.

The provisions of this recommended practice should be reviewed by department managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with the 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.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness* (ANSI/AAMI ST41:1999), but it does provide important information about the development and intended use of the document.

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, 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 nosocomial infections in health care facilities is the effective reprocessing and sterilization of 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 control practices, effective quality control, and other aspects of device processing prior to, during, and after sterilization.

Ethylene oxide gas must be used with care because of its toxicity and (when used undiluted) its flammability and explosiveness. For these reasons, EO should only be used to sterilize 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 (CO_2) 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) of the U.S. Department of Labor 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 D.) 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. At this time, no federal EPA emission control regulations affect health care facilities. 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 D) can be obtained from either state OSHA offices or the federal office (Occupational Safety and Health Administration, Office of Information Services, Room N-3637, New Department of Labor Building, 3rd Street and Constitution Avenue, N.W., Washington, D.C. 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 Toxic Substances [TAIS #7408], 401 M Street, S.W., Washington, D.C. 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; 301-443-8913; or by checking the CDRH Internet Home Page, 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 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, infection control).

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Ethylene oxide sterilization in health care facilities: Safety and effectiveness

1 Scope

1.1 General

This recommended practice provides guidelines for EO sterilization 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 assure the safe use of EO by defining equipment and procedures, including ventilation recommendations and (if applicable) emission controls, to minimize personnel exposure to EO.

NOTE—For purposes of this recommended practice, “health care facilities” means hospitals, nursing homes, extended-care facilities, free-standing 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

These guidelines include recommendations for

a) design considerations for EO sterilization processing facilities, including traffic control; the location of work areas; general and local exhaust ventilation systems; and storage of equipment, supplies, and EO gas sources;

b) installation, operation, care, and maintenance of EO sterilizers, EO sterilizer/aerators, and aeration cabinets;

c) staff qualifications, supervision, training, health, and other personnel considerations;

d) processing recommendations;

e) quality control;

f) environmental 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 AAMI 1999 and IEC 1997);

b) detailed design criteria for central service departments (see AAMI 1994b);

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;

d) the reprocessing of items 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 E.

2 Definitions, symbols, and abbreviations

2.1 absorb: To take up or receive a vapor or gas into a solid material.

2.2 absorbent towel: All-cotton towel having a plain weave with only the warp yarns tightly twisted.

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2.3 action level: Concentration of airborne EO within the employee breathing zone, above which OSHA requirements apply. The action level is currently set by OSHA at 0.5 ppm, calculated as an 8-hour TWA. See also **excursion limit** and **permissible exposure limit**.

2.4 adsorb: To collect (a gas, liquid, or dissolved substance) in condensed form on a surface.

2.5 AIA: American Institute of Architects

2.6 air flow: Air movement as measured in volume of air per unit time (e.g., cubic feet per minute or liters per second).

2.7 air gap: Space left between the sterilizer vent termination and the sewer pipe.

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

2.8 air velocity: Air flow rate as measured by the average distance that air travels per unit time (e.g., cubic feet per second).

2.9 asepsis: Prevention of contact with microorganisms.

2.10 best available control technology (BACT): Application of 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.

2.11 bioburden: Number and types of viable microorganisms with which an item is contaminated; also known as **bioload** or **microbial load**.

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

2.12 biological indicator (BI): Sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored.

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

2.13 calibration: Process of checking and correcting for errors inherent in instrumentation to ensure measurement accuracy.

2.14 ceiling limit: Concentration of an airborne chemical contaminant that should not be exceeded during any part of the work day.

NOTE—If instantaneous monitoring is not feasible, the ceiling should be assessed as a 15-minute TWA exposure that should not be exceeded at any time during a work day.

2.15 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.

2.16 CFR: Code of Federal Regulations.

2.17 challenge test pack: Test pack used in qualification, installation, and ongoing quality assurance testing of hospital sterilizers.

2.18 chemical indicator: Sterilization process monitoring device designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber.

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 chemical indicator does not prove that the item accompanied by the indicator is sterile.

2.19 chemical integrator: Chemical indicator designed to react to all critical parameters over a specified range of sterilization cycles. NOTE—The stated values are those required to achieve a stated inactivation by referring to a stated test organism with a stated D value and (if applicable) z value.

2.20 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.

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2.21 culture: Growth of microorganisms in or on a nutrient medium that supports their multiplication; to grow microorganisms in or on such a medium.

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

2.23 cycle time: Total elapsed time of a sterilization cycle from the time the door is closed and the process is initiated until the cycle is completed and the door is opened. Cycle time may include prevacuum time, exposure time, postvacuum time, and aeration time.

2.24 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.

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

2.26 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.

2.27 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.

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

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

2.30 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.

2.31 dust cover: Protective device used to help maintain the sterility of an item by protecting it from the environment; also known as a **sterility maintenance cover**. Usually made of 2- to 3-mil-thick plastic, the dust cover also serves as a barrier to contaminants such as lint, moisture, and vermin.

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

NOTE—This 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.

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

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

2.34 EPA: Environmental Protection Agency.

2.35 excursion limit (EL): Term adopted by OSHA to define a short-term exposure limit (STEL) for ethylene oxide. The EL for ethylene oxide is currently 5 ppm as a 15-minute TWA.

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

2.36 exhaust duct: Pipe 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.

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

2.38 expiration date: Date calculated by adding to the date of sterilization the shelf life of a sterilized item.

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

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

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

2.41 FDA: Food and Drug Administration.

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

2.43 Gram's method of staining: Method of differential staining used in microbiological identification. See also Stanier *et al.* (1976).

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

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

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

2.47 huck towel: An all-cotton surgical towel with a honeycomb-type weave; both warp and fill yarns are tightly twisted.

2.48 hydrochlorofluorocarbons: Compounds consisting of hydrogen, chlorine, fluorine, and carbon.

NOTE—Hydrochlorofluorocarbons differ from 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 (automobile air conditioners use CFC-12). 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.

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

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

2.51 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.

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

2.53 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.

2.54 local exhaust hood: Inlet designed to capture contaminated air and conduct it into an exhaust duct system. Also termed **venting hood**, **pick-up hood**, and **pick-up duct**.

2.55 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 sterilization operation.

2.56 material safety data sheet (MSDS): Document specifying the properties of a material and the precautions necessary to handle and dispose of the material safely.

2.57 medium: See **culture medium**.

2.58 microorganisms: Animals or plants of microscopic size.

NOTE—As used in health care, the term generally refers to bacteria, fungi, viruses, and bacterial spores.

2.59 muslin: Loosely woven (by convention, 140 threads per square inch), 100% cotton cloth.

2.60 NFPA: National Fire Protection Association.

2.61 NIOSH: National Institute for Occupational Safety and Health.

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2.62 OSHA: Occupational Safety and Health Administration.

2.63 parametric release: Declaring a product is sterile, based on physical and/or chemical process data rather than on the basis of sample testing or biological indicator results.

2.64 permissible exposure limit (PEL): Time-weighted average maximum concentration of an air contaminant to which a worker can be exposed, according to OSHA standards listed in Title 29 (Section 1910, Subpart Z, Toxic and Hazardous Substances) of the *Code of Federal Regulations* (CFR). The PEL for EO is currently 1 ppm (8-hour TWA).

2.65 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).

2.66 photoionization detector: Sensing device that uses intense ultraviolet radiation to ionize certain components of an air sample and measures the flow of current between two electrodes.

2.67 ppm: Parts per million. 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).

2.68 processing area: Area of a health care facility in which clean materials, instruments, and other medical devices are received and processed for subsequent sterilization. This area is commonly referred to as the preparation and packaging area of Central Service.

2.69 pyrogen: Fever-producing substance. NOTE—Debris from killed microorganisms can be pyrogenic; limiting the bioburden before sterilization minimizes this debris.

2.70 qualification test: As used in this document, a test performed by the sterilizer manufacturer as part of the overall program of establishing that a given sterilizer design and sterilization cycle meet a standard level of performance under simulated, worst-case, in-use conditions. The data generated by this test enable health care personnel to assess, during inhospital installation testing, the performance of individual EO sterilizers against the standard of performance claimed by the manufacturer.

2.71 quality assurance test: Periodic test which is conducted by qualified health care personnel as part of an ongoing quality assurance program and which is designed to provide a substantial challenge to the sterilizer under actual use conditions.

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

2.73 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.

2.74 routine test pack: Pack used for routine testing.

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

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

2.77 short-term exposure limit (STEL): 15-minute time-weighted average exposure that should not be exceeded at any time during a work day even if the 8-hour time-weighted average complies with the permissible exposure limit. 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 1997).

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

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

2.80 sterile: State of being free from all living microorganisms. NOTE—In practice, sterility is usually described as a probability function, e.g., as the probability of a surviving microorganism being one in a million.

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

2.82 sterility assurance level (SAL): Probability of a viable microorganism being present on a product unit after sterilization.

NOTES—

1. SAL is normally expressed as $10^{-[n]}$.

2. A SAL of 10^{-6} means that there is less than or equal to one chance in a million that a single viable microorganism is present on a sterilized item. It is generally accepted that a sterility assurance level of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (that is, 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.

2.83 sterilization: Validated process used to render a product free of all forms of viable microorganisms.

NOTE—In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

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

2.85 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.

2.86 threshold limit value (TLV): Time-weighted average concentration of an air contaminant to which nearly all workers may be repeatedly exposed day after day without adverse effect; TLV refers specifically to time weighting over an 8-hour or 10-hour work day and 40-hour work week.

2.87 time-weighted average (TWA): Integration of all of the concentrations of a chemical to which a worker has been exposed during the sampling time, reported as an average over the sampling time.

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.

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

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

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, and traffic control can decrease 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 AAMI (1994b).

3.2 Centralization

Centralized EO processing, sterilization, and aeration in health care facilities is strongly encouraged. If centralization is not possible, consistent policies and procedures should be maintained throughout the health care facility, with special emphasis on necessary engineering controls and safe work practices.

Rationale: Ethylene oxide sterilization is a complex and potentially hazardous process requiring sophisticated equipment, adequate space, trained personnel, and ongoing exposure monitoring. Also, 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

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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. Adequate space to allow service access to the equipment must be provided (see also 4.2.3). 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 8 and annex B).

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 only be determined by environmental monitoring, as outlined in section 8 and annex B. See also 3.2.

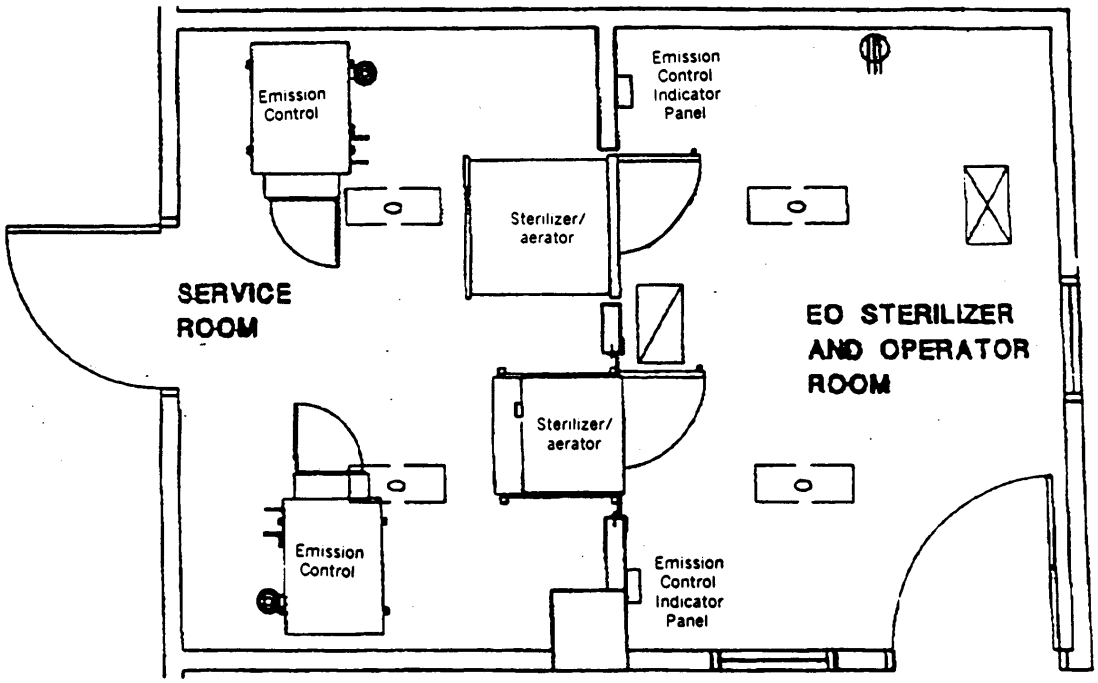

Figure 1—Example of an EO sterilization containment area

3.4 Routing of traffic

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

Rationale: Traffic control around gas or steam sterilization equipment is an important aspect of infection control. 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 maintenance personnel.

Rationale: See the rationale for 4.4.3.

3.6 Storage of supplies

As part of traffic control, supplies should not be stored in the immediate vicinity of sterilization/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 (NIOSH) 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 (Glaser 1977). Also, items stored in the sterilizer equipment access area could absorb residual EO from the sterilizer exhaust.

3.7 Temperature and humidity

In all work areas, a temperature range of 20^{o} C to 23^{o} C (68^{o} F to 73^{o} F) and a relative humidity range of 30% to 60% should be maintained.

NOTE—Ideal relative humidity in the processing area is 50% and should not be less than 35% for best results in achieving sterilization.

Rationale: Work areas should be comfortable for properly attired personnel. In addition, temperatures and humidities higher than those recommended can promote microbial growth and thus increase bioburden; excess humidity can also affect package seal integrity or produce too much moisture. Temperatures and humidities (especially humidities) lower than those recommended can adversely affect EO penetration (and thus sterilization) as well as the performance of some products (such as biological indicators). The specific temperature and humidity ranges set forth here are based on American Institute of Architects (AIA) recommendations for decontamination areas (AIA 1996). Although the AIA permits higher temperatures for other work areas, the committee felt that the environmental controls for all work areas should be consistent.

3.8 Ventilation recommendations for areas housing EO sterilization/aeration equipment

3.8.1 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 make-up air to total exhaust volumetric flow rate;

c) the concentration of EO in the supply air;

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

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

3.8.2 Local exhaust ventilation

3.8.2.1 Local exhaust ventilation systems

Local exhaust ventilation (LEV) systems, including the exhaust hood, associated ductwork, and the 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 via a fan and duct system. Local exhaust ventilation is an accepted and 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., Roy 1981; Samuels and Eastin 1980).

3.8.2.2 Local exhaust ventilation parameters

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

a) the 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) the capture velocity and ambient air velocity around the sources to be controlled;

f) the system design specifications.

3.8.2.3 Sites for local exhaust ventilation

The following areas could 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) for sterilizers that discharge to a sanitary floor drain, the area immediately above the drain line;

d) EO gas cylinder connection areas;

e) the area near the aerator vent.

See also 4.4.2.2, 4.4.2.3, 4.4.3, 4.4.4, 4.4.5, and 4.5.

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

3.8.2.4 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 will depend 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.

3.8.2.5 Exhaust source

The health care facility should establish that the exhaust capacity of the system (expressed as cubic feet of air per minute) is capable of handling the output from all sterilizers, aerators, and exhaust hoods connected to the dedicated exhaust system, without degrading the designed performance characteristics of any of the connections. 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 NFPA (1996a).

Rationale: AAMI (1984) provides recommendations for the design of LEV systems. The importance of adequate air movement is described in 3.8.3.5. The provisions concerning nonsparking exhaust sources and electrical grounding are designed to reduce fire hazard. See also Glaser (1977).

3.8.2.6 Exhaust ducts

A separate exhaust duct to the outside will normally be required. The exhaust duct should terminate away from areas where people walk or work. The duct should be located at least 25 feet (7.6 meters) 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 4.4.2.

Rationale: See ACGIH (1995) for further construction details for exhaust ducts, and refer to earlier discussions of the importance of consulting with the manufacturer.

3.8.2.7 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.

3.8.3 General room ventilation

3.8.3.1 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;

e) system design specifications.

3.8.3.2 Ventilation systems

A positive differential air pressure with respect to areas outside the clean area of the department should be maintained. (See also 4.4.3.) 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.

3.8.3.3 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.

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3.8.3.4 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 movement away from sterilizer operators and other personnel.

Rationale: See 3.8.3.3.

3.8.3.5 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 based on 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 upon 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 (1996).

3.8.3.6 Ventilation monitoring

Since general ventilation is essential for EO sterilization areas, ventilation rates should be monitored and documented periodically by the health care facility engineer, other qualified inhouse 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 make-up air or recirculation parameters should be obtained. The monitoring results should be compared with the system design specifications to determine if the system is functioning as designed.

Rationale: Monitoring is necessary to verify ongoing conformance with the recommendations of 3.8.3.4 and 3.8.3.5.

3.9 Emergency eyewash/shower equipment

Suitable eyewash/shower equipment must be available, with unobstructed access, for immediate emergency use in all locations where EO and other chemicals are used.

The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units (ANSI 1990). Among other things, ANSI Z358.1:1990 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 and/or 100 feet travel distance of all chemical usage locations. The eyewash facilities should be identified with a highly visible sign and should be maintained in accordance with the manufacturer’s instructions. 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 in order to provide first aid to employees exposed to injurious chemicals and materials. The availability of eyewash units for immediate emergency use is required by OSHA. 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), and ANSI (1990).

3.10 Environmental discharge controls

3.10.1 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 (BACT).

Several emission control technologies are available for use in health care facilities. All are based on the assumption that the reduction of toxic gas to an acceptable level will be accomplished before the materials sterilized 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, while 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 C.

3.10.2 Ethylene glycol

Ethylene glycol, in low concentration, is generated as a byproduct of EO reacting with water. Several options are available for disposal of ethylene glycol, which is a low-hazard substance: 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 C.

3.10.3 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. Hydrochlorofluorocarbon (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 C.

4 Installation, venting, care, and maintenance of EO sterilization/aeration equipment and EO gas sources

4.1 General rationale

This section covers the installation, venting, routine care, and maintenance of EO sterilizers, EO aerators, and EO abatement (emission control) and ventilation systems. All such equipment used in health care facilities should be evaluated and monitored to ensure that they have been designed, installed, or modified to help the health care facility meet the OSHA standard and to otherwise minimize personnel exposure. A safe work environment can be ensured by proper attention to EO sterilizer and aerator installation, venting, and emission control; appropriate equipment maintenance and record-keeping; correct EO gas source storage and handling methods; and well-defined procedures for handling EO leaks and spills. Inadequate attention to the venting of equipment and improper operating procedures have been shown to cause high ambient concentrations of EO (Glaser 1977). In addition, proper equipment installation and maintenance will minimize equipment “down time,” help prevent equipment malfunctions, and help ensure effective sterilization processing.

4.2 Installation

4.2.1 Regulatory requirements

The health care facility is responsible for thoroughly investigating and complying with federal, state, and local regulatory codes, including but not limited to electrical, plumbing, fire prevention, safety, and ventilation codes. The health care facility also has the responsibility of obtaining any necessary permits for the use of EO and of complying with state or local requirements pertaining to EO emissions or disposal. Voluntary guidelines should also be considered.

Rationale: Compliance with federal, state, and local regulations is mandatory.

4.2.2 Manufacturer’s instructions

The purchaser should require that sterilizer, aerator, and emission-control equipment manufacturers supply comprehensive instruction manuals. The manufacturer’s installation instructions should be followed.

Rationale: The manufacturer is best able to advise the health care facility concerning proper equipment installation. It is necessary to verify the correct functioning of newly installed or reinstalled equipment before use to ensure that

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the equipment can be operated safely and effectively and that EO levels in the work environment meet the OSHA standard.

4.2.3 Equipment location

Selecting an appropriate location for EO equipment should be a joint decision between the hospital engineer and the department manager, with advice from the manufacturer's representative. Sterilization and aeration equipment should be placed in a well-ventilated area (see 3.8). Adequate space for service access to the equipment should be provided; most manufacturers specify the amount of space required.

Rationale: The health care facility is principally responsible for ensuring a safe work environment, but the manufacturer's advice will help ensure equipment effectiveness and ease of servicing. The importance of adequate ventilation is discussed in 3.8, but see also ACGIH (1995), Roy (1981), and Samuels and Eastin (1980).

4.3 Installation testing

4.3.1 Sterilizers

After installation of the sterilizer and before the health care facility either takes possession of the sterilizer or puts it into routine service, installation and acceptance testing should be carried out using the procedures outlined in 7.6.

Rationale: Proper performance of an EO sterilizer is a function not only of its design, but also of the electrical system and other utilities unique to the specific health care facility. The effectiveness of the sterilizer can only be verified in the actual hospital environment in which it will be used.

4.3.2 Emission control and ventilation systems

Emission control and ventilation systems should be tested for performance efficacy, and the results documented and retained in accordance with applicable ordinances and regulations. Where state or local emission control regulations apply, operating permits must be obtained before the sterilizer is put into routine service.

Rationale: While no federal regulations for hospital EO sterilizer emissions currently exist, many states and local authorities have promulgated emission-control regulations. All applicable regulatory requirements must be met before production use of the equipment begins.

4.4 Venting of EO sterilizers

4.4.1 General considerations

All EO sterilizers should be vented out of the workplace to the outside atmosphere, an emission control system, or a sanitary floor drain. The sterilizer manufacturer's written instructions for venting should be followed. For older equipment still in use, when written instructions are no longer available, the health care facility should modify the equipment or ventilation system, as needed, to minimize personnel exposure to EO, to comply with the OSHA standard, and to comply with federal, state, and local environmental emission regulations (see also annex C). Sponge-type or water tray "absorbers" for ventilated gases must not be used.

Rationale: Failure to comply with the manufacturer's written instructions for venting could result in excessive personnel exposure to EO and, if applicable, the withdrawal of the sterilizer warranty. The lack of such instructions does not relieve the health care facility of the responsibility to appropriately modify the equipment or ventilation system, the need for which can be determined by environmental monitoring (see section 8 and annex B). Sponge-type or water-tray absorbers are prohibited because they are ineffective and potentially hazardous.

4.4.2 Sterilizers venting to outside atmosphere

4.4.2.1 Chamber vent lines

Sterilizers venting to the outside atmosphere should be vented by means of a dedicated vent line that is properly installed and that is constructed of EO-impervious material. The vent line should not terminate within 25 feet (7.6 meters) of any building air intake source; 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 emission regulations might also dictate a longer distance or prohibit altogether the discharge of EO into the environment.

Chamber vent lines must not be run out of windows or under doors, nor venting accomplished in other ways that would either release EO within the building or allow the reentry of EO-contaminated air into the building. Ethylene oxide should not be released near pedestrian traffic, inside or outside the facility. The length of the vent line outside

the building should be minimized to avoid constrictions caused by freezing. All EO emissions must comply with local environmental requirements.

Rationale: Compliance with the preceding recommendations not only helps ensure that occupational exposure to EO is minimized but also helps prevent the passive exposure of patients, other hospital workers, visitors, and individuals in or near the health care facility. The specific recommendations for constructing the vent line are based on ACGIH (1995) and AIA (1996). These documents are regularly updated, and health care personnel should consult the latest editions.

CAUTION—Ethylene oxide could enter other work areas if the exhaust system is not operational. Since existing nonrecirculating exhaust ducts could have other air intake sources, sterilizers and aerators should not be used if the ventilation system is not functioning.

4.4.2.2 Venting of sterilizer relief valves

Sterilizer relief valves must be vented out of the workplace to the outside atmosphere—via a nonrecirculating system, a dedicated ventilation system, or both—or to an emission control system. Sterilizer relief valves should not be vented to equipment access rooms, even if the rooms are well ventilated.

Rationale: Pressure-type sterilizers are typically equipped with a safety device to release gas if pressure builds up. Although such safety devices rarely discharge, they could be a source of EO exposure unless they are properly vented out of the workplace. Sterilizer relief valves should not be vented to equipment access rooms, even if the rooms are well ventilated, because of the risk of excessive EO exposure to maintenance and repair personnel who might be present during discharge of the relief valve.

4.4.2.3 Ventilation of sterilizer door areas

For those sterilizers not factory-equipped with a door exhaust vent, a local exhaust hood should be installed as close as possible to the sterilizer door. Although the exhaust hood usually should be located above the sterilizer door, its exact placement should be determined by consulting the sterilizer manufacturer. The purpose of the exhaust hood is to capture EO gas at the end of the sterilization cycle before items are removed from the chamber and transferred to an aerator. The exhaust hood is particularly important when the sterilizer does not have a postvacuum exhaust cycle and the door-cracking method is used (see the manufacturer's instructions). The exhaust hood can also capture EO escaping from gasket leaks; for this reason, the exhaust hood should be functioning continuously during sterilizer operation. The local exhaust system should be designed to maintain adequate air movement to capture EO at the front of the sterilizer and thereby minimize personnel exposure. The hood should be connected to a dedicated or nonrecirculating exhaust system that goes to the outside atmosphere or to an emission control system.

Rationale: One of the major sources of EO exposure occurs when the sterilizer door is opened at the completion of a sterilization cycle.

4.4.3 Sterilizers venting to sanitary floor drain

The health care facility should ensure that EO discharged with water at the floor drain does not reflux into the work environment. This may be accomplished by one or more of the following means:

A local exhaust ventilation (LEV) system (e.g., a capture box) may be installed around the sterilizer discharge point to capture and remove EO vapors. A capture box should enclose all open areas of the floor drain upstream of the trap, and the trap should be checked periodically to ensure that it is properly filled with water.

A liquid/gas separator can be installed, so that liquid is directed toward the sanitary floor drain and the gas is discharged through a dedicated vent system (see 4.4.2). All other openings in the drain line upstream of the trap should be sealed or enclosed under a capture box. Some states do not allow single-pass-through liquid/gas separators. In these states, the seal fluid must be recirculated. The excess water that accumulates in the separator from process fluid discharges is emptied into the drain when the separator/seal fluid container overfills.

NOTE—If the drain line is not sealed or the liquid/gas separator is not adequately ventilated, the separator might not be entirely effective, and a capture box might still be needed.

The floor drain may be located in a well-ventilated (10 air exchanges per hour or more) sterilizer access room where workers are not normally present. If this method is chosen, the enclosure housing the sterilizer point of discharge should be under negative pressure with respect to the surrounding areas, and it should be near the exhaust point of the area. This area must have restricted access, with written procedures for personnel entry (see 3.5). The negative-pressure condition in the enclosure housing the sterilizer discharge point should be verified with smoke tubes, documenting that air is entering through all openings (e.g., vents and cracks).

NOTE—While the last method is sometimes used, it is the least active means of controlling EO and therefore the least desirable, since it depends on general room ventilation and the leak tightness of the access area. Consequently, the potential for worker

exposure to high concentrations of EO exists. Also, the recommendation for negative pressure might conflict with requirements for containing microbial contaminants; in this case, a capture box will be necessary.

Rationale: Studies have shown that EO escapes from the discharge point of sterilizers that vent to sanitary floor drains. This escape of EO is caused by the air gap required by most plumbing codes. Also, the heat from sterilizers generates an upward air flow that can push air out of openings at the top of enclosures housing the sterilizer discharge points (even though exhaust ventilation is applied) if the ventilation flow rate is insufficient. Therefore, it is necessary to ensure that EO does not reflux into the work environment.

4.4.4 Sterilizers without exhaust to outside atmosphere or sanitary floor drain

Certain table-top sterilizers are designed without venting mechanisms other than the door or lid. The health care facility must determine that the system effectively minimizes employee exposure to EO gas. The manufacturer should be consulted about the need for and the appropriate means of exhausting EO, such as local exhaust ventilation (including a laboratory hood). Also, the manufacturer's data can be used to verify system effectiveness in minimizing EO gas in the workplace.

Rationale: These sterilizers do not incorporate venting mechanisms, and thus their effectiveness in controlling the EO concentration in the environment should be evaluated. The manufacturer of any sterilizer should be consulted when equipment or ventilation system modifications are being considered, to ensure that the modifications are needed and that they will not adversely affect the operation or effectiveness of the sterilizer. Although LEV systems are widely recognized as effective in reducing ambient EO concentrations, the committee does not intend to prohibit the use of alternative approaches if they are proven to be safe and effective.

4.4.5 Ventilation of EO gas cylinders

Engineering controls such as a local exhaust hood or a commercially available gas cylinder cabinet should be installed as close as possible to the EO gas cylinders connected to the sterilizer. The local exhaust system should be designed so that strong air movement draws the EO away from personnel during cylinder changeovers. The hood should be connected to a dedicated or nonrecirculating system that exhausts the EO to the outside atmosphere or to an emission control system. (See also 4.8.2.3 and 4.8.2.4.) The sterilizer manufacturer's instructions should be followed when using special control systems (e.g., load stations).

NOTE—To minimize personnel exposure to EO, the use of engineering controls is preferable to the use of respirators (29 CFR 1910.134)

Rationale: The purpose of the exhaust hood is to capture EO released to the air during cylinder changeovers and EO leakage around line connections.

4.5 Venting of EO aeration cabinets

4.5.1 Vent lines

The health care facility should only use EO aerators that vent to the outside atmosphere or to an emission control system. Aerators should never be vented to recirculating air systems. Ethylene oxide aerators should be vented using a dedicated, properly installed and operational vent line. Ducts should be constructed to ensure that EO is not released to the work environment. Venting to the outside can be accomplished either through a dedicated exhaust system or, if building codes allow, through an existing nonrecirculating exhaust duct that leads directly to the outside or to an emission control system. The outside termination of the exhaust duct should be at least 25 feet (7.6 meters) away from building air intake sources; 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 emission regulations might also dictate a longer distance or might prohibit altogether the discharge of EO into the environment.

Rationale: Ethylene oxide could enter other work areas if the exhaust source is not operational. Since existing nonrecirculating exhaust ducts might have other air intake sources, the aerator should not be used if the ventilation system is not operational. See also the rationale for 4.4.2.1 and, for additional details concerning the proper design of venting systems, ACGIH (1995) and AIA (1996).

4.5.2 Equipment modifications

Some aerators that are not currently vented can be modified or redesigned to incorporate a venting system, but such modifications should not be made without first consulting the manufacturer.

Rationale: Use of an unvented aerator could cause increased EO concentrations in the workplace. Some existing aerators cannot be modified to incorporate a venting system and should be replaced. Aerator equipment should not be modified without consulting the manufacturer because the vent system has to be designed to maintain the

required temperature profile within the aeration cabinet. If the temperature in the aerator is too low, aeration time will be significantly prolonged; operating the aerator at too high a temperature could damage the items being aerated.

4.6 Ventilation system alarms

A system to detect ventilation system failures and to alert personnel with audible and/or visual alarms should be installed for personnel protection. Several suitable types of alarm systems are available. For example, a sail switch or differential pressure switch can be installed in the ductwork near the fan, or a static pressure gauge can be used.

NOTE—Connecting the ventilation and alarm system to an emergency power distribution system should be considered during the design phase, in case of main power failure.

Rationale: Ventilation failures, which could result from malfunctioning fans, obstructed ductwork, or power outages, could lead to excessive levels of EO in the workplace.

4.7 Maintenance of EO sterilizers, aerators, emission control systems, and ventilation systems

4.7.1 Manufacturer's instructions

The equipment manufacturer must provide written instructions for routine care and preventive maintenance. These instructions should provide all information necessary to carry out the procedures recommended in 4.7.2 and 4.7.3 and should specify the frequency with which these procedures should be performed. Specific rather than general information should be provided for each equipment model. The manufacturer's instructions must be kept by the user for as long as the equipment is in service.

Rationale: Since preventive maintenance, calibration, and repair might be performed by personnel other than the manufacturer's employees or representatives, detailed and complete information is required.

4.7.2 Routine care of sterilizers and aerators

Sterilizers and aerators should be cleaned and inspected daily according to the manufacturer's written instructions (see 4.7.1). Examples of items requiring daily care and cleaning are recording charts and pens, door gaskets, the chamber drain screen, the internal chamber, and external surfaces. Before each load, the gasket seals of sterilizer and aerator doors should be inspected for cracks, tears, debris, and other foreign substances. Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturer's written instructions.

Rationale: Periodic inspection and cleaning reduces the frequency of equipment malfunction and the risk of accidental contamination of sterile items. Also, EO can escape from the equipment into the workplace through faulty or poorly maintained gaskets, valves, and fittings.

4.7.3 Preventive maintenance

4.7.3.1 General

Maintenance should be carried out by a qualified individual. Particular attention should be given to the inspection, maintenance, and replacement of components subject to wear, such as recording devices (as applicable), filters, drain pipes, valves, and door gaskets. Simple charts showing the locations and replacement dates of components will show trends in deterioration and provide the framework of a preventive maintenance program. The maintenance program may be inhouse or contracted with the equipment manufacturer or other qualified service company. Preventive maintenance and repair records should be retained (see 4.7.3.6).

Rationale: Malfunction of critical components can cause sterilization failures or failures of the sterilization parameter recording system.

4.7.3.2 Scheduled maintenance

Lubrication of appropriate parts and replacement of expendable parts should be performed, as needed, by qualified personnel. Sterilizer and aerator valves and fittings should be inspected at least every two weeks and replaced as necessary. Intake air duct filters for the restricted access area should be inspected and cleaned regularly as part of scheduled preventive maintenance. Certain maintenance tasks that require special tools or calibration equipment not available in the health care facility should be performed by the manufacturer, the manufacturer's representative, or another qualified service facility. The frequency of maintenance will depend on how often the equipment is used and might vary from institution to institution; the manufacturer's instructions should be consulted for guidance.

Rationale: Ethylene oxide gas can escape from the equipment into the work area through faulty or poorly maintained gaskets, valves, and fittings. Proper operation of air ducts helps ensure adequate ventilation. It might not be economical for health care facilities to acquire expensive, rarely used special tools or calibration equipment. The

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normal service life of mechanical components sometimes depends solely on frequency of use, sometimes on age, and sometimes on both.

4.7.3.3 Leak testing

Positive-pressure sterilizers and aerators should be tested for leaks at least every 2 weeks. Door gaskets, cylinder and vacuum piping, hoses, filters, valves, and fittings should be checked. Also, with the sterilizer door open and the gas entry solenoid valves closed, leakage should be monitored at least every 2 weeks at the EO gas line entrance port within the sterilizer. For sterilizers that operate at subatmospheric pressure, the manufacturer's instructions should be consulted for guidance on leak testing.

NOTE—Sterilizers using EO/HCFC mixtures can be leak-tested either with halide leak detectors or EO monitors. An EO-specific monitor must be used for 100% EO systems. Halide leak detectors are neither effective with 100% EO systems nor safe to use (because of the explosion hazard).

Rationale: Undetected leaks can cause unacceptable EO exposure levels in the workplace. Based on the recommendations of the Environmental Protection Agency, OSHA suggests biweekly leak testing of valves and fittings (see annex D).

4.7.3.4 Calibration

Periodic calibration should be performed as specified in the manufacturer's instruction manual (see 4.7.1), and the results should be documented. Examples of items requiring calibration are pressure and temperature gauges, humidity control apparatus (if applicable), timers, controls, and recording devices. The instruments used for calibration should be traceable to the primary standards of the National Institute for Standards and Technology. In the event of a sterilizer malfunction or the repair or replacement of any component affecting sterilizer performance, appropriate recalibration should be performed. Calibration may be performed by the manufacturer, the manufacturer's representative, the health care facility engineering staff, or contract service personnel. Those performing this service should have sufficient training to understand the operation and calibration of the specific sterilizer type.

Rationale: Proper calibration of controls, indicators, and recording devices is critical for effective and reliable sterilization. Because the repair or replacement of components often has subtle effects on other seemingly unrelated devices, it is imperative that calibration be performed only by qualified personnel.

4.7.3.5 Emission control systems

The reactive components of emission control systems (e.g., catalytic cells, acid baths) should be replaced or replenished regularly, based on the results of periodic monitoring of emission-control efficiency.

Rationale: The effective life of the chemical components of emission control systems is finite; also, other ambient chemicals can react with the active elements. Therefore, it is important to monitor emission-control efficiency over time to maintain the expected performance. Catastrophic failure of emission control systems is unlikely; but, since performance efficiency degrades over time, the planned replenishment (or replacement) of the active components is required.

4.7.3.6 Recordkeeping

A maintenance record should be kept for each sterilizer, aerator, and emission control system. This record should be maintained by the supervisor responsible for the equipment, by the hospital engineering staff, by the service person/organization who performed the servicing, and/or by whomever else is deemed appropriate by the health care facility. Included in this maintenance record should be sufficient information to identify the equipment and to establish a continuous history of all scheduled and unscheduled service. At least the following information should be recorded:

a) the date of service;

b) the model and serial number of the sterilizer, aerator, and (if applicable) emission control system;

c) the location of the equipment (hospital identification, if applicable);

d) the name of the individual from the health care facility who requested and authorized the service;

e) the reason for the service request;

f) a description of the service performed (e.g., calibration, repair);

g) EO cylinder changes, if applicable;

h) the types and quantities of parts replaced;

i) the name of the person who performed the service;

j) the date the work was completed;

k) the signature and title of the person who acknowledged completion of the work.

These records must be maintained for the length of time specified by regulatory agencies (e.g., state health departments).

Rationale: Accurate and complete records are required for process verification and are useful in malfunction analysis. Complete maintenance records also permit correlation between ambient EO concentrations and specific equipment.

4.8 Storage and handling of EO gas sources

4.8.1 Unit-dose containers of 100% EO

4.8.1.1 Storage of unit-dose containers

The health care facility should consult with the unit-dose container manufacturer to determine how many unit doses may be stored in the sterilizer area. In general, however, if each dose contains 50 or more grams of EO, only one day's supply of cartridges, up to a maximum of 12 cartridges, should be stored in the immediate area of the sterilizer. If more than 48 cartridges are to be stored in one place in inventory, the area should be suitable for flammable liquid storage and should conform to NFPA (1996b).

Rationale: The recommendations of NFPA Code No. 30 (NFPA 1996b), which is the applicable national code on the storage of flammable liquids, deal with the storage of Class I flammable liquids (such as 100% EO) inside office, educational, and institutional occupancies. Subsection 4-5.4.2 states: "Not more than 10 gallons of Class I and Class II liquids combined shall be stored in a single fire area outside of a storage cabinet or a separate inside storage area unless in safety cans." The NFPA recommendation permitting 10 gallons (32.8 kilograms of 100% EO) concerns bulk storage. The AAMI committee considered it prudent to recommend that if more than 48 cartridges of 100% EO (maximum weight, 8.2 kilograms) are held in inventory, they should be stored in an area suitable for flammable liquid storage. Since health care facilities do not require large quantities of EO, the AAMI committee judged that adopting more stringent recommendations would decrease the hazard without causing hardship.

4.8.1.2 Transport of unit-dose containers

If it is necessary for a health care facility to transport unit-dose containers of 100% EO from one location to another, the facility must use the same approved packaging, labeling, and mode of transport as the original manufacturer or vendor. Shipping instructions should therefore be obtained from the manufacturer or vendor.

Rationale: Unit-dose containers contain toxic and possibly flammable/explosive concentrations of EO. They therefore present a significant hazard if not handled properly. Following the U.S. Department of Transportation (DOT) regulations regarding shipment by the original manufacturer or vendor helps to minimize this hazard.

4.8.1.3 Disposal of unit-dose containers

Empty unit-dose containers should be disposed of along with normal nonincinerated waste. Unused, outdated, or underweight unit-dose containers should be returned or disposed of in accordance with the manufacturer's instructions. If such containers are not to be returned to the manufacturer, the health care facility should contract with a licensed hazardous waste disposal company to dispose of the containers. The disposal company must comply with EO health and safety requirements and with applicable local regulations.

Rationale: Disposing of empty unit-dose containers with nonincinerated waste will prevent the incineration of full containers that might accidentally be discarded along with spent containers. Incineration of full containers is an explosion hazard. Unused, outdated, or underweight unit-dose containers likewise present a fire and explosion hazard if not disposed of properly.

4.8.2 Storage and handling of EO gas cylinders (tanks) and supply line filters

4.8.2.1 Storage of EO gas cylinders

Cylinders of EO gas mixtures must be stored in a designated area that meets building codes and OSHA regulations and that conforms to the temperature specifications of the gas supplier or manufacturer. Tanks should be stored and used in an upright position and should be securely fastened to a solid structure by suitable straps or chains. Gas cylinders in inventory, as well as those connected to the sterilizer equipment, should be placed in an area away from

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the flow of traffic. A safety inspection plan for tanks should be established by the health care facility's in-house safety committee in cooperation with the gas supplier.

Rationale: Conformance with these recommendations will reduce the possibility of damage to cylinder valves, which could cause significant personnel exposure to EO, and of toppling cylinders, which could cause serious injury.

4.8.2.2 Transport of EO gas cylinders

Ethylene oxide gas tanks should be transported on equipment designed to secure the tanks and cylinders during transit. Gas cylinders that have been used and removed from service should be handled with the same care as full cylinders. The cylinder valve should be closed, and the outlet plugged after use. The cylinder should be leak-tested and returned to the sterilant manufacturer. The return bill of lading should indicate that the cylinders are empty and that they last contained _____ [repeat the DOT classification used on bill of lading for the full cylinder]. Gas cylinders must be shipped in accordance with DOT regulations (49 CFR 173).

Rationale: Empty, nondisposable cylinders contain a residual amount of sterilant gas by virtue of their construction, and they should be transported as if they were full, under DOT shipping regulations. See also 4.8.2.1.

4.8.2.3 EO supply lines

Hand valves, petcocks, or other means of closing or safely venting the connecting lines should be installed on the gas supply line at the connection to the supply cylinders. If possible, the gas supply line should be purged of EO before the tank fittings are loosened; kits are commercially available for this purpose. The EO gas supplier and the sterilizer manufacturer should be consulted before modifying the EO supply lines.

Rationale: Depressurizing or purging the charge line to a proper vent before loosening the tank fitting will prevent pressurized liquid or gas from being ejected into the room. Supply lines should not be modified without consulting the EO supplier and the sterilizer manufacturer because the lines contain liquid EO and can rupture under certain conditions if not connected properly.

4.8.2.4 Changing EO gas cylinders and supply line filters

Personnel changing gas cylinders or supply line filters should avoid contact with EO and HCFCs. See 4.10 for additional information.

Rationale: Direct contact with HCFCs can cause severe frost injury to tissue. Skin contact with EO as a liquid or in very high concentrations as a gas can cause irritation, and prolonged contact can lead to chemical burns. Splashes to the eye can be severely irritating and damaging.

4.8.2.5 Supply line filter disposal

Used filters from EO supply lines should be aerated before disposal. If an aeration cabinet is available immediately, the filter should be placed in a labeled, EO-permeable bag and transported to the aerator, where it may be aerated with other items. If it is necessary to store the filter before aeration, it should be placed in a labeled, EO-impermeable bag (e.g., foil package or pouch) that is not opened until it is inside the aerator. If combination sterilizer/aerators are used in the health care facility, filter maintenance should be scheduled so that the filter can be included in the next full-cycle load, or else the filter should be stored in the meantime. After aeration, the filter may be disposed of with ordinary waste.

Rationale: Used filters retain high concentrations of EO that will be released into the work environment if the filters are not aerated before disposal.

4.9 EO leaks and spills

4.9.1 General

The OSHA standard requires that each facility in which EO is used have a written emergency plan. In an emergency, appropriate sections of the plan must be followed. The plan must include procedures for alerting personnel (e.g., an alarm system), avoiding EO contact, evacuating and accounting for personnel, and reentering the area after the spill or leak. An audible and/or visible alarm system (e.g., a hospital switchboard or an intercom system) is required for areas with more than 10 employees. OSHA has specific requirements for the installation, maintenance, and testing of alarms. Direct voice communications can be used in areas with 10 or fewer employees, provided that all employees can hear the alarm; such workplaces need not have a backup system. Personnel entering a spill or leak area for corrective action must wear self-contained breathing apparatus approved for EO by NIOSH.

Rationale: See 4.10 and annex D.

4.9.2 Emergency team

The health care facility should appoint an “emergency team” responsible for developing and executing written emergency response procedures for EO leaks and spills. This “emergency team” should consist of a representative of the facility’s safety committee, a physician, an engineer, the central service supervisor, and any other personnel deemed appropriate (e.g., local fire officials). The emergency response team must meet the training requirements specified in the OSHA Hazardous Waste Operations and Emergency Response Standard (29 CFR 1910.120).

Rationale: To ensure rapid, efficient response to emergency situations, it is important the specific individuals be assigned responsibility for developing and implementing procedures for handling EO leaks and spills. The composition of the “emergency team” should reflect all expertise relevant to the control of EO.

4.9.3 Emergency plan

The emergency team should prepare a written emergency plan consisting of at least the following elements:

a) a description of the alarm system and the procedures for its use, maintenance, and testing;

b) the procedures for evacuating and accounting for personnel in the event of a spill or leak;

c) the procedures for medically treating persons who have come into contact with liquid EO or liquid HCFCs or who are overcome by EO vapors (see 4.9.4);

d) the procedures for reporting an emergency to appropriate authorities (e.g., the safety officer; local fire, health, and safety personnel; or representatives of the gas supplier or sterilizer manufacturer);

e) the procedures for hazardous material cleanup;

NOTE—A Material Safety Data Sheet must be obtained from the gas manufacturer or supplier.

f) the procedures for determining if it is safe to reenter a spill or leak area;

g) a description of the employee training program;

h) the amount and location of EO used and stored in the health care facility;

i) the known rate of air exchange;

j) the potential for the general ventilation system to carry EO from the site of the EO leak or spill to other areas in the hospital, and a prescribed course of action to prevent the dispersal of EO to other areas;

k) procedures for assessing the risks and benefits of evacuating other departments in the event that EO is dispersed throughout the facility;

l) the recommendations of the gas supplier and sterilizer manufacturer for emergency procedures;

m) a description of the respiratory protection program, outlining the safe use, location, storage, fit testing, and periodical inspection of self-contained breathing apparatus and the procedures to be used for medical assessment of staff required to use the apparatus (respirators and protective attire such as gloves and aprons must be readily accessible but stored away from areas where EO leaks or spills could occur);

n) designation of the persons responsible for supervising the handling of EO leaks or spills.

Rationale: A well-designed plan of action, with which personnel are thoroughly familiar, will help reduce the potential adverse effects of an EO leak or spill. The plan should include information concerning the ventilation system so that appropriate evacuation decisions can be made. For example, in the case of a dedicated exhaust ventilation system that carries EO directly to the outside, it might not be necessary to evacuate the entire hospital if an EO leak or spill occurs. It is important that employee protective equipment be stored away from the EO sterilization processing area so that workers can reach it without exposing themselves to high EO concentrations caused by the leak or spill.

4.9.4 First aid

4.9.4.1 Liquid EO

Personnel who have come into contact with liquid EO should immediately remove contaminated clothing and shoes and thoroughly wash contaminated skin. In the case of eye contact with liquid EO or EO mixtures, the eyes should be flushed with copious amounts of water for at least 15 minutes. Exposed personnel should be evaluated by a physician immediately after these emergency measures. Contaminated reusable clothing should be aerated and

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laundered before it is worn again, and rubber goods should be aerated before use. Contaminated leather shoes should be removed immediately and aerated. Disposable garments should be aerated and then discarded.

NOTE—Leather items are sometimes purposely sterilized; in such instances, care must be taken to ensure adequate aeration.

Rationale: Exposure to liquid EO can cause chemical burns or severe skin irritation. Flushing with water dilutes and removes the EO or EO mixture. Frostbite-like symptoms can also occur due to the rapid evaporation of EO and/or HCFC from the skin surface. Liquid EO can also cause eye irritation and injury to the cornea. Prolonged flushing with water can also damage the eyes, however, so caution should be exercised.

4.9.4.2 EO gas

Personnel who have inadvertently inhaled EO gas should be moved immediately to fresh air. If breathing is difficult, oxygen should be administered. Such personnel should see a physician as soon as possible. In severe cases, cardiopulmonary resuscitation could be necessary to restore breathing, after which oxygen should be administered.

Rationale: Sections 4.9.4.1 and 4.9.4.2 describe standard first-aid procedures for handling acute exposure to toxic chemicals. See also 5.4.1.1 and 5.4.2.2.

4.10 Personal protective equipment

When eye or skin contact with EO or EO mixtures could occur, such as in EO sterilizer maintenance, in the changing of EO cylinders, or in the event of an EO leak or spill, the employer must select, provide, and maintain, at no cost to the employee, appropriate protective clothing or equipment that complies with OSHA standards and that protects areas of the body that could come into contact with liquid EO or EO in solution. In addition, the employer must ensure that the employee wears the protective clothing and equipment provided.

Maintenance personnel and personnel responsible for dealing with EO leaks or spills should wear heavy-duty chemical gloves, such as butyl, neoprene, or nitrile rubber gloves; goggles or a face shield; and an impervious apron or full-body covering. These items should be removed quickly if they become saturated. For the various types of attire recommended, health care facilities should obtain written specifications from the manufacturer regarding the breakthrough penetration of EO. Selection should be made based on the estimated time for a specific task and the expected exposure to EO.

If monitoring or air sampling results indicate that excessive EO exposure could occur without the use of respirators, personnel must wear a respirator certified for EO use by NIOSH (i.e. a full face mask with an EO-approved canister, a positive-pressure continuous-flow air-line respirator, or a positive-pressure self-contained breathing apparatus). (See paragraph 1910.1047[g] and Table 1 of the OSHA standard, provided in annex D.) Individuals responsible for changing EO gas cylinders and supply-line filters and other individuals who could be required to use a respirator must be properly trained in the use of respirators and must be fit-tested. Training must be repeated annually. Also, individuals assigned to these tasks must have been examined by a physician to determine their ability to wear a respirator. Training, medical examinations, and the procedure for periodic inspection, cleaning, and storage of respirators must be documented.

NOTE—To minimize personnel exposure to EO, the use of engineering controls, as discussed in 4.4.5, is preferable to the use of respirators (29 CFR 1910.134).

Rationale: The heavy-duty chemical gloves, face shield or goggles, and apron or cover attire are worn to reduce the risk of coming into contact with very high concentrations of liquid/gaseous EO and HCFCs. As indicated in 4.8.2.4, direct contact with HCFCs can cause severe frost injury to tissue. Skin contact with EO as a liquid or in very high concentrations as a gas can cause irritation, and prolonged contact can lead to chemical burns; butyl rubber gloves offer extended protection against EO (Trawick and Crowder 1988). Splashes to the eye can be severely irritating and damaging.

Inhalation exposure to EO during routine maintenance procedures must be prevented by engineering controls, not respirators. However, respirators might be needed to prevent personnel exposure to EO during nonroutine procedures, such as the changing of gas charge line filters or the cleanup of EO spills, particularly if a local exhaust hood or gas cylinder cabinet is not properly installed in the area, if the hood/cabinet has insufficient air movement, or if purging procedures are inadequate to prevent EO overexposure.

The OSHA standard states that only three types of government-approved respirators that are effective against EO can be used. If engineering controls are inadequate and respirators are needed, proper training and fit-testing are required to ensure that respirator use is safe and effective. A physical exam is necessary to ensure that the wearing of a respirator will not be harmful. Proper inspection, cleaning, and storage of respirators will keep them in proper operating condition in case of an emergency.

4.11 Equipment manuals

The complete manufacturer's description, operating instructions, maintenance procedures, guarantees, and service records should be maintained in an equipment file within the department, and a duplicate set should be maintained in the files of the engineering or maintenance department.

The health care facility should require equipment manufacturers, as part of the purchase contract, to maintain and provide upon request the operating and service manuals for 10 years after the date of manufacture or for the specified life of the product. For changes affecting safety or efficacy, the manufacturer should additionally be required to furnish copies of all changes in operating and service manuals for 10 years after the date of manufacture or for the specified life of the equipment.

Rationale: To ensure proper equipment operation and servicing, it is important that information supplied by the manufacturer be maintained and be readily accessible. Equipment could be in service for many years, and the hospital should ensure that up-to-date information concerning equipment modifications will be available for the life of the equipment. See also 4.7.1.

5 Personnel considerations

5.1 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 knowledgeable personnel. The other personnel considerations covered in this section are key elements in minimizing bioburden and containing environmental contamination, which are essential for effective sterilization.

5.2 Qualifications

5.2.1 Supervisory personnel

All preparation and sterilization of items, including cleaning, decontamination, 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. Suggested minimum qualifications include

a) successful completion of a central service certification examination;

   NOTE—Information concerning certification of central service processing technicians can be obtained from the National Institute for the Certification of Healthcare Sterile Processing and Distribution Personnel (P.O. Box 558, Annandale, NJ 08801; 908-730-8902); the International Association of Healthcare Central Service Materiel Management (213 Institute Place, Suite 307, Chicago, IL 60610; 312-440-0078); or the National Health Information Center (P.O. Box 1133, Washington, DC 20013).

b) participation in continuing education programs and courses, including programs on federal and local regulations and courses directly related to EO sterilization. Special emphasis should be placed on personnel safety; the health risks of exposure to EO; safe use of EO, including current regulations; and decontamination, sterilization, and storage and distribution of sterile medical devices;

c) participation in facility and departmental programs designed for personnel responsible for EO sterilization processing;

d) attendance at educational seminars and familiarity with the current literature on EO sterilization;

e) demonstration and improvement of expertise through participation (as a member or resource person) in committees within the health care facility (e.g., risk management, infection control, safety, hazardous materials, standardization, policy/procedures).

Rationale: Ethylene oxide sterilization and aeration are complex and potentially hazardous processes that should be supervised by knowledgeable personnel with extensive experience, especially in sterilization processing and infection control. To ensure both effective processing and their own safety, it is important that these personnel be thoroughly familiar with the potential hazards of EO and with techniques to reduce human exposure to EO.

5.2.2 Sterilizer and aerator operators

The responsibility for EO sterilization and aeration should be assigned to one or more qualified individuals on each shift. Among the qualifications for assuming this responsibility are

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a) demonstrated comprehensive knowledge of the specific EO sterilizing system used by the health care facility (a variety of systems are in general use);

b) demonstrated competence in all aspects of EO sterilization (including cleaning and packaging of items to be sterilized, sterilizing procedures, equipment operation, safety precautions, and aeration requirements).

NOTE—One method of demonstrating competence in EO sterilization is the successful completion of a central service certification examination.

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, they are also responsible for transferring sterilized items to the aerator upon 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 of 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.

5.3 Training and continuing education

5.3.1 Sterilization personnel

Personnel engaged in EO sterilization processing must receive initial orientation and on-the-job training. This training should include instruction on EO sterilizer operation, aerator operation, parameters of EO sterilization, basic microbiological principles, the infection control policies and procedures of the institution, safety precautions, and potential hazards. In addition, there should be ongoing continuing education at regular intervals to review and update workers' knowledge and skills and to maintain their competency and certification. Personnel training and continuing education must be documented.

Rationale: Orientation, training, and continuing education decrease the possibility of operator error during EO sterilization processing and help ensure that personnel are conversant with the latest data and techniques. 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. Also, such training is required by OSHA (29 CFR 1910.1047) and by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO 1998).

5.3.1.1 Inservice

Inservice programs on EO sterilization processing must be regularly scheduled 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.

5.3.1.2 Orientation

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

5.3.1.3 Manufacturer's instructions

Operators of EO sterilizers, aerators, and sterilizer/aerators should follow the manufacturer's written instructions.

5.3.1.4 Recordkeeping

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

5.3.2 Other personnel

Personnel who are not assigned to the sterilization department but who have responsibility for maintenance of EO sterilizers, aerators, ventilation systems, and/or emission control systems, or for the changing of EO supply sources should have adequate training in safe work practices and engineering controls. 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. Also, such training is required by the OSHA standard on occupational exposure to EO (29 CFR 1910.1047) and by JCAHO (1998).

5.4 Personnel health

5.4.1 Information concerning the potential hazards of exposure to EO

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 the requirements of the OSHA standard on occupational exposure to EO (29 CFR 1910.1047) and must identify the areas and tasks in which there is potential exposure to EO.

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.

5.4.1.1 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, due to the rapid evaporation of EO from the skin surface. Liquid EO can also cause eye irritation and injury to the cornea. Ingestion of 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.

5.4.1.2 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.

5.4.1.3 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.

5.4.2 Medical surveillance and treatment

5.4.2.1 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 by or under the supervision of 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;

d) any laboratory or other test that the examining physician deems necessary based on sound medical practice.

If requested by the employee, 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 the wearing of 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 at 5-year intervals, 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.

5.4.2.2 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 broken ampule, 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 in two to three days, depending on the severity of involvement. In severe instances, anti-inflammatory medications might be useful. See also 4.9.4.

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

5.4.2.3 Recordkeeping

Medical records must be kept for the duration of employment and for 30 years following termination of employment, at which point they must be transferred to the U.S. Assistant Secretary of Labor.

Rationale: These recordkeeping requirements are based on OSHA regulations (29 CFR 1910.20).

5.4.3 First aid

See 4.9.4.

5.5 Attire

For recommendations concerning general work attire in sterilization processing areas, see AAMI (1994b).

6 Processing recommendations

6.1 General rationale

This section covers guidelines for processing medical devices before, during, and after sterilization. These guidelines apply mainly to the reprocessing and resterilization of items intended for reuse. Proper work practices in preparing items for sterilization, implementing sterilization cycles, and handling, storing, and distributing sterilized items are essential to personnel safety, effective sterilization processing, and sterility maintenance.

6.2 Items suitable for EO sterilization

Ethylene oxide sterilization processing should be limited to essential uses, i.e. the processing of heat- and/or moisture-sensitive items that are compatible with EO. For items that must be EO sterilized, the device manufacturer's instructions for cleaning, preparation, and sterilization parameters should be followed.

NOTE—Liquids, oils, and powders (e.g., talc) should not be EO sterilized.

Rationale: Limiting EO sterilization processing to essential uses helps minimize occupational exposure to EO. Careful attention to the device manufacturer's instructions is necessary in order to ensure sterility and to avoid damage to the device. (For example, endoscopes could be damaged if not properly vented.)

Ethylene oxide sterilization of liquids is inadvisable because EO in combination with liquids could produce byproducts that are harmful and that are unlikely to be removed by aeration. It is difficult to achieve sterilization of oils and powders by EO. Oils and other petroleum products are not penetrable by EO and are generally sterilized by dry heat. Talc in volume is also a barrier to EO penetration and is generally sterilized by dry heat (see also OR Manager,1992).

6.3 Receiving

6.3.1 General considerations

Although these recommendations address mainly the work practices of processing personnel, it should be remembered that sterility assurance "begins at the loading dock," i.e., at the point where the health care facility assumes responsibility for incoming medical equipment, devices, and supplies. Therefore, sterility assurance

measures should be used from the outset of receipt of items; in particular, clean or sterile items should be handled separately from foodstuffs, waste material, soiled laundry, and other potential sources of contamination.

6.3.2 Contaminated items

6.3.2.1 Reusable items from patient care areas

All materials to be reused should arrive at the decontamination area, where they should be considered contaminated and should be reprocessed as such. 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 inadvertent personnel contact with or exposure to the contaminated items during transfer. Containers should be selected based on the characteristics of the items being transported; in particular, containers should prevent spillage of liquids, if applicable. 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.

Devices that have been in contact with tissue, blood, or other body fluids and that will be reprocessed should be cleaned of gross debris at the point of use, provided that personnel are wearing protective attire and that adequate facilities are available. Devices should be prevented from drying out 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 by adding water or a moist towel to the transport container.

Rationale: Contaminated items harbor microorganisms that could cause infection. Containment minimizes airborne or contact spread of microorganisms and thus reduces the risk of cross-infection. Keeping items moist prevents the drying of soil on device surfaces and facilitates subsequent cleaning and decontamination.

6.3.2.2 Newly purchased reusable items

Some items, such as surgical instruments, are received nonsterile from the manufacturer and require further cleaning before they are sterilized. After they have been removed from their external shipping containers, such items should be transported directly to the decontamination area for cleaning.

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, the bioburden should be reduced by cleaning before the device is packaged for sterilization. Also, anticorrosive agents such as oils or greases might be left on the device by the manufacturer to protect it during shipping, and such agents will interfere with sterilization if not removed. It is necessary to remove external shipping containers 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.

6.3.3 Clean, nonsterile, disposable items

After they have been removed from their external shipping containers, clean, nonsterile items such as prepackaged disposables may be received directly into preparation areas without further cleaning. (Such items are sometimes used in the preparation or packaging of items to be EO sterilized.)

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

6.3.4 Sterile items

Items that previously have been packaged, sterilized, and issued to operating rooms or similar departments (e.g., as part of a case-cart or exchange-cart system) might be returned unused to the processing area. Before such items are accepted into a preparation or storage area, the integrity of the packaging should be assessed. Items that have been opened or that have damaged packaging should either be disposed of (if labeled for single use only) or unwrapped and reprocessed through decontamination (if reusable), as appropriate. If the packaging is intact and there is no evidence of contamination, the packaged item may be received into the sterile storage area; such items should be among the first used, when needed.

NOTE—Items returned from the operating room unused should be transported on a clean cart and should not enter the decontamination area.

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Items that previously have been packaged, sterilized, and issued to patient care units or other areas in which the environment is not controlled should be discarded if they are single-use items or unwrapped and reprocessed through decontamination if they are reusable.

Rationale: These recommendations are based on the assumptions that an appropriate packaging material has been selected (i.e. one that will maintain sterility unless the package is opened or damaged) and that the packaged items are properly handled. Consequently, the retrieval and reissue of unused sterile items are only recommended 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.

6.4 Cleaning

Items to be sterilized should be thoroughly cleaned and, when applicable, disassembled for sterilization. Saline solutions should not be used for cleaning. See also AAMI (1996b).

Rationale: The purpose of cleaning and rinsing is to remove all adherent visible debris from an item and to reduce the numbers of particulates, microorganisms, and pyrogens. Debris such as blood, mucus, oil, or other foreign matter interferes with the sterilization process by acting as a barrier to the sterilizing agent. Cleaning reduces the bioburden and enhances the probability of sterilization. Ethylene oxide might react with residual saline during sterilization processing and produce the toxic residue ethylene chlorohydrin.

6.5 Ethylene oxide decontamination

Ethylene oxide sterilization should not be used as a decontamination process before items have been cleaned.

Rationale: Items to be decontaminated could contain soil, protein, crystals, or solutions that could render the EO sterilization or aeration process ineffective and that could potentially harm personnel.

6.6 Preconditioning (humidification)

The moisture content of a device and its packaging material significantly affect the EO sterilization process. It is advisable to maintain relative humidity in the range of 35% to 60% throughout the preparation, processing, and storage areas. Drops of moisture should be dried or wiped from the device before packaging. Porous items should not be dried by heated forced air. Certain items might require special preconditioning procedures; the manufacturer of the device should be consulted for instructions.

NOTE—Although the recommended humidity range for all work areas is 30% to 60% (see 3.7), ideal relative humidity in processing areas is 50% and should not be less than 35% for best results in achieving sterilization.

Rationale: Moisture hydrates microorganisms, making them more susceptible to destruction by EO. Drying porous items by heated forced air reduces the moisture content too much; the humidity could be insufficient to allow EO penetration of microbial cell walls. However, visible drops of water are undesirable. Water drops protect microorganisms from EO and can thereby inhibit sterilization. Excessive moisture also increases the possibility that ethylene glycol will be formed, and ethylene glycol is not removed by aeration.

6.7 Packaging

6.7.1 Selection of packaging materials

An effective packaging material for EO sterilization processing should, as a minimum

a) allow adequate humidification and EO penetration of the package contents;

b) allow adequate aeration of the package contents;

c) provide an adequate barrier to microorganisms or their vehicles;

d) resist tearing or puncture;

e) have proven seal integrity (i.e., will neither delaminate upon opening nor reseal after opening);

f) allow for ease of aseptic presentation;

g) be free of toxic ingredients and nonfast dyes;

h) be low-linting;

i) be shown by value analysis to be cost-effective.

Many packaging materials and systems are appropriate for use in EO sterilization. See table 1 for a list of materials considered to be acceptable or unacceptable for EO sterilization.

NOTE—Manufacturers claiming that their sterilization container systems can be used in EO sterilization should provide scientific evidence that their products are suitable for this sterilization method. Certain EO-absorbent, reusable sterilization packaging systems (e.g., containers, organizers, and trays) can retain or accumulate EO residuals, making them difficult to aerate. Manufacturers of such systems should be able to demonstrate that the packaging will allow adequate aeration after each use.

Rationale: The primary functions of any package containing a sterile medical item are to allow the sterilization of the contents, to maintain the sterility of the contents until the package is opened, and to provide for the removal of the contents without contamination. The packaging for items to be EO sterilized has to be gas-permeable and allow for proper aeration. Extreme caution should be exercised in using any packaging material not specifically warranted by the manufacturer for use in EO sterilization.

Table 1—Packaging for EO sterilization

Acceptable	Unacceptable
Polyethylene plastic bags (designed for use as a sterile package and not more than 5 mils thick)	Packages that are made entirely of any of the following materials:
Peel pouches:	Foil
Spun-bonded olefin (Tyvek®) polyethylene-polyester laminate	Cellophane
Paper/polyethylene-polyester laminate	Polyvinylchloride (PVC)
Paper/polypropylene-polyester laminate	Impervious polypropylene film
Wraps:	Polyester (Mylar®)
Woven textile	Polyamide (nylon)
Nonwoven textile	Polyvinylidene chlorine (Saran® wrap)
Paper, coated and uncoated	
Rigid sterilization container systems (designed to be used in EO sterilizers)	
Plastic trays with paper or Tyvek® lids	

6.7.2 Package configurations and preparation

Rubber bands, tape (other than packaging sealing tape), safety pins, paper clips, staples, and similar items should not be used to seal packages. Before peel pouches are sealed, excess air should be removed so that the sealed seams will not be blown out during the sterilization process or by subsequent handling. If one peel pouch is to be placed inside another pouch, the pouches should be of appropriate size to avoid folding the inner pouch over and over onto itself to fit the outer pouch. The pouches should allow for adequate air removal, humidification, and EO penetration and aeration. Instruments that must be EO sterilized because they might be damaged by steam sterilization should be placed in perforated or wire-mesh-bottomed trays or in specially designed containers, with all instruments held open and unlocked. Instruments that can be easily disassembled into component parts may be disassembled for sterilization. Individual instruments may be packaged in an acceptable packaging material, with the instrument prepared and positioned to ensure adequate EO contact with all surfaces.

Rationale: Unacceptable methods used to seal packages could compromise the integrity of the package. It is necessary to package and position items to be sterilized so as to facilitate contact with the sterilant.

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6.8 Loading the sterilizer

6.8.1 Load composition

To the extent practical, the operator should attempt to sterilize full loads of items having a common aeration time.

Rationale: As compared to sterilizing the same volume in partial loads, sterilizing full loads of items having a common aeration time is cost-effective and reduces the potential for occupational exposure and for environmental release of EO. This practice also reduces the temptation for workers to attempt to retrieve items with short aeration times from cabinets in which other items might not be fully aerated and thus helps avoid unnecessary exposure to EO.

6.8.2 Load configuration

If aeration is not a contiguous part of the cycle in the same chamber, items to be sterilized should be loaded into metal baskets, particularly when sterilizer carts are not available. Items should be placed loosely and well within the confines of the basket, shelf, or cart. Packaged items should not touch chamber walls.

Rationale: Overloading impedes proper air removal, humidification of the load, and sterilant penetration and evacuation. Proper loading ensures that the sterilized items will not touch the operator's hands during transfer from the sterilizer to the aerator. Metal baskets do not absorb EO and therefore can be handled prior to aeration.

6.9 Sterilization parameters

6.9.1 General

In general, the most common parameters are EO concentrations from 450 to 1200 milligrams per liter (mg/L), temperatures from 37^{o} C to 63^{o} C (99^{o} F to 145^{o} F), exposure times from 60 to 360 minutes, and chamber humidities from 40% to 80%.

Rationale: These general guidelines are based on Burgess and Reich (1997).

6.9.2 Sterilizer manufacturer's instructions

The cycle parameters should be verified using the sterilizer manufacturer's written instructions for the specific sterilizer and load configuration to be used.

Rationale: Sterilizers vary in design and performance characteristics, so the cycle parameters should always be verified and the sterilizer manufacturer's instructions followed.

6.9.3 Device and packaging manufacturers' instructions

The sterilization and aeration instructions provided by the manufacturer of the device and the manufacturer of the packaging system (e.g., rigid sterilization container) should be compared to those provided by the sterilizer manufacturer. (See also AAMI,1996c.) Any differences should be resolved in order to assure an appropriate sterilization process.

Rationale: The design of some instruments and certain types of packaging can affect EO penetration, temperature and moisture equilibration, and exposure time.

6.9.4 Monitoring

See section 7.

6.10 Unloading the sterilizer

6.10.1 General considerations

Operator exposure to EO can be significantly reduced if precautions are taken during sterilizer unloading.

Rationale: A number of studies have shown that one of the highest probabilities for occupational exposure to EO occurs at the end of the sterilization cycle (Daley *et al.* ,1979; Glaser,1977; Samuels,1978a; Samuels,1978b).

6.10.2 Sterilizers without purge cycles

For this type of sterilizer, the sterilizer door should be opened immediately upon completion of the cycle (unless the sterilizer manufacturer instructs otherwise in writing). The door should be left ajar but should stay within the capture zone of the local exhaust system. Employees should leave the area near the capture zone for at least 15 minutes

before transferring the load to the aerator. Employees should be monitored to ensure that this procedure effectively minimizes exposure (see section 8).

Rationale: Failure to open the door immediately at the end of the cycle allows time for EO levels to build up in the chamber due to desorption from the sterilized items. Therefore, the EO concentration in the chamber will be higher when the door is finally opened. The waiting period allows most of the EO gas to dissipate from the chamber and to be removed by the exhaust ventilation system.

6.10.3 Sterilizers with purge cycles

The safest door-opening procedure at the end of a sterilization cycle depends on the type of purge cycle incorporated into the particular sterilizer. The sterilizer manufacturer's most recent recommendations should be consulted.

NOTE—A purge cycle does not reduce recommended aeration times unless the sterilizer manufacturer provides specific written instructions to the contrary.

Rationale: Due to their purge characteristics, some new sterilizers should be unloaded immediately after the door is opened because the EO concentration in the chamber is lowest at this time. For other sterilizers, it is safest if workers leave the area for a period of time after opening the sterilizer door. Therefore, advice should be sought from the manufacturer.

6.10.4 Sterilizers with integral aeration

Most models of modern EO sterilizers are capable of combining sterilization and aeration in the same chamber as a continuous process. Such equipment may also be used as a sterilizer only, with aeration carried out in a separate chamber. When the equipment is used in the "sterilizer only" mode, or if the sterilization/aeration cycle is interrupted and the door has to be opened (e.g., to retrieve a biological-indicator test pack), the manufacturer's instructions for door-opening procedures must be followed (see 6.10.3).

NOTE—In units with combined cycles, the aeration cycle parameters might differ significantly from those of stand-alone aerators. The device manufacturer's recommendations concerning aeration might need to be interpreted in the light of these differing characteristics.

Rationale: When sterilization and aeration occur as sequential processes in the same chamber without interruption, potential occupational exposure to EO during door opening and load transfer is minimized. The efficiency and effectiveness of aeration is affected by load characteristics, temperature, and air-flow patterns and velocity. Altering any of these variables can affect the amount of aeration time required.

6.10.5 Sterilizers with "detoxification"

Some models of EO sterilizers are capable of removing EO from materials in the sterilizing chamber by a "detoxification" process, in which steam at subatmospheric pressure is used to extract EO. The manufacturer's instructions for operating the sterilizer and dealing with interrupted cycles should be followed.

The detoxification time necessary for a particular material or device depends on many variables, including the composition, thickness, design configuration, and weight of the device; the characteristics of the sterilization cycle (i.e., temperature, sterilant concentration, exposure time); the detoxification temperature; and the intended application of the device. The size and configuration of the load, air-flow patterns, and sterilizer size do not significantly affect detoxification time. Health care personnel should consult the sterilizer manufacturer's label claims for specific recommendations on this process.

Rationale: Detoxification is a relatively new, proprietary process for the removal of EO, and it differs from conventional aeration. Consequently, it is especially important to follow the manufacturer's instructions for operation of the sterilizer.

6.10.6 Handling of EO-sterilized items before aeration

The transfer of products from a sterilizer to an aerator should be performed in as short a time as possible. (When it is necessary for an operator to handle items that have not been aerated, such as a biological-indicator test pack, personnel should be monitored to verify the safety of the practices followed. See also 7.8.) Items sterilized by EO should remain on the sterilizer cart or in the basket during transport to the aerator and during aeration. (Sufficient all-metal baskets or carts should be purchased to limit handling of individual packs.) Protective gloves are not needed when transferring metal baskets and carts from the sterilizer to the aerator because metal does not absorb EO. If it is necessary to handle individually packaged items, butyl, neoprene, or nitrile rubber gloves should be worn. Carts should be pulled to the aerator, not pushed from behind.

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NOTE—Butyl gloves are expensive, and nitrile and neoprene gloves are available that can be used for this purpose. The manufacturer's specifications on EO penetration rates should be checked.

Rationale: To prevent personnel from breathing EO gas or coming into contact with EO residues, EO-sterilized items should be handled as little as possible before aeration. Some EO sterilized items rapidly release EO into the air upon removal from the sterilizer. The EO given off by the items contributes to the general background concentration of EO in the workplace and might present an exposure hazard to the sterilizer/aerator operator. If carts are pushed from behind, air will flow over the cart toward the employee's breathing zone, causing unnecessary exposure to EO.

6.11 Aeration recommendations

6.11.1 General considerations

All EO-sterilized materials that absorb EO should be properly aerated before handling and use, preferably in a sterilizer/aerator. Aeration cabinets specifically designed for this function (i.e., cabinets having filtered air exchanges and controlled air flow and temperature) may also be used. Ambient aeration is not acceptable.

Rationale: Items sterilized by EO must be adequately aerated so that residual EO can be reduced to a level safe for both personnel and patients. Ideally, sterilizer/aerators should be used for this purpose because personnel need not handle degassing items at all. Ambient aeration increases background levels of EO, thus increasing the risk of occupational exposure to EO, and it is prohibited by OSHA (29 CFR 1910.1047).

6.11.2 Metal and glass items

Unwrapped, nonporous metal and glass items do not require aeration because they are impermeable to EO. Such items should be easily retrievable from the load in case their removal is necessary before the aeration of other items in the load. However, metal or glass items that are wrapped in EO-absorbent material should be aerated, as should items or packages consisting of a combination of absorbent and nonabsorbent materials.

NOTE—Packaging and wrapping materials retain EO for varying periods of time. Manufacturers of these materials should be consulted for aeration parameters.

Rationale: See 6.11.1.

6.11.3 Aeration capacity

If a separate aeration cabinet is used, its capacity should match or exceed the sterilization processing capacity (i.e., the volume of items processed per day).

Rationale: Adequate aeration capacity is essential for worker and patient health and safety.

6.11.4 Aeration times

The aeration time necessary for a particular material or device depends on many variables, including

a) the composition, thickness, design configuration, and weight of the device and its wrapping material and/or sterilization container system;

b) the characteristics of the sterilization system used (i.e., the temperature, EO concentration, and duration of exposure);

c) the characteristics of the aeration system used (i.e., the temperature, rate of air exchange, and air-flow pattern);

d) the size and arrangement of packages in the sterilizer/aerator or aeration cabinet and the number of highly EO-absorptive materials being aerated;

e) the intended application of the device (i.e., external or implantable use), which will influence the level of EO residuals permissible.

Health care personnel should ask device manufacturers and packaging suppliers to recommend aeration times and conditions for their products. Manufacturers of sterilizers, sterilizer/aerators, and aeration cabinets should also be consulted because they might have information on specific materials or medical devices sterilized or aerated in their own equipment. Because of the many aeration process variables, it is not practical to recommend specific minimum aeration times here. As a guideline, however, it has been determined that a typical polymer that is difficult to aerate, polyvinylchloride tubing, could require approximately 12 hours to aerate in an aeration cabinet at 50^{o} C (122^{o} F), 8 hours at 60^{o} C (140^{o} F). Some materials will require less time, others much more time. (See Danielson,1998; Stetson et al.,1976; Whitbourne and Page,1993; Whitbourne and West, 1975; and Whitbourne et al.,1997.)

After obtaining all of the information available from the manufacturers of the devices, sterilizers, and aerators, health care personnel should perform their own safety evaluation of their aeration procedures with regard to airborne EO (see section 8). Items should not be retrieved from the sterilizer/aerator or aeration cabinet until the aeration time for the most challenging materials has been completed. The aeration process should not be interrupted unless medical necessity outweighs the risk of employee and patient exposure to EO and unless adequate precautions have been taken to protect employees.

Rationale: It is strongly urged that health care personnel require device and packaging manufacturers to provide information on the necessary aeration parameters for their products. However, because many types of sterilizers, sterilizer/aerators, and aerators are commercially available, each with a unique cycle, device and wrapping material manufacturers might not be able to provide complete information applicable to the health care facility's particular sterilizing and aeration conditions. Conversely, manufacturers of sterilizers, sterilizer/aerators, and aerators will not be able to determine aeration times for the thousands of devices in the multitude of wraps, package sizes, and compositions used in health care facilities. Furthermore, because hospital loads vary so greatly from one another and from day to day, none of the manufacturers can predict the contents of a particular aeration load. Therefore, the committee feels that while as much information as possible should be gathered from all device and equipment manufacturers, in the final analysis it is up to the health care facility to determine how much aeration is required to minimize environmental EO and to provide a safe device for patient care.

6.12 Sterile storage

6.12.1 Handling and inspection

Written procedures should specify a minimum amount of handling of all sterile items. As items are removed from the sterilizer cart, they should be visually inspected. Any items with torn, compressed, or otherwise damaged packaging should not be used; instead, such items should be returned to the decontamination area for reprocessing.

Rationale: Packages that are compressed, torn, or otherwise damaged are considered contaminated (see also 6.12.3).

6.12.2 Plastic dust covers

6.12.2.1 General considerations

If it is known that the items being sterilized will be subjected to potential contamination from moisture or rough handling, they should be packaged in all-plastic bags designed for EO sterilization. If this is not possible, an acceptable alternative is to apply a plastic dust cover (sterility maintenance cover) after sterilization. The cover should be clearly designated as a dust cover to prevent its being mistaken for a sterile wrap.

Rationale: Plastic provides a barrier to moisture and dust; this barrier might be necessary to preserve the sterile integrity of the package, especially one that is not going to be used immediately or that will be transported long distances. Because a dust cover is applied after sterilization and aeration, the outer layer of actual packaging material should be considered contaminated for purposes of sterile presentation. See also 6.12.5.

6.12.2.2 Application of dust covers

If dust covers are to be applied to EO sterilized packages, they should be applied only after the aeration cycle is complete and as soon as possible after the items have cooled. Before personnel handle sterilized items, their hands should be clean and dry.

NOTE—Some dust covers (sterility maintenance covers) can be applied before EO sterilization (see 6.12.2.1). Check the manufacturer's recommendations.

Rationale: Dust covers should be applied as soon as possible after sterilization and aeration to enhance maintenance of sterility. Hands should be clean and dry to prevent contamination of the package by perspiration.

6.12.2.3 Sealing of dust covers

The dust cover should be sealed using either a heat sealer designed to seal plastic to plastic or an alternative method that is similarly effective.

Rationale: For the dust cover to be an effective barrier to moisture, it is necessary to seal it.

6.12.2.4 Application of control data

The lot or load number and expiration statement should be visible through the dust cover, or an additional label should be used on the dust cover (see also 7.2.1).

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Rationale: The dust cover is only a protective device. The identity and traceability of the package within have to be maintained.

6.12.3 Storage of supplies

Sterile supplies should be stored far enough from the floor, the ceiling, and outside walls to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes. The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised. Medical and surgical supplies should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they can become wet. Storage of supplies on floors, window sills, and areas other than designated shelving, counters, or carts should be avoided. See also 6.13.1.

Rationale: Adequate space is needed around sterile items to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that might form on the interior surfaces of outside walls. Also, fire codes specify minimum distances below the ceiling (usually 18 inches) to ensure the effectiveness of sprinkler systems. Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces. Sterile items should not be stored anywhere except on or in designated shelving, counters, or containers because other areas might not be sufficiently clean, and window sills collect condensate that forms due to differences in temperature between inside and outside air.

6.12.4 Storage shelving

Closed or covered cabinets are recommended for the storage of seldom-used sterile supplies. Open shelving may be used, but requires special attention to traffic control, area ventilation, and housekeeping. Shelving or carts used for sterile storage should be maintained in a clean, dry condition. Outside shipping containers and corrugated cartons should not be used as containers in sterile storage areas. See also 6.3.2.2.

Rationale: Closed cabinets limit dust accumulation, discourage handling, and minimize inadvertent contact with sterile items. Shipping containers have been exposed to unknown and potentially high microbial contamination, and those that are corrugated serve as generators of and reservoirs for dust; hence, shipping containers should never be allowed in the sterile storage area.

6.12.5 Shelf life

The shelf life of a packaged sterile item is event-related and depends on the quality of the wrapper material, the storage conditions, the conditions during transport, and the amount of handling. Shelf life is not simply a matter of sterility maintenance but also a function of material life and inventory control. There should be written policies and procedures for how shelf life is determined and for how it is indicated on the product. This indication may take the form of a specific expiration date or a day-to-day expiration date (e.g., “sterile unless the integrity of the package is compromised” or some equivalent language). When dust covers are used, there should be specific policies and procedures for assessing shelf life in the event that the cover is removed but the packaged item is not used immediately. In general, stock should be rotated according to the principle, “first in, first out.”

Rationale: The contamination of a sterile item is event-related, and the probability of its occurrence increases over time and with increased handling.

6.13 Distribution

6.13.1 Handling and inspection

Supplies should be handled carefully. Care should be taken to avoid crushing, bending, compressing, or puncturing the packaging or otherwise compromising the sterility of the contents. Packaging should be thoroughly inspected visually for integrity and labeling before an item is issued.

Rationale: See the rationale statement for 6.12.3.

6.13.2 Distribution containers

Sterile items should be transported in a covered or enclosed cart with a solid bottom shelf. If items are placed inside plastic or paper bags or boxes for transport, the items should be arranged within the containers so as to prevent their being crushed or otherwise damaged or contaminated. Reusable covers for carts or other transport vehicles should be cleaned after each use and should have a reclosable opening. Carts should be decontaminated and dried before they are reused for transporting sterile supplies. For automated cart distribution systems and pneumatic systems, the manufacturer’s instructions on distribution and decontamination procedures should be followed.

Rationale: Covered or enclosed carts protect sterile items from inadvertent contact with personnel and other sources of contamination and from environmental challenges that might exist along the transportation route. A solid bottom shelf on the cart prevents contamination via the so-called “rooster-tail effect,” in which the wheels pick up contaminants from the floor and spin them upwards. Surfaces in direct contact with sterile packaging should have minimum bioburden to decrease the risk of microbial penetration of the sterile barrier of the packaged items. Carts and reusable covers should be cleaned after each use because even though they are used with sterile items, contamination is picked up from the environment during transport outside the department.

7 Quality control

7.1 General rationale

This section covers product identification and traceability; mechanical, chemical, and biological monitoring of EO sterilization cycles; product recalls; and related quality control measures. Sterility assurance requires continuous attention to all aspects of the EO sterilization process and the performance of the sterilizer.

NOTE—Quality control is usually thought of only as product and process monitoring, and section 7 is primarily concerned with those applications. In its broadest sense, however, quality control involves continuous supervision of personnel performance and work practices and ongoing verification of adherence to established policies and procedures.

7.2 Product identification and traceability

7.2.1 Lot control numbers

Each item or pack intended for use as a sterile product should be labeled with a lot control identifier. The lot control identifier should designate the sterilizer identification number or code, the date of sterilization, and the cycle number (cycle run of the sterilizer). The policy of the individual health care facility determines when the lot control label is affixed to the package. If packages are to be labeled before sterilization, the labeling should be done immediately before the load is processed. If it is the policy to label packages after sterilization, the labeling should not be done until the packages are aerated; for multiload aerators, care should be taken not to mix items from different lots.

Rationale: Lot identification enables retrieval of items in the event of a recall and the tracing of problems to their source. Presterilization labeling should be done after sterilizer and cycle assignment is determined and as the cart is loaded in order to avoid mixups between sterilized and nonsterilized loads. For poststerilization labeling, labeling packages after aeration helps prevent personnel exposure to EO.

7.2.2 Sterilizer records

For each sterilization cycle, the following information should be recorded and maintained:

a) the lot number;

b) the general contents of the lot or load (e.g., implantables);

c) the exposure time and temperature;

d) the name or initials of the operator;

e) the aeration time and temperature;

f) the results of biological monitoring;

g) the response of the internal chemical indicator (if placed in the biological-indicator test pack);

h) any reports of inconclusive or nonresponsive chemical indicators found later in the load (see also 7.4.3.2[c]).

The recording chart or tape, if applicable, should also be dated and maintained, and each cycle on the chart should be reviewed and signed by the operator. A record of repairs and preventive maintenance should also be kept for each sterilizer (see 4.7.3.6). All of the foregoing information may be incorporated into a sterilizer log system or filed as individual documentation records. All sterilizer records must be retained in the central service department or another designated storage area for a period of time not less than that specified by state or local statutes or, if statutes are nonspecific, by the infection control committee of the individual institution.

Rationale: Documentation ensures monitoring of the process as it is occurring, ensures that cycle parameters have been met, and establishes accountability. In addition, documentation helps personnel determine whether recalls are necessary and the extent of recalls, should evidence subsequent to lot release (such as a positive biological indicator) suggest sterility problems. Knowing the contents of the lot or load enables personnel to decide how critical a recall might be.

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7.2.3 Expiration dating

Each item intended for use as a sterile product should be labeled with a "processed" date and/or an expiration date or statement that will assist in proper stock rotation. This information may be incorporated into the lot identification on the label or imprinted or affixed separately on the outside of the package.

Rationale: Labeling items with expiration dates or statements is necessary for proper stock rotation (see also 6.12.5).

7.3 Physical monitoring

7.3.1 Use of electronic or mechanical monitors

Physical monitors include time, temperature, and pressure recorders; displays; computer printouts; and gauges. The operator should ensure at the beginning of the cycle that the recording chart is marked with the correct date and with the sterilizer and cycle identification, and that the pen or printer is functioning properly on the chart. At the end of the cycle and before items are removed from the sterilizer, the operator should examine the record to verify that cycle parameters were met and then sign it (7.2.2). Sterilizers that do not have recording devices should not be used.

NOTE—Most temperature sensors indicate temperature at a single point in the chamber, not at the center of packs. Improper load configuration or package composition can interfere with air evacuation and EO penetration, conditions that will not be revealed in the temperature recording. Therefore, physical monitoring and other indicators of sterilizer performance should never be considered a substitute for careful adherence to prescribed packaging and loading procedures.

Rationale: Physical monitoring provides real-time assessment of the sterilization cycle conditions and in some cases provides permanent records by means of chart recordings or computer-driven printouts. Physical monitoring is needed to detect malfunctions as soon as possible, so that alternative procedures can be used in the event of failures.

7.3.2 Sterilizer malfunction

If the records indicate any malfunction or suspicious operation, the department head or designee should be notified. After examination, if the malfunction cannot be corrected immediately, the cycle should be aborted in accordance with the sterilizer manufacturer's instructions. The load should be considered nonsterile, and the sterilizer should be removed from service. The hospital engineer or preventive maintenance contract service should then be notified and the malfunction corrected. A faulty sterilizer cannot be made operational without identifying and correcting the underlying problem; merely extending the cycle time, for example, is not appropriate. After a sterilizer has been repaired, a cycle with a challenge test pack should be run before the sterilizer is returned to service (see 7.6.4).

NOTE—After the introduction of gas, even if the cycle is aborted, the load should be aerated because it will be saturated with EO. The supervisor should determine, based on his/her professional judgment, the appropriate subsequent disposition of the load.

Rationale: Simply altering the cycle parameters of a malfunctioning sterilizer will not correct a problem; the sterility of future loads will be jeopardized if the sterilizer continues to be used without repair. To restore a sterilizer to proper performance, it is necessary to identify the exact cause of the malfunction. Common problems detected by mechanical monitoring include inadequate vacuum, improper temperature, and inadequate exposure time.

7.4 Chemical indicators

7.4.1 Definition

A chemical indicator is a sterilizing process monitoring device designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect problems associated with incorrect packaging, incorrect loading of the sterilizer, malfunctions of the sterilizer, or incorrect preconditioning. The "pass" response of a chemical indicator does not prove that the item accompanied by the indicator is sterile.

7.4.2 Selecting chemical indicators

Health care personnel should select chemical indicators that comply with AAMI (1996a), and they should also obtain data from manufacturers on the reliability, safety, and performance characteristics of their products. In addition, manufacturers of chemical indicators should be required to provide written information on how to interpret indicator results, the reliability of the indicator in maintaining end-point color change (if applicable) during storage of sterilized items, the sterilization conditions that the indicator will detect, the shelf life of the indicator, and the storage requirements before and after sterilization.

NOTE—AAMI (1988) provides guidelines for the selection and use of chemical indicators in steam sterilization monitoring. Many of the general principles described in that document are equally applicable to chemical indicators intended for use in EO sterilization monitoring.

Rationale: Various types of external and internal chemical indicators are available, each with different response characteristics; i.e. they differ in the sterilizing conditions that they will detect and verify. The degree of quality control needed is a judgment based on a risk/benefit assessment, and the choice of chemical indicator depends highly on the specific needs, resources, and sterilization equipment of the individual health care facility.

7.4.3 Using chemical indicators

7.4.3.1 External chemical indicators

Sterilizer indicator tape, an indicating label, or an indicating printed legend should be affixed to or printed on each hospital-assembled package intended for sterilization. An indicating label or a piece of indicating tape should be attached to or printed on each commercially acquired package if inhospital sterilization is to be performed. Except for packages that allow visual inspection of an internal indicator, such as those with paper/plastic packaging, external indicators should be used on all packages. The external chemical indicator should visually denote that the package has been exposed to physical conditions present in the EO sterilizer. The tape, label, or legend should be examined after aeration and also before use of the item to verify that it indicates that the item has been exposed to a sterilization process.

Rationale: The purpose of an external chemical indicator is to differentiate between processed and nonprocessed items, not to establish whether the parameters for adequate sterilization were met.

7.4.3.2 Internal chemical indicators

7.4.3.2(a) Placement and frequency of use

An internal chemical indicator should be used within each package to be sterilized. The chemical indicator should be placed in that area of the package considered to be least accessible to EO penetration; this might or might not be the center of the package.

Rationale: There are no practical means of verifying the sterility of individual items. Chemical indicators do not verify sterility, but they do allow detection of certain procedural errors and equipment malfunctions. The use of chemical indicators that respond to the parameters of EO sterilization is beneficial in providing quality patient-care products.

7.4.3.2(b) Retrieval and interpretation

The chemical indicator is retrieved at the time of use and interpreted by the user. The user should be adequately trained and knowledgeable about the performance characteristics of the monitoring system.

Rationale: Internal chemical indicators cannot be retrieved without compromising the sterile integrity of the packaging and thus must be retrieved and interpreted at the time of use.

7.4.3.2(c) Nonresponsive or inconclusive chemical indicators

If the interpretation of the indicator suggests inadequate EO processing, the contents of the package should not be used. The interpreter should inform the appropriate supervisor, who should return the complete unused package, including load identification and the chemical indicator, for appropriate follow-up. The department head or designee in the sterilizing department should then decide whether or not to recall that sterilized load. This decision should be based on the results of mechanical monitoring, the results of chemical indicators elsewhere in the load, and the results of biological monitoring. If the biological monitoring results are not yet available, the remaining packages from the same load should be quarantined and not used until the results of the biological indicators are obtained.

Rationale: If a chemical indicator is nonresponsive or inconclusive, it is possible that the entire load is nonsterile; that is, the sterilization process failed. The use of chemical indicators is only one way to verify sterilizer and cycle performance, however, and chemical indicators vary widely in their response characteristics. It is also possible that errors in loading or packaging have resulted in sterilization failures in some, but not all, packages in the load. Therefore, a single nonresponsive or inconclusive chemical indicator should not be considered *prima facie* evidence that the load is nonsterile. The supervisor should exercise professional judgment in determining whether or not to recall the entire load, taking into account all factors having a bearing on the efficacy of the cycle and all performance indicators.

7.5 Biological indicators

7.5.1 Definition

A biological indicator is a sterilization process monitoring device consisting of a standardized, viable population of microorganisms known to be resistant to the mode of sterilization being monitored (in this case, EO). Biological indicators are intended to demonstrate whether or not the conditions in the sterilizing chamber were adequate to

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achieve sterilization. A negative biological indicator does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

7.5.2 Selecting biological indicators

Health care personnel should select biological indicators, consisting of spores of *Bacillus subtilis* var. *niger*, that comply with AAMI (1994a). In addition, data should be obtained from manufacturers on the reliability, safety, and performance characteristics of their products. Manufacturers of biological indicators should also be required to provide written instructions on the storage, handling, use, and microbiological testing of their products.

Rationale: Various types of biological indicators are available, each with different response characteristics. The degree of quality control needed is a value judgment based on risks and benefits, and the choice of biological indicator depends highly on the specific needs, resources, and sterilization equipment of the individual health care facility.

7.5.3 Frequency of use of biological indicators

Biological-indicator challenge test packs (7.6.1) should be used for qualification testing by sterilizer manufacturers (7.6.2) and for initial installation testing (7.6.3) and periodic quality assurance testing (7.6.4) in the health care facility. A routine biological-indicator test pack (7.7.2) should be used in each sterilization cycle unless a challenge test pack is part of the load. Each load containing implantable devices should be monitored and, whenever possible, quarantined until the results of the biological-indicator testing are available.

Rationale: It is not possible to monitor directly, by physical or mechanical means, all of the critical parameters of EO sterilization (e.g., chamber gas concentration or load relative humidity). The condition of the sterilizer, the expertise of the sterilizer operator, and other factors determining the success or failure of an EO sterilization cycle could vary from one cycle to another. The less frequently the sterilizer is used, the greater the opportunity for the occurrence of an unnoticed event that could affect sterilization. Because of the potential consequences to the patient of the implantation of a nonsterile device, the sterilization of implantables should be closely monitored. Ideally, for maximum sterility assurance, each load of implantables should be quarantined until it is verified that biological-indicator testing has yielded negative results. It is recognized, however, that in emergency situations it might not be possible to maintain the quarantine of implantables for which there is an immediate need. Therefore, the recommendation concerning quarantine of implantables pending the outcome of biological-indicator testing states that implantables should be quarantined "whenever possible." (See also the rationale statements for 7.6.2, 7.6.3, 7.6.4, and 7.7.2.)

7.6 Qualification, installation, and periodic quality assurance testing

7.6.1 Challenge test pack

The challenge test pack should consist of the items described below (see also figures 2, 3, and 4). These materials are intended to challenge all of the parameters necessary for EO sterilization. The fact that these materials are recommended for use as test pack components does not mean that these types of materials, in themselves, should be sterilized by EO. Most of the recommended materials are heat stable and are steam sterilized for use in patient care. Some of the recommended components are disposable items and are not recommended for reprocessing and reuse in patient care.

The components of the challenge test pack are

a) four clean, approximately 18-inch by 30-inch surgical towels (woven, 100% cotton absorbent), each folded in thirds and then in half to create six layers per towel and then stacked one on top of another (figure 2a or 2c);

   NOTE—Before being assembled in the pack, the towels should not be ironed, and they should not have been taken directly from the dryer. Also, they should not have been stored in areas in which the relative humidity is low (i.e., lower than 30%).

b) two biological indicators, each of which is placed in a separate plastic syringe of sufficient size that the plunger diaphragm does not touch the biological indicator when the plunger is inserted into the barrel of the syringe (figure 3). The biological indicators should not be removed from the protective covering supplied by the manufacturer. The instructions of the biological-indicator manufacturer should be consulted to ensure that the biological indicator selected is appropriate for use in the specific sterilizer being challenged. The manufacturer's instructions should also be consulted to determine the correct orientation of the biological indicator in the syringe. The needle end of the syringe shall be open (i.e., the tip guard must be removed). At least one additional biological indicator from the lot used for testing should be left unexposed to the sterilant, incubated, and treated as a positive control;

NOTE—Syringes to be used in patient care or laboratory applications are not customarily sterilized with the plunger inserted into the barrel.

c) one adult plastic airway (figure 4);

d) one 10-inch-long section of amber latex tubing with an internal diameter of 3/16 inch and a wall thickness of 1/16 inch (figure 4);

e) a chemical indicator;

f) two clean, approximately 24-inch by 24-inch wrappers, either woven or nonwoven (figure 4). Manufacturers should use two 100% cotton muslin wrappers, each two layers in thickness. Health care personnel should use the wrapping material that they customarily use in sterilization processing.

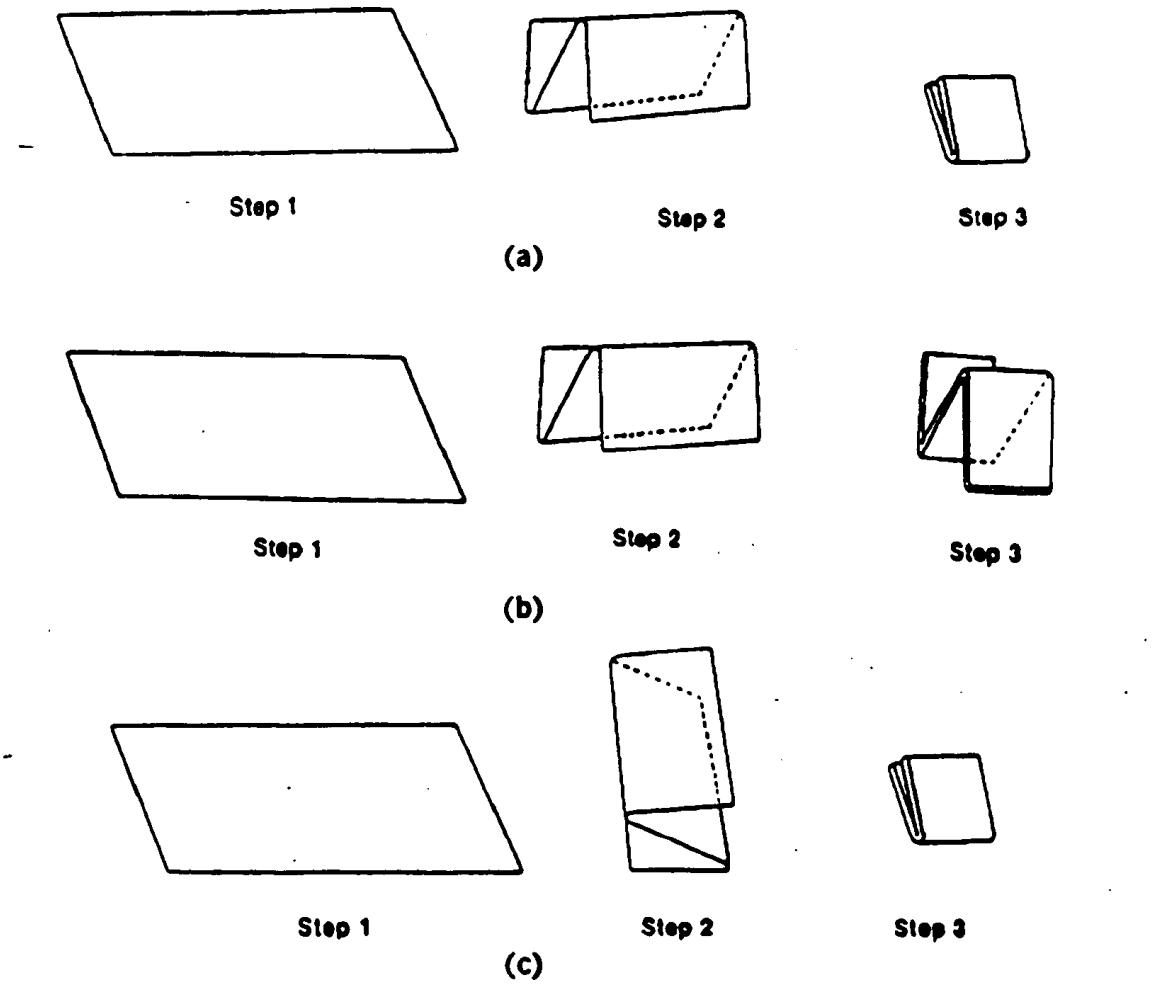

Figure 2—Folding of surgical towels

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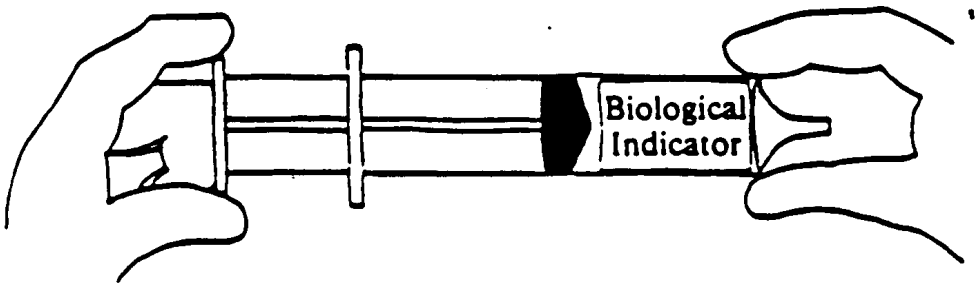

Figure 3—Placement of biological indicator in syringe

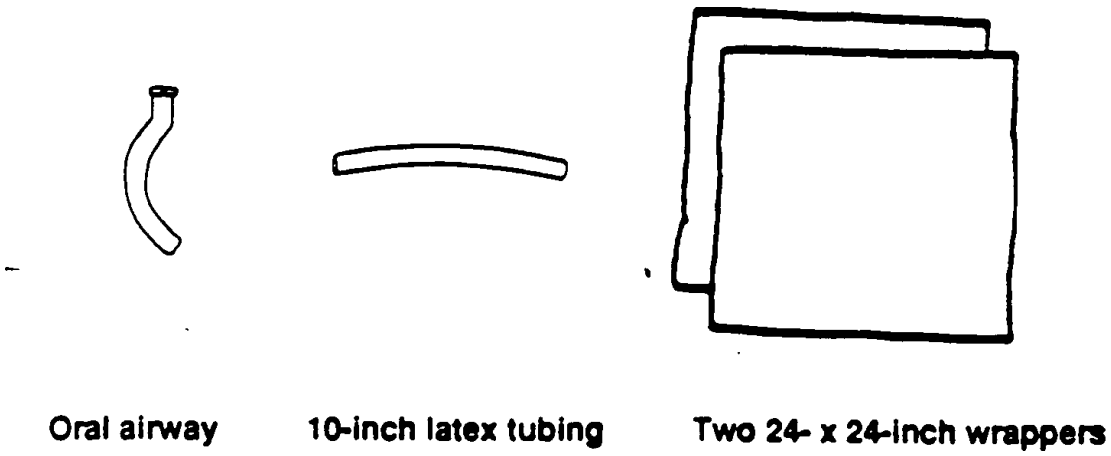

Figure 4—Some components of the challenge test pack

Prior to assembly, the test pack components should be held at room temperature (20° C to 23° C [68° F to 73° F]) and a relative humidity of at least 35% for a minimum of 2 hours. If the towels are inadvertently ironed, stored in an area in which the relative humidity is lower than 30%, or otherwise dried out, the minimum temperature/humidity equilibration time should be extended to 24 hours.

For assembly of the test pack, the syringes, latex tubing, plastic airway, and chemical indicator are placed between the folded cotton towels in the center of the stack (figure 5). The stack is then sequentially wrapped and secured with tape (figure 6).

NOTE—Commercially available test packs for routine biological monitoring should not be used for challenge testing unless the manufacturer's specifications indicate that the commercial test pack has been validated against the AAMI challenge test pack.

Rationale: This challenge test pack is designed to challenge all of the parameters upon which sterilization depends. The towels and muslin fabric act as moisture and EO absorbents as well as heat sinks; the rubber and plastics as EO absorbents; the plastic syringes with barrel as heat sinks, EO absorbents, and diffusion restricters; and the biological indicators as a microbial challenge. Placing the biological indicators in the center of the pack challenges the heating, humidification, and gas diffusion characteristics of the sterilizer.

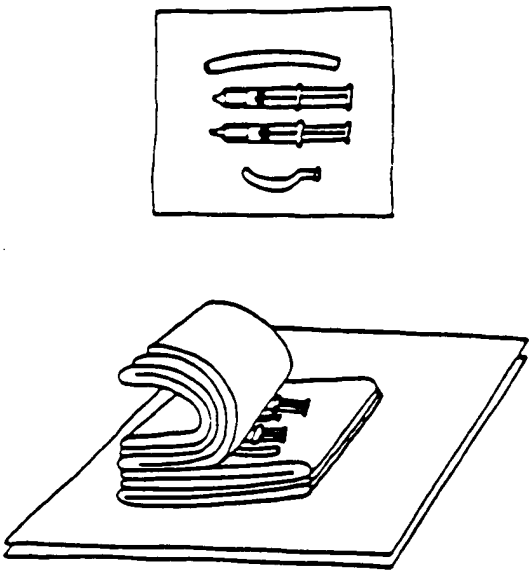

Figure 5—Placement of components in challenge test pack

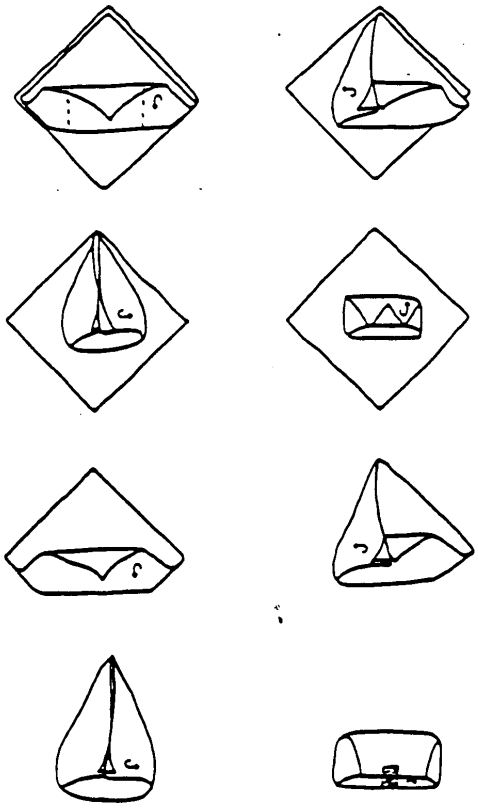

Figure 6—Wrapping the challenge test pack

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The towels for the test pack, together with the other components, are intended to create a somewhat greater challenge to the sterilizer than does the load itself. The pack is intentionally composed of materials that are readily available to both manufacturers and health care facilities (e.g., absorbent towels, plastic devices). The use of items such as surgical towels to serve as heat sinks and moisture absorbers should not be construed as a recommendation that towels be routinely sterilized by EO; the same is true of the disposable materials, which are used only for test purposes. These items provide the challenges described, yet avoid the need to reserve expensive and limited inventory materials specifically for use in sterilization test packs. See also section A.1 of annex A.

NOTE—There are insufficient data upon which to base a recommendation either for or against the reuse, for purposes of the test pack, of items labeled for single use only. The decision concerning the reuse of single-use items—and, if applicable, the number of times such items are reused—should be based on the professional judgment of the user and on the policy of the health care facility. It should be noted, however, that under no circumstances should single-use items previously used in patient care be used as components of the test pack.

7.6.2 Qualification testing by sterilizer manufacturers

Challenge test pack testing should be conducted by the sterilizer manufacturer as part of initial design qualification, upon any change that might affect efficacy, and at least once every 2 years. The testing should be performed on separate loads for three consecutive cycles. The test procedure is described in AAMI (1999).

Rationale: The purpose of qualification testing by the manufacturer is to assess sterilizer performance under simulated worst-case (“small load”) in-use conditions, both as one element of overall design qualification and to enable health care personnel to assess the performance of individual EO sterilizers during installation testing against the standard of performance claimed by the manufacturer.

7.6.3 Installation testing

7.6.3.1 General considerations

Challenge pack testing should be conducted in the health care facility by health care personnel in cooperation with the manufacturer. The testing should be performed between the time the EO sterilizer is installed and the time it is released for use in the health care facility. Three consecutive cycles, with negative results from the test biological indicators, should be conducted prior to release.

NOTE—Commercially available test packs for routine biological monitoring should not be used for challenge testing unless the manufacturer’s specifications indicate that the commercial test pack has been validated against the AAMI challenge test pack.

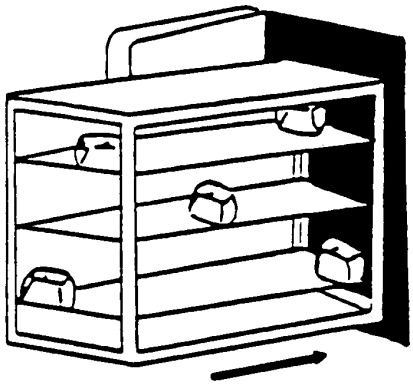
Rationale: The purpose of installation testing is to assess sterilizer performance in the environment where it will be used. Satisfactory test runs verify the results of the manufacturer’s qualification testing and ensure that the sterilizer functions effectively in the facility where it is installed.

7.6.3.2 Positioning of test packs

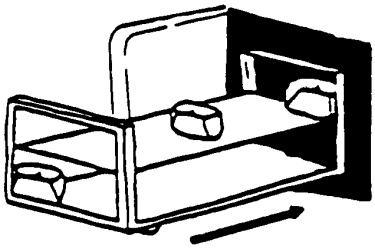
The challenge test packs should be positioned in the following manner:

a) For EO sterilizers with chamber volumes of 80 to 100 cubic feet, five test packs should be used: one placed in the center of the chamber; one each in two diagonally opposite corners of the rear of the chamber; and one each in two diagonally opposite corners of the front of the chamber (figure 7a).

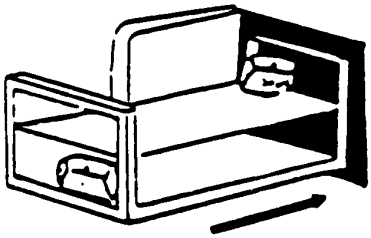
b) For EO sterilizers with chamber volumes of 40 to 79 cubic feet, three test packs should be used: one placed in the center of the chamber; one in a rear corner; and the third in the diagonally opposite front corner of the chamber. In multishelved chambers, one of the two diagonally placed packs should be on an upper shelf and the other on a lower shelf (figure 7b).



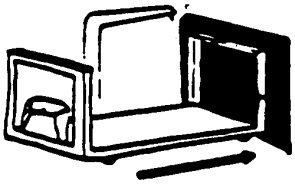
a) 80-100 cubic-foot chamber volume



b) 40-79 cubic-foot chamber volume



c) 16-39 cubic-foot chamber volume



d) < 16 cubic-foot chamber volume

Figure 7—Positioning of challenge test packs

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c) For EO sterilizers with chamber volumes of 16 to 39 cubic feet, two test packs should be used: one placed in a rear corner and the other in the diagonally opposite front corner of the chamber. In multishelved chambers, one of the packs should be on an upper shelf and the other on a lower shelf (figure 7c).

d) For EO sterilizers with chamber volumes of less than 16 cubic feet, one test pack is used, and the pack is placed in the front of the chamber near the door (figure 7d).

NOTE—Chamber volume in cubic feet can be calculated by multiplying chamber height in inches by chamber length in inches by chamber width in inches and then dividing the resulting value by 1,728 (the number of cubic inches in a cubic foot). For example, a sterilizer having a 24- by 36- by 48-inch chamber has a chamber volume of 24 cubic feet.

Rationale: These locations for the test packs are likely to be the areas of the chamber where it is most difficult to sterilize products. The sterility of the load could be compromised by stratification of the sterilant gas and air and by variation in the temperature distribution throughout the load.

7.6.3.3 Test procedure

The test procedure is as follows:

a) Before being exposed to the sterilization cycle, the challenge test packs should be labeled with appropriate sterilizer information.

b) The packs should be placed in wire baskets, metal sterilizer carts, or other carriers that do not absorb EO. The packs should be positioned, as per 7.6.3.2, in an otherwise empty chamber. A sterilization cycle should be run according to the sterilizer manufacturer's instructions.

c) Upon completion of the cycle, the door of the sterilizer or sterilizer/aerator should be opened according to the sterilizer manufacturer's instructions (6.10.1, 6.10.2, 6.10.3, and 6.10.4). For guidelines on the aeration of test packs, see 7.8.

d) The test biological indicator should be removed and incubated according to the instructions of the biological-indicator manufacturer. During the removal and transfer process, care should be taken to avoid contamination of the culture by environmental microorganisms. Upon completion of the incubation period, the results should be read and recorded.

NOTE—One additional biological indicator from the lot used for testing should be left unexposed to the sterilant, incubated, and treated as a control to verify the presterilization viability of the test spores. If the control fails to grow, the biological indicators used in the test pack should be assumed to be nonviable. Therefore, the test results should be considered invalid, and the test repeated.

Rationale: Labeling the challenge test packs allows the test results to be traced to a specific cycle. Carriers that do not absorb EO are recommended for use in all EO sterilization cycles in order to minimize handling of individually processed items until aeration is completed. These measures help ensure personnel safety by reducing exposure to EO. The testing is conducted in an otherwise empty chamber because (a) the air stratification that occurs under these conditions creates the most severe challenge to sterilizer performance, and (b) factory and in-hospital test results can be more directly compared if load composition is not a variable. The recommendations concerning how the sterilizer door should be opened are intended to help protect personnel from excessive exposure to EO, which is just as important during testing as during routine sterilization.

7.6.3.4 Acceptance criteria

Three consecutive test runs with negative results from the test biological indicators verify that the sterilizer has arrived in good order from the manufacturer, has been properly installed, and will function effectively in the facility where it is installed. See 7.9 for guidelines on microbiological testing of positive biological indicators.

Rationale: See 7.6.3.1.

7.6.4 Periodic quality assurance testing

Challenge pack testing should be conducted at least quarterly and (a) after any major redesign, relocation, or corrective maintenance of the EO sterilizer; (b) any time that major changes are made in packaging procedures or materials; and (c) any time that major changes are made in the composition of the load (e.g., increased processing of absorbent materials). The positioning of the test packs, the test procedure, and the acceptance criteria are the same as for installation testing (7.6.3.2, 7.6.3.3, and 7.6.3.4, respectively), except that the test cycles are run in a fully loaded chamber.

Rationale: Using challenge test packs on a regular basis helps ensure that EO sterilizers are performing properly under conditions of actual use and that users are alerted to subtle problems that might not be revealed by the less severe challenge used for routine monitoring (see 7.7). Wrapping materials, wrapping techniques, loading

procedures, and changes in the equipment affect not only EO gas penetration of items to be sterilized but also the effectiveness of other cycle parameters. Consequently, challenge testing should be repeated when any of these variables change. Quality assurance testing is intended to challenge the sterilizer under the conditions of actual use and so is conducted in a load typical of that ordinarily processed in the health care facility; in addition, empty chamber testing for quality assurance would result in unnecessary and costly down time.

7.6.5 Product testing

In addition to biological monitoring with routine and challenge biological-indicator test packs as described in 7.6.3, 7.6.4, and 7.7, health care facilities might wish to periodically place biological indicators in actual products being processed. For example, such testing might be advisable for devices that are highly EO-, moisture-, or heat-absorbent, or for devices for which limited information on sterilization parameters is available from the manufacturer.

The biological indicator should be placed in the area of the pack deemed to be the most difficult to sterilize (assuming that the area is accessible); chemical indicators may also be used. Product test samples should be properly identified and placed among other products in a routine sterilizer load. After the sterilization process, the product test samples should be aerated and the biological and chemical indicators retrieved. Product test samples should be reprocessed before they are used in patient care.

The use of biological indicators to demonstrate that sterilization conditions have been met within a pack does not necessarily demonstrate that all parts of the product are sterile; such an assessment requires quantitative and qualitative microbiological methods that are not commonly available in health care facilities. Sophisticated sterility or residual testing must be conducted under laboratory conditions and will usually require the services of a contract laboratory. Periodic product testing is not a substitute for challenge pack testing or routine biological monitoring.

Rationale: Because load characteristics, pack configurations, and device designs vary considerably, periodic product testing enables health care personnel to gain confidence in the ability of the system to sterilize particular products. However, individual products present an unknown challenge, whereas the challenge and degree of resistance provided by the standard biological-indicator test packs have been shown to be sufficient to establish cycle efficacy. Therefore, periodic product testing is not a substitute for the other types of biological monitoring recommended in this section. Retrieving the biological and chemical indicators from product test samples contaminates them, so they should not be used in patient care unless reprocessed.

7.7 Routine biological monitoring

7.7.1 Frequency of monitoring

A routine test pack with biological indicator or an equivalent disposable test pack should be used in each sterilization cycle. Each load containing implantable devices should be monitored and, whenever possible, quarantined until the results of the biological-indicator testing are available.

Rationale: This test frequency is consistent with the recommendations of the Centers for Disease Control (CDC, 1985). See also the rationale statement for 7.5.3.

7.7.2 Routine test pack

The routine test pack should be made up as follows:

a) One biological indicator should be placed in a plastic syringe of sufficient size that the plunger diaphragm does not touch the biological indicator when the plunger is inserted into the barrel of the syringe (figure 3). The biological indicator should not be removed from the protective covering supplied by the manufacturer. The instructions of the biological-indicator manufacturer should be consulted to ensure that the biological indicator selected is appropriate for use in the specific sterilizer being monitored. The manufacturer's instructions should also be consulted to determine the correct orientation of the biological indicator in the syringe. The needle end of the syringe shall be open (i.e., the tip guard must be removed).

   NOTE—One additional biological indicator from the lot used for testing should be left unexposed to the sterilant, incubated, and treated as a positive control. It should also be noted that syringes to be used in patient care or laboratory applications are not customarily sterilized with the plunger inserted in the barrel.

b) The syringe and a chemical indicator should be placed in the folds of a clean surgical towel (woven, 100% cotton huck), which has been folded lengthwise into thirds and then in thirds again to create nine layers (figure 2b).

c) These items should be placed in one peel pouch or wrapper large enough to contain the test pack components and typical of that customarily used in the health care facility (figure 8).

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Before assembly, the test pack components should be held at room temperature (20° C to 23° C [68° F to 73° F]) and at a relative humidity of 35% for at least 2 hours.

NOTE—Although the recommended humidity range for all work areas is 30% to 60% (see 3.7), ideal relative humidity in processing areas is 50% and should not be less than 35% for best results in achieving sterilization.

Rationale: This routine test pack closely resembles the configuration of some items usually sterilized by EO. The plastic syringe acts as a heat sink, EO absorbent, and diffusion restricter. The biological indicator represents a microbial challenge to the sterilization process. The towel is included, although towels are not ordinarily sterilized by EO, in order to simulate heat and moisture absorption. Placing the syringe within the folds of the towel presents the greatest challenge. This test pack is not designed to represent as severe a challenge as the challenge test pack of 7.6.1. It is presented as a simplified, alternative test pack that will facilitate more frequent monitoring of sterilization loads. See also the rationale for 7.6.1 and annex A, which describes the round-robin testing that was performed to quantify the resistance of the routine test pack.

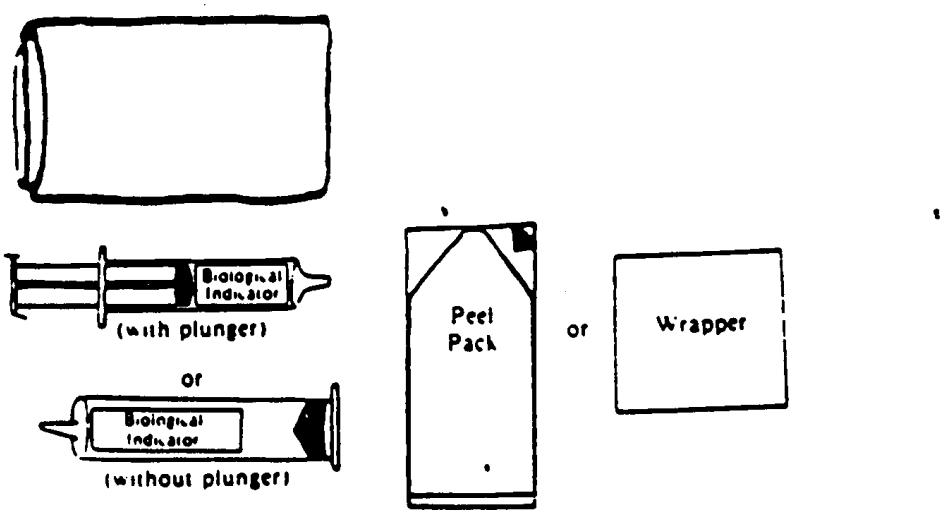

Figure 8—Components of the routine BI test pack (drawing not to scale)

7.7.3 Positioning of the test pack

Only one routine test pack is used, regardless of sterilizer chamber size, and the pack is placed in the center of the sterilizer load.

NOTE—In small sterilizers, where load configuration does not permit placement of the routine test pack in the center of the load, the front portion of the sterilizer may be used.

Rationale: See annex A.

7.7.4 Test procedure

The test procedure is as follows:

a) The routine test pack should be assembled at the same time as the EO-sterilized load.

b) The test pack should be labeled with appropriate sterilizer information.

c) The sterilization cycle should be run according to the sterilizer manufacturer's instructions.

d) Upon completion of the cycle, the biological indicator and other components of the pack should be handled according to the health care facility's protocol for minimizing worker exposure to EO. (See 7.8 for further information.)

Rationale: The test pack is labeled to allow traceability of the test results to the specific cycle. See also 7.6.3.3.

7.7.5 Acceptance criteria

For this test, adequate EO sterilizer performance is evidenced by the inactivation of all microorganisms in the test pack biological indicator and the survival of all controls.

Rationale: See annex A.

7.7.6 Positive biological indicator results

The following actions should be taken if a biological indicator tests positive:

a) Positive biological indicator results (other than those from viability controls) should be immediately reported by phone or messenger to the appropriate supervisor. This notification should be followed by a written report. The report and notification should include the following information:

   1) the time and date of the questionable sterilizer cycle;

   2) a description of the sterilizer and load, with reference to the appropriate lot control number;

   3) the results of physical and mechanical monitoring and of internal chemical indicators (if applicable) as obtained from the user department;

   4) any other information that could be useful in determining whether the report is valid or is questionable due to human error.

b) The microbiology laboratory should perform a presumptive identification of the microorganisms present on the positive biological indicator (see 7.9) and, if applicable, review the biological-indicator transfer technique.

c) The head of the sterilizing department or the appropriate designee, with appropriate hospital maintenance and sterilizer service personnel, should attempt to determine the cause of sterilization failure and arrange for corrective action.

d) Because a sterilization failure has occurred, items processed in that sterilizer should be considered nonsterile. They should be retrieved, if possible, and reprocessed.

e) After the cause of the sterilization failure has been determined and corrected, the sterilizer in question should be immediately rechallenged with a biological-indicator challenge test pack (7.6.1). Until the results of retesting are satisfactory (one cycle with negative biological indicators), the performance of the sterilizer should be considered suspect.

Rationale: To assure quality patient-care products that are safe and effective, it is important to have a continuous quality improvement process. Conducting the above protocol when positive biological indicator results occur will provide valuable data in support of correcting the problem and aid in identifying potential improvements in work practices.

7.8 Aeration of test packs

The sterilizer manufacturer should be consulted about the need for aeration of test packs prior to removal of the biological indicators. Regardless of the recommendations of individual manufacturers, however, the personnel carrying out test procedures should be aware of the following general considerations:

a) The contents of the test packs should be aerated completely prior to reprocessing and reuse.

b) If test packs are aerated prior to removal of biological indicators, then the entire contents of the sterilized load should be aerated for at least an equivalent length of time. Regardless of when the biological indicator is retrieved, the remainder of the load should be fully aerated; the duration of aeration depends on the contents of the load and on the temperature used for the aeration cycle (see 6.11.4).

c) The removal of biological indicators from unaerated test packs should be carried out in a well-ventilated room, using appropriate EO exposure-control methods to minimize operator exposure to the sterilant.

Rationale: Manufacturers and scientists differ in their recommendations on the need to aerate test packs prior to removal of biological indicators. Aeration of the test pack before removing the biological indicators prolongs the exposure of the biological indicators to EO. Nevertheless, worker safety ought to be given primary consideration.

The sterilizer manufacturer should be consulted about test pack aeration because the amount of residual EO left in the pack will vary from sterilizer to sterilizer, as a result of differences in EO exposure conditions (e.g., varying gas concentrations and relative humidities) and differences in end-of-cycle vacuum and air purge parameters.

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7.9 Microbiological testing

For positive biological indicators, a microbiology laboratory should do a presumptive identification to determine whether the recovered microorganism is indeed the test microorganism that was on the biological-indicator spore strip or is a laboratory contaminant. To determine if the microorganism is *Bacillus subtilis*, it is first necessary to check for the presence of bacilli (large rods) by means of phase microscopy or a wet mount under bright field conditions. If bacilli are present, a Gram stain should be performed. If the organism is gram-positive, the specific type of organism (species) should be determined according to the protocol provided by the biological-indicator manufacturer. If the test procedures reveal the presence of gram-positive bacilli of the species *B. subtilis*, there has been a sterilization failure. If only gram-negative bacilli or other microorganisms are recovered, the organisms are incidental contaminants introduced subsequent to the sterilization process; they do not indicate a sterilization failure. Subcultures of the biological-indicator media might produce no growth, but this has no bearing on the interpretation of results.

NOTE—For self-contained biological indicators, the manufacturer's instructions should be consulted for the procedure by which to retrieve positive biological indicators for presumptive identification.

Rationale: B. subtilis is a gram-positive large rod that is highly resistant to sterilization by EO when in the spore state. Biological indicators contain only spores of this species, not vegetative cells. The presence, after exposure to an EO sterilization cycle, of vegetative cells (the large rods) identified to be those of *B. subtilis* indicates that the test spores survived and were able to germinate. Subcultures of the biological indicator might not produce growth because the vegetative cells might have consumed all nutrients in the culture media and/or might have produced enough metabolic waste to kill themselves. The microscopic examination to determine morphology and the Gram stain procedure can be carried out on dead organisms. Incidental contaminants could be introduced through improper handling of the biological indicator after sterilization or by errors in laboratory technique.

7.10 Product release

Product release should be an active decision based upon evaluation of all available data from the sterilization process for the particular load. The decision to release product should be made by an experienced, knowledgeable person at the conclusion of the sterilization cycle. Loads that do not meet the criteria for release should be clearly identified so that they are not mistakenly distributed.

Rationale: Releasing sterilized devices based on all quality control measures is critical in providing safe and effective products for the care and treatment of patients.

7.11 Product recalls

Written policies and procedures for the recall of items from issued/stored loads should be developed in cooperation with the infection control committee and risk management of the individual institution. These policies and procedures should be documented, and records should be maintained. Recall of processed supplies is at the discretion of the department head or designee. Whenever there is evidence of a sterilization failure, the infection control officer should be notified so that follow-up surveillance of patients can be conducted.

Rationale: To ensure patient safety, the health care facility should establish recall procedures to expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions such as quarantine of the sterilizer, notification of physicians, and surveillance of patients.

8 Environmental and employee monitoring

8.1 General rationale

To ensure a safe work environment and to establish compliance with federally mandated limits and voluntary guidelines on occupational exposure to EO, actual EO concentrations must be measured in the workplace during and after the use of sterilization equipment. Determinations of 8-hour TWAs and of 15-minute excursion levels are required to verify compliance with the OSHA standard. If EO levels in employee breathing zones (EBZs) are shown to be lower than the 0.5-ppm TWA "action level" defined by OSHA, many of the requirements of the OSHA standard do not apply to the health care facility. Many air sampling and monitoring techniques are currently in use. Data are available on the relative effectiveness and benefit/cost ratio of some of the methods and programs available for EO monitoring in the hospital work environment (see annex B). However, the recommendations of this section and annex B are only guidelines. Monitoring technology continues to evolve, and it is incumbent upon health care personnel to keep abreast of the latest developments.

8.2 Instrumentation

8.2.1 Selection of monitoring methods

Some EO monitoring methods must be supervised by a technically qualified person trained in air sampling strategies and monitoring techniques. Other monitoring methods are less complex and, with instructions available from the manufacturer, can be used reliably by health care personnel to monitor the workplace. The monitoring method chosen will depend on the frequency of EO use, the level of monitoring needed, the type of monitoring needed (e.g., employee monitoring vs. area monitoring), the availability of sampling and analytical instrumentation, and whether the health care facility chooses to initiate its own monitoring program or to use an outside service. Another consideration is the interpretation of monitoring data for assessment of worker safety. Because of these complexities, health care personnel should seek the advice of an industrial hygienist or other qualified professional when designing a monitoring program.

Rationale: Health care facilities vary in financial and technical resources and in the volume of EO sterilization processing; no single monitoring method is best for all institutions. Some EO monitoring techniques and procedures involve a considerable amount of time, effort, cost, and data analysis. The relationship between the costs and benefits of sampling should be carefully considered, without losing sight of the ultimate goal: a safe and healthful workplace for sterilizer equipment operators and other personnel.

8.2.2 Reliability and use of instrumentation

The instructions for use provided by the monitoring equipment and sampling apparatus manufacturers should be followed. Information on the accuracy, reproducibility, and reliability of the instrumentation is also necessary. In particular, monitoring instrumentation and methods must be proven capable of accurately and reproducibly determining EO concentrations in the range of (and below) the OSHA limit on occupational exposure. When reviewing any EO monitoring equipment, the user should determine that components and other characteristics of workroom air (e.g., inert diluents, water vapor, solvent vapors, and temperature variations) will not interfere with the instrument's ability to accurately measure the EO concentration.

Rationale: The OSHA standard requires that employee monitoring devices be accurate, with a confidence level of 95%, to within 25% for airborne concentrations of EO at the 1-ppm TWA and to within 35% at the 0.5-ppm TWA action level or the 5-ppm excursion limit. The manufacturer is the best source of information on the performance characteristics of monitoring equipment, and the manufacturer's instructions for use should be followed to ensure proper operation of the equipment and accurate results.

8.3 Procedures

8.3.1 Monitoring sites

Sampling should be conducted in all work areas where workers might be exposed to EO. The EO sterilizer area should be monitored, as well as the breathing zone of each employee directly involved in the sterilization process. Monitoring should be conducted during sterilizer operation and use, not during simulated sterilization runs with less-than-normal loads.

Rationale: Monitoring should yield a meaningful description of the EO concentration in the workplace. Although OSHA requires that at least representative monitoring (the monitoring of representatives of each job classification) be done, the AAMI committee judged that more rigorous sampling is necessary to define the exposure potential of the workplace and ensure the protection of sterilizer operators and other employees at high risk of exposure.

8.3.2 Frequency of monitoring

Monitoring should be performed initially upon establishing the monitoring program and periodically thereafter. According to the OSHA standard, if the initial monitoring indicates employee exposures above the 1-ppm 8-hour TWA and/or the 5-ppm 15-minute excursion limit, then each such employee should be monitored at least quarterly and more often as needed. If the initial monitoring indicates employee exposures that are above the 0.5-ppm action level but below the 1-ppm 8-hour TWA, then each such employee should be monitored semiannually. Monitoring may be discontinued or the frequency of monitoring reduced if two consecutive measures, taken at least 7 days apart, indicate that employee exposures are below the 0.5-ppm action level. In addition to the requirements of the OSHA standard, hospital-specific factors (e.g., the amount of EO used by the health care facility and the frequency of sterilizer use) influence the appropriate frequency of routine monitoring, which might be needed as often as monthly or as infrequently as semiannually.

Monitoring should also be conducted upon installation of new or replacement EO sterilizers, aerators, or emission control systems and upon major modifications of the ventilation system.

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NOTE—When a small quantity of EO is being used (less than 15 grams in any one day) and when a worst-case determination has been made that the OSHA standard will not be exceeded, consideration can be given to relaxing these monitoring frequency recommendations. This exception is based on the assumption that the room volume and room ventilation are sufficient to rapidly dissipate the EO released during processing by small sterilizers. If this is not the case, such sterilizers must only be operated inside functional exhaust ventilation hoods connected to the outside through either a dedicated or nonrecirculating system.

Rationale: Initial monitoring to determine EO levels in the employee breathing zone is required by OSHA unless monitoring after 15 June 1983 revealed EO levels below the action level of 0.5 ppm TWA. (OSHA exempts health care facilities from much of its standard if the action level and the excursion limit are not exceeded in the work environment.) For sterilizing systems that use small quantities of EO, monitoring is not required by OSHA if data are available (e.g., from the manufacturer) demonstrating that the highest possible release of EO would result in airborne concentrations of less than the action level. These and the other OSHA requirements described in 8.3.2 are part of a minimum standard intended for all facilities where EO is manufactured or used. The AAMI committee recommends more frequent monitoring of health care facilities than is required by OSHA because of the many variables involved in hospital EO sterilization processing. Frequent monitoring helps ensure that ambient EO concentrations are at or below the limits established by regulation and will help detect ventilation system inadequacies. Frequent and adequate monitoring is essential to employee safety and health.

8.3.3 Sterilizer system leak checks

A system leak check should be performed initially and then as often as necessary (at least every 2 weeks) to ensure sterilizer system integrity. This system leak check qualitatively determines sterilizer and aerator “gas-tight” integrity and includes tests for background (secondary) sources of worker exposure to EO. Secondary sources of exposure include the sterilizer relief valve, which should be vented directly to the outside; the area between the solenoid valve and the gas cylinder; the connections at the gas cylinder; the sterilizer door gasket; the gas lines; and the sterilizer vacuum lines, if applicable. Between sterilization cycles, the only potential sources of EO are the aerator, the gas tanks (sources), and the line leading to the solenoid valve.

Rationale: It is necessary to conduct system leak checks much more frequently than thorough monitoring because of the high probability of leakage and therefore of worker exposure. Numerous studies have shown that acute releases of EO can occur, even with properly installed, maintained, and operated sterilization equipment. Frequent leakage testing will also help detect equipment malfunctions. Expensive, very sensitive EO detection instrumentation (e.g., gas chromatography or infrared spectroscopy) need not be used for routine leak testing. Inexpensive qualitative techniques (e.g., halide leak detectors for EO/HCFC systems and detectors of combustible gases such as combustible gas analyzers or semiconductor devices) are sufficient. Therefore, the high cost of monitoring can be substantially reduced through the proper combination of monitoring surveys and system leak checks.

8.3.4 Ventilation system monitoring

Once the ventilation system is installed in the EO sterilization area, thorough monitoring should be performed to ensure that the system is adequate and effective and that the various main sources of EO exposure are controlled. These main sources of EO exposure include the floor drain (if the sterilizer is vented to the floor drain), the aerator door and exhaust, the sterilizer door and its gasket, and the connections on the gas cylinders. As noted earlier, the aerator should be properly vented to the outside by a dedicated exhaust ventilation system. Thorough monitoring should be performed after the initial installation of the ventilation system; periodically thereafter, system operation should be verified.

Rationale: Adequate ventilation helps ensure low occupational exposure to EO (see section 3).

8.3.5 Short-term exposures

Health care personnel should determine exposure levels during short periods of time when airborne EO concentrations could be particularly high, e.g., during the charge and exhaust phases of sterilization cycles, during the changing of EO cylinders, during sterilizer unloading, and during transfer of a sterilized load to the aerator. These short-term exposure levels should be calculated when the sterilization equipment is installed, after any major repairs, after changes in the ventilation system, and after any changes in work practices. Short-term exposure levels must not exceed the OSHA excursion limit of 5 ppm, measured over a 15-minute exposure period.

Rationale: Calculating short-term exposure levels is useful for developing ventilation strategies and evaluating work practices and hence for preventing excessive employee exposure to EO. Since 1988, health care facilities have been required to comply with OSHA’s excursion limit.

8.4 Calculations and interpretation of data

Environmental concentrations of EO are quantified in two ways for purposes of assessing worker exposure. The permissible exposure limit (PEL) is measured over an 8-hour sampling period (see annex B for methodology). The PEL can be determined according to the following equation:

$$\text{Estimated 8-hour TWA (ppm)} = \frac{(C_1 \times t_1) + (C_2 \times t_2) \ldots + (C_n \times t_n)}{t_1 + t_2 \ldots + t_n}$$

where C_1 is the concentration (ppm) of EO at time interval t_1 (seconds or minutes) and C_2, C_n, and t_2, t_n are other concentrations and respective time intervals.

For example, the following data are collected:

0 ppm at baseline

25 ppm for 12 seconds

15 ppm for 1.5 minutes

75 ppm for 2.0 minutes

5 ppm for 60 minutes

0 ppm for the balance of the 8-hour sampling period

All time periods are converted to minutes and the time period for the last reading (0 ppm) is determined:

0 ppm at baseline

25 ppm for 0.2 minutes

15 ppm for 1.5 minutes

75 ppm for 2.0 minutes

5 ppm for 60 minutes

0 ppm for 416.3 minutes (480 minutes – [0.2 + 1.5 + 2.0 + 60 = 63.7] minutes)

The 8-hour TWA can now be calculated as follows:

$$\text{TWA} = \frac{(0 \times 0) + (25 \times 0.2) + (15 \times 1.5) + (75 \times 2.0) + (5 \times 60) + (0 \times 416.3)}{0 + 0.2 + 1.5 + 2.0 + 60 + 416.3}$$

$$= \frac{0 + 5 + 22.5 + 150 + 300 + 0 \text{ (ppm.minutes)}}{480 \text{ minutes}}$$

$$= \frac{477.5 \text{ (ppm.minutes)}}{480 \text{ minutes}}$$

$$= 0.994 \text{ ppm}$$

$$= 1.0 \text{ ppm as the 8-hour TWA}$$

It should be noted that the TWA is below all of the measured values except for 0 ppm.

In a similar manner, a calculation can be made to determine the excursion limit:

$$\text{Estimated 15-minute TWA (ppm)} = \frac{(C_1 \times t_1) + (C_2 \times t_2) \ldots + (C_n \times t_n)}{t_1 + t_2 \ldots + t_n}$$

For example, the following data are collected:

0 ppm at baseline

25 ppm for 30 seconds

20 ppm for 30 seconds

15 ppm for 1.0 minute

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5 ppm for 2.0 minutes

0 ppm for 11 minutes

All time periods are converted to minutes. The 15-minute TWA can now be calculated as follows:

$$\text{TWA} = \frac{(0 \times 0) + (25 \times 0.5) + (20 \times 0.5) + (15 \times 1) + (5 \times 2) + (0 \times 11)}{0 + 0.5 + 0.5 + 1 + 2 + 11}$$

$$= \frac{0 + 12.5 + 10 + 15 + 10 + 0 \text{ (ppm.minutes)}}{15 \text{ minutes}}$$

$$= \frac{47.5 \text{ (ppm.minutes)}}{15 \text{ minutes}}$$

= 3.17 ppm as the 15-minute TWA

Again, it should be noted that the TWA is below all of the measured values except for 0 ppm.

8.5 Recordkeeping

Environmental and EBZ monitoring must be documented, and records maintained in the department files or another designated location. The documentation must include at least the following information:

a) the name and qualifications of the person or organization that conducted the monitoring;

b) the date the survey was made;

c) the sampling or analytical method used;

d) the test protocol and instrumentation;

e) the ventilation system characteristics at the time of sampling;

f) the results (locations and measured EO concentrations);

g) any recommendations for corrective actions.

Employees must be notified of their personal monitoring results within 15 days of when the monitoring report is available, and a copy of the monitoring records must be kept in each employee's file. In accordance with the OSHA standard, these records must be maintained by the health care facility for the duration of employment and for at least 30 years thereafter. If EBZ monitoring shows EO levels exceeding the PEL or EL, corrective actions must be taken and documented, as required by OSHA. The results of environmental monitoring should be posted in an area that is readily accessible to employees.

Rationale: Good recordkeeping enables the health care facility to establish a continuous history of the work environment. Also, records of monitoring results are required by OSHA. If environmental monitoring results are posted, workers will know that potentially dangerous concentrations of EO could exist in the workplace, and the importance of proper work practices will be reinforced. Also, if the posted results show that all areas and occupations are below the action level, employees will be encouraged to continue the safe practices that made this possible.

Annex A
(informative)

Biological-indicator test packs

A.1 Introduction

The biological-indicator test packs of 7.6.1 and 7.7.2 were originally recommended in *Good hospital practice: performance evaluation of ethylene oxide sterilizers—ethylene oxide test packs* (AAMI,1985). These packs were designed based on the scientific experience and professional judgment of the members of the AAMI Ethylene Oxide Sterilization Hospital Practices Working Group.

In the course of preparing a revised and expanded edition of AAMI (1985), the Working Group decided to sponsor a round-robin study to evaluate the resistance of the test pack recommended for routine monitoring of EO sterilizer performance (7.7.2). Annex A describes the methods used in the round-robin study and the test results. This work was also reported in Hart et al. (1993).

Because of its makeup, the challenge test pack of 7.6.1 offers substantially more resistance than the routine test pack. However, the resistance of the challenge test pack has not been quantified.

A.2 Materials and methods

A.2.1 Test strategy

The general test strategy of the round-robin study was to compare the resistance of the routine test pack containing a biological indicator to that of a biological indicator *not* contained within a test pack. Three types of self-contained biological indicators (Assert™ Biological Indicator No. 001500, Attest™ Biological Indicator No. 1264, and Proof Plus™ Biological/Chemical Indicator No. NA 052) and one type of spore strip (Castle® Tec-Test Biological Culturing System) were studied. All laboratories used biological indicators from the same lots.

A.2.2 Test laboratories

Five laboratories participated in the study: American Sterilizer Company, MDT Corporation, Sterilization Technical Services, 3M Health Care, and Weck Instruments.

A.2.3 Sterilization equipment

All laboratories used BIER (biological indicator-evaluator resistometer) EO exposure vessels complying with AAMI (1982) and providing the following constant sterilization cycle parameters: 600 ± 30 mg/L EO, 54° C ± 1° C, 60% ± 10% relative humidity. (A BIER EO gas vessel is a test chamber that [unlike a commercial sterilizer] allows control and monitoring of all critical cycle parameters during the exposure phase: gas concentration, temperature, relative humidity, and time.)

A.2.4 Test pack components and assembly

Each test pack used in the study consisted of a 20-ml plastic syringe with diaphragm and plunger (but no needle or needle guard), a 7-inch by 13-inch paper/film pouch, one 100% cotton surgical towel (18 inches ± 1 inch x 30 inches ± 1 inch), and two biological indicators (one placed inside the syringe and the other attached with EO indicator tape to the outside of the test pack). Prior to assembly, the test pack components were preconditioned at 18° C to 24° C (65° F to 75° F) and at a relative humidity of 60% ± 15% for 2 to 24 hours.

The test packs were assembled in accordance with 7.7.2. One biological indicator was placed inside the syringe, and the syringe was placed in the center of the folds of the surgical towel. (The Assert™ and Proof Plus™ biological indicators were oriented so that their caps were next to the tip of the syringe. The spore strips in glassine envelopes were placed in the syringe.) The other biological indicator was attached with EO indicator tape to the upper corner of the test pack closest to the tip of the syringe, which was pointed towards the rear of the BIER vessel.

A.2.5 Exposure conditions

Each test cycle was run in the following manner:

a) A prevacuum was drawn to evacuate the vessel to 1.00 psia (pounds per square inch absolute).

b) The load was prehumidified to 60% ± 10% relative humidity for 30 minutes. The vacuum was increased to 2.11 to 2.55 psia.

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c) The vessel was operated at 54° C ± 1° C.

d) The chamber fan was turned off during the cycle.

e) The chamber was charged with 12/88 sterilant by increasing the pressure differential by 19.7 ± 1.0 psia to provide a gas concentration of 600 ± 30 mg/l EO.

f) Each cycle was replicated three times for each of the following exposure times: 10, 20, 30, 40, 50, 70, and 80 minutes.

g) Six postvacuum pulses or a 5- to 10-minute postcycle vacuum were drawn.

A.2.6 Test procedure

The test procedure was as follows:

a) The test pack materials were preconditioned and assembled in accordance with A.2.4.

b) A “dummy” cycle was run as per A.2.5 except for a 5-minute prehumidification time and a 5-minute exposure time.

c) The chamber was loaded with four test packs, each containing a different type of biological indicator. The packs were positioned vertically, with the outside-of-test-pack biological indicators located at the upper rear of the vessel. The pouch surfaces were oriented paper to paper.

d) At the end of the cycle, the test packs were removed from the chamber and placed in a chemical or laminar-flow hood. The biological indicators were immediately removed from the test packs and aerated at room temperature for 30 to 45 minutes.

e) Within 2 hours of the end of the aeration cycle, the biological indicators were activated and cultured in accordance with the manufacturers’ instructions at 36° C ± 1° C. The self-contained biological indicators were incubated for 48 hours, the spore strips for 5 days.

A.2.7 Data collected

For each of the seven test cycles (each of which was replicated three times), the number of surviving biological indicators (positives) and the number of killed biological indicators (negatives) were recorded.

A.3 Results

The results of the study, summarized in table A.1, show the mean kill time for each type of biological indicator according to whether it was inside the test pack or outside the test pack. Statistical analysis of these data revealed that the mean kill time for the biological indicators inside the test pack was significantly greater than for biological indicators outside the test pack, demonstrating that the test pack indeed offers substantial resistance to the sterilization process.

Table A.1—Mean kill time (minutes) and standard deviation for biological indicators inside the test pack vs. outside the test pack

Biological indicator	Outside test pack	Inside test pack
1	19.0 ± 4.0	31.3 ± 9.7
2	26.7 ± 5.5	43.3 ± 9.9
3	26.0 ± 5.6	42.3 ± 9.0
4	26.7 ± 5.5	49.3 ± 11.4
Overall	24.6 ± 6.1	41.6 ± 11.9

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Annex B
(informative)

Selecting airborne ethylene oxide monitoring equipment or services for an EO sterilization facility

B.1 Introduction

This annex was developed to assist health care personnel in the selection of equipment or services for the measurement of airborne EO in the workplace and the assessment of worker exposure to airborne EO. This annex is intended to (a) help users understand the conceptual approaches that can be used to monitor airborne EO concentrations or worker exposure to EO; (b) describe most of the kinds of EO monitoring equipment and services currently available; and (c) summarize certain advantages and disadvantages of the available equipment and services.

What is an "ideal" airborne EO monitor? Most experts would agree that an "ideal" EO monitor for an EO sterilization facility would satisfactorily meet the following specifications:

a) It would accurately measure airborne EO in the range of less than 0.5 ppm.

b) It would be specific for EO.

c) It would be reliable.

d) It would be inexpensive to own and operate.

e) It could be used to detect leaks as well as to determine worker EO exposure levels.

f) It would be easy to use, requiring minimal technical ability on the part of the operator.

The same experts who agree on specifications would also probably agree that such an ideal monitor does not (as of this writing) exist. The absence of such a monitor is not an excuse, however, not to monitor. All managers of locations where EO is used have a clearly defined legal requirement to monitor and minimize worker exposure to EO.

B.2 General approaches to EO monitoring

B.2.1 Personnel monitoring

Two general types of monitoring are performed in facilities where EO is used: personnel monitoring and area monitoring. Personnel monitoring is performed to determine the concentration of airborne contaminants in the EBZ. This measured concentration is assumed to be the amount actually inhaled by personnel. Personnel monitors are devices worn by the worker for a certain length of time. These devices measure the EO concentration in the worker's breathing zone during the time the monitor is worn, providing a measure of the amount of EO inhaled during that time. The results are expressed as a TWA concentration. The time periods selected are usually either the individual's full work shift, to measure an 8-hour TWA, or short intervals during process-related tasks, to measure EO excursion levels.

Personnel monitoring provides the best indication of employee exposure to EO. However, a significant disadvantage of some personnel monitors is that laboratory analysis is required; therefore, the results of the sampling cannot be obtained until some time after the sampling has been performed. For example, if a worker is exposed to a high concentration of EO (e.g., because of an unknown leak, a failure in the ventilation system, or poor work practices), the worker has no way of knowing about the high EO concentration until after the results are received from the monitor analyst. This time delay could range from several days to several weeks after the sampling period. However, several currently available personnel monitors do not require laboratory analysis, and consequently there is no time delay. These monitors can be developed onsite (e.g., in the health care facility) to provide immediate test results.

Another limitation of all personnel monitoring devices is that the results usually indicate an average concentration over time and therefore might not yield information about concentration variations within specific segments of the sampling period. For example, a low TWA concentration could actually be the result of a very high short-term exposure with little or no exposure during the remainder of the sampling period.

B.2.2 Area monitoring

Area monitoring is performed to determine the general (i.e., environmental) concentration of airborne contaminants in a prescribed space or area. There might or might not be personnel in the area monitored, and the concentration of airborne contaminant measured might not be the concentration of contaminant actually inhaled by personnel if they are present. Some area monitors are electronic devices or electronically controlled devices that measure, more or less instantaneously, the EO present at the sampling point of the device. Area monitoring can also be performed using "grab sampling" techniques. In "grab sampling," the air containing the suspected contaminant is sampled by rapidly pumping a representative portion of air into an EO-impervious bag that contains a sealing valve. The air sample thus "grabbed" can be analyzed immediately to determine the concentration of impurity, or it can be sent to a laboratory for analysis.

Some area monitors use only a single sampling point; hence, the EO concentration will be measured at that point only. Other devices incorporate a "multipoint" sampling apparatus that draws samples of air into the instrument successive times from several points. Some multipoint samplers are able to collect samples from 20 or more points. The price for such equipment usually increases as the sample point capability increases. Some area monitoring equipment can be used to measure more than one kind of air contaminant (e.g., waste anesthetic gases or hydrogen peroxide as well as EO), although not necessarily at the same time in the same place. Selecting this type of equipment could therefore satisfy two or more needs.

The disadvantages of area monitoring equipment is that even though it can provide "instant" EO measurement data (unless a "grab" sample is sent to a laboratory for analysis), the measured concentration does not necessarily represent personnel exposure and might not be a time-weighted average.

B.3 Area and personnel monitoring devices

B.3.1 General considerations

Six types of area monitoring equipment and two types of personnel monitoring equipment are described here. For each type of equipment, the following topics are addressed:

a) *Principle of operation:* The manner in which the equipment detects or indicates EO concentration is briefly described.

b) *Portability:* A brief statement indicates whether or not the equipment can be routinely moved about the workplace.

c) *Ease of operation:* The ease with which the equipment can be used is characterized in two categories: "preparation and use" and "data collection."

   "Preparation and use" describes the complexities involved in preparing the equipment for use (e.g., calibration, special training requirements, sampler conditioning) and in actually using the device. "Data collection" describes the complexities involved in determining the test results (ppm EO).

   In these two categories, each type of equipment is rated as "simple," "moderate," or "difficult." "Simple": The instructions provided by the equipment supplier are generally adequate for any user. "Moderate": One or more aspects of the equipment require that the user receive inservice or other special training. "Difficult": One or more aspects of the equipment require the skills of an individual with special expertise, such as a technician or scientist, who has been trained, or has the qualifications to be trained, in the proper use of the equipment.

   As an example, some passive sampling devices require little or no preparation to use, and their actual "use" involves nothing more than clipping the device in place. Determining the results of such monitoring, however, sometimes requires relatively complex extraction and analysis techniques. Hence, this type of device would be rated "simple" in the category of "preparation and use," but "difficult" in the category of "data collection."

d) *Accuracy:* Accuracy (the difference between the measured concentration of EO and the true EO concentration) is likely to vary among device types within a given generic category of measuring device. The accuracy characterizations listed here are broad because they apply to generic categories. A perfectly accurate measurement device would be perfectly precise and perfectly reproducible. For the purposes of this annex, the extent to which a measuring device is not perfectly accurate is related to the extent to which it is not perfectly precise or reproducible.

e) *EO specificity:* Some equipment will measure the presence of air components other than EO; that is, it is not "specific" to EO. Appropriate comments are made.

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f) *Lower detectable limit for EO:* The lower detectable limit listed is the lowest measurable concentration of EO claimed by the equipment manufacturer. AAMI has not verified the validity of this information, nor does AAMI endorse such claims. The lower detectable limits are presented as a point of reference only, to aid the user in selecting equipment or methods of analysis. The user should require the supplier to document claims regarding detection limits.

The cost of various monitoring technologies is not addressed here due to the many variables involved, e.g., available options and accessories, degree of automation, and maintenance cost.

B.3.2 Personnel monitoring devices

B.3.2.1 Applications

Some personnel monitors can also be used as area monitors. For example, if engineering controls have just been installed in an area where EO vapors had been escaping into the workplace, a personnel monitoring device carefully placed near the new equipment could be used to measure ambient EO concentrations in that area while employees are not present. Although personnel monitoring devices are used in this mode occasionally, their primary function is actual personnel monitoring, as described in B.2.1.

B.3.2.2 Types of personnel monitoring devices

At least four EO personnel monitoring methods are known to be in current use. The two most popular methods are charcoal tubes and passive sampling devices.

B.3.2.2.1 Charcoal tubes

Principle of operation: In this technique, a small, portable, battery-powered suction pump (usually clipped to the worker's belt) is connected via plastic tubing to a glass tube packed with a special type of activated or hydrogen-bromide (HBR) treated charcoal. The pump draws a known volume of air through the glass tube, and the contaminants (including EO) are adsorbed or chemically derivatized (i.e., converted to another stable chemical) by the charcoal. By clipping the glass tube to the lapel of the worker's shirt or blouse, EBZ samples can be collected.

The worker usually wears this equipment throughout the work day or during short-duration, process-related tasks when excursion levels warrant monitoring.

At the conclusion of the sampling period, the tubes are sealed and sent to a laboratory for analysis. At the laboratory, the charcoal is removed from the glass tubes and treated with a solvent that desorbs the EO from the charcoal. The EO-solvent mixture is then analyzed by gas chromatography to determine the overall amount of EO adsorbed or chemically derivatized during the sampling period. Knowing the duration of the sampling period, the volume of air drawn through the charcoal tube, and the amount of EO adsorbed allows calculation of a TWA EO value.

The desorption process and analytical technique are moderately complex and should only be attempted by laboratories with experienced analytical chemists or technicians.

Activated-charcoal-type tubes to be analyzed by a service laboratory should be packed in dry ice and preferably shipped via "overnight mail." These requirements obviously affect the overall cost of such a system. (Several days' worth of tubes can be collected, stored in a refrigerated environment, and shipped together. The service laboratory should be consulted on this point.)

Portability: Completely portable.

Ease of operation:

Preparation and use—moderate to difficult.

Date collection—difficult.

Accuracy: Variable, depending mainly upon the ability of the analyst and the accuracy of calibration.

EO specificity: Specific to EO.

Lower detectable limit for EO: Levels as low as 0.1 ppm for activated charcoal, 3 parts per billion for HBR-treated charcoal.

Other comments: Portable pumps should have a feature that allows the user to detect whether or not the pump stopped functioning during the collection of samples (as might occur, for instance, if the battery fails). Pumps must be calibrated before and after each use. (As batteries "run down," the rate of air flow might change.) The pump

supplier should be asked about the expected life of the pump and batteries; all types of pumps contain parts that will eventually wear out.

Blank and control samples must also be collected. The analytical laboratory should be consulted about the proper techniques for blank and control sampling.

The user should insist upon written documentation from the tube supplier verifying that the charcoal is suitable for EO collection. (Some types of charcoal are very poor adsorbents for EO, especially in high humidity.) The tube supplier should also be required to provide written documentation of the requirements for charcoal refrigeration and, for accurate results, the maximum length of time between sample collection and sample analysis.

Multiple charcoal tubes might be necessary for 8-hour sampling.

B.3.2.2.2 Passive sampling devices

Principle of operation: Like charcoal tubes, passive sampling devices (PSDs) are clipped to the worker's lapel. Passive sampling devices rely upon the natural diffusion of EO into a sorbent or reactant material and hence do not require the use of a pump. These devices are normally worn throughout the full day or during short periods when the task-related excursion level is determined.

After the sampling has been completed, the PSD is either sealed and sent to a laboratory for analysis or (depending on the type of PSD) processed and read onsite. For PSDs requiring laboratory analysis, the analysis can be performed by a laboratory at the sampling site (if properly equipped), by a contract service laboratory, or by the PSD supplier (most suppliers offer analytical services for a fee). Two types of PSDs do not require laboratory analysis; they provide onsite exposure analysis and results within 10 minutes.

It might be necessary to collect blank and control samples. The PSD manufacturer or the analytical laboratory should be asked for recommendations.

Several companies currently market PSDs. One kind of PSD collects diffused EO onto specially treated charcoal that converts the EO to a stable derivative (2-bromoethanol). During the laboratory analysis, the 2-bromoethanol is extracted from the charcoal and analyzed by gas chromatography to determine the EO concentration.

One kind of PSD system designed to be directly read onsite produces an intermediary alkylation product as EO comes into contact with the badge substrate. This intermediary produces a colorimetric reaction when the badge is immersed in a developer solution and read directly in ppm EO via a small, compact reader.

Portability: Completely portable.

Ease of operation:

Preparation and use—simple.

Data analysis—moderate to difficult.

Accuracy: Variable; the PSD supplier or contract analytical laboratory should be consulted. The manufacturer should be required to supply documentation to support accuracy claims for both the PEL and the excursion limit.

EO specificity: A few air contaminants can interfere. The PSD manufacturer should be asked to supply a written statement specifying which contaminants might interfere with the PSD materials.

Lower detectable limit for EO: Most PSDs are able to detect less than 0.5 ppm EO as an 8-hour TWA and less than 5 ppm as a 15-minute excursion level.

Other comments: In some cases, PSDs are easier to analyze than charcoal tubes. The absence of the portable pump is an obvious advantage (no battery, no pump calibration, and the PSDs are lighter).

Passive sampling devices might be suitable for area monitoring if the minimum air flow across the face of the PSD is attained as specified by the PSD manufacturer.

The following questions should be asked of the PSD supplier:

a) What gases will interfere with the performance of the PSD?

b) Can potential interferences be measured in order to obtain a true EO measurement?

c) What is the lower detectable EO limit for the PSD?

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d) To perform the analysis in the hospital's own laboratory, what accessories will be needed and what do they cost?

e) Has the PSD been field-tested by independent laboratories? (A copy of the protocol and individual laboratory results should be provided.)

f) Does the PSD meet the accuracy criteria for sampling techniques, as specified by OSHA? (A copy of the protocol and individual laboratory results should be provided.)

g) Are other area health care facilities or organizations using this PSD? If so, which ones?

h) How long will it take to receive the results of the sampling if the PSDs are sent to the manufacturer's laboratory or a contract laboratory for analysis?

i) Are other benefits offered, such as a tracking system to provide at least an annual recapitulation of the results of periodic monitoring?

B.3.2.2.3 Other personnel monitoring systems

Two other systems have been used for EO monitoring, although to a lesser degree than either charcoal tubes or PSDs: nonpermeable bags and impingers.

A nonpermeable-bag system consists of a portable pump (similar to that used with charcoal tubes), which collects EBZ air and pumps it into a bag made of a material that is not permeable to EO (e.g., Tedlar® or Teflon®). At the conclusion of the sampling period, the bag is sent to a laboratory for gas chromatographic analysis. Overflow of EO vapors and/or leakage should be prevented.

In impingers, air is drawn through a vial containing an acidic solution. The EO from the air is converted to a derivative, which is then analyzed with a gas chromatograph. Spillage or breakage of the vials should be prevented in order to avoid chemical burns.

For information on portability, ease of operation, EO specificity, the lower detectable limit for EO, and other characteristics of these devices, the manufacturer's specifications should be consulted.

B.3.3 Area monitoring devices

B.3.3.1 Applications

As noted in section B.2.2, area monitors measure the EO concentration in the air sampled from a given point or points in the workplace. In general, they are not suitable as personnel monitors unless they are completely portable (and can be carried with or by the worker while work is performed) or unless the measurements taken from the area monitor can be correlated with actual personnel exposure levels.

In some cases, two or more health care facilities could purchase one set of monitoring equipment and share its use and costs. This approach could help justify the expenditure of a large sum of money for the equipment and the training of the operator or analyst, and it could be particularly advantageous if the purchased equipment is capable of monitoring several air contaminants.

B.3.3.2 Types of area monitoring devices

The following types of area monitoring devices are currently available: metal oxide semiconductors, electrochemical sensors, gas chromatographs, infrared spectrophotometers, photoionization detectors, and gas detector tubes.

B.3.3.2.1 Metal oxide semiconductors

Principle of operation: Metal oxide semiconductors, also referred to as solid-state sensors, incorporate solid-state elements that allow the permeation of selected air contaminants. The change in electrical resistance of the element, which is produced by the presence of the air contaminant, is measured. The measured change is related to the concentration of the air contaminant.

Portability: Both portable and stationary models are available.

Ease of operation:

Preparation and use—moderate.

Data collection—simple.

Accuracy: Variable.

EO specificity: Usually poor. Depending on the design of the solid-state element, many air contaminants other than EO could be sensed; thus, a false positive reading for EO could be obtained.

Lower detectable limit for EO: Not less than 1 ppm, but usually set at higher levels due to sensitivity to other airborne contaminants that might be present.

Other comments: These systems are sensitive to most hydrocarbons and therefore are generally used as leak detectors with factory-set alarm levels at 20 ppm and 50 ppm due to the low EO specificity.

B.3.3.2.2 Electrochemical sensors

Principle of operation: Ambient room air is delivered either by a pump or diffusion to a cell within the device. When the contaminant diffuses through the cell membrane face, an electrochemical reaction takes place, producing an electrical voltage proportional to the concentration of the contaminant. This voltage is then amplified, temperature-compensated, and fed to a microprocessor, which simultaneously determines the concentration of the contaminant.

Portability: Both portable and stationary models are available.

Ease of operation:

Preparation and use—simple to moderate.

Data collection—simple.

Accuracy: Adequate if used properly.

EO specificity: Contaminants other than EO can produce interferences.

Lower detectable limit for EO: Less than 1 ppm.

Other comments: Data acquisition (PC based) modules are available that can be connected to area monitors to track EO levels continuously and simultaneously from each point. Systems are also available that are capable of monitoring both EO and hydrogen peroxide.

B.3.3.2.3 Gas chromatographs

Principle of operation: Gas chromatographs draw in a sample of air and pass it through a packed column that separates the desired airborne contaminant and routes the component to a detector. The detectors are usually flame ionization detectors or photoionization detectors. In the presence of the contaminant, the detector measures the generated ions. The measured response is proportional to the contaminant concentration.

Portability: Most are stationary. Sophisticated units can be equipped with multipoint samplers that incorporate microprocessors for control, data generation, and analysis.

Ease of operation:

Preparation and use—moderate to difficult, depending on the degree of automation.

Data collection—moderate to difficult, depending on the degree of automation.

Accuracy: Adequate if used properly.

EO specificity: Usually excellent.

Lower detectable limit for EO: As low as 20 parts per billion for some photoionization detectors, 1 to 5 ppm for most flame ionization detectors.

Other comments: Calibration of the instrument is critical and is required. The user should require the instrument supplier to provide specific calibration instructions. Calibration can be difficult in some instances.

B.3.3.2.4 Infrared spectrophotometers

Principle of operation: A sample of air is drawn into a cell, where it is exposed to infrared light. Certain contaminants absorb certain wavelengths of infrared light. By measuring the amount of absorption, the concentration of the contaminant can be determined.

Portability: Multipoint sampling units are stationary. Some other types are portable.

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Ease of operation:

Preparation and use—moderate to difficult.

Data collection—simple to difficult.

Accuracy: Variable.

EO specificity: Variable.

Lower detectable limit for EO: Less expensive units usually do not detect EO concentrations lower than 5 ppm. More expensive units are capable of detecting concentrations of approximately 0.3 ppm.

Other comments: Steam or water vapor can interfere with the analysis or damage certain parts of some infrared analyzers. Temperature changes will also affect the analysis. See also "Other comments" for gas chromatographs (B.3.3.2.3). Some units are capable of downloading data to a PC/printer.

B.3.3.2.5 Photoionization detectors (without gas chromatographs)

Principle of operation: Air is supplied to a detector, where certain contaminants interact with ultraviolet light, producing ions. These ions produce an electric current, the strength of which is related to the contaminant concentration.

Portability: Most are portable.

Ease of operation:

Preparation and use—moderate.

Data collection—simple.

Accuracy: Variable.

EO specificity: Numerous contaminants other than EO can produce positive interferences.

Lower detectable limit for EO: Some are capable of detecting concentrations lower than 1 ppm.

Other comments: See "Other comments" for gas chromatographs (B.3.3.2.3).

B.3.3.2.6 Gas detector tubes

Principle of operation: A hand pump draws air through a glass tube packed with a chemically treated substance that changes color upon exposure to certain contaminants. The degree of color change is proportional to the concentration of the contaminant.

Portability: Excellent.

Ease of operation:

Preparation and use—simple.

Data collection—simple.

Accuracy: Usually very poor at low concentrations of EO.

EO specificity: Substances other than EO can react with the color-changing chemical.

Lower detectable limit for EO: Some are capable of detecting concentrations in the range of 1 ppm to 10 ppm. Others are designed for concentrations higher than 10 ppm.

Other comments: Tubes have a limited "shelf life." Storage temperature limits should be verified with the supplier. Since tubes can generally only be used for a single air sample and are then discarded, they might not be suitable for TWA determinations, but could be used for process-related tasks of short duration (i.e. for excursion-level determinations).

B.3.3.3 Continuous monitoring

Although the OSHA standard on occupational exposure to EO (29 CFR 1910.1047) does not specifically require a health care facility to have a continuous monitoring system, it does specify that means must be developed to promptly alert employees of a leak or spill. Therefore, for the health and safety of employees, AAMI recommends

continuous monitoring of the workplace environment. Monitors should be capable of monitoring the various locations in which leaks or spills could occur. Therefore, the appropriate monitor depends on the number of points requiring this type of monitoring. The equipment should be capable of being set at a level that will avoid a high frequency of interferences from other chemicals used in the workplace. The equipment should also be capable of providing both visible and audible alarms.

B.3.3.4 Summary

As indicated previously, there are advantages and disadvantages of each type of area monitor. In selecting such equipment, careful review of the unit's intended use and capabilities is required. In general, the following questions should be answered to the prospective user's satisfaction before an area monitor is purchased:

a) Does the workplace contain air contaminants other than EO that could interfere with the monitor's detection system? (The user should insist upon a written statement from the manufacturer.)

b) Does the analyzer require calibration? If so, how is the calibration performed? If a gaseous reference sample is required, the user should insist upon a written statement from the gas supplier regarding the stability and availability of the gas mixture, as well as any other special handling instructions.

c) What maintenance work might be necessary for the instrument? Who will perform the maintenance? (In other words, will it be necessary to return the instrument to the factory, or is field service available?)

d) What other health care facilities or organizations have purchased this instrument? (The user might wish to contact the health care facilities or organizations and ask them if they are satisfied with the instrument.)

e) What is the lowest concentration of EO that can be measured accurately by the instrument? At that level, what is its accuracy and repeatability? Written documentation should be requested.

f) Is any special training required to operate the instrument? If so, does the instrument manufacturer provide such training?

g) Is the unit capable of computer interface and data recall?

h) Is the monitoring equipment "intrinsically safe" (i.e. explosion-proof)? If only intrinsically safe equipment is permitted in the facility, the manufacturer must certify that the equipment meets this requirement.

B.4 Contract services

B.4.1 Advantages and disadvantages of contract services

Many companies and organizations offer services that include EO monitoring. The breadth of additional services available varies significantly from contractor to contractor. Some will perform only personnel monitoring (using one of the techniques described in B.3.2); others will conduct a complete survey of the health care facility to identify sources of EO leakage and will provide recommendations for possible solutions to identified problems.

Using a contract service has the following advantages:

a) Reputable contractors are familiar with the causes of potential EO exposure, enabling them to save time at the outset in identifying where problems could exist. Engineering or work-practice solutions can then be designed and implemented.

b) Contract services can be performed on a shared-service basis; that is, several health care facilities can jointly contract with the contractor. Discounts for services might be available under such circumstances.

c) The same contractor might be able to provide services meeting similar needs in other departments (e.g., monitoring waste anesthetic gases in the operating room).

The major disadvantage of relying solely on contract services is that once the contractor completes the work, there is no ongoing means of identifying the airborne EO in the facility. This could be an unacceptable situation, depending on the amount of EO sterilization performed, the location of the EO sterilization facility, the number of people normally present in and around the EO sterilization facility, and other factors. In this case, some form of ongoing monitoring program using the methods previously described should be implemented.

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B.4.2 Finding contract service organizations

There are a variety of ways to find contract service organizations:

a) The local or state health department, occupational health consulting services, workmen's compensation or other insurance carriers, or universities can be approached to determine if they provide consultant services and, if not, to secure their recommendations.

b) Nearby health care facilities can be contacted to learn their experiences with consultants and to obtain their recommendations.

c) Sterilizer manufacturers and EO suppliers can usually provide suggestions.

d) Technical journals, such as the *American Industrial Hygiene Association Journal,* often contain consultant advertisements.

e) The American Industrial Hygiene Association can provide a list of consultants and accredited laboratories in the region.

f) If a local consultant is not available, a cooperative effort (shared service) to bring in a reputable consultant can be considered.

B.4.3 Selection criteria

Once a list of possible service organizations is prepared, the following steps should be taken in the selection process:

a) The consultant should be asked for references, preferably nearby clients with similar operations.

b) The consultant should describe the specific qualifications and years of technical experience of the individuals who perform the work. (Certified Industrial Hygienist and Professional Engineer are usually good credentials. Certified Safety Professional or Biomedical Equipment Technician could also be valid, with appropriate experience.)

c) The individuals who perform the work should be interviewed. During the interview, the following questions should be asked:

   1) How many EO facilities has the individual tested?

   2) Is the individual familiar with the EO sterilization process? (Ask follow-up questions.)

   3) What kind of equipment will be used to perform the work? What interferences might affect the EO monitoring?

   4) What areas of the facility will be examined?

d) If charcoal tubes, PSDs, or other personnel samples are to be collected, the contractor should be asked to verify that blank or control samples are submitted.

e) The contractor should specify who performs the analysis of the adsorbent and describe the level of experience of this individual.

f) The general operation, the number and types of sterilizers, the work practices, the number of employees per shift, and the facility layout should be discussed before monitoring begins. Agreement should be reached in advance about which activities will be monitored and which ancillary tests (e.g., ventilation tests) will be performed. Both personnel monitoring and area monitoring are desirable. It should be specified that all work shifts when EO is used will be surveyed.

g) The contractor should be asked whether ventilation checks will be performed (e.g., local exhaust hoods, air exchange rate, location of building intake in relation to the sterilizer exhaust points, positive/negative pressure areas).

h) The contractor should describe the report that will be issued upon completing the work and provide an example of the report format. The user and contractor should agree upon the date on which the report will be issued and who will receive a copy. The report should contain at least the following information:

   1) the date monitoring was performed;

   2) a detailed description of the operations performed;

3) the names or identity numbers of the personnel monitored;

4) if applicable, the most recent calibration date of the monitoring devices and the calibration technique used;

5) the exact locations of the sampling devices (photographs or maps are very helpful);

6) the specific times that samples were collected, with notations concerning other pertinent activities (e.g., the sterilizer door was opened, the sterilized items were transferred to the aerator, the EO cylinder was changed);

7) the EO concentrations, in ppm, at each sample location (as an 8-hour TWA, 6-hour TWA, 15-minute excursion level, or other specified time period);

8) a description of the sampling and analytical techniques used;

9) the name of the contractor's organization;

10) the names and qualifications of the survey personnel who did the work at the facility;

11) the temperature and relative humidity of the area that was surveyed;

12) an authorized signature with a title.

i) The contractor's fee should be discussed.

j) The possibility of follow-up visits should be discussed. How many visits and when they will be scheduled should be determined.

k) Once the contractor has been selected, it is important to ensure that the contractor will provide ample advance notice before coming to the facility so that the appropriate supervisor can schedule time for the survey and so that actual normal operations (including EO sterilization processes) will occur during the survey. A "simulated load" outside the normal routine should not be surveyed.

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Annex C
(informative)

Ethylene oxide and hydrochlorofluorocarbon emission control technologies

C.1 Introduction

Federal, state, and local regulations affecting the discharge of EO, diluent gas mixtures, and breakdown residuals to the atmosphere and water supply have been promulgated and implemented. Many jurisdictions require engineering controls to reduce airborne emissions of toxic substances, such as EO, through the application of Best Available Control Technology (BACT). Similar emission requirements are in place for HCFCs.

There are many sources of EO emissions, including fugitive emissions from materials sterilized, the sterilizing chamber, the sterilizer vacuum system, and sterilant supply tank connections. These are also potential sources of HCFC emissions, the diluent carrier now being used to make EO nonflammable. The specific technologies for controlling EO and HCFC emissions vary in concept and complexity. Some technologies are appropriate for hospital use, while others are not.

Some emission control technologies involve the use of hazardous chemicals. It is important to follow the equipment manufacturer's instructions for safe handling. Spent or used chemicals should be disposed of in accordance with state and local regulations.

Before investing in emission control equipment, health care personnel should verify with the equipment manufacturer that the system is suitable both for EO mixtures currently in use in the health care facility and for potential future mixtures.

C.2 Emission control technologies

C.2.1 Catalytic conversion

Catalytic converters operate at relatively low temperatures (250° F to 550° F) to convert EO to carbon dioxide and water vapor flamelessly and usually very efficiently. Such systems are suitable for hospital use because the diluent gas (HCFC or CO_2) passes through them without reacting (unless the conversion temperature causes breakdown of the HCFC). A given amount of catalyst can convert a fixed amount of EO. As the catalyst is depleted, it loses efficiency and therefore must be replaced periodically. Other fugitive hydrocarbons will react with the catalyst if allowed to enter the device with the makeup air supply. The exhaust duct from the catalytic converter might be at a relatively high temperature and require special materials if installed indoors.

C.2.2 Acid hydrolysis

Acid "scrubbers" are well-established EO emission treatment devices in the chemical industry and in large-scale commercial/industrial sterilization applications. Effluent EO gas reacts in an acid bath to form ethylene glycol. The diluent gases (HCFC or CO_2) pass through the liquid to the atmosphere unchanged. As the ethylene glycol concentration in the liquid increases, the rate of reaction slows. Periodically, the liquid bath must be changed to maintain the efficiency of the conversion. That process involves neutralizing the acid bath by treatment with a strong, caustic agent (such as sodium hydroxide) for handling and disposal.

C.2.3 Absorption

Certain filtering media can be used to absorb EO in low concentrations, such as those found in EO gas aerators or fugitive-emission ducting. These absorptive systems are passive devices that absorb a fixed amount of EO over a period of time and so must be changed on a regular basis.

C.2.4 Open-flame incineration

This technique is commonly used in the chemical industry for the disposal of "sour" gas and is suitable for disposing of relatively large quantities of 100% EO. The chemical reaction converts the EO to carbon dioxide and water vapor, which are released into the atmosphere. The open flame is usually fuel-fed to ensure that the intensity and concentration of the flame are sufficient to "burn" the EO. The technique is generally not suitable for EO/HCFC mixtures because incineration of HCFC produces highly corrosive byproducts.

C.2.5 Recovery/reclamation systems

Recovery/reclamation systems are connected to the discharge of EO sterilizers to capture the gases removed from the sterilizing chamber. Some systems capture only the diluent carrier from the sterilizer discharge; others capture both the EO and the diluent carrier. The gas is reprocessed for reuse rather than discharged into the atmosphere. Recovery technology could offer some savings from reprocessed sterilant vs. new sterilant costs, depending on the circumstances of the health care facility and the purchase or credit agreement offered by the gas supplier. Users of large volumes of EO might benefit most from this alternative.

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Annex D*
(Informative)

Occupational exposure to ethylene oxide, final standard (29 CFR 1910.1047)

§1910.1047—Ethylene oxide

a) Scope and application

1) This section applies to all occupational exposures to ethylene oxide (EtO), Chemical Abstracts Service Registry No. 75-21-8, except as provided in paragraph (a)(2) of this section.

2) This section does not apply to the processing, use, or handling of products containing EtO where objective data are reasonably relied upon that demonstrate that the product is not capable of releasing EtO in airborne concentrations at or above the action level under the expected conditions of processing, use, or handling that will cause the greatest possible release.

3) Where products containing EtO are exempted under paragraph (a)(2) of this section, the employer shall maintain records of the objective data supporting that exemption and the basis for the employer's reliance on the data, as provided in paragraph (k)(1) of this section.

b) Definitions

For the purpose of this section, the following definitions shall apply.

"Action level" means a concentration of airborne EtO of 0.5 ppm calculated as an eight (8)-hour time-weighted average.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (l) of this section, or any other person authorized by the Act or regulations issued under the Act.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that is likely to or does result in an unexpected significant release of EtO.

"Employee exposure" means exposure to airborne EtO which would occur if the employee were not using respiratory protective equipment.

"Ethylene oxide" or "EtO" means the three-membered ring organic compound with chemical formula C_2H_4O.

c) Permissible exposure limits

1) *8-hour time-weighted average (TWA).* The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of one (1) part EtO per million parts of air (1 ppm) as an (8)-hour time-weighted average (8-hour TWA).

2) *Excursion limit.* The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes.

d) Exposure monitoring

1) General

* Reprinted from Code of Federal Regulations (CFR)

i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 15-minute short-term exposures of each employee.

ii) Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for each shift for each job classification in each work area. Representative 15-minute short-term employee exposures shall be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the excursion limit for each shift for each job classification in each work area.

iii) Where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer need only determine representative employee exposure for that operation during one shift.

2) Initial monitoring

i) Each employer who has a workplace or work operation covered by this standard, except as provided for in paragraph (a)(2) or (d)(2)(ii) of this section, shall perform initial monitoring to determine accurately the airborne concentrations of EtO to which employees may be exposed.

ii) Where the employer has monitored after June 15, 1983 and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section.

iii) Where the employer has previously monitored for the excursion limit and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section.

3) Monitoring frequency (periodic monitoring)

i) If the monitoring required by paragraph (d)(2) of this section reveals employee exposure at or above the action level but at or below the 8-hour TWA, the employer shall repeat such monitoring for each such employee at least every 6 months.

ii) If the monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure above the 8-hour TWA, the employer shall repeat such monitoring for each such employee at least every 3 months.

iii) The employer may alter the monitoring schedule from quarterly to semiannually for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee's exposure has decreased to or below the 8-hour TWA.

iv) If the monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure above the 15 minute excursion limit, the employer shall repeat such monitoring for each such employee at least every 3 months, and more often as necessary to evaluate the employee's short-term exposures.

4) Termination of monitoring

i) If the initial monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure to be below the action level, the employer may discontinue TWA monitoring for those employees whose exposures are represented by the initial monitoring.

ii) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level, the employer may discontinue TWA monitoring for those employees whose exposures are represented by such monitoring.

iii) If the initial monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure to be at or below the excursion limit, the employer may discontinue excursion limit monitoring for those employees whose exposures are represented by the initial monitoring.

iv) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are at or below the excursion limit, the employer may discontinue excursion limit monitoring for those employees whose exposures are represented by such monitoring.

5) Additional monitoring

Notwithstanding the provisions of paragraph (d)(4) of this section, the employer shall institute the exposure monitoring required under paragraphs (d)(2)(i) and (d)(3) of this section whenever there has been a change

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in the production, process, control equipment, personnel or work practices that may result in new or additional exposures to EtO or when the employer has any reason to suspect that a change may result in new or additional exposures.

6) Accuracy of monitoring

i) Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of EtO at the 1 ppm TWA and to within plus or minus 35 percent for airborne concentrations of EtO at the action level of 0.5 ppm.

ii) Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 35 percent for airborne concentrations of EtO at the excursion limit.

7) Employee notification of monitoring results

i) The employer shall, within 15 working days after the receipt of the results of any monitoring performed under this standard, notify the affected employee of these results in writing either individually or by posting of results in an appropriate location that is accessible to affected employees.

ii) The written notification required by paragraph (d)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce employee exposure to or below the TWA and/or excursion limit, wherever monitoring results indicated that the TWA and/or excursion limit has been exceeded.

e) Regulated areas

1) The employer shall establish a regulated area wherever occupational exposures to airborne concentrations of EtO may exceed the TWA or wherever the EtO concentration exceeds or can reasonably be expected to exceed the excursion limit.

2) Access to regulated areas shall be limited to authorized persons.

3) Regulated areas shall be demarcated in any manner that minimizes the number of employees within the regulated area.

f) Methods of compliance

1) Engineering controls and work practices

i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the TWA and to or below the excursion limit, except to the extent that such controls are not feasible.

ii) Wherever the feasible engineering controls and work practices that can be instituted are not sufficient to reduce employee exposure to or below the TWA and to or below the excursion limit, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

iii) Engineering controls are generally infeasible for the following operations: collection of quality assurance sampling from sterilized materials; removal of biological indicators from sterilized materials; loading and unloading of tank cars; changing of ethylene oxide tanks on sterilizers; and vessel cleaning. For these operations, engineering controls are required only where the Assistant Secretary demonstrates that such controls are feasible.

2) Compliance program

i) Where the TWA or excursion limit is exceeded, the employer shall establish and implement a written program to reduce employee exposure to or below the TWA and to or below the excursion limit by means of engineering and work-practice controls, as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section.

ii) The compliance program shall include a schedule for periodic leak detection surveys and a written plan for emergency situations, as specified in paragraph (h)(i) of this section.

iii) Written plans for a program required in paragraph (f)(2) shall be developed and furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. Such plans shall be reviewed at least every 12 months, and shall be updated as necessary to reflect significant changes in the status of the employer's compliance program.

iv) The employer shall not implement a schedule of employee rotation as a means of compliance with the TWA or excursion limit.

g) Respiratory protection and personal protective equipment

1) General

For employees who use respirators required by this section, the employer must provide respirators that comply with the requirements of this paragraph. Respirators must be used during:

i) Periods necessary to install or implement feasible engineering and work-practice controls.

ii) Work operations, such as maintenance and repair activities and vessel cleaning, for which engineering and work-practice controls are not feasible.

iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the TWA.

iv) Emergencies.

2) Respirator program

The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m).

3) Respirator selection

The employer must select the appropriate respirator from Table 1 of this section.

Table 1—Minimum Requirements for Respiratory Protection for Airborne EtO

Condition of use or concentration of airborne ETO (ppm)	Minimum required respirator
Equal to or less than 50	(a) Full facepiece respirator with EtO approved canister, front- or back-mounted
Equal to or less than 2,000	(a) Positive-pressure supplied air respirator, equipped with full facepiece, hood, or helmet, or (b) Continuous-flow supplied air respirator (positive pressure) equipped with hood, helmet or suit
Concentration above 2,000 or unknown concentration (such as in emergencies)	(a) Positive-pressure self-contained breathing apparatus (SCBA), equipped with full facepiece, or (b) Positive-pressure full facepiece supplied air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus
Firefighting	(a) Positive-pressure self-contained breathing apparatus equipped with full facepiece
Escape	(a) Any respirator described above

NOTE—Respirators approved for use in higher concentrations are permitted to be used in lower concentrations.

4) Protective clothing and equipment

When employees could have eye or skin contact with EtO or EtO solutions, the employer must select and provide, at no cost to the employee, appropriate protective clothing or other equipment in accordance with 29 CFR 1910.132 and 1910.133 to protect any area of the employee's body that may come in contact with the EtO or EtO solution, and must ensure that the employee wears the protective clothing and equipment provided.

h) Emergency situations

1) Written plan

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i) A written plan for emergency situations shall be developed for each workplace where there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with respiratory protection as required by paragraph (g) of this section until the emergency is abated.

iii) The plan shall include the elements prescribed in 29 CFR 1910.38, “Employee emergency plans and fire prevention plans.”

2) Alerting employees

Where there is the possibility of employee exposure to EtO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly. Affected employees shall be immediately evacuated from the area in the event that an emergency occurs.

i) Medical surveillance

1) General

i) *Employees covered*

A) The employer shall institute a medical surveillance program for all employees who are or may be exposed to EtO at or above the action level, without regard to the use of respirators, for at least 30 days a year.

B) The employer shall make available medical examinations and consultations to all employees who have been exposed to EtO in an emergency situation.

ii) *Examination by a physician*

The employer shall ensure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and are provided without cost to the employee, without loss of pay, and at a reasonable time and place.

2) Medical examinations and consultations

i) *Frequency*

The employer shall make available medical examinations and consultations to each employee covered under paragraph (i)(1)(i) of this section on the following schedules:

A) Prior to assignment of the employee to an area where exposure may be at or above the action level for at least 30 days a year.

B) At least annually each employee exposed at or above the action level for at least 30 days in the past year.

C) At termination of employment or reassignment to an area where exposure to EtO is not at or above the action level for at least 30 days a year.

D) As medically appropriate for any employee exposed during an emergency.

E) As soon as possible, upon notification by an employee either (1) that the employee has developed signs or symptoms indicating possible overexposure to EtO, or (2) that the employee desires medical advice concerning the effects of current or past exposure to EtO on the employee’s ability to produce a healthy child.

F) If the examining physician determines that any of the examinations should be provided more frequently than specified, the employer shall provide such examinations to affected employees at the frequencies recommended by the physician.

ii) *Content*

A) Medical examinations made available pursuant to paragraphs (i)(2)(i)(A) through (D) of this section shall include:

1) A medical and work history with special emphasis directed to symptoms related to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

2) A physical examination with particular emphasis given to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

3) A complete blood count to include at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin.

4) Any laboratory or other test which the examining physician deems necessary by sound medical practice.

B) The content of medical examinations or consultation made available pursuant to paragraph (i)(2)(i)(E) of this section shall be determined by the examining physician, and shall include pregnancy testing or laboratory evaluation of fertility, if requested by the employee and deemed appropriate by the physician.

3) Information provided to the physician

The employer shall provide the following information to the examining physician:

i) A copy of this standard and Appendices A, B, and C.

ii) A description of the affected employee's duties as they relate to the employee's exposure.

iii) The employee's representative exposure level or anticipated exposure level.

iv) A description of any personal protective and respiratory equipment used or to be used.

v) Information from previous medical examinations of the affected employee that is not otherwise available to the examining physician.

4) Physician's written opinion

i) The employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination and shall include:

A) The physician's opinion as to whether the employee has any detected medical conditions that would place the employee at an increased risk of material health impairment from exposure to EtO;

B) Any recommended limitations on the employee or upon the use of personal protective equipment such as clothing or respirators; and

C) A statement that the employee has been informed by the physician of the results of the medical examination and of any medical conditions resulting from EtO exposure that require further explanation or treatment.

ii) The employer shall instruct the physician not to reveal in the written opinion given to the employer specific findings or diagnoses unrelated to occupational exposure to EtO.

iii) The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days from its receipt.

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j) Communication of EtO hazards to employees

1) Signs and labels

i) The employer shall post and maintain legible signs demarcating regulated areas and entrances or accessways to regulated areas that 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

ii) The employer shall ensure that precautionary labels are affixed to all containers of EtO whose contents are capable of causing employee exposure at or above the action level or whose contents may reasonably be foreseen to cause employee exposure above the excursion limit, and that the labels remain affixed when the containers of EtO leave the workplace. For the purposes of this paragraph, reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers. The labels shall comply with the requirements of 29 CFR 1910.1200(f) of OSHA's Hazard Communication standard, and shall include the following legend:

A)

DANGER
CONTAINS ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD

B) A warning statement against breathing airborne concentrations of EtO.

iii) The labeling requirements under this section do not apply where EtO is used as a pesticide, as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*), when it is labeled pursuant to that Act and regulations issued under that Act by the Environmental Protection Agency.

2) Material safety data sheets

Employers who are manufacturers or importers of EtO shall comply with the requirements regarding development of material safety data sheets as specified in 29 CFR 1910.1200(g) of OSHA's Hazard Communication standard.

3) Information and training

i) The employer shall provide employees who are potentially exposed to EtO at or above the action level with information and training on EtO at the time of initial assignment and at least annually thereafter.

ii) Employees shall be informed of the following:

A) The requirements of this section with an explanation of its contents, including Appendices A and B;

B) Any operations in their work area where EtO is present;

C) The location and availability of the written EtO final rule; and

D) The medical surveillance program required by paragraph (i) of this section with an explanation of the information in Appendix C.

iii) Employee training shall include at least:

A) Methods and observations that may be used to detect the presence or release of EtO in the work area (such as monitoring conducted by the employer, continuous monitoring devices, etc.);

B) The physical and health hazards of EtO;

C) The measures employees can take to protect themselves from hazards associated with EtO exposure, including specific procedures the employer has implemented to protect employees from exposure to EtO, such as work practices, emergency procedures, and personal protective equipment to be used; and

D) The details of the hazard communication program developed by the employer, including an explanation of the labeling system and how employees can obtain and use the appropriate hazard information.

k) Recordkeeping

1) Objective data for exempted operations

i) Where the processing, use, or handling of products made from or containing EtO are exempted from other requirements of this section under paragraph (a)(2) of this section, or where objective data have been relied on in lieu of initial monitoring under paragraph (d)(2)(ii) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

ii) This record shall include at least the following information:

A) The product qualifying for exemption;

B) The source of the objective data;

C) The testing protocol, results of testing, and/or analysis of the material for the release of EtO;

D) A description of the operation exempted and how the data support the exemption; and

E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

2) Exposure measurements

i) The employer shall keep an accurate record of all measurements taken to monitor employee exposure to EtO as prescribed in paragraph (d) of this section.

ii) This record shall include at least the following information:

A) The date of measurement;

B) The operation involving exposure to EtO which is being monitored;

C) Sampling and analytical methods used and evidence of their accuracy;

D) Number, duration, and results of samples taken;

E) Type of protective devices worn, if any; and

F) Name, social security number and exposure of the employees whose exposures are represented.

iii) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.1020.

3) Medical surveillance

i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance by paragraph (i)(1)(i) of this section, in accordance with 29 CFR 1910.1020.

ii) The record shall include at least the following information:

A) The name and social security number of the employee;

B) Physicians' written opinions;

C) Any employee medical complaints related to exposure to EtO; and

D) A copy of the information provided to the physician as required by paragraph (i)(3) of this section.

iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.1020.

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4) Availability

i) The employer, upon written request, shall make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying.

ii) The employer, upon request, shall make any exemption and exposure records required by paragraphs (k)(1) and (2) of this section available for examination and copying to affected employees, former employees, designated representatives and the Assistant Secretary, in accordance with 29 CFR 1910.1020 (a) through (e) and (g) through (i).

iii) The employer, upon request, shall make employee medical records required by paragraph (k)(3) of this section available for examination and copying to the subject employee, anyone having the specific written consent of the subject employee, and the Assistant Secretary, in accordance with 29 CFR 1910.1020.

5) Transfer of records

i) The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.1020(h).

ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director at least 90 days prior to disposal and transmit them to the Director.

l) Observation of monitoring

1) Employee observation

The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to EtO conducted in accordance with paragraph (d) of this section.

2) Observation procedures

When observation of the monitoring of employee exposure to EtO requires entry into an area where the use of protective clothing or equipment is required, the observer shall be provided with and be required to use such clothing and equipment and shall comply with all other applicable safety and health procedures.

m) Dates

1) Effective date

i) The paragraphs contained in this section shall become effective August 21, 1984, except for paragraphs (a)(2), (d), (e), (f)(2), (g)(3), (h), (i), and (j) which shall become effective on March 12, 1985.

ii) The requirements in this section which pertain only to or are triggered by the excursion limit shall become effective June 6, 1988, except for the excursion limit provisions in paragraphs (a)(2), (d), (f)(2), (g)(3) and (j) of this section which shall become effective August 25, 1988.

2) Start-up dates

i) The start-up date for the requirements in those paragraphs that were effective on August 21, 1984, including institution of work practice controls specified in paragraph (f)(1), shall be February 19, 1985, except as provided for in paragraph (m)(2)(ii), and the start-up date for paragraphs (a)(2), (d), (e), (f)(2), (g)(3), (h), (i), and (j) of this section shall be September 9, 1985.

ii) Engineering controls specified by paragraph (f)(1) of this section shall be implemented by August 21, 1985.

iii) Compliance with the requirements in this section which pertain to or are triggered by the excursion limit shall be by September 6, 1988, except for compliance with the excursion limit provisions of paragraphs (a)(2), (d), (f)(2), (g)(3) and (j) of this section, which shall be by October 6, 1988, and implementation of engineering controls specified for compliance with the excursion limit, which shall be by December 6, 1988.

3) Labeling

i) Paragraph (j)(1)(ii)(A) of this section as amended is effective January 9, 1986.

ii) Paragraph (j)(1)(iii) of this section is effective October 11, 1985.

n) Appendices

The information contained in the appendices is not intended by itself to create any additional obligations not otherwise imposed or to detract from any existing obligation.

Appendix A to §1910.1047—Substance Safety Data Sheet for Ethylene Oxide (Non-Mandatory)

I. Substance identification

A) *Substance:* Ethylene oxide (C_2H_4O).

B) *Synonyms:* dihydrooxirene, dimethylene oxide, EO, 1,2-epoxyethane, EtO, ETO, oxacyclopropane, oxane, oxidoethane, alpha/beta-oxidoethane, oxiran, oxirane.

C) Ethylene oxide can be found as a liquid or vapor.

D) EtO is used in the manufacture of ethylene glycol, surfactants, ethanolamines, glycol ethers, and other organic chemicals. EtO is also used as a sterilant and fumigant.

E) *Appearance and odor:* Colorless liquid below 10.7 deg. C (51.3 deg. F) or colorless gas with ether-like odor detected at approximately 700 parts EtO per million parts of air (700 ppm).

F) *Permissible exposure:* Exposure may not exceed 1 part EtO per million parts of air averaged over the 8-hour workday.

II. Health hazard data

A) Ethylene oxide can cause bodily harm if you inhale the vapor, if it comes into contact with your eyes or skin, or if you swallow it.

B) *Effects of overexposure*

1) Ethylene oxide in liquid form can cause eye irritation and injury to the cornea, frostbite, and severe irritation and blistering of the skin upon prolonged or confined contact. Ingestion of EtO can cause gastric irritation and liver injury. Acute effects from inhalation of EtO vapors include respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, shortness of breath, and cyanosis (blue or purple coloring of skin). Exposure has also been associated with the occurrence of cancer, reproductive effects, mutagenic changes, neurotoxicity, and sensitization

2) EtO has been shown to cause cancer in laboratory animals and has been associated with higher incidences of cancer in humans. Adverse reproductive effects and chromosome damage may also occur from EtO exposure.

a) *Reporting signs and symptoms:* You should inform your employer if you develop any signs or symptoms and suspect that they are caused by exposure to EtO.

III. Emergency first aid procedures

A) *Eye exposure*

If EtO gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper eyelids. Get medical attention immediately. Contact lenses should not be worn when working with this chemical.

B) *Skin exposure*

If EtO gets on your skin, immediately wash the contaminated skin with water. If EtO soaks through your clothing, especially your shoes, remove the clothing immediately and wash the skin with water using an emergency deluge shower. Get medical attention immediately. Thoroughly wash contaminated clothing before reusing. Contaminated leather shoes or other leather articles should not be reused and should be discarded.

C) *Inhalation*

If large amounts of EtO are inhaled, the exposed person must be moved to fresh air at once. If breathing has stopped, perform cardiopulmonary resuscitation. Keep the affected person warm and at rest. Get medical attention immediately.

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D) *Swallowing*

When EtO has been swallowed, give the person large quantities of water immediately. After the water has been swallowed, try to get the person to vomit by having him or her touch the back of the throat with his or her finger. Do not make an unconscious person vomit. Get medical attention immediately.

E) *Rescue*

Move the affected person from the hazardous exposure. If the exposed person has been overcome, attempt rescue only after notifying at least one other person of the emergency and putting into effect established emergency procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the location of the emergency equipment before the need arises.

IV. Respirators and protective clothing

A) *Respirators*

You may be required to wear a respirator for nonroutine activities, in emergencies, while your employer is in the process of reducing EtO exposures through engineering controls, and in areas where engineering controls are not feasible. As of the effective date of this standard, only air-supplied, positive-pressure, full-facepiece respirators are approved for protection against EtO. If air-purifying respirators are worn in the future, they must have a label issued by the National Institute for Occupational Safety and Health under the provisions of 42 CFR part 84 stating that the respirators have been approved for use with ethylene oxide. For effective protection, respirators must fit your face and head snugly. Respirators must not be loosened or removed in work situations where their use is required.

EtO does not have a detectable odor except at levels well above the permissible exposure limits. If you can smell EtO while wearing a respirator, proceed immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

B) *Protective clothing*

You may be required to wear impermeable clothing, gloves, a face shield, or other appropriate protective clothing to prevent skin contact with liquid EtO or EtO-containing solutions. Where protective clothing is required, your employer must provide clean garments to you as necessary to assure that the clothing protects you adequately.

Replace or repair protective clothing that has become torn or otherwise damaged.

EtO must never be allowed to remain on the skin. Clothing and shoes which are not impermeable to EtO should not be allowed to become contaminated with EtO, and if they do, the clothing should be promptly removed and decontaminated. Contaminated leather shoes should be discarded. Once EtO penetrates shoes or other leather articles, they should not be worn again.

C) *Eye protection*

You must wear splashproof safety goggles in areas where liquid EtO or EtO-containing solutions may contact your eyes. In addition, contact lenses should not be worn in areas where eye contact with EtO can occur.

V. Precautions for safe use, handling, and storage

A) EtO is a flammable liquid, and its vapors can easily form explosive mixtures in air.

B) EtO must be stored in tightly closed containers in a cool, well-ventilated area, away from heat, sparks, flames, strong oxidizers, alkalines, and acids, strong bases, acetylide-forming metals such as cooper, silver, mercury and their alloys.

C) Sources of ignition such as smoking material, open flames and some electrical devices are prohibited wherever EtO is handled, used, or stored in a manner that could create a potential fire or explosion hazard.

D) You should use non-sparking tools when opening or closing metal containers of EtO, and containers must be bonded and grounded in the rare instances in which liquid EtO is poured or transferred.

E) Impermeable clothing wet with liquid EtO or EtO-containing solutions may be easily ignited. If you are wearing impermeable clothing and are splashed with liquid EtO or EtO-containing solution, you should immediately remove the clothing while under an emergency deluge shower.

F) If your skin comes into contact with liquid EtO or EtO-containing solutions, you should immediately remove the EtO using an emergency deluge shower.

G) You should not keep food, beverages, or smoking materials in regulated areas where employee exposures are above the permissible exposure limits.

H) Fire extinguishers and emergency deluge showers for quick drenching should be readily available, and you should know where they are and how to operate them.

I) Ask your supervisor where EtO is used in your work area and for any additional plant safety and health rules.

VI. Access to information

A) Each year, your employer is required to inform you of the information contained in this standard and appendices for EtO. In addition, your employer must instruct you in the proper work practices for using EtO emergency procedures, and the correct use of protective equipment.

B) Your employer is required to determine whether you are being exposed to EtO. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits.

C) Your employer is required to keep records of your exposures and medical examinations. These exposure records must be kept by the employer for at least thirty (30) years. Medical records must be kept for the period of your employment plus thirty (30) years.

D) Your employer is required to release your exposure and medical records to your physician or designated representative upon your written request.

VII. Sterilant use of EtO in hospitals and health care facilities

This section of Appendix A, for informational purposes, sets forth EPA's recommendations for modifications in workplace design and practice in hospitals and health care facilities for which the Environmental Protection Agency has registered EtO for uses as a sterilant or fumigant under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.* These new recommendations, published in the Federal Register by EPA at 49 FR 15268, as modified in today's Register, are intended to help reduce the exposure of hospital and health care workers to EtO to 1 ppm. EPA's recommended workplace design and workplace practices are as follows:

1) Workplace design

a) *Installation of gas line hand valves*

Hand valves must be installed on the gas supply line at the connection to the supply cylinders to minimize leakage during cylinder change.

b) *Installation of capture boxes*

Sterilizer operations result in a gas/water discharge at the completion of the process. This discharge is routinely piped to a floor drain which is generally located in an equipment or an adjacent room. When the floor drain is not in the same room as the sterilizer and workers are not normally present, all that is necessary is that the room be well ventilated.

The installation of a "capture box" will be required for those work place layouts where the floor drain is located in the same room as the sterilizer or in a room where workers are normally present. A "capture box" is a piece of equipment that totally encloses the floor drain where the discharge from the sterilizer is pumped. The "capture box" is to be vented directly to a non-recirculating or dedicated ventilation system. Sufficient air intake should be allowed at the bottom of the box to handle the volume of air that is ventilated from the top of the box. The "capture box" can be made of metal, plastic, wood or other equivalent material. The box is intended to reduce levels of EtO discharged into the work room atmosphere. The use of a "capture box" is not required if: (1) The vacuum pump discharge floor drain is located in a well ventilated equipment or other room where workers are not normally present or (2) the water sealed vacuum pump discharges directly to a closed sealed sewer line (check local plumbing codes).

If it is impractical to install a vented "capture box" and a well ventilated equipment or other room is not feasible, a box that can be sealed over the floor drain may be used if: (1) The floor drain is located in a

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room where workers are not normally present and EtO cannot leak into an occupied area, and (2) the sterilizer in use is less than 12 cubic feet in capacity (check local plumbing codes).

c) *Ventilation of aeration units*

i) *Existing aeration units*

Existing units must be vented to a non recirculating or dedicated system or vented to an equipment or other room where workers are not normally present and which is well ventilated. Aerator units must be positioned as close as possible to the sterilizer to minimize the exposure from the off-gassing of sterilized items.

ii) *Installation of new aerator units (where none exist)*

New aerator units must be vented as described above for existing aerators. Aerators must be in place by July 1, 1986.

d) *Ventilation during cylinder change*

Workers may be exposed to short but relatively high levels of EtO during the change of gas cylinders. To reduce exposure from this route, users must select one of three alternatives designed to draw off gas that may be released when the line from the sterilizer to the cylinder is disconnected:

i) Location of cylinders in a well ventilated equipment room or other room where workers are not normally present.

ii) Installation of a flexible hose (at least 4” in diameter) to a non-recirculating or dedicated ventilation system and located in the area of cylinder change in such a way that the hose can be positioned at the point where the sterilizer gas line is disconnected from the cylinder.

iii) Installation of a hood that is part of a non-recirculating or dedicated system and positioned no more than one foot above the point where the change of cylinders takes place.

e) *Ventilation of sterilizer door area*

One of the major sources of exposure to EtO occurs when the sterilizer door is opened following the completion of the sterilization process. In order to reduce this avenue of exposure, a hood or metal canopy closed on each end must be installed over the sterilizer door. The hood or metal canopy must be connected to a non-recirculating or dedicated ventilation system or one that exhausts gases to a well ventilated equipment or other room where workers are not normally present. A hood or canopy over the sterilizer door is required for use even with those sterilizers that have a purge cycle and must be in place by July 1, 1986.

f) *Ventilation of sterilizer relief valve*

Sterilizers are typically equipped with a safety relief device to release gas in case of increased pressure in the sterilizer. Generally, such relief devices are used on pressure vessels. Although these pressure relief devices are rarely opened for hospital and health care sterilizers, it is suggested that they be designed to exhaust vapor from the sterilizer by one of the following methods:

i) Through a pipe connected to the outlet of the relief valve ventilated directly outdoors at a point high enough to be away from passers by, and not near any windows that open, or near any air conditioning or ventilation air intakes.

ii) Through a connection to an existing or new non-recirculating or dedicated ventilation system.

iii) Through a connection to a well ventilated equipment or other room where workers are not normally present.

g) *Ventilation systems*

Each hospital and health care facility affected by this notice that uses EtO for the sterilization of equipment and supplies must have a ventilation system which enables compliance with the requirements of sections (b) through (f) in the manner described in these sections and within the timeframes allowed. Thus, each affected hospital and health care facility must have or install a non-recirculating or dedicated ventilation equipment or other room where workers are not normally present in which to vent EtO.

h) *Installation of alarm systems*

An audible and visual indicator alarm system must be installed to alert personnel of ventilation system failures, i.e. when the ventilation fan motor is not working.

2) Workplace practices

All the workplace practices discussed in this unit must be permanently posted near the door of each sterilizer prior to use by any operator.

a) *Changing of supply line filters*

Filters in the sterilizer liquid line must be changed when necessary, by the following procedure:

i) Close the cylinder valve and the hose valve.

ii) Disconnect the cylinder hose (piping) from the cylinder.

iii) Open the hose valve and bleed slowly into a proper ventilating system at or near the in-use supply cylinders.

iv) Vacate the area until the line is empty.

v) Change the filter.

vi) Reconnect the lines and reverse the value position.

vii) Check hoses, filters, and valves for leaks with a fluorocarbon leak detector (for those sterilizers using the 88 percent chlorofluorocarbon, 12 percent ethylene oxide mixture (12/88)).

b) *Restricted access area*

i) Areas involving use of EtO must be designated as restricted access areas. They must be identified with signs or floor marks near the sterilizer door, aerator, vacuum pump floor drain discharge, and in-use cylinder storage.

ii) All personnel must be excluded from the restricted area when certain operations are in progress, such as discharging a vacuum pump, emptying a sterilizer liquid line, or venting a non-purge sterilizer with the door ajar or other operations where EtO might be released directly into the face of workers.

c) *Door opening procedures*

i) *Sterilizers with purge cycles*

A load treated in a sterilizer equipped with a purge cycle should be removed immediately upon completion of the cycle (provided no time is lost opening the door after cycle is completed). If this is not done, the purge cycle should be repeated before opening door.

ii) *Sterilizers without purge cycles*

For a load treated in a sterilizer not equipped with a purge cycle, the sterilizer door must be ajar 6” for 15 minutes, and then fully opened for at least another 15 minutes before removing the treated load. The length of time of the second period should be established by peak monitoring for one hour after the two 15-minute periods suggested. If the level is above 10 ppm time-weighted average for 8 hours, more time should be added to the second waiting period (door wide open). However, in no case may the second period be shortened to less than 15 minutes.

d) *Chamber unloading procedures*

i) Procedures for unloading the chamber must include the use of baskets or rolling carts, or baskets and rolling tables to transfer treated loads quickly, thus avoiding excessive contact with treated articles, and reducing the duration of exposures.

ii) If rolling carts are used, they should be pulled not pushed by the sterilizer operators to avoid offgassing exposure.

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e) *Maintenance*

A written log should be instituted and maintained documenting the date of each leak detection and any maintenance procedures undertaken. This is a suggested use practice and is not required.

i) *Leak detection*

Sterilizer door gaskets, cylinder and vacuum piping, hoses, filters, and valves must be checked for leaks under full pressure with a Fluorocarbon leak detector (for 12/88 systems only) every two weeks by maintenance personnel. Also, the cylinder piping connections must be checked after changing cylinders. Particular attention in leak detection should be given to the automatic solenoid valves that control the flow of EtO to the sterilizer. Specifically, a check should be made at the EtO gasline entrance port to the sterilizer, while the sterilizer door is open and the solenoid valves are in a closed position.

ii) *Maintenance procedures*

Sterilizer/aerator door gaskets, valves, and fittings must be replaced when necessary as determined by maintenance personnel in their bi-weekly checks; in addition, visual inspection of the door gaskets for cracks, debris, and other foreign substances should be conducted daily by the operator.

Appendix B to §1910.1047—Substance Technical Guidelines for Ethylene Oxide (Non-Mandatory)

I. Physical and chemical data

A) *Substance identification*

1) *Synonyms*: dihydrooxirene, dimethylene oxide, EO, 1,2-epoxyethane, EtO, ETO, oxacyclopropane, oxane, oxidoethane, alpha/beta-oxidoethane, oxiran, oxirane.

2) *Formula*: (C_2H_4O).

3) *Molecular weight*: 44.06.

B) *Physical data*

1) *Boiling point* (760 mmHg): 10.70° C (51.3° F);

2) *Specific gravity* (water = 1): 0.87 (at 20° C or 68° F);

3) *Vapor density* (air = 1): 1.49;

4) *Vapor pressure* (at 20° C): 1,095 mmHg;

5) *Solubility in water*: complete;

6) *Appearance and odor*: colorless liquid; gas at temperature above 10.7° F or 51.3° C with ether-like odor above 700 ppm.

II. Fire, explosion, and reactivity hazard data

A) *Fire*

1) *Flash point*: less than O° F (open cup).

2) *Stability*: decomposes violently at temperatures above 800° F.

3) *Flammable limits in air, percent by volume*: Lower: 3, Upper: 100.

4) *Extinguishing media*: Carbon dioxide for small fires, polymer or alcohol foams for large fires.

5) *Special fire fighting procedures*: Dilution of ethylene oxide with 23 volumes of water renders it non-flammable.

6) *Unusual fire and explosion hazards*: Vapors of EtO will burn without the presence of air or other oxidizers. EtO vapors are heavier than air and may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which EtO is being used.

7) For purposes of compliance with the requirements of 29 CFR 1910.106, EtO is classified as a flammable gas. For example, 7,500 ppm, approximately one-fourth of the lower flammable limit, would be considered to pose a potential fire and explosion hazard.

8) For purposes of compliance with 29 CFR 1910.155, EtO is classified as a Class B fire hazard.

9) For purposes of compliance with 29 CFR 1919.307, locations classified as hazardous due to the presence of EtO shall be Class I.

B) *Reactivity*

1) Conditions contributing to instability: EtO will polymerize violently if contaminated with aqueous alkalis, amines, mineral acids, metal chlorides, or metal oxides. Violent decomposition will also occur at temperatures above 800^{o} F.

2) Incompatabilities: Alkalines and acids.

3) Hazardous decomposition products: Carbon monoxide and carbon dioxide.

III. Spill, leak, and disposal procedures

A) If EtO is spilled or leaked, the following steps should be taken:

1) Remove all ignition sources.

2) The area should be evacuated at once and re-entered only after the area has been thoroughly ventilated and washed down with water.

B) Persons not wearing appropriate protective equipment should be restricted from areas of spills or leaks until cleanup has been completed.

C) Waste disposal methods

Waste material should be disposed of in a manner that is not hazardous to employees or to the general population. In selecting the method of waste disposal, applicable local, State, and Federal regulations should be consulted.

IV. Monitoring and measurement procedures

A) *Exposure above the Permissible Exposure Limit*

1) *Eight-hour exposure evaluation*

Measurements taken for the purpose of determining employee exposure under this section are best taken with consecutive samples covering the full shift. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee).

2) *Monitoring techniques*

The sampling and analysis under this section may be performed by collection of the EtO vapor on charcoal adsorption tubes or other composition adsorption tubes, with subsequent chemical analysis. Sampling and analysis may also be performed by instruments such as real-time continuous monitoring systems, portable direct reading instruments, or passive dosimeters as long as measurements taken using these methods accurately evaluate the concentration of EtO in employees' breathing zones.

Appendix D describes the validated method of sampling and analysis which has been tested by OSHA for use with EtO. Other available methods are also described in Appendix D. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that the method of monitoring should be accurate, to a 95 percent confidence level, to plus or minus 25 percent for concentrations of EtO at 1 ppm, and to plus or minus 35 percent for concentrations at 0.5 ppm. In addition to the method described in Appendix D, there are numerous other methods available for monitoring for EtO in the workplace. Details on these other methods have been submitted by various companies to the rulemaking record, and are available at the OSHA Docket Office.

B) Since many of the duties relating to employee exposure are dependent on the results of measurement procedures, employers should assure that the evaluation of employee exposures is performed by a technically qualified person.

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V. Protective clothing and equipment

Employees should be provided with and be required to wear appropriate protective clothing wherever there is significant potential for skin contact with liquid EtO or EtO-containing solutions. Protective clothing shall include impermeable coveralls or similar full-body work clothing, gloves, and head coverings, as appropriate to protect areas of the body which may come in contact with liquid EtO or EtO-containing solutions.

Employers should ascertain that the protective garments are impermeable to EtO. Permeable clothing, including items made of rubber, and leather shoes should not be allowed to become contaminated with liquid EtO. If permeable clothing does become contaminated, it should be immediately removed, while the employer is under an emergency deluge shower. If leather footwear or other leather garments become wet from EtO they should be discarded and not be worn again, because leather absorbs EtO and holds it against the skin.

Any protective clothing that has been damaged or is otherwise found to be defective should be repaired or replaced. Clean protective clothing should be provided to the employee as necessary to assure employee protection. Whenever impermeable clothing becomes wet with liquid EtO, it should be washed down with water before being removed by the employee. Employees are also required to wear splash-proof safety goggles where there is any possibility of EtO contacting the eyes.

VI. Miscellaneous precautions

A) Store EtO in tightly closed containers in a cool, well-ventilated area and take all necessary precautions to avoid any explosion hazard.

B) Non-sparking tools must be used to open and close metal containers. These containers must be effectively grounded and bonded.

C) Do not incinerate EtO cartridges, tanks or other containers.

D) Employers should advise employees of all areas and operations where exposure to EtO occurs.

VII. Common operations

Common operations in which exposure to EtO is likely to occur include the following: Manufacture of EtO, surfactants, ethanolamines, glycol ethers, and specialty chemicals, and use as a sterilant in the hospital, health product and spice industries.

Appendix C to §1910.1047—Medical Surveillance Guidelines for Ethylene Oxide (Non-Mandatory)

I. Route of entry

Inhalation

II. Toxicology

Clinical evidence of adverse effects associated with the exposure to EtO is present in the form of increased incidence of cancer in laboratory animals (leukemia, stomach, brain), mutation in offspring in animals, and resorptions and spontaneous abortions in animals and human populations respectively. Findings in humans and experimental animals exposed to airborne concentrations of EtO also indicate damage to the genetic material (DNA). These include hemoglobin alkylation, unscheduled DNA synthesis, sister chromatid exchange, chromosomal aberration, and functional sperm abnormalities.

Ethylene oxide in liquid form can cause eye irritation and injury to the cornea, frostbite, severe irritation, and blistering of the skin upon prolonged or confined contact. Ingestion of EtO can cause gastric irritation and liver injury. Other effects from inhalation of EtO vapors include respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, dyspnea and cyanosis.

III. Signs and symptoms of acute overexposure

The early effects of acute overexposure to EtO are nausea and vomiting, headache, and irritation of the eyes and respiratory passages. The patient may notice a “peculiar taste” in the mouth. Delayed effects can include pulmonary edema, drowsiness, weakness, and incoordination. Studies suggest that blood cell changes, an increase in chromosomal aberrations, and spontaneous abortion may also be causally related to acute overexposure to EtO.

Skin contact with liquid or gaseous EtO causes characteristic burns and possibly even an allergic-type sensitization. The edema and erythema occurring from skin contact with EtO progress to vesiculation with a tendency to coalesce into blebs with desquamation. Healing occurs within three weeks, but there may be a residual brown pigmentation. A 40–80 percent solution is extremely dangerous, causing extensive blistering

after only brief contact. Pure liquid EtO causes frostbite because of rapid evaporation. In contrast, the eye is relatively insensitive to EtO, but there may be some irritation of the cornea.

Most reported acute effects of occupational exposure to EtO are due to contact with EtO in liquid phase. The liquid readily penetrates rubber and leather, and will produce blistering if clothing or footwear contaminated with EtO are not removed.

IV. Surveillance and preventive considerations

As noted above, exposure to EtO has been linked to an increased risk of cancer and reproductive effects including decreased male fertility, fetotoxicity, and spontaneous abortion. EtO workers are more likely to have chromosomal damage than similar groups not exposed to EtO. At the present, limited studies of chronic effects in humans resulting from exposure to EtO suggest a causal association with leukemia. Animal studies indicate leukemia and cancers at other sites (brain, stomach) as well. The physician should be aware of the findings of these studies in evaluating the health of employees exposed to EtO.

Adequate screening tests to determine an employee's potential for developing serious chronic diseases, such as cancer, from exposure to EtO do not presently exist. Laboratory tests may, however, give evidence to suggest that an employee is potentially overexposed to EtO. It is important for the physician to become familiar with the operating conditions in which exposure to EtO is likely to occur. The physician also must become familiar with the signs and symptoms that indicate a worker is receiving otherwise unrecognized and unacceptable exposure to EtO. These elements are especially important in evaluating the medical and work histories and in conducting the physical exam. When an unacceptable exposure in an active employee is identified by the physician, measures taken by the employer to lower exposure should also lower the risk of serious long-term consequences.

The employer is required to institute a medical surveillance program for all employees who are or will be exposed to EtO at or above the action level (0.5 ppm) for at least 30 days per year, without regard to respirator use. All examinations and procedures must be performed by or under the supervision of a licensed physician at a reasonable time and place for the employee 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 inclusion of the following elements in the routine examination:

i) Medical and work histories with special emphasis directed to symptoms related to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

ii) Physical examination with particular emphasis given to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

iii) Complete blood count to include at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin.

iv) Any laboratory or other test which the examining physician deems necessary by sound medical practice.

If requested by the employee, the medical examinations shall include pregnancy testing or laboratory evaluation of fertility as deemed appropriate by the physician.

In certain cases, to provide sound medical advice to the employer and the employee, the physician must evaluate situations not directly related to EtO. For example, employees with skin diseases may be unable to tolerate wearing protective clothing. In addition, those with chronic respiratory diseases may not tolerate the wearing of 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 at five year intervals, and a pulmonary function test to be repeated every three years. The pulmonary function test should include measurement of the employee's forced vital capacity (FVC), forced expiratory volume at one second (FEV(1)), as well as calculation of the ratios of FEV(1) to FVC, and measured FVC and measured FEV(1) to expected values corrected for variation due to age, sex, race, and height.

The employer is required to make the prescribed tests available at least annually to employees who are or will be exposed at or above the action level, for 30 or more days per year; more often than specified if recommended by the examining physician; and upon the employee's termination of employment or reassignment to another work area. While little is known about the long term consequences of high short-term exposures, it appears prudent to monitor such affected employees closely in light of existing health data. The employer shall provide physician recommended examinations to any employee exposed to EtO in emergency conditions. Likewise, the employer shall make available medical consultations including physician recommended exams to employees who believe they are suffering signs or symptoms of exposure to EtO.

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The employer is required to provide the physician with the following information: a copy of this standard and its appendices; a description of the affected employee's duties as they relate to the employee exposure level; and information from the employee's previous medical examinations which is not readily available to the examining physician. Making this information available to the physician will aid in the evaluation of the employee's health in relation to assigned duties and fitness to wear personal protective equipment, when required.

The employer is required to obtain a written opinion from the examining physician containing the results of the medical examinations; the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of his or her health from exposure to EtO; any recommended restrictions upon the employee's exposure to EtO, or upon the use of protective clothing or equipment such as respirators; and a statement that the employee has been informed by the physician of the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure to EtO, and a copy of the opinion must be provided to the affected employee.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to aid in the determination of initial placement of employees and to assess the employee's ability to use protective clothing and equipment.

Appendix D to §1910.1047—Sampling and Analytical Methods for Ethylene Oxide (Non-Mandatory)

A number of methods are available for monitoring employee exposures to EtO. Most of these involve the use of charcoal tubes and sampling pumps, followed by analysis of the samples by gas chromatograph. The essential differences between the charcoal tube methods include, among others, the use of different desorbing solvents, the use of different lots of charcoal, and the use of different equipment for analysis of the samples.

Besides charcoal, methods using passive dosimeters, gas sampling bags, impingers, and detector tubes have been utilized for determination of EtO exposure. In addition, there are several commercially available portable gas analyzers and monitoring units.

This appendix contains details for the method which has been tested at the OSHA Analytical Laboratory in Salt Lake City. Inclusion of this method in the appendix does not mean that this method is the only one which will be satisfactory. Copies of descriptions of other methods available are available in the rulemaking record, and may be obtained from the OSHA Docket Office. These include the Union Carbide, Dow Chemical, 3M, and DuPont methods, as well as NIOSH Method S-286. These methods are briefly described at the end of this appendix.

Employers who note problems with sample breakthrough using the OSHA or other charcoal methods should try larger charcoal tubes. Tubes of larger capacity are available. In addition, lower flow rates and shorter sampling times should be beneficial in minimizing breakthrough problems. Whatever method the employer chooses, he must assure himself of the method's accuracy and precision under the unique conditions present in his workplace.

Ethylene oxide

Method No.: 30
Matrix: Air
Target Concentration: 1.0 ppm (1.8 mg/m^3)

Procedure: Samples are collected on two charcoal tubes in series and desorbed with 1 percent CS_2 in benzene. The samples are derivatized with HBr and treated with sodium carbonate. Analysis is done by gas chromatography with an electron capture detector.

Recommended Air Volume and Sampling Rate: 1 liter and 0.05 Lpm

Detection Limit of the Overall Procedure: 13.3 ppb (0.024 mg/m^3) (Based on 1.0 liter air sample).

Reliable Quantitation Limit: 52.2 ppb (0.094 mg/m^3) (Based on 1.0 liter air sample).

Standard Error of Estimate: 6.59 percent (See Backup Section 4.6).

Special Requirements: Samples must be analyzed within 15 days of sampling date.

Status of Method: The sampling and analytical method has been subjected to the established evaluation procedures of the Organic Method Evaluations Branch.

Date: August 1981.

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1 General Discussion

1.1 Background

1.1.1 History of Procedure

Ethylene oxide samples analyzed at the OSHA Laboratory have normally been collected on activated charcoal and desorbed with carbon disulfide. The analysis is performed with a gas chromatograph equipped with a FID (Flame ionization detector) as described in NIOSH Method S286 (Ref. 5.1). This method is based on a PEL of 50 ppm and has a detection limit of about 1 ppm.

Recent studies have prompted the need for a method to analyze and detect ethylene oxide at very low concentrations.

Several attempts were made to form an ultraviolet (UV) sensitive derivative with ethylene oxide for analysis with HPLC. Among those tested that gave no detectable product were: p-anisidine, methylimidazole, aniline, and 2,3,6-trichlorobenzoic acid. Each was tested with catalysts such as triethylamine, aluminum chloride, methylene chloride and sulfuric acid but no detectable derivative was produced.

The next derivatization attempt was to react ethylene oxide with HBr to form 2-bromoethanol. This reaction was successful. An ECD (electron capture detector) gave a very good response for 2-bromoethanol due to the presence of bromine. The use of carbon disulfide as the desorbing solvent gave too large a response and masked the 2-bromoethanol. Several other solvents were tested for both their response on the ECD and their ability to desorb ethylene oxide from the charcoal. Among those tested were toluene, xylene, ethyl benzene, hexane, cyclohexane and benzene. Benzene was the only solvent tested that gave a suitable response on the ECD and a high desorption. It was found that the desorption efficiency was improved by using 1 percent CS_2 with the benzene. The carbon disulfide did not significantly improve the recovery with the other solvents. SKC Lot 120 was used in all tests done with activated charcoal.

1.1.2 Physical Properties (Ref. 5.2-5.4)

Synonyms: Oxirane; dimethylene oxide, 1,2-epoxy-ethane; oxane; C_2H_4O; ETO

Molecular Weight: 44.06

Boiling Point: 10.7^{o} C (51.3^{o} F)

Melting Point: 111^{o} C

Description: Colorless, flammable gas

Vapor Pressure: 1095 mm. at 20^{o} C

Odor: Ether-like odor

Lower Explosive Limits: 3.0 percent (by volume)

Flash Point (TOC): Below 0^{o} F

Molecular Structure: CH_2—CH_2

1.2 Limit Defining Parameters

1.2.1 Detection Limit of the Analytical Procedure

The detection limit of the analytical procedure is 12.0 picograms of ethylene oxide per injection. This is the amount of analyte which will give a peak whose height is five times the height of the baseline noise (see Backup Data Section 4.1).

1.2.2 Detection Limit of the Overall Procedure

The detection limit of the overall procedure is 24.0 ng of ethylene oxide per sample. This is the amount of analyte spiked on the sampling device which allows recovery of an amount of analyte equivalent to the detection limit of the analytical procedure (see Backup Data Section 4.2).

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1.2.3 Reliable Quantitation Limit

The reliable quantitation limit is 94.0 nanograms of ethylene oxide per sample. This is the smallest amount of analyte which can be quantitated within the requirements of 75 percent recovery and 95 percent confidence limits (see Backup Data Section 4.2).

It must be recognized that the reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at the routine operating parameters. In this case, the limits reported on analysis reports will be based on the operating parameters used during the analysis of the samples.

1.2.4 Sensitivity

The sensitivity of the analytical procedure over a concentration range representing 0.5 to 2 times the target concentration based on the recommended air volume is 34105 area units per ug/mL. The sensitivity is determined by the slope of the calibration curve (see Backup Data Section 4.3). The sensitivity will vary somewhat with the particular instrument used in the analysis.

1.2.5 Recovery

The recovery of analyte from the collection medium must be 75 percent or greater. The average recovery from spiked samples over the range of 0.5 to 2 times the target concentration is 88.0 percent (see Backup Section 4.4). At lower concentrations the recovery appears to be non-linear.

1.2.6 Precision (Analytical Method Only)

The pooled coefficient of variation obtained from replicate determination of analytical standards at 0.5X, 1X and 2X the target concentration is 0.036 (see Backup Data Section 4.5).

1.2.7 Precision (Overall Procedure)

The overall procedure must provide results at the target concentration that are 25 percent or better at the 95 percent confidence level. The precision at the 95 percent confidence level for the 15 day storage test is plus or minus 12.9 percent (see Backup Data Section 4.6). This includes an additional plus or minus 5 percent for sampling error.

1.3 Advantages

1.3.1 The sampling procedure is convenient.

1.3.2 The analytical procedure is very sensitive and reproducible.

1.3.3 Reanalysis of samples is possible.

1.3.4 Samples are stable for at least 15 days at room temperature.

1.3.5 Interferences are reduced by the longer GC retention time of the new derivative.

1.4 Disadvantages

1.4.1 Two tubes in series must be used because of possible breakthrough and migration.

1.4.2 The precision of the sampling rate may be limited by the reproducibility of the pressure drop across the tubes. The pumps are usually calibrated for one tube only.

1.4.3 The use of benzene as the desorption solvent increases the hazards of analysis because of the potential carcinogenic effects of benzene.

1.4.4 After repeated injections, there can be a buildup of residue formed on the electron capture detector which decreases sensitivity.

1.4.5 Recovery from the charcoal tubes appears to be nonlinear at low concentrations.

2 Sampling Procedure

2.1 Apparatus

2.1.1 A calibrated personal sampling pump whose flow can be determined within plus or minus 5 percent of the recommended flow.

2.1.2 SKC Lot 120 Charcoal tubes: glass tube with both ends flame sealed, 7 cm long with a 6 mm O.D. and a 4-mm I.D., containing 2 sections of coconut shell charcoal separated by a 2-mm portion of urethane foam. The adsorbing section contains 100 mg of charcoal, the backup section 50 mg. A 3-mm portion of urethane foam is placed between the outlet end of the tube and the backup section. A plug of silylated glass wool is placed in front of the adsorbing section.

2.2 Reagents

2.2.1 None required.

2.3 Sampling Technique

2.3.1 Immediately before sampling, break the ends of the charcoal tubes. All tubes must be from the same lot.

2.3.2 Connect two tubes in series to the sampling pump with a short section of flexible tubing. A minimum amount of tubing is used to connect the two sampling tubes together. The tube closer to the pump is used as a backup. This tube should be identified as the backup tube.

2.3.3 The tubes should be placed in a vertical position during sampling to minimize channeling.

2.3.4 Air being sampled should not pass through any hose or tubing before entering the charcoal tubes.

2.3.5 Seal the charcoal tubes with plastic caps immediately after sampling. Also, seal each sample with OSHA seals lengthwise.

2.3.6 With each batch of samples, submit at least one blank tube from the same lot used for samples. This tube should be subjected to exactly the same handling as the samples (break, seal, transport) except that no air is drawn through it.

2.3.7 Transport the samples (and corresponding paperwork) to the lab for analysis.

2.3.8 If bulk samples are submitted for analysis, they should be transported in glass containers with Teflon-lined caps. These samples must be mailed separately from the container used for the charcoal tubes.

2.4 Breakthrough

2.4.1 The breakthrough (5 percent breakthrough) volume for a 3.0 mg/m ethylene oxide sample stream at approximately 85 percent relative humidity, 22^{o} C and 633 mm is 2.6 liters sampled at 0.05 liters per minute. This is equivalent to 7.8 mg of ethylene oxide. Upon saturation of the tube, it appeared that the water may be displacing ethylene oxide during sampling.

2.5 Desorption Efficiency

2.5.1 The desorption efficiency, from liquid injection onto charcoal tubes, averaged 88.0 percent from 0.5 to 2.0 x the target concentration for a 1.0 liter air sample. At lower ranges, it appears that the desorption efficiency is non-linear (see Backup Data Section 4.2).

2.5.2 The desorption efficiency may vary from one laboratory to another and also from one lot of charcoal to another. Thus, it is necessary to determine the desorption efficiency for a particular lot of charcoal.

2.6 Recommended Air Volume and Sampling Rate

2.6.1 The recommended air volume is 1.0 liter.

2.6.2 The recommended maximum sampling rate is 0.05 Lpm.

2.7 Interferences

2.7.1 Ethylene glycol and Freon 12 at target concentration levels did not interfere with the collection of ethylene oxide.

2.7.2 Suspected interferences should be listed on the sample data sheets.

2.7.3 The relative humidity may affect the sampling procedure.

2.8 Safety Precautions

2.8.1 Attach the sampling equipment to the employee so that it does not interfere with work performance.

2.8.2 Wear safety glasses when breaking the ends of the sampling tubes.

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2.8.3 If possible, place the sampling tubes in a holder so the sharp end is not exposed while sampling.

3 Analytical Method

3.1 Apparatus

3.1.1 Gas chromatograph equipped with a linearized electron capture detector.

3.1.2 GC column capable of separating the derivative of ethylene oxide (2-bromoethanol) from any interferences and the 1 percent CS_2 in benzene solvent. The column used for validation studies was: 10 ft x 1/8 inch stainless steel 20 percent SP-2100, .1 percent Carbowax 1500 on 100/120 Supelcoport.

3.1.3 An electronic integrator or some other suitable method of measuring peak areas.

3.1.4 Two milliliter vials with Teflon-lined caps.

3.1.5 Gas tight syringe—500 µL or other convenient sizes for preparing standards.

3.1.6 Microliter syringes—10 µL or other convenient sizes for diluting standards and 1 µL for sample injections.

3.1.7 Pipets for dispensing the 1 percent CS_2 in benzene solvent. The Glenco 1 mL dispenser is adequate and convenient.

3.1.8 Volumetric flasks—5 mL and other convenient sizes for preparing standards.

3.1.9 Disposable Pasteur pipets.

3.2 Reagents

3.2.1 Benzene, reagent grade.

3.2.2 Carbon disulfide, reagent grade.

3.2.3 Ethylene oxide, 99.7 percent pure.

3.2.4 Hydrobromic acid, 48 percent reagent grade.

3.2.5 Sodium carbonate, anhydrous, reagent grade.

3.2.6 Desorbing reagent, 99 percent Benzene/1 percent CS_2.

3.3 Sample Preparation

3.3.1 The front and back sections of each sample are transferred to separate 2-mL vials.

3.3.2 Each sample is desorbed with 1.0 mL of desorbing reagent.

3.3.3 The vials are sealed immediately and allowed to desorb for one hour with occasional shaking.

3.3.4 Desorbing reagent is drawn off the charcoal with a disposable pipet and put into clean 2-mL vials.

3.3.5 One drop of HBr is added to each vial. Vials are resealed and HBr is mixed well with the desorbing reagent.

3.3.6 About 0.15 gram of sodium carbonate is carefully added to each vial. Vials are again resealed and mixed well.

3.4 Standard Preparation

3.4.1 Standards are prepared by injecting the pure ethylene oxide gas into the desorbing reagent.

3.4.2 A range of standards are prepared to make a calibration curve. A concentration of 1.0 µL of ethylene oxide gas per 1 mL desorbing reagent is equivalent to 1.0 ppm air concentration (all gas volumes at 25^{o} C and 760 mm) for the recommended 1 liter air sample. This amount is uncorrected for desorption efficiency (see Backup Data Section 4.2. for desorption efficiency corrections).

3.4.3 One drop of HBr per mL of standard is added and mixed well.

3.4.4 About 0.15 grams of sodium carbonate is carefully added for each drop of HBr (a small reaction will occur).

3.5 Analysis

3.5.1 GC Conditions

Nitrogen flow rate: 10 mL/min

Injector Temperature: 250° C

Detector Temperature: 300° C

Column Temperature: 100° C

Injection size: 0.8 µL

Elution time: 3.9 minutes

3.5.2 Peak areas are measured by an integrator or other suitable means.

3.5.3 The integrator results are in area units and a calibration curve is set up with concentration vs. area units.

3.6 Interferences

3.6.1 Any compound having the same retention time [as] 2-bromoethanol is a potential interference. Possible interferences should be listed on the sample data sheets.

3.6.2 GC parameters may be changed to circumvent interferences.

3.6.3 There are usually trace contaminants in benzene. These contaminants, however, posed no problem of interference.

3.6.4 Retention time data on a single column is not considered proof of chemical identity. Samples over the 1.0 ppm target level should be confirmed by GC/Mass Spec or other suitable means.

3.7 Calculations

3.7.1 The concentration in ug/ml for a sample is determined by comparing the area of a particular sample to the calibration curve, which has been prepared from analytical standards.

3.7.2 The amount of analyte in each sample is corrected for desorption efficiency by use of a desorption curve.

3.7.3 Analytical results (A) from the two tubes that compose a particular air sample are added together.

3.7.4 The concentration for a sample is calculated by the following equation:

$$\text{ETO, mg/m}^3 = \frac{AXB}{C}$$

where:

A = µg/mL
B = desorption volume in milliliters
C = air volume in liters

3.7.5 To convert mg/m^3 to parts per million (ppm) the following relationship is used:

$$\text{ETO, ppm} \quad \frac{\text{mg/m}^3 \text{ X } 24.45}{44.05}$$

where:

mg/m^3 = results from 3.7.4
24.45 = molar volume at 25° C and 760mm Hg
44.05 = molecular weight of ETO

3.8 Safety Precautions

3.8.1 Ethylene oxide and benzene are potential carcinogens and care must be exercised when working with these compounds.

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3.8.2 All work done with the solvents (preparation of standards, desorption of samples, etc.) should be done in a hood.

3.8.3 Avoid any skin contact with all of the solvents.

3.8.4 Wear safety glasses at all times.

3.8.5 Avoid skin contact with HBr because it is highly toxic and a strong irritant to eyes and skin.

4 Backup Data

4.1 Detection Limit Data

The detection limit was determined by injecting 0.8 µL of a 0.015 µg/mL standard of ethylene oxide into 1 percent CS_2 in benzene. The detection limit of the analytical procedure is taken to be 1.20 X 105 µg per injection. This is equivalent to 8.3 ppb (0.015 mg/m^3) for the recommended air volume.

4.2 Desorption Efficiency

Ethylene oxide was spiked onto charcoal tubes and the following recovery data were obtained.

Amount spiked (µg)	Amount recovered (µg)	Percent recovery
4.5	4.32	96.0
3.0	2.61	87.0
2.25	2.025	90.0
1.5	1.365	91.0
1.5	1.38	92.0
.75	.6525	87.0
.375	.315	84.0
.375	.312	83.2
.1875	.151	80.5
.094	.070	74.5

At lower amounts, the recovery appears to be non-linear.

4.3 Sensitivity Data

The following data were used to determine the calibration curve.

Injection	0.5 x .75 µg/mL	1 x 1.5 µg/mL	2 x 3.0 µg/mL
1	30904	59567	111778
2	30987	62914	106016
3	32555	58578	106122
4	32242	57173	109716
x	31672	59558	108408

Slope = 34.105

4.4 Recovery

The recovery was determined by spiking ethylene oxide onto lot 120 charcoal tubes and desorbing with 1 percent CS_2 in benzene. Recoveries were done at 0.5, 1.0, and 2.0 X the target concentration (1 ppm) for the recommended air volume.

Percent Recovery

Sample	0.5x	1.0x	2.0x
1	88.7	95.0	91.7
2	83.8	95.0	87.3
3	84.2	91.0	86.0
4	88.0	91.0	83.0
5	88.0	86.0	85.0
x	86.5	90.5	87.0

Weighted Average = 88.2

4.5 Precision of the Analytical Procedure

The following data were used to determine the precision of the analytical method:

Concentration	0.5 x .75 µg/mL	1 x 1.5 µg/mL	2 x 3.0 µg/mL
Injection	.7421	1.4899	3.1184
	.7441	1.5826	3.0447
	.7831	1.4628	2.9149
	.7753	1.4244	2.9185
Average	.7612	1.4899	2.9991
Standard deviation	.0211	.0674	.0998
CV	.0277	.0452	.0333

$$CV = \frac{3(.0277)^2 + 3(.0452)^2 + 3(.0333)^2}{3 + 3 + 3}$$

$$CV = 0.036$$

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4.6 Storage Data

Samples were generated at 1.5 mg/m^3 ethylene oxide at 85 percent relative humidity, 22^o C and 633 mm. All samples were taken for 20 minutes at 0.05 Lpm. Six samples were analyzed as soon as possible and fifteen samples were stored at refrigerated temperature (5^o C) and fifteen samples were stored at ambient temperature (23^o C). These stored samples were analyzed over a period of nineteen days.

Percent Recovery

Day analyzed	Refrigerated	Ambient
1	87.0	87.0
1	93.0	93.0
1	94.0	94.0
1	92.0	92.0
4	92.0	91.0
4	93.0	88.0
4	91.0	89.0
6	92.0	
6	92.0	
8		92.0
8		86.0
10	91.7	
10	95.5	
10	95.7	
11		90.0
11		82.0
13	78.0	
13	81.4	
13	82.4	
14		78.5
14		72.1
18	66.0	
18	68.0	
19		64.0
19		77.0

4.7 Breakthrough Data

Breakthrough studies were done at 2 ppm (3.6 mg/m(3)) at approximately 85 percent relative humidity at 22^o C (ambient temperature). Two charcoal tubes were used in series. The backup tube was changed every 10 minutes and analyzed for breakthrough. The flow rate was 0.050 Lpm.

The 5 percent breakthrough volume was reached when 2.6 liters of test atmosphere were drawn through the charcoal tubes.

Tube No.	Time (minutes)	Percent breakthrough
1	10	(1)
2	20	(1)
3	30	(1)
4	40	1.23
5	50	3.46
6	60	18.71
7	70	39.2
8	80	53.3
9	90	72.0
10	100	96.0
11	110	113.0
12	120	133.9

[1]None

5 References

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5.2 "IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man," International Agency for Research on Cancer: Lyon, 1976; Vol. II, p. 157.

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Summary of Other Sampling Procedures

OSHA believes that several other types of monitoring equipment and techniques exist for monitoring time-weighted averages. Considerable research and method development is currently being performed, which will lead to improvements and a wider variety of monitoring techniques. A combination of monitoring procedures can be used. There probably is no one best method for monitoring personal exposure to ethylene oxide in all cases. There are advantages, disadvantages, and limitations to each method. The method of choice will depend on the need and requirements. Some commonly used methods include the use of charcoal tubes, passive dosimeters, Tedler gas sampling bags, detector tubes, photoionization detection units, infrared detection units and gas chromatographs. A number of these methods are described below.

A) Charcoal Tube Sampling Procedures

Qazi-Ketcham method (Ex. 11-133)—This method consists of collecting EtO on Columbia JXC activated carbon, desorbing the EtO with carbon disulfide and analyzing by gas chromatography with flame ionization detection. Union Carbide has recently updated and revalidated this monitoring procedures. This method is capable of determining both eight-hour time-weighted average exposures and short-term exposures. The method was validated to 0.5 ppm. Like other charcoal collecting procedures, the method requires considerable analytical expertise.

ASTM-proposed method—The Ethylene Oxide Industry Council (EOIC) has contracted with Clayton Environmental Consultants, Inc. to conduct a collaborative study for the proposed method. The ASTM-proposed method is similar to the method published by Qazi and Ketcham in the November 1977 American Industrial Hygiene Association Journal, and to the method of Pilney and Coyne, presented at the 1979 American Industrial Hygiene Conference. After the air to be sampled is drawn through an activated charcoal tube, the ethylene oxide is desorbed from the tube using carbon disulfide and is quantitated by gas chromatography utilizing a flame ionization detector. The ASTM-proposed method specifies a large two-section charcoal tube, shipment in dry ice, storage at less than $5^{o}C$, and analysis within three weeks to prevent migration and sample loss. Two types of charcoal tubes are being tested—Pittsburgh Coconut-Based (PCB) and Columbia JXC charcoal. This collaborative study will give an indication of the inter- and intralaboratory precision and accuracy of the ASTM-proposed method. Several laboratories have considerable expertise using the Qazi-Ketcham and Dow methods.

B) Passive Monitors

Ethylene oxide diffuses into the monitor and is collected in the sampling media. The DuPont Pro-Tek badge collects EtO in an absorbing solution, which is analyzed colorimetrically to determine the amount of EtO present. The 3M [350] badge collects the EtO on chemically treated charcoal. Other passive monitors are currently being developed and tested. Both 3M and DuPont have submitted data indicating their dosimeters meet the precision and accuracy requirements of the proposed ethylene oxide standard. Both presented laboratory validation data to 0.2 ppm (Exs. 11-65, 4-20, 108, 109, 130).

C) Tedlar Gas Sampling Bags

Samples are collected by drawing a known volume of air into a Tedlar gas sampling bag. The ethylene oxide concentration is often determined on-site using a portable gas chromatograph or portable infrared spectometer.

D) Detector tubes

A known volume of air is drawn through a detector tube using a small hand pump. The concentration of EtO is related to the length of stain developed in the tube. Detector tubes are economical, easy to use, and give an immediate readout. Unfortunately, partly because they are nonspecific, their accuracy is often questionable. Since the sample is taken over a short period of time, they may be useful for determining the source of leaks.

E) Direct Reading Instruments

There are numerous types of direct reading instruments, each having its own strengths and weaknesses (Exs. 135B, 135C, 107, 11-78, 11-153). Many are relatively new, offering greater sensitivity and specificity. Popular ethylene oxide direct reading instruments include infrared detection units, photoionization detection units, and gas chromatographs.

Portable infrared analyzers provide an immediate, continuous indication of a concentration value; making them particularly useful for locating high concentration pockets, in leak detection and in ambient air monitoring. In infrared detection units, the amount of infrared light absorbed by the gas being analyzed at selected infrared wavelengths is related to the concentration of a particular component. Various models have either fixed or variable infrared filters, differing cell pathlengths, and microcomputer controls for greater sensitivity, automation, and interference elimination.

A fairly recent detection system is photoionization detection. The molecules are ionized by high energy ultraviolet light. The resulting current is measured. Since different substances have different ionization

potentials, other organic compounds may be ionized. The lower the lamp energy, the better the selectivity. As a continuous monitor, photoionization detection can be useful for locating high concentration pockets, in leak detection, and continuous ambient air monitoring. Both portable and stationary gas chromatographs are available with various types of detectors, including photoionization detectors. A gas chromatograph with a photoionization detector retains the photoionization sensitivity, but minimizes or eliminates interferences. For several GC/PID units, the sensitivity is in the 0.1-0.2 ppm EtO range. The GC/PID with microprocessors can sample up to 20 sample points sequentially, calculate and record data, and activate alarms or ventilation systems. Many are quite flexible and can be configured to meet the specific analysis needs for the workplace.

DuPont presented their laboratory validation data of the accuracy of the Qazi-Ketcham charcoal tube, the PCB charcoal tube, Miran 103 IR analyzer, 3M number 3550 monitor and the Du Pont C-70 badge. Quoting Elbert V. Kring:

We also believe that OSHA's proposed accuracy in this standard is appropriate. At plus or minus 25 percent at one part per million, and plus or minus 35 percent below that. And, our data indicates there's only one monitoring method, right now, that we've tested thoroughly, that meets that accuracy requirements. That is the Du Pont Pro-Tek badge. . . . We also believe that this kind of data should be confirmed by another independent laboratory, using the same type dynamic chamber testing. (Tr. 1470)

Additional data by an independent laboratory following their exact protocol was not submitted. However, information was submitted on comparisons and precision and accuracy of those monitoring procedures which indicate far better precision and accuracy of those monitoring procedures than that obtained by Du Pont (Ex. 4-20, 130, 11-68, 11-133, 130, 135A).

The accuracy of any method depends to a large degree upon the skills and experience of those who not only collect the samples but also those who analyze the samples. Even for methods that are collaboratively tested, some laboratories are closer to the true values than others. Some laboratories may meet the precision and accuracy requirements of the method; others may consistently far exceed them for the same method.

[49 FR 25796, June 22, 1984, as amended at 50 FR 9801, Mar. 12, 1985; 50 FR 41494, Oct. 11, 1985; 51 FR 25053, July 10, 1986; 53 FR 11436, 11437, Apr. 6, 1988; 53 FR 27960, July 26, 1988; 54 FR 24334, June 7, 1989; 61 FR 5507, Feb. 13, 1996; 63 FR 1972, Jan. 8, 1998]

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Annex E
(informative)

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