NFPA 560

Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation

2007 Edition

NFPA, 1 Batterymarch Park, Quincy, MA 02169-7471
An International Codes and Standards Organization

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NFPA 560

Standard for the

Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation

2007 Edition

This edition of NFPA 560, *Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation*, was prepared by the Technical Committee on Industrial and Medical Gases. It was issued by the Standards Council on December 1, 2006, with an effective date of December 20, 2006, and supersedes all previous editions.

This edition of NFPA 560 was approved as an American National Standard on December 20, 2006.

Origin and Development of NFPA 560

In June 1990, a request was made by a manufacturer of ethylene oxide to develop a new standard for the storage, handling, and use of ethylene oxide for sterilization and fumigation. This request addressed the replacement of the nonflammable mixture of ethylene oxide and freon with pure ethylene oxide, which was occurring concurrent with the reduced use of freon for environmental reasons. The request was reviewed by the NFPA Standards Council, which published a notice in the August 1990 edition of *Fire News* asking for public input on the recommendation.

At its January 1991 meeting, the NFPA Standards Council approved the request and the development of the standard was assigned to the NFPA Technical Committee on Industrial and Medical Gases (IMGAS). The IMGAS Committee established a task force on ethylene oxide, which developed a draft standard that was made available for public review. Notice of its availability was published in the December 1993/January 1994 edition of *Fire News* with a public proposal closing date of January 21, 1994. The IMGAS Committee reviewed the proposals, and the Committee's report was published in the 1995 Annual Meeting Report on Proposals. Further revisions were published in the 1995 Annual Meeting Report on Comments.

The 2002 edition contained requirements in Chapter 11 that addressed the use of oxidizing emission control devices. These requirements were based on the recommendations of a NIOSH report generated after several incidents occurred that involved oxidizing emission control device operations.

The 2002 edition was also revised to conform to the new *Manual of Style for NFPA Technical Documents* requirements.

The 2007 edition includes the following changes:

– Elimination of the concept of special rooms to achieve consistency with *NFPA 5000®, Building Construction and Safety Code®*

– Addition of the definition of *Sterilization Building*

– Correlation of gas storage requirements with NFPA 55, *Standard for the Storage, Use, and Handling of Compressed Gases and Cryogenic Fluids in Portable and Stationary Containers, Cylinders, and Tanks*

– Updated definitions

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Technical Committee on Industrial and Medical Gases

Michael W. St. Clair, *Chair*
Ostrander, OH [U]
Rep. NFPA Industrial Fire Protection Section

William J. Satterfield, III, *Secretary*
Hydrogen Safety, LLC/Rode & Associates, LLC, RI [SE]

John J. Anicello, Airgas Inc., CA [M]
Rodney L. Barnes, BWXT-Y12, TN [U]
Ronald R. Czischke, Underwriters Laboratories Inc., IL [RT]
Keith Ferrari, Praxair, NC [M]
Larry L. Fluer, Fluer, Inc., CA [IM]
Rep. Compressed Gas Association
Rick Ginn, Wright Brothers, Inc., OH [M]
Rep. National Welding Supply Association
Jeff Grant, Ballard Power Systems, Canada [U]
Martin T. Gresho, Sandia National Laboratories, CA [U]
Anthony J. McErlean, Air Liquide America, PA [IM]
Rep. Compressed Gas Association
George Mills, MM EC, Ltd., IL [U]
Rep. American Society for Healthcare Engineering
David Namyst, Intel Corporation, CA [M]
Robert R. Nii, U.S. Department of Energy, ID [U]
Peter W. Steiner, Air Products and Chemicals, Inc., PA [IM]
Rep. Compressed Gas Association
Gary F. Trojak, The Chlorine Institute, Inc., VA [M]
Randolph Viscomi, ARC Specialty Products Corporation, NJ [IM]
Steven E. Younis, Prospective Technology, Inc., MA [SE]

Alternates

Rob Cameron, Airgas-Nor Pac, Inc., WA [M]
(Alt. to J. J. Anicello)
David J. De Fina, Sterigenics International, Inc., IL [IM]
(Alt. to R. Viscomi)
Leonard A. Farello, Intel Corporation, NM [M]
(Alt. to D. Namyst)
Eugene Y. Ngai, Air Products and Chemicals, Inc., PA [IM]
(Alt. to P. W. Steiner)
Jeffrey M. Shapiro, International Code Consultants, TX [M]
(Alt. to G. F. Trojak)
Roger A. Smith, Compressed Gas Association, VA [IM]
(Alt. to L. L. Fluer)
Robert A. Zeman, Underwriters Laboratories Inc., IL [RT]
(Alt. to R. R. Czischke)

Nonvoting

Charles B. Henrici, Elk Grove Village, IL [SE]
(Member Emeritus)

Carl H. Rivkin, NFPA Staff Liaison

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NOTE: Membership on a committee shall not in and of itself constitute an endorsement of the Association or any document developed by the committee on which the member serves.

Committee Scope: This Committee shall have primary responsibility for documents on the storage, transfer, and use of industrial gases. Included are the storage and handling of such gases in their gaseous or liquid phases; the installation of associated storage, piping, and distribution equipment; and operating practices. The Committee also has a technical responsibility for contributions in the same areas for medical gases and clean rooms.

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NFPA 560

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Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation

2007 Edition

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Changes other than editorial are indicated by a vertical rule beside the paragraph, table, or figure in which the change occurred. These rules are included as an aid to the user in identifying changes from the previous edition. Where one or more complete paragraphs have been deleted, the deletion is indicated by a bullet (•) between the paragraphs that remain.

A reference in brackets [ ] following a section or paragraph indicates material that has been extracted from another NFPA document. As an aid to the user, the complete title and edition of the source documents for extracts in mandatory sections of the document are given in Chapter 2 and those for extracts in informational sections are given in Annex C. Editorial changes to extracted material consist of revising references to an appropriate division in this document or the inclusion of the document number with the division number when the reference is to the original document. Requests for interpretations or revisions of extracted text shall be sent to the technical committee responsible for the source document.

Information on referenced publications can be found in Chapter 2 and Annex C.

Chapter 1 Administration

1.1 Scope. This standard shall apply to the storage and handling of ethylene oxide in portable containers for its use in sterilization and fumigation. It also shall apply to flammable mixtures of ethylene oxide with other chemicals.

1.1.1 This standard shall not apply to the following:

(1) Nonflammable mixtures of ethylene oxide with other chemicals
(2) Ethylene oxide manufacturing facilities, and container filling, refilling, or transfilling facilities
(3)*The off-site transportation of portable containers of ethylene oxide
(4) Facilities using ethylene oxide as a chemical feedstock
(5) Ethylene oxide in chambers 0.283 m^3 (10 ft^3) or less in volume, or for containers holding 200 g (7.05 oz) of ethylene oxide or less

1.2 Purpose. The purpose of this document is to give requirements to reduce the occurrence of fire explosions in the use of ethylene oxide sterilizing systems.

1.3 Alternate Materials, Equipment, and Procedures. The provisions of this standard are not intended to prevent the use of any material, method of construction, or installation procedure not specifically prescribed by this standard, provided any such alternate is acceptable to the authority having jurisdiction (*see* 3.2.1). The authority having jurisdiction shall require that sufficient evidence be submitted to substantiate any claims made regarding the safety of such alternates.

1.4 Retroactivity. The provisions of this standard reflect a consensus of what is necessary to provide an acceptable degree of protection from the hazards addressed in this standard at the time the standard was issued.

1.4.1 Unless otherwise specified, the provisions of this standard shall not apply to facilities, equipment, structures, or installations that existed or were approved for construction or installation prior to the effective date of the standard. Where specified, the provisions of this standard shall be retroactive.

1.4.2 In those cases where the authority having jurisdiction determines that the existing situation presents an unacceptable degree of risk, the authority having jurisdiction shall be permitted to apply retroactively any portions of this standard deemed appropriate.

1.4.3 The retroactive requirements of this standard shall be permitted to be modified if their application clearly would be impractical in the judgment of the authority having jurisdiction, and only where it is clearly evident that a reasonable degree of safety is provided.

1.5 Equivalency. Nothing in this standard is intended to prevent the use of systems, methods, or devices of equivalent or superior quality, strength, fire resistance, effectiveness, durability, and safety over those prescribed by this standard.

1.5.1 Technical documentation shall be submitted to the authority having jurisdiction to demonstrate equivalency.

1.5.2 The system, method, or device shall be approved for the intended purpose by the authority having jurisdiction.

Chapter 2 Referenced Publications

2.1 General. The documents or portions thereof listed in this chapter are referenced within this standard and shall be considered part of the requirements of this document.

2.2 NFPA Publications. National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169-7471.

NFPA 13, *Standard for the Installation of Sprinkler Systems,* 2007 edition.

NFPA 16, *Standard for the Installation of Foam-Water Sprinkler and Foam-Water Spray Systems,* 2007 edition.

NFPA 55, *Standard for the Storage, Use, and Handling of Compressed Gases and Cryogenic Fluids in Portable and Stationary Containers, Cylinders, and Tanks,* 2005 edition.

NFPA 70, *National Electrical Code®,* 2005 edition.

NFPA 259, *Standard Test Method for Potential Heat of Building Materials,* 2003 edition.

NFPA 5000®, Building Construction and Safety Code®, 2006 edition.

2.3 Other Publications.

2.3.1 ASME Publications. American Society for Mechanical Engineers, Three Park Avenue, New York, NY 10016-5990.

ASME *Boiler and Pressure Vessel Code,* 1992 edition.

ASME B31.3, *Process Piping,* 2004 edition.

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2.3.2 Other Publications. *Merriam-Webster's Collegiate Dictionary*, 11th edition, Merriam-Webster, Inc., Springfield, MA, 2003.

2.4 References for Extracts in Mandatory Sections.

NFPA 55, *Standard for the Storage, Use, and Handling of Compressed Gases and Cryogenic Fluids in Portable and Stationary Containers, Cylinders, and Tanks,* 2005 edition.

NFPA 58, *Liquefied Petroleum Gas Code,* 2004 edition.

Chapter 3 Definitions

3.1 General. The definitions contained in this chapter shall apply to the terms used in this standard. Where terms are not defined in this chapter or within another chapter, they shall be defined using their ordinarily accepted meanings within the context in which they are used. *Merriam-Webster's Collegiate Dictionary*, 11th edition, shall be the source for the ordinarily accepted meaning.

3.2 NFPA Official Definitions.

3.2.1* Authority Having Jurisdiction (AHJ). An organization, office, or individual responsible for enforcing the requirements of a code or standard, or for approving equipment, materials, an installation, or a procedure.

3.2.2 Labeled. Equipment or materials to which has been attached a label, symbol, or other identifying mark of an organization that is acceptable to the authority having jurisdiction and concerned with product evaluation, that maintains periodic inspection of production of labeled equipment or materials, and by whose labeling the manufacturer indicates compliance with appropriate standards or performance in a specified manner.

3.2.3* Listed. Equipment, materials, or services included in a list published by an organization that is acceptable to the authority having jurisdiction and concerned with evaluation of products or services, that maintains periodic inspection of production of listed equipment or materials or periodic evaluation of services, and whose listing states that either the equipment, material, or service meets appropriate designated standards or has been tested and found suitable for a specified purpose.

3.2.4 Shall. Indicates a mandatory requirement.

3.2.5 Should. Indicates a recommendation or that which is advised but not required.

3.3 General Definitions.

3.3.1 Aeration Room. A room or area with controlled temperature or airflow where ethylene oxide sterilized products are held initially for offgassing.

3.3.2 Atmospheric Vents. All points where pipes, stacks, or ducts are open to the atmosphere, including discharge points from emissions control devices, vent pipes from safety valves, vent pipes from filters or pumps, and other vents.

3.3.3 Chime Ring. The two raised rings circling the outer shell of DOT 5P (1A1) ethylene oxide drums. These rings protect the drum but are not intended for lifting purposes.

3.3.4 Container. For the purposes of this standard, a cylinder, drum, or other pressure vessel built to DOT, ASME, or other pressure vessel code and used to transport or store ethylene oxide.

3.3.5 Cylinder. A portable compressed gas container, fabricated to or authorized for use by the U.S. Department of Transportation (DOT), or fabricated to Transport Canada (TC) or the ASME *Boiler and Pressure Vessel Code*, Section VIII, *Rules for the Construction of Unfired Pressure Vessels.*

3.3.6 Drum. For the purposes of this standard, containers built to DOT specification 5P (1A1).

3.3.7 Ethylene Oxide Container. A compressed gas container used for ethylene oxide or flammable mixtures of ethylene oxide with other chemicals.

3.3.8 Limited Combustible. A building construction material not complying with the definition of noncombustible material that, in the form in which it is used, has a potential heat value not exceeding 3500 Btu/lb (8141 kJ/kg), where tested in accordance with NFPA 259, *Standard Test Method for Potential Heat of Building Materials*, and complies with (a) or (b): (a) materials having a structural base of noncombustible material, with a surfacing not exceeding a thickness of ⅛ in. (3.2 mm) that has a flame spread index not greater than 50; and (b) materials, in the form and thickness used, other than as described in (a), having neither a flame spread index greater than 25 nor evidence of continued progressive combustion and of such composition that surfaces that would be exposed by cutting through the material on any plane would have neither a flame spread index greater than 25 nor evidence of continued progressive combustion. (Materials subject to increase in combustibility or flame spread index beyond the limits herein established through the effects of age, moisture, or other atmospheric condition shall be considered combustible.) [**55,** 2005]

3.3.9 Outgassing. Release of adsorbed or absorbed ethylene oxide after sterilization.

3.3.10 Pressure Relief Device. A device designed to open to prevent a rise of internal pressure in excess of a specified value due to emergency or abnormal conditions. [**58,** 2004]

3.3.11 Special Buildings. For the purposes of this standard, a building used exclusively for the ethylene oxide sterilization process.

3.3.12* Sterilization Building. A detached building, which is comprised of all ancillary systems and rooms supporting the sterilization process, including the mechanical rooms, electrical room, preconditioning room or preconditioning cells, conveyance rooms, preheat room, sterilizer room, aeration room or cells, emissions control area, ethylene oxide drum storage room, gas transfer room, unprocessed and processed product storage areas, control room, process maintenance areas, and offices directly related to the sterilization process.

3.3.13 Storage. An inventory of compressed gases or cryogenic fluids in containers that are not in the process of being examined, serviced, refilled, loaded, or unloaded. [**55,** 2005]

Chapter 4 Receiving and Unloading Ethylene Oxide Containers

4.1 Scope. This chapter shall apply to the handling of both full and empty ethylene oxide containers at a facility, including the following:

(1) Handling of the containers between the truck and the dock
(2) Inspecting containers at the dock
(3) Handling of the containers within the facility

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4.2 Procedures.

4.2.1 Drums shall not be lifted by placing the forks under the chime rings on the drums.

4.2.2 Prior to the unloading of ethylene oxide containers, the vehicle engine shall be turned off, the brakes set, and the wheels chocked.

4.2.3 Smoking or open flames shall not be permitted within 7.62 m (25 ft) of any area where ethylene oxide containers are handled.

4.2.4 Ethylene oxide cylinders shall be secured to hand trucks or lift trucks during movement.

4.2.5 Ethylene oxide containers shall be kept upright at all times. Containers shall not be stacked or rolled.

4.2.6 Immediately after off-loading, ethylene oxide containers shall be inspected and the following checks shall be performed:

(1) An examination for evidence of damage to the container or valves
(2) A confirmation that the valves are equipped with valve outlet plugs or caps
(3) An inspection of the container labeling to confirm that each container is labeled ethylene oxide
(4)*A leak test of the container including valves and fuse plugs

4.2.6.1 Ethylene oxide containers shall not be moved to storage until the inspection is complete.

4.2.7 In the event that any container fails incoming inspection, the ethylene oxide supplier shall be notified. If a leaking container is found, the facility procedures for handling ethylene oxide leaks and spills shall be followed.

4.2.8 Ethylene oxide containers shall not be stored in the receiving area.

Exception: Areas dedicated to the receiving and storage of ethylene oxide only.

Chapter 5 Storage of Ethylene Oxide

5.1 General.

5.1.1 Storage areas shall be secured against unauthorized entry.

5.1.2 Storage of ethylene oxide in combination with other compressed or liquefied gases shall be in accordance with NFPA 55, *Standard for the Storage, Use, and Handling of Compressed Gases and Cryogenic Fluids in Portable and Stationary Containers, Cylinders, and Tanks.*

5.1.3 Ethylene oxide containers shall be kept upright at all times. Containers shall not be stacked.

5.2 Indoor Storage.

5.2.1 Storage Within Buildings. Storage within buildings shall be in accordance with NFPA 55, *Standard for the Storage, Use, and Handling of Compressed Gases and Cryogenic Fluids in Portable and Stationary Containers, Cylinders, and Tanks.*

5.2.2 Storage Within Sterilization Buildings.

5.2.2.1* The maximum quantity of ethylene oxide stored in a special sterilization building or special room shall be 4536 kg (10,000 lb).

5.2.2.2 The construction of all such special sterilization buildings shall comply with Chapter 13.

5.2.2.3 Special sterilization buildings or rooms shall be classified for purposes of ignition source control in accordance with 9.1.1.

5.2.2.4 Heated indoor storage areas shall be arranged so that stored cylinders or other containers cannot be spot-heated or heated above 51.7°C (125°F).

5.3 Storage Outside of Buildings.

5.3.1 Location of Storage Outside of Buildings. Storage outside of buildings shall be located in accordance with Table 5.3.1.

Table 5.3.1 Outdoor Storage of Ethylene Oxide Minimum Horizontal Distances

Quantity of Ethylene Oxide Stored	Distance to nearest important building or group of buildings or line of adjoining property that can be built upon	Distance to busy thoroughfares or sidewalks, line of adjoining property occupied by schools, churches, hospitals, athletic fields, or other points of public gathering
363 kg (800 lb) or less	0	0
363–1089 kg (801–2400 lb)	0	3 m (10 ft)
1089–2722 kg (2401–6000 lb)	3 m (10 ft)	3 m (10 ft)
2722–4536 kg (6001–10,000 lb)	6 m (20 ft)	6 m (20 ft)
Over 4536 kg (Over 10,000 lb)	7.6 m (25 ft)	7.6 m (25 ft)

5.3.2 Requirements for Outdoor Storage Areas. Outdoor storage areas shall have a minimum of 25 percent of the perimeter open to the atmosphere. This open space shall be permitted to incorporate chain link fence, lattice construction, open block, or similar materials for the full height and width of the opening.

5.3.2.1 Storage areas shall be kept clear of dry vegetation and combustible materials for a minimum distance of 4.6 m (15 ft).

5.3.2.2 Cylinders stored outside shall not be placed on the ground (earth) or on surfaces where water can accumulate.

5.3.2.3 Storage areas shall be provided with physical protection from vehicle damage.

5.3.2.4* Storage areas shall be permitted to be covered with canopies of noncombustible construction.

Chapter 6 Piping Systems

6.1 Scope. This chapter shall apply to ethylene oxide piping systems including pipe, tubing, flanges, gaskets, valves, fittings, flexible connectors, and the pressure containing parts of other components such as expansion joints and strainers, and devices used to mix, separate, distribute, meter, and control the flow of ethylene oxide. This chapter shall not apply to scrubber and vent systems.

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6.2 Materials for Piping, Valves, and Fittings.

6.2.1 Materials. All metallic materials used shall be specified in ASME B31.3, *Process Piping*. The requirements of the hazardous materials section shall apply. The following restrictions shall also apply:

(1) All metallic materials used shall have a minimum melting point of greater than 815.6°C (1500°F).
(2) No furnace butt-welded steel product shall be used.

6.2.2* Joining Methods. Joints shall be made gas-tight and shall be either welded, flanged, brazed, or threaded. Joints shall be welded when located in concealed spaces within buildings. The following shall also apply:

(1) *Welding*. All welding processes and procedures shall be in conformance with ASME B31.3, *Process Piping*. The Oxy-Fuel Gas Welding (OFW) procedure shall not be used on any component or system fabricated to this standard.
(2) *Brazing*. All brazing processes and procedures shall be in strict conformance with ASME B31.3, *Process Piping*. All braze alloys shall have a minimum melting point of 537.8°C (1000°F). The failure of the braze joint in the event of a fire exposure shall not in any way result in the release of additional fuel that can accelerate or spread the existing fire.
(3) *Soldering*. Soldering shall not be used for pressure containment or structural purposes. Soldering for hermetic/environmental sealing purposes as part of a mechanical sealing system shall be permitted. The failure of any soldering application in the event of a fire shall not allow a release of fuel that can accelerate or spread the existing fire.
(4) *Threading*. Threaded joints shall be made with a thread sealant or lubricant compatible with ethylene oxide.

6.3* Preparation for Dismantling of Piping. Any piping and valves that have been used to transport ethylene oxide to or from a sterilizer to the emission control or release point shall be drained and purged prior to dismantling. The piping shall be purged free of flammable concentrations of ethylene oxide prior to cutting or welding on the lines. The piping shall be inspected for evidence of polymer prior to cutting or welding. If found, all polymer shall be removed prior to cutting or welding.

6.4 Valves. Valves shall be designed for a minimum operating pressure of 1030 kPa (150 psi). All material used, including valve seat discs, packing, seals, and diaphragms shall be in accordance with Section 6.2.

6.5 Testing. Pressure piping systems shall be tested in accordance with ASME B31.3, *Process Piping*, prior to use.

6.6* Identification. Ethylene oxide lines shall be identified.

Chapter 7 Gas Dispensing Areas

7.1 General. In addition to the requirements in Chapter 5, Storage of Ethylene Oxide, the following shall apply to areas where ethylene oxide is dispensed from containers. Ethylene oxide storage shall be permitted in dispensing areas.

7.1.1* Indoor dispensing areas shall be equipped with a continuous gas detection system that provides an alarm when ethylene oxide levels exceed 25 percent of the lower limit of flammability (7500 ppm).

7.1.2* Exhaust ventilation shall be installed in all indoor dispensing areas used for ethylene oxide. Exhaust ventilation shall comply with the following:

(1) Mechanical ventilation shall be operated continuously at a rate of not less than 0.3 $m^3/min \cdot m^2$ (1 $ft^3/min \cdot ft^2$) of floor area of dispensing area.
(2) Exhaust ventilation shall not be recirculated within a room or building.

Exception: Where the air is treated to reduce the ethylene oxide concentration to below that which represents a hazard, recirculation shall be permitted. Controls shall be provided to ensure the performance of the treatment and recirculation system.

(3) The ventilation system shall be designed to prevent accumulation of ethylene oxide anywhere in the dispensing area.
(4) Loss of ventilation shall activate a visual and audible alarm and shall stop the flow of ethylene oxide at the remotely operated shutoff valve closest to the container.

7.2 Ethylene Oxide Containers.

7.2.1 No more than two ethylene oxide containers shall be connected to each sterilizer.

7.2.2 Before connections are made, containers shall be grounded.

7.2.3 The ethylene oxide supply line shall have a reverse flow prevention device to prevent contamination of the supply container where automatic switchover of containers is used.

7.2.4 Each ethylene oxide piping system from the containers to the process chamber shall have two remotely operated shutoff valves in the flow stream.

7.2.5 The valve required in 7.2.4 closest to the container shall be located 1.5 m (5 ft) or less from the container. The valves shall be operable from the sterilizer control room or other location outside the dispensing area.

7.2.6 Any supply piping containing liquid ethylene oxide that can be isolated shall be equipped with a pressure relief device.

7.3 Nitrogen System.

7.3.1 Nitrogen used for head space pressurization shall be no less than 99.9 percent nitrogen and shall contain no impurities that are chemically incompatible with ethylene oxide.

7.3.2 A reverse flow prevention device shall be provided to prevent ethylene oxide from entering the nitrogen supply system.

7.3.3 A particulate filter shall be provided to prevent rust from being introduced into an ethylene oxide container.

7.3.4 Refillable containers shall be pressurized with nitrogen to 345 kPa (50 psi) prior to disconnection and shipment to the supplier.

7.4 Vaporizer.

7.4.1 A valve shall be provided to control liquid flow to the vaporizer. This valve shall be permitted to be one of the valves required in 7.2.4.

7.4.2* An indicating or recording device shall be provided at the control panel to demonstrate that ethylene oxide temperature is within the range of 16°C (60°F) to 93.3°C (200°F). An alarm shall be provided for out-of-range conditions.

7.5 Liquid Ethylene Oxide Piping. Ethylene oxide shall not be piped outside the confines of the process area.

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Chapter 8 Operations

8.1 Operating Procedures Manual.

8.1.1 Each facility shall prepare and maintain an operating procedures manual covering facility start-up, operation, and shutdown. These manuals shall include procedures for the safe operation of the facility under normal and nonroutine operation conditions. Manuals shall be accessible to facility operators at all times.

8.1.2 Operating procedures manuals shall include operator actions to be taken if toxic or flammable concentrations of ethylene oxide are detected in the facility.

8.1.3 Operating procedures shall include procedures for purging and inerting equipment and piping.

8.1.4 Operating procedures shall include procedures for addressing leakage and spills of ethylene oxide.

8.2* Sterilizer Operation.

8.2.1* Purging. The vessel shall be purged to reduce the ethylene oxide concentration to less than 25 percent of the lower limit of flammability prior to opening the chamber door.

8.2.2* Post-Cycle Ventilation. A nonrecirculating ventilation system or equivalent means shall be provided to prevent ethylene oxide accumulation due to product outgassing prior to and during unloading of the sterilizer.

8.2.3 Cycle Abort. Ethylene oxide sterilizers shall be equipped with a manually initiated cycle abort feature accessible to the operator. This also shall be operable from outside the sterilizer area. A key-locked device shall not be permitted. The cycle abort operation shall remove flammable concentrations of ethylene oxide from the sterilizer.

8.3 Area Monitoring for Ethylene Oxide. Ethylene oxide sterilizer areas shall be monitored continuously for ethylene oxide concentrations.

8.3.1 The gas detection system shall provide an audible and visual warning signal to indicate when concentrations of ethylene oxide reach a level of 25 percent of the lower limit of flammability of ethylene oxide.

8.3.2* The gas detection system shall automatically shut off the supply at the ethylene oxide containers when the concentration of ethylene oxide exceeds 25 percent of the lower limit of flammability.

8.4 Emergency Stop. An emergency stop device shall be provided to halt all operating equipment including valves, rotating equipment, and heating apparatus on the sterilizer and gas dispensing equipment. The emergency stop shall be activated by a manually initiated feature accessible in the control room or at the control panel.

Chapter 9 Electrical Installation

9.1 Area Electrical Classification.

9.1.1 The sterilizer room, gas dispensing room, ethylene oxide container storage area, aeration rooms, and emission control area shall be classified as a Class I, Division 2, Group B area in accordance with NFPA 70, *National Electrical Code*®.

Exception: Aeration rooms shall be permitted to be unclassified electrically where it is demonstrated that flammable concentrations of ethylene oxide cannot occur during all normal and nonroutine operating conditions, including power failure.

9.1.2 The interior of the sterilization vessel shall be classified Class I, Division 1, Group B.

9.2* Static Electricity Control. All piping shall be bonded to an earth ground.

9.3 Grounding Requirements. All equipment shall be grounded in accordance with NFPA 70, *National Electrical Code*, Article 250.

Chapter 10 Sterilizer Construction

10.1* Vessel. Sterilizers operating at 100 kPa (15 psig) or higher shall be designed, built, and stamped in accordance with the ASME *Boiler and Pressure Vessel Code*, Section VIII.

10.2 Rotating Equipment. Rotating equipment exposed to flammable concentrations of ethylene oxide shall be designed to prevent sparking and localized overheating of surfaces during normal and nonroutine operation.

10.3 Pressure Relief Device. A pressure relief device, set to open at the sterilizer's design pressure, shall be installed on each sterilizer. Pressure relief devices shall be inspected annually for corrosion or accumulation of material (such as polymer buildup) that could prevent operation.

10.3.1 The point of discharge of the pressure relief device shall not be located in an area where potential ignition sources exist or where ethylene oxide vapors could re-enter the building.

10.3.2 Shutoff valves shall not be installed in relief device discharge piping.

Chapter 11 Disposal and Emissions

11.1* Scope. This chapter shall apply to the disposal and emission of ethylene oxide from sterilization facilities.

11.2 Wet Scrubbers. Where a wet scrubber is used, the following requirements shall apply:

(1) Wet scrubbing systems shall be designed so that scrubber solution cannot enter ethylene oxide vent or process lines.
(2) Sources of pure ethylene oxide liquid shall be prevented from being fed directly to scrubber systems designed only for ethylene oxide gas treatment.

11.3 Flare Stacks. Where a flare stack is used, the following requirements shall apply:

(1) Flame arresters shall be installed to prevent flame flashback into the sterilizer.
(2) Flare stack failure shall initiate a shutdown of the flare stack feed and an audible alarm.

11.4 Catalytic Converter. Where a catalytic converter is used, it shall be designed to shut down or be bypassed if the temperature exceeds the maximum temperature determined by the catalyst supplier.

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11.5 Oxidizing Emission Control Devices.

11.5.1 All interlocks and safeguards shall be in place before sterilization begins.

11.5.2 Sterilization products that sit idle in the sterilization or aeration room shall be periodically washed or vented.

11.5.3 Ethylene oxide concentration in the sterilizer before the back vents shall be monitored to avoid venting high ethylene oxide concentrations to the oxidizing emission control device.

11.5.4 Confined spaces shall be vented to the outside after power loss.

11.5.5 Ethylene oxide lines shall not be purged to an oxidizing emission control device.

11.5.6 Regular preventive maintenance shall be performed.

Chapter 12 Maintenance

12.1 General Requirements. A written program shall be developed for the following maintenance activities:

(1) Confined space entry
(2) Purging of equipment and piping
(3) Welding (hot work) permit system
(4) Lockout/tagout
(5) Preventive maintenance for key equipment

12.2 Maintenance Manuals. Manuals shall be accessible to facility operators and maintenance personnel at all times.

Chapter 13 Construction

13.1 Scope. This chapter covers the construction, ventilation, and heating of structures that house ethylene oxide storage, dispensing, and use. These structures shall be used exclusively for these purposes and for the housing of other materials having similar hazards, or they shall be permitted to be rooms attached to, or located within, buildings used for other purposes.

13.2 Separate Structures or Buildings.

13.2.1 Construction of Structures or Buildings.

13.2.1.1 Separate structures or buildings shall be one story in height and shall have walls, floors, ceilings, and roofs constructed of noncombustible or limited combustible materials. Exterior walls, ceilings, and roofs shall be constructed in one of the following ways:

(1) Of lightweight material designed for explosion venting.
(2)*If of heavy construction, such as solid brick masonry, concrete block, or reinforced concrete construction, explosion venting windows or panels in walls or roofs shall be provided.

13.2.1.2 The floor of such structures or buildings shall not be located below ground level. Any space beneath the floor shall be of solid fill, or the perimeter of the space shall be entirely unenclosed.

13.2.2* Structure or Building Ventilation. The structure or building shall be provided with general ventilation through the use of air supply inlets and exhaust outlets. These inlets and outlets shall be arranged to provide movement of well-mixed airthroughout the space. Air circulation shall be at least 0.3 m^3/m^2 (1 cfm/ft^2) of floor area and shall be permitted to be provided by natural or mechanical means.

13.2.3 Structure or Building Heating. Heating shall be by electrical appliances listed for Class I, Group B, Division 2 locations in accordance with NFPA 70, *National Electrical Code,* or shall be by means of steam or hot water radiation or other heating transfer medium with the heat source located in one of the following locations:

(1) Outside of the building
(2) In a separate room with a 2-hour fire resistance rating pressurized relative to the remainder of the building

13.2.4 Sterilization Rooms. The sterilization room shall be provided with Protection Level 2 and 4 controls as specified by *NFPA 5000, Building Construction and Safety Code.*

13.2.4.1 Sterilizing rooms with quantities of hazardous materials including ethylene oxide in quantities less than the Maximum Allowable Quantity per Control Area as established by *NFPA 5000, Building Construction and Safety Code,* shall not be required to have protection Level 2 and 4 controls.

13.2.5* Explosion Control. Explosion control shall be provided in accordance with NFPA 55, *Standard for the Storage, Use, and Handling of Compressed Gases and Cryogenic Fluids in Portable and Stationary Containers, Cylinders, and Tanks,* Section 6.9.

13.2.5.1 When explosion venting is provided, interior walls, and other walls of the sterilization room not designed as explosion venting, shall be designed to withstand an overpressure of at least 4.8 kPa (100 lb/ft^2).

Chapter 14 Fire Protection

14.1 Sprinklers. Facilities using ethylene oxide shall be protected by an automatic sprinkler system in accordance with NFPA 13, *Standard for the Installation of Sprinkler Systems.*

14.1.1 Ethylene Oxide Storage Areas. Ethylene oxide storage areas shall be equipped with a deluge system in accordance with NFPA 16, *Standard on the Installation of Foam-Water Sprinkler and Foam-Water Spray Systems.*

Annex A Explanatory Material

Annex A is not a part of the requirements of this NFPA document but is included for informational purposes only. This annex contains explanatory material, numbered to correspond with the applicable text paragraphs.

A.1.1.1(3) For regulations on the transportation of gases, see 49 CFR 100–179, "Transportation," and *Transportation of Dangerous Goods* regulations of Transport Canada.

A.3.2.1 Authority Having Jurisdiction (AHJ). The phrase "authority having jurisdiction," or its acronym AHJ, is used in NFPA documents in a broad manner, since jurisdictions and approval agencies vary, as do their responsibilities. Where public safety is primary, the authority having jurisdiction may be a federal, state, local, or other regional department or individual such as a fire chief; fire marshal; chief of a fire prevention bureau, labor department, or health department; building official; electrical inspector; or others having statutory authority. For insurance purposes, an insurance inspection department, rating bureau, or other insurance company representative may be the authority having jurisdiction. In many circumstances, the property owner or his or her designated agent assumes the role of the authority having jurisdiction; at government installations, the commanding officer or departmental official may be the authority having jurisdiction.

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A.3.2.3 Listed. The means for identifying listed equipment may vary for each organization concerned with product evaluation; some organizations do not recognize equipment as listed unless it is also labeled. The authority having jurisdiction should utilize the system employed by the listing organization to identify a listed product.

A.3.3.12 Sterilization Building. This building can include the mechanical room, electrical room, nitrogen tank and vaporizers area, chiller area, preconditioning room or preconditioning cells, conveyance rooms, preheat room, sterilizer room, aeration room or cells, emissions control area, ethylene oxide drum storage room, gas transfer room, shipping and receiving office(s), unprocessed and processed product storage areas, control room, maintenance areas, offices for the process support personnel, and any other rooms or systems as applicable in supporting the sterilization process.

A.4.2.6(4) Ethylene oxide containers should be tested for leakage prior to moving them inside a facility. Leak detection solutions can be used to test for leaks around valves and fuse plugs. This is often referred to as a soap test. Inexpensive hand-held leak detection instruments also are available.

A.5.2.2.1 Storage of over 2268 kg (5000 lb) of ethylene oxide can also be covered by 29 CFR 1910.119, "Process Safety Management of Highly Hazardous Chemicals" (OSHA). Hazard analyses are required by OSHA for facilities storing more than 2268 kg (5000 lb) of ethylene oxide in one location. Hazard analyses are recommended for all facilities that store, use, and handle ethylene oxide. Refer to 29 CFR 1910.119, "Process Safety Management of Highly Hazardous Chemicals," for guidance on conducting such an analysis. The analysis should address the hazards of the operation, identification of any previous incidents, engineering and administrative controls to protect against hazards, consequences of the failure of engineering and administrative controls, facility site, and human factors, and qualitative evaluation of the range of possible effects on employee safety and health due to the failure of controls.

A.5.3.2.4 The rate of formation of ethylene oxide polymers increases as the temperature increases. Therefore, to minimize polymer formation, ethylene oxide containers should be sheltered from intense sunlight. Ethylene oxide containers should not be stored under plastic sheets. This can produce a greenhouse effect that results in release of the fusible plugs.

A.6.2.2 Welding is the preferred method of joining pipe. The use of welding is important in preventing leakage of ethylene oxide.

For information on safety in cutting and welding see NFPA 51B, *Standard for Fire Prevention During Welding, Cutting, and Other Hot Work*.

A.6.3 Cleaning the inside of lines used for ethylene oxide is necessary prior to opening the piping system to remove the combustible, oily ethylene oxide by-products (which also contain absorbed ethylene oxide), such as polymers or glycols. These by-products can build up gradually over time.

A.6.6 For information on identification of piping, see ASME A13.1, *Scheme for the Identification of Piping Systems*.

A.7.1.1 Additional detection at lower levels may be required to meet the requirements of the Occupational Safety and Health Administration of the U.S. Department of Labor (*see* 29 CFR 1910.1047, "Ethylene Oxide").

A.7.1.2 Local exhaust hoods are an effective means used to control ethylene oxide levels at the source of potential release.

A.7.4.2 Monitoring of temperature in the ethylene oxide vapor stream provides a means to detect liquid ethylene oxide downstream of the vaporizer. The vaporizer should be equipped with a controller to maintain the desired temperature range for vaporization of ethylene oxide or ethylene oxide mixtures.

A.8.2 Sterilization is performed in a closed vessel under controlled conditions of temperature, humidity, pressure, and ethylene oxide gas concentration. The process is a single-pass, batch operation where a number of steps are performed to complete the cycle. Process cycle parameters can vary widely to meet product sterilization requirements and can use flammable gas mixtures in the sterilizer.

A.8.2.1 Lower concentrations of ethylene oxide are required by OSHA (*see* 29 CFR 1910.1047, "Ethylene Oxide") for personnel exposure.

The use of nitrogen in enclosed spaces can pose an asphyxiation hazard.

A.8.2.2 Outgassing, depending on product characteristics, can be of sufficient magnitude to produce flammable mixtures of ethylene oxide.

A.8.3.2 Ethylene oxide gas supply shutoff is a minimum requirement; other operations such as emergency ventilation might also be appropriate.

Additional detection at lower levels can be required to meet the requirements of OSHA (*see* 29 CFR 1910.1047, "Ethylene Oxide").

A.9.2 For information on prevention of static electricity see NFPA 77, *Recommended Practice on Static Electricity*.

A.10.1 Flame arresters should be installed to prevent flame propagation from potential ignition sources external to the vessel. Locations for consideration are the vacuum pump suction line, air inbleed port, relief valve discharge, and other potential problem areas where flashbacks could occur.

A.11.1 The emphasis of this chapter is on those issues specifically related to fire safety. Sterilization facilities are required to comply with federal, state, and local environmental health and safety regulations.

A.13.2.1.1(2) For information on venting of deflagrations, see NFPA 68, *Guide for Venting of Deflagrations*.

A.13.2.2 In order to comply with this requirement and OSHA (*see* 29 CFR 1910.1047, "Ethylene Oxide"), specific local exhaust ventilation might be necessary in storage and dispensing areas, on the sterilizer, and in aeration rooms.

A.13.2.5 For information on venting of deflagrations see NFPA 68, *Guide for Venting of Deflagrations*.

Annex B Significant Properties of Ethylene Oxide

This annex is not a part of the requirements of this NFPA document but is included for informational purposes only.

B.1 Hazards of Ethylene Oxide (Based on NFPA's *Fire Protection Guide to Hazardous Materials*, 2002.) Figure B.1 illustrates the hazards of ethylene oxide.

SYNONYMS: di-methylene oxide; EO; EtO; 1,2-epoxyethane; oxirane

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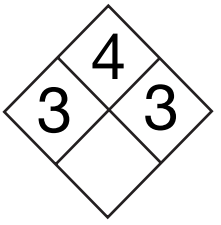
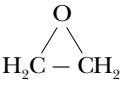


FIGURE B.1 Hazards of Ethylene Oxide.

FORMULA:



DOT CLASS: Class 2.3, Poisonous gas

SHIPPING LABEL: POISON GAS and FLAMMABLE GAS

ID NO.: UN 1040

CAS NO.: 75-21-8

MOL. WT.: 44.0

STATEMENT OF HAZARDS: Flammable gas. Low ignition energy. Explosive decomposition can occur. Hazardous polymerization can occur. Serious health hazard.

EMERGENCY RESPONSE PERSONAL PROTECTIVE EQUIPMENT: Wear special protective clothing and positive pressure self-contained breathing apparatus.

SPILL OR LEAK PROCEDURES: Eliminate all ignition sources. Releases may require isolation or evacuation. Approach release from upwind. Stop or control the leak, if this can be done without undue risk. Use water spray to cool and disperse vapors, protect personnel, and dilute spills to form nonflammable mixtures. Water solutions no longer flammable in open areas when diluted as 1 part in 22 parts water. In enclosed areas such as sewers, dilution to 1 part in 100 parts water can be required to eliminate flash potential. Control runoff and isolate discharged material for proper disposal.

FIRE-FIGHTING PROCEDURES: Use flooding quantities of water as fog. Use water spray, dry chemical, "alcohol-resistant" foam, or carbon dioxide. Use water spray to keep fire-exposed containers cool. Explosive decomposition can occur under fire conditions. Fight fire from protected location or maximum possible distance.

HEALTH HAZARDS: Serious health hazard. May be harmful if absorbed through skin or inhaled. Pulmonary edema can result. Irritating to skin, eyes, and respiratory system.

FIRE AND EXPLOSION HAZARDS: Flammable gas. Volatile flammable liquid below room temperature. Explosive decomposition can occur in vapor or liquid phases. Vapor forms explosive mixtures with air over a wide range. Vapors are heavier than air and can travel to a source of ignition and flash back. Closed containers can rupture violently when heated.

FLASH POINT: –20°C (–4°F)

AUTOIGNITION TEMPERATURE: 429°C (804°F) [AIT in the absence of air is 570°C (1058°F)]

FLAMMABLE LIMITS: LOWER 3.0% UPPER 100.0%

INSTABILITY AND REACTIVITY HAZARDS: Highly reactive. Hazardous polymerization can occur especially if contaminated. Reacts with acids, alkalies, salts, combustible materials. Can undergo runaway reaction with water. Many materials can accelerate this reaction.

STORAGE RECOMMENDATIONS: Store in a cool, dry, well-ventilated location. Store away from heat, oxidizing materials, and sunlight. Separate from acids, alkalies, salts, and combustible materials. Outside or detached storage is preferred. Can react in insulation, forming low molecular weight polyethylene glycols that can spontaneously heat and ignite at less than 100°C (212°F).

USUAL SHIPPING CONTAINERS: Insulated steel cylinders; pressurized tanks on trucks, rail cars, barges. Safety relief valves required.

PHYSICAL PROPERTIES: Colorless gas with sweet ether-like odor.

MELTING POINT: –112°C (–170°F)

BOILING POINT: 11°C (51°F)

SPECIFIC GRAVITY: 0.89 @ 0°C

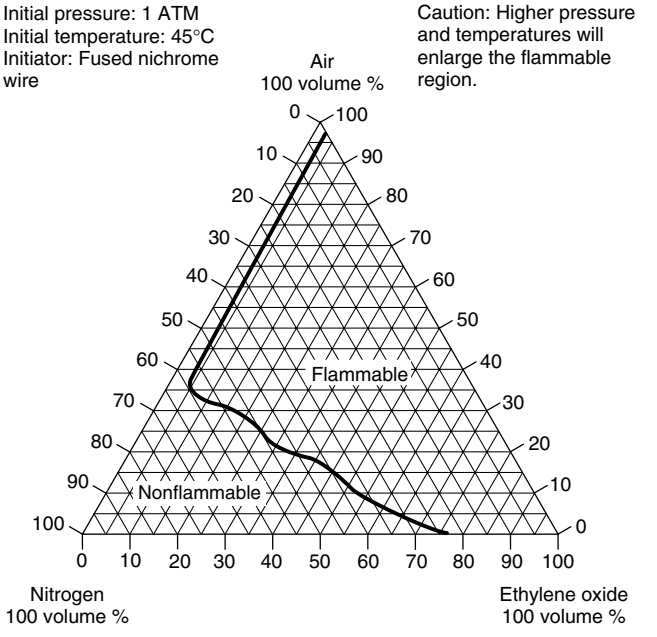
SOLUBILITY IN WATER: Soluble

VAPOR DENSITY: 1.51

VAPOR PRESSURE: 1095 mm Hg @ 20°C

ELECTRICAL EQUIPMENT: Class I, Group B (C)

B.2 Nonflammable Mixtures of Ethylene Oxide. Ethylene oxide is often mixed with a second, inert component and shipped as a liquefied gas mixture for use by sterilizer operators. Several of these mixtures are nonflammable. Table B.2 indicates the maximum amount of ethylene oxide that a nonflammable mix can contain, as well as typical ethylene oxide contents of commercially available nonflammable mixtures. Figure B.2(a) through Figure B.2(c) show how the flammable range for ethylene oxide varies as a function of pressure for nitrogen and air atmospheres.



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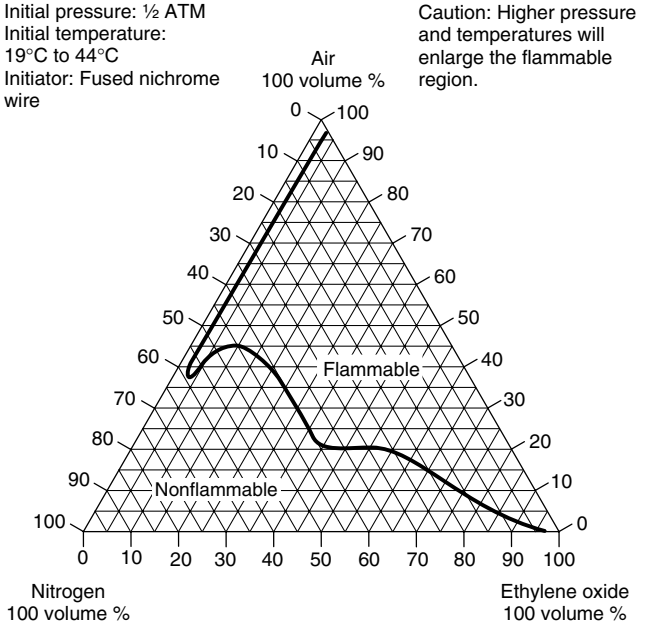
FIGURE B.2(a) Flammability of Ethylene Oxide-N_2-Air Mixtures at 1 Atmosphere.

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Table B.2 Nonflammable Mixtures of Ethylene Oxide*

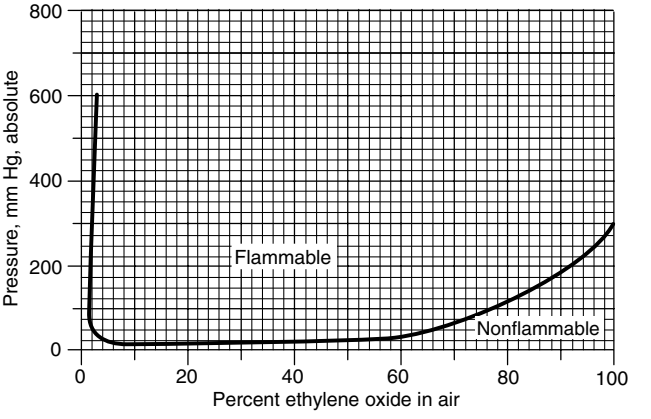
Second Component Chemical Name	Common Name	Chemical Formula	Max. Ethylene Oxide Wt %	Typical Ethylene Oxide Wt %	Max. Ethylene Oxide Vol %
Dichloro difluoromethane	CFC-12	CF_2Cl_2	12.5	12.0	28.0
Carbon dioxide	—	CO_2	9.0	8.5	9.0
2 Chloro-2,1,1,1 Tetrafluoroethane	HCFC-124	$CHClF\text{-}CF_3$	9.3	8.6	24.2
2,1,1,1 Tetrafluoroethane	HFC-134a	CH_2FCF_3	6.1	N/A	13.0
2,2,1,1,1 Pentafluoroethane	HFC-125	CHF_2CF_3	8.5	N/A	21.2

* Measured in accordance with ASTM E 681, *Standard Test Method for Concentration Limits of Flammability of Chemicals*, with an ignition energy of 40 J.



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FIGURE B.2(b) Flammability of Ethylene Oxide-CO_2-Air Mixtures at 1 Atmosphere.



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FIGURE B.2(c) Flammability of Ethylene Oxide Mixtures at Subatmospheric Pressures.

Annex C Informational References

C.1 Referenced Publications. The documents or portions thereof listed in this annex are referenced within the informational sections of this standard and are not part of the requirements of this document unless also listed in Chapter 2 for other reasons.

C.1.1 NFPA Publications. National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169-7471.

NFPA 51B, *Standard for Fire Prevention During Welding, Cutting, and Other Hot Work*, 2003 edition.

NFPA 68, *Standard on Explosion Protection by Deflagration Venting*, 2007 edition.

NFPA 77, *Recommended Practice on Static Electricity*, 2007 edition.

NFPA, *Fire Protection Guide to Hazardous Materials*, 2002 edition.

C.1.2 Other Publications.

C.1.2.1 ASME Publications. American Society of Mechanical Engineers, Three Park Avenue, New York, NY 10016-5990.

ASME A13.1, *Scheme for the Identification of Piping Systems*, 1981 (R 1985).

C.1.2.2 ASTM Publications. ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959.

ASTM E 681, *Standard Test Method for Concentration Limits of Flammability of Chemicals*, 1985.

C.1.2.3 TC Publications. Transport Canada, 330 Sparks Street, Ottawa, ON K1A 0N5 Canada.

Transportation of Dangerous Goods.

C.1.2.4 U.S. Government Publications. U.S. Government Printing Office, Washington, DC 20402.

Title 29, Code of Federal Regulations, Part 1910.119, "Process Safety Management of Highly Hazardous Chemicals" (OSHA).

Title 29, Code of Federal Regulations, Part 1910.1047, "Ethylene Oxide" (OSHA).

Title 49, Code of Federal Regulations, Parts 100–179, "Transportation."

C.2 Informational References. The following documents or portions thereof are listed here as informational resources only. They are not a part of the requirements of this document.

NFPA 69, *Standard on Explosion Prevention Systems*, 2002 edition.

C.3 References for Extracts in Informational Sections. (Reserved)

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- Committee votes by written ballot on Proposals. If two-thirds approve, Report goes forward. Lacking two-thirds approval, Report returns to Committee.
- Report on Proposals (ROP) is published for public review and comment.

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3.3.78 Effective Ground-Fault Current Path. An intentionally constructed, permanent, low impedance electrically conductive path designed and intended to carry ~~underground~~ electric fault current ~~conditions~~ from the point of a ground fault on a wiring system to the electrical supply source.

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