

# Ethylene Oxide Regulations



## General Regulations & Standards



**U.S. Department of Labor**  
Occupational Safety & Health Administration

OSHA 29 CFR 1910.1047(c)(1)	"The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 1 part per million parts of air ( <b>1.0 ppm</b> ) as an 8-hour Time Weighted Average (TWA) <b>Permissible Exposure Limit (PEL)</b>
OSHA 29 CFR 1910.1047(c)(2)	"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 ( <b>5 ppm</b> ) as averaged over a sampling period of 15 minutes. <b>Excursion Limit (EL)</b>
OSHA 29 CFR 1910.1047(h)(2)	"Where there is a possibility of employee exposure to EtO due to an emergency, means will be developed to alert potentially affected employees to such occurrences promptly"
Occupational Health and Safety Act of 1970, Section 5	"Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees"



NTIS Pub PB-94-195047 (1995)	Immediately Dangerous to Life or Health Concentration ( <b>IDLH</b> ) = <b>Ethylene Oxide 800 ppm</b>
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ANSI/AAMI ST:41:1999/(R) Section B.3.3.3	"...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 and should also be capable of providing both visible and audible alarms"
Section B.3.3.2.2	"Data acquisition (PC based) modules that can be connected to area monitors to track EO levels continuously and simultaneously from each point..... to the <b>lower detectable limit for EO of Less than 1 ppm</b> "



Standard EC.02.02.01 (2009) Element of Performance #10	"The hospital monitors levels of hazardous gases and vapors to determine that they are in safe range. Note: Law and regulation determine the frequency of monitoring hazardous gases and vapors as well as acceptable ranges."
Element of Performance #9	"The hospital minimizes risks associated with selection, handling, storage, transport, use and disposing hazardous gases and vapors. Note: Hazardous gases and vapors include, but are not limited to, gluteraldehyde, ethylene oxide, vapors generated while using cauterizing equipment and lasers, and gases such as nitrous oxide."

## Ethylene Oxide Record Keeping Regulations



**U.S. Department of Labor**  
Occupational Safety & Health Administration

29 CFR 1910.1020(d)(1)(ii)	"Each employee exposure record shall be preserved and <b>maintained for at least thirty (30) years..</b> "
29 CFR 1910.1020(c)(5)(i)	"Employee exposure record means a record containing any of the following kinds of information: Environmental (workplace) monitoring or measuring of a toxic substance or harmful physical agent."
29 CFR 1910.1020 (e)(1)(i)	"Whenever an employee or designated representative requests access to a record, the employer shall assure that access is provided in a reasonable time, place and manner."



ANSI/AAMI ST:41:1999/(R)	"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 (employee breathing zone) monitoring shows EO levels <b>exceeding the PEL or EL</b> , 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."
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# Ethylene Oxide Regulations



## Ethylene Oxide Storage Regulations



U.S. Department of Labor  
Occupational Safety & Health Administration

<p>29 CFR 1910.1047 (e) (1)</p> <p>29 CFR 1910.1047 (e) (2)/(3)</p>	<p>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.</p> <p>Access to regulated areas shall be limited to authorized persons. Regulated areas shall be demarcated in any manner that minimizes the number of employees within the regulated area.</p>
<p>OSHA CFR 1910.1047 Appendix B, Section VI</p> <p>Appendix A, Section V</p> <p>Appendix A, Section VII</p>	<p>A: Store EtO in tightly closed containers in a cool, well-ventilated area and take all necessary precautions to avoid any explosion hazard.</p> <p>C: Employers should advise employees of all areas and operations where exposure to EtO occur</p> <p>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 copper, silver, mercury and their alloys.</p> <p>C: Existing aeration units must be vented to a non-recirculating or dedicated system or vented to 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 off-gassing of sterilized items.</p>



National Fire  
Protection Association  
The authority on fire, electrical, and building safety

<p>ANSI/AAMI T:41:1999/(R)2005 Sections 4.8 and 4.8.1 (with reference to NFPA Code 30 (NFPA 1996b)</p>	<p>“The healthcare 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, <b>up to a maximum of 12 cartridges</b>, should be stored in the immediate areas of the sterilizer. If more that 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)(*).”</p> <p>Exhaust ventilation should only be provided when warranted by the materials in the cabinet, for example for particularly toxic or noxious materials. If provided, the manufacturer’s instructions should be followed. Typically, this will involve small diameter steel duct or pipe leading directly and by the shortest route to the exterior of the building. Exhaust must be taken from the bottom of the cabinet.</p>
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National Institute for  
Occupational Safety and Health



<p>DHHS (DIOSH) Publication No. 2007-164, in conjunction with EPA Publication No. 550-F-99-018</p>	<ul style="list-style-type: none"> <li>• Store EtO in tightly closed cylinders or tanks in a cool, shaded, well-ventilated, explosion proof area.</li> <li>• Store cylinders or tanks away from heat, sparks, flames, strong oxidizers, alkalines, acids, and acetylike-forming metals such as copper silver, mercury and their alloys. The storage room should be explosion-proof according to the definition of the National Fire Protection Association (NFPA 560) [NFPA 1995]</li> <li>• Do not smoke, use electrical devices, or create open flames when EtO is handled, used or stored</li> <li>• Use non-sparking tools when opening or closing metal containers f EtO or whenever EtO might be present</li> <li>• Keep containers individually bonded and grounded to the earth when liquid EtO is poured or transferred.</li> </ul>
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## Health Risks

<p>International Agency for Research on Cancer Centre International de Recherche sur le Cancer</p>	<p>Evaluation of Carcinogenic Risks to Humans, Volume 60 Ethylene Oxide is <b>carcinogenic to humans (group 1)</b></p>
<p>National Toxicology Program</p>	<p>Report on Carcinogens, Eleventh Edition, Profile: Ethylene Oxide CAS No. 75-21-8 Ethylene oxide is <b>known to be a human carcinogen</b></p>
	<p>Ethylene Oxide:</p> <ul style="list-style-type: none"> <li>o 8 Hour Time Weighted Average Threshold Limit Value = <b>1.0 ppm</b></li> </ul>

