

# Ethylene Oxide Tank Changing Regulations



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

29 CFR 1910.1047(f)(1)(iii)	"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."
29 CFR 1910.1047 App A (IV)	"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."
29 CFR 1910.1047 App A VII(d)	<p><b>Respirators.</b> You may be required to wear a respirator for non-routine 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-face piece respirators are approved for protection against EtO. If air-purifying respirators are worn in the future, they must have a label issued by NIOSH 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."</p>
29 CFR 1910.1047 App A VII(2)(e)	<p><b>Ventilation during cylinder change -</b> 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:</p> <ol style="list-style-type: none"> <li>i. Location of cylinders in a well ventilated equipment room or other room where workers are not normally present.</li> <li>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.</li> </ol>
29 CFR 1910.1047 App A VI(C)	<p>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."</p> <p><b>Leak detection.</b> 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 gas line entrance port to the sterilizer, while the sterilizer door is open and the solenoid valves are in a closed position</p>
	"Do not incinerate EtO cartridges, tanks or other containers."



ANSI/AAMI ST:41:1999/(R) Section B.3.3.3	<ul style="list-style-type: none"> <li>• "When eye or skin contact with EO [EtO] or EO mixtures could occur, such as...in the changing of EO cylinders,... 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."</li> <li>• "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."</li> <li>• "Training must be repeated annually"</li> <li>• "...individuals assigned to these tasks must have been examined by a physician to determine their ability to wear a respirator."</li> </ul> <p>"Training, medical examinations, and the procedure for periodic inspection, cleaning, and storage of respirators must be documented."</p>
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