

Canadian Ethylene Oxide Regulations (Workplace Safety)



General Regulations & Standards



Canadian Standards Association



Canadian Centre for Occupational Health and Safety

Canadian Labour Code

CSA Z314.9-09, 5.1.2	Type A sterilizers (tanks) shall be installed in a dedicated room. Type B sterilizers (canisters) should be installed in a dedicated room.																					
CSA Z314.9-09, 12.1 and 12.4	A sign stating the following shall be placed on doors leading into EtO sterilization area: DANGER ETHYLENE OXIDE CANCER HAZARD AND REPRODUCTIVE HAZARD. AUTHORIZED PERSONNEL ONLY																					
CSA Z314.9-09, 10.2	Limit access and traffic flow in EtO sterilization area to appropriate staff																					
Canadian Labour Code, Section 124	Every employer shall ensure that the health and safety at work of every person employed by the employer is protected.																					
CCOHS SOR/86-304, 10.19(1)	An employee shall be kept free from exposure to a concentration of (a) an airborne chemical agent in excess of the value for that chemical agent adopted by the American Conference of Governmental Industrial Hygienists (ACGIH) in its publication entitled Threshold Limit Values and Biological Exposure Indices dated 1994-95. <i>Note: The following represents Federal and Provincial provinces for ethylene oxide</i> <table border="1" data-bbox="479 751 1432 1050"> <thead> <tr> <th></th> <th>TLV 8 Hour</th> <th>TLV 15 Minutes</th> </tr> </thead> <tbody> <tr> <td>Federal, Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland, Nova Scotia, Prince Edward, Quebec</td> <td>1.0 parts per million</td> <td></td> </tr> <tr> <td>British Columbia</td> <td>0.1 parts per million</td> <td>1.0 parts per million</td> </tr> <tr> <td>Northwest Territories</td> <td>10 parts per million</td> <td>50 parts per million</td> </tr> <tr> <td>Nunavut</td> <td>10 parts per million</td> <td>50 parts per million</td> </tr> <tr> <td>Saskatchewan</td> <td>1.0 parts per million</td> <td>2.0 parts per million</td> </tr> <tr> <td>Yukon</td> <td>50 parts per million</td> <td>75 parts per million</td> </tr> </tbody> </table>		TLV 8 Hour	TLV 15 Minutes	Federal, Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland, Nova Scotia, Prince Edward, Quebec	1.0 parts per million		British Columbia	0.1 parts per million	1.0 parts per million	Northwest Territories	10 parts per million	50 parts per million	Nunavut	10 parts per million	50 parts per million	Saskatchewan	1.0 parts per million	2.0 parts per million	Yukon	50 parts per million	75 parts per million
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Alarms & Workplace Monitoring Requirements



Canadian Standards Association



Association for the Advancement of Medical Instrumentation

CSA Z314.9-09, 8.1 and 8.3.2.1	Alarm systems shall be installed for: (a) LEV system failure, (b) Ethylene oxide detection, (c) fire and (d) smoke. All alarm system shall have both audible (e.g. horn, klaxon) and visible (e.g. flashing colored light) (EO ALARMS) Sensors shall be placed in order to detect presence of EO in worker's breathing zone (a) above sterilizer scavenging system, (b) above container storage exhaust hood, (c) centre of the service room, (d) centre of EO sterilization area, and (e) any area where EO concentration is likely to be high
CSA Z314.9.09, 16.1	Exposure limits, methods of testing, frequency of testing, and records shall be maintained in accordance with applicable requirements. A workplace monitoring program shall be established to help the health care facility meet these requirements and to protect personnel from hazards associated with ethylene oxide. Notes: 1. <i>In Canada, federal and provincial/territorial regulations include requirements for the monitoring of hazardous substances in the workplace.</i> 2. <i>Further information and guidance on workplace monitoring can be found in ANSI/AAMI ST:41</i>
CSA Z314.9.09, 16.2	Where provincial/territorial regulations are absent, the following guidelines should be followed: (a) both area and personal monitoring shall be undertaken.
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"
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 (OSHA) lower detectable limit for EO of Less than 1 ppm"

Ethylene Oxide Storage Regulations



CSA Z314.9-09, 15.1.3.2	(Type A – TANKS) Designated storage shall be vented
CSA Z314.9-09, 15.2.2.1	(Type B – CANISTERS) All cartridges, except those set out for immediate use, shall be kept in a properly vented flammable storage cabinet that is rated for the maximum quantity of EO contained in all the cartridges.
CSA Z314.9-09, 15.2.2.2	Maximum number of cartridges kept outside the flammable storage cabinet shall be 12

Recordkeeping Requirements



CSA Z314.9-09 13.1.1 and 13.1.2	The healthcare facility should ensure documentation is kept in accordance with applicable federal and provincial/territorial regulations. Facilities shall establish a policy for retention of records concerning EO sterilizer operations and personnel exposure.
Health Canada	Records for incidents resulting from exposure to hazardous substances shall be retained for 30 years

Emissions Requirements



CSA Z314.9-09, 5.4.1	Ethylene oxide sterilizer shall have an emission control system to control and safely dispose of liquid and gas effluent produced by the sterilization and aeration process.
CSA Z314.9-09, 6.6.1 and 6.7	(Facilities that use 10 kg or more of ethylene oxide per year for sterilization), concentration of EtO released from aerator to the atmosphere is below 1 ppm, tested annually.

Health Risks

International Agency for Research on Cancer Centre International de Recherche sur le Cancer	Evaluation of Carcinogenic Risks to Humans, Volume 60 Ethylene Oxide is carcinogenic to humans (group 1)
National Toxicology Program	Report on Carcinogens, Eleventh Edition, Profile: Ethylene Oxide CAS No. 75-21-8 Ethylene oxide is known to be a human carcinogen
	Ethylene Oxide: o 8 Hour Time Weighted Average Threshold Limit Value = 1.0 ppm