

Exemption § 106.417 Checklist (Previously Standard Exemption 89) Ethylene Oxide (EtO) Sterilization Facilities

The following checklist has been developed so the Texas Commission on Environmental Quality (TCEQ) can confirm you meet exemption requirements. The questions are derived from § 106.4, previously § 116.211, and the exemption list. Please read all questions and check YES or NO (equivalent to True or False), or give specific information as applicable to your facility. If you do not meet all conditions of a specific exemption, you will not be allowed to operate the facility under exemption and you must apply for a construction permit as required under § 116.111 prior to construction.

For additional assistance with your application, including resources to help calculate your emissions, please visit the Small Business and Local Government Assistance (SBLGA) webpage at the following link: www.TexasEnviroHelp.org

Please Complete the Following:	
All sterilizers must meet the following conditions:	YES NO
EtO will be handled by appropriately trained personnel	YES NO
Written records shall be maintained for a minimum of two years	□ YES □ NO
Records will include the date and time of each sterilizer operation cycle	YES NO
Records will include the total pounds of EtO purchased and used per calendar year (listed as monthly totals)	□ YES □ NO
Records will include leak test results	YES NO
Leak tests of each sterilizer system will be performed at least every six months	□ YES □ NO
The EtO concentration will not exceed 10 ppm (measured at a distance of 1 centimeter from any portion of the sterilizer system)	YES NO
If a concentration greater than 10 ppm is detected, the sterilizer will be shutdown until the condition is corrected	🗌 YES 🗌 NO
The Sterilizer gas mixture will be:	
100% EtO 12% EtO / 88% CFC-12	
$\square 10\% \text{ EtO / } 90\% \text{ CO}_2 \qquad \square \text{Other:}$	
The sterilizer vent system exhaust stack will be uncapped and exhaust vertically upward	YES NO
The stack height shall be extended to at least 15 feet above the roof line of the building	YES NO
The stack tip shall be located at least 25 feet from any opening to the building interior, such as fresh air intake, unsealed windows, or pedestrian traffic areas	🗌 YES 🗌 NO
Stack exit velocity will be at least 50 feet per second	YES NO
In addition to the conditions of (a), the following conditions apply <u>only to sterilizers that use less than</u> 100 pounds of EtO per year:	🗌 YES 🗌 NO
Sterilizer will use less than 100 lb per year of EtO	YES NO
This sterilizer system vents entirely to atmosphere and will not use more than 0.5 pounds of EtO per cycle	YES NO
This sterilizer system uses non-recirculating, water sealed vacuum systems and will not use more than 2 pounds of EtO charged per cycle	YES NO
Combination of sterilizers on the same or contiguous property will use less than 100 lbs per year of EtO	YES NO
In addition to the conditions of (a) above, sterilizers that use between 100 and 1,000 lbs or EtO per year must answer the following:	🗌 YES 🗌 NO
Sterilizer will use between 100 and 1,000 lb/yr of EtO	YES NO
Construction at the facility has begun	YES NO



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Please Complete the Following:				
Form PI-7 is complete and attached		YES NO)	
The sterilizer chamber exhaust shall vent through an emission control device that will continuously achieve an EtO removal efficiency of 99%		nieve 🗌 YES 🗌 NO)	
Thermal incineration will not be used to control sterilizer exhaust emissions if chlorofluorocarbons are used as a diluent		used YES NO)	
Within 60 days of start-up, the control device performance will be verified through stack testing		YES NO)	
There will be no discharge of water containing dissolved EtO through a sanitary sewer system		YES NO)	
Any combination of sterilizers located on the same or contiguous property under common ownership will be limited to a total EtO usage of 1,000 pounds per year		vill 🗌 YES 🗌 NO)	
Name:				
Company:				
Title:				
Facility Name:				
Location:				
Phone No.:	Fax No.:			
E-mail Address:	Account ID No.:			
Signature of Company Officer:		Date:		