Guidelines for Reporting Ethylene Oxide Emissions from Sterilization Processes
December 2024

STACK EMISSION SOURCES FROM ETHYLEN OXIDE STERILIZERS:

Ethylene oxide is used to sterilize medical equipment/devices which are moisture or heat sensitive and cannot be sterilized by steam/heat. Ethylene oxide stack emission sources from sterilization process are identified as follows:

1. Sterilization Chamber Vent:

   Products are loaded into a sterilization chamber and ethylene oxide gas is injected into this chamber. After the sterilizing time is complete, the chamber undergoes several air exchanges to reduce the concentration of ethylene oxide within the products. Emissions from the sterilization chamber are vented to an air pollution control equipment.

2. Chamber Exhaust Vent:

   The chamber exhaust vent is the vent at the back of sterilization chamber. This vent is activated when the door of sterilization chamber is opened for transferring the products. The chamber exhaust vent reduces the worker exposure to ethylene oxide when products are transferred out of the chamber. Emissions from the chamber exhaust vent are also vented to air pollution control equipment.

3. Aeration Room Vent:

   After sterilization, the products are transferred to an aeration room, where ethylene oxide continues to be off gassed. Emissions from the aeration room are controlled by air pollution control equipment.

4. Fugitive Emissions:

   Fugitive ethylene oxide emissions from the sterilization processes include leaks from storage and dispensing, pre-aeration and post-aeration handling of sterilized products, leaks from vacuum pumps, and non-oxidizer air pollution control equipment.

For annual emission reports, ethylene oxide emissions from sterilizers can be reported as four separate processes if each stack emission source (identified as Item Nos. 1, 2 and 3 above) has its own air pollution control system. However, these stack emission sources (Item Nos. 1, 2 and 3) may also be vented to the same air pollution control equipment. Therefore, emissions from multiple

emission sources can be combined and reported under one process if these emission sources have a common APC system.

Fugitive emission must be reported as a separate process and control efficiency is not applicable for fugitive emission.

EMISSION FACTORS:

Emission factors from the most recent South Coast AQMD approved source test should be used for reporting ethylene oxide emissions from sterilization processes. If a source test is not available, the default emission factors in the table below may be used for reporting ethylene oxide emissions:

Processes	Emission Factors	Control Efficiency
Fugitive Emissions	0.0064 lb/lb[*]	NA
Sterilization chamber	Use EF from most recent source test results *or* 0.9336 lb/lb (uncontrolled emission factor)[*]	Use control efficiency from most recent source test results
Aeration Room	Use EF from most recent source test results *or* 0.04 lb/lb (uncontrolled emission factor)[*]	
Chamber Exhaust Vent	Use EF from most recent source test results *or* 0.01 lb/lb (uncontrolled emission factor)[*]	

[*]*Data from EPA Presentation on Ethylene Oxide/Commercial Sterilizers "Emissions Calculations and Exposure Modeling" (May 12, 2022) (https://www.4cleanair.org/wp-content/uploads/EtO-Sterilizer-National-Webinar-for-SLTs-Part-2_May-12-2022_FINAL_.pdf)*

If emissions from sterilization chamber, aeration room and chamber exhaust vent are vented to common air pollution control equipment, reporters should use the emission factor developed from the most recent South Coast AQMD approved source test. If emission factors from source test are not available, the combined uncontrolled emission factor (0.9836 lb/lb) may be used for the sterilization chamber, aeration room, and chamber exhaust vent. Fugitive emissions should be added as a separate process or device with the emission factor of 0.0064 lb/lb.

HOW TO REPORT:

The following information is required for reporting ethylene oxide emissions from sterilizers:

1. Annual throughput of ethylene oxide.
2. Ethylene oxide emission factors and control efficiencies for the APC system(s) from most recent South Coast AQMD approved source test results.

Instructions on How to Enter Information in AER webtool:

Click "Emission Sources (ES)" (item No. 5 in Navigation Menu on the left). The reporting tool displays existing emission sources in the green table shown at the bottom of the screen. If the sterilization equipment is not listed, click on the "Add New Emission Source" link.

Fill out information for the Emission Source such as A/N, ES Name, Operating ES Status. After entering the operating ES status, the orange Categorize Emission Sources button will appear. Click on orange Categorize Emission Sources button, the AER Webtool will take user to Categorize Emission Source screen for selecting the emission process.

Ethylene oxide emissions from sterilizers can be reported as fource separate processes:

(1) Emissions from sterilization chamber
(2) Emissions from aeration room
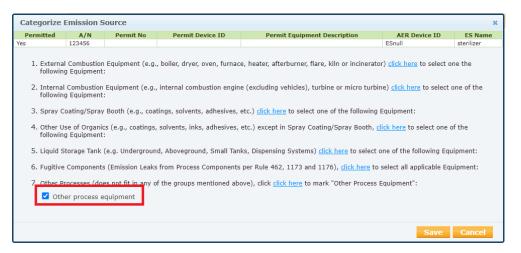(3) Emissions from chamber exhaust vent, and

(4) Fugitive emissions

If the emissions from Items No. 1, 2 and 3 (listed above) are vented to common air pollution control equipment, reporter can combine emissions from Items No. 1, 2 and 3 into one process.

In this tutorial, we assume EtO emissions from sterilization, aeration chambers and chamber exhaust vents are vented to a common APC system.

1.Adding process for emissions from sterilization/aeration chambers and chamber exhaust vents (Process ID P1):

From Categorize Emission Source screen, click on No. 7 and click on the check box Other Process Equipment to select this option. Click on the orange Save button to save the selected process.

Click on orange "Save and Proceed to Process Reporting" button.

Click the blue Open link next to Process ID P1(Other Process Emissions) in the Process References pop-up box (see below).

Click on the blue "Open" link in the green table under Step 1. Identify the Process Name and fill out the Activity Code by selecting the appropriate information from the drop-down menu from each box. The sample entries for the sector, industry, operation, process, and rule for sterilization operations are shown on the screenshot below. Click the orange "Save" button to close the pop-up window for Step 1.

Click the blue Open link on the Step 2 Throughput section. Enter the Annual Throughput, unit of throughput, Throughput Type, and Throughput Origin as shown below. Click the orange Save button.

Click on the orange "Add New" button under Step 3 (Criteria Emissions).

Click on the blue open link next to VOC in the pollutant column, enter Emission Factor, Control Efficiency and Emission Factor Data Source in the pop-up window. Click the "Save" button to close the window for Criteria Emission Information.

Click on the orange "Add New" button on the bottom of the green table under Step 4 (Toxic (TAC/ODC) Emissions).

Select Ethylene Oxide as the TAC pollutant. Enter the Emission Factor, Control Efficiency and Emission Factor Data Source. Click "Save" button to close the window for Toxic (TAC/ODC) Emissions Information.

Click on the orange "Back to Emission Source Process Reference" button to go back Process Reference.

2. Adding process for Fugitive Emissions (Process ID P2):

From the Process Reference window, click on "Add Process/Material/Fuel", fill out the "Process name", then Click "OK". The webtool will add Process ID P2.

Repeat the same procedure as Process ID P1 above.

For Process ID P2 (Fugitive Emission), use emission factor of 0.0064 lbs/lbs, and no control efficiency should be used for fugitive emission reporting.

As stated earlier, this example assumes that the sterilization process is vented to a common air pollutant control device. However, if each part of the sterilization process is vented to its own air pollution control device, then the fugitive emissions should be added as a separate device similar to how the sterilization operation was added as a device in the proceeding instructions.