

Community Meeting on Ethylene Oxide and Risks in the Communities of Fajardo, Puerto Rico



Website:

<https://www.epa.gov/eto>

Email:

eto@epa.gov

Why we are here today

1

Pollution is increasing health risks in your neighborhood.

2

We are working to reduce this risk in three ways.

3

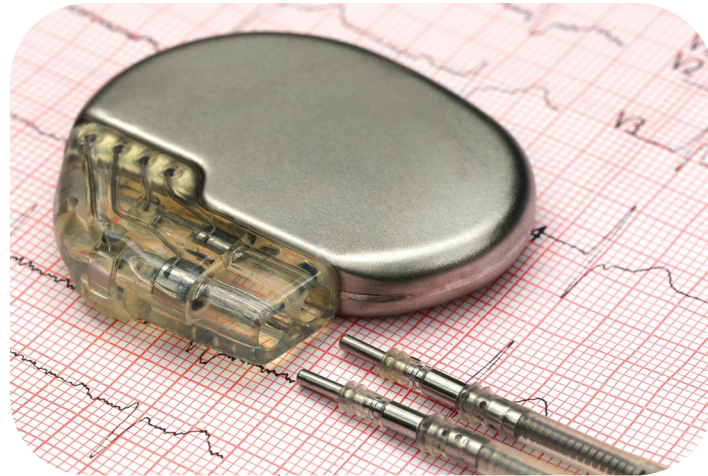
We want to hear from you.



What is Ethylene Oxide?

- Gas
- Colorless
- Flammable
- **Odorless**

*(in low concentrations
we see in communities)*

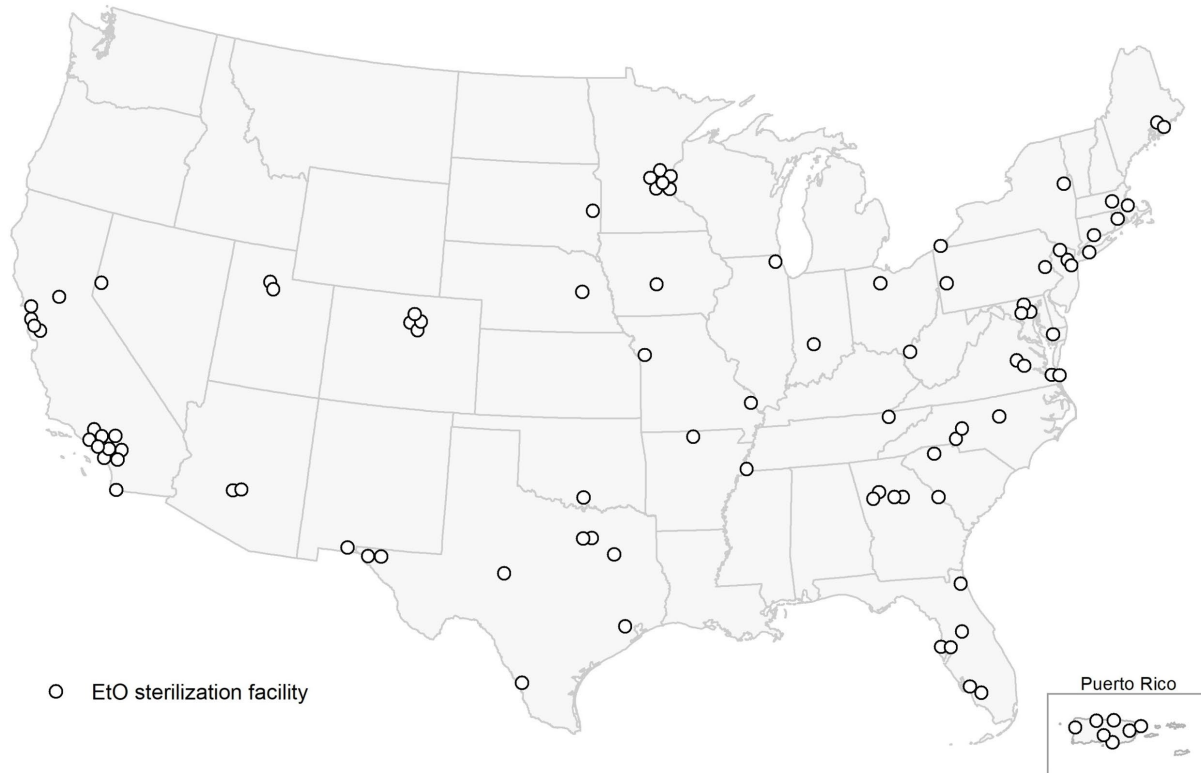


EtO Uses

- Used to Make Other Products
- Sterilizes



National Context



- Approximately **100** commercial sterilizers in the United States
- Customed, Inc. is **one of 23** with the **highest risk**
- More information on all facilities at <https://www.epa.gov/eto>

Current knowledge suggests the following risks are not a concern

No indication of risk:

- From soil or water
- Acute or emergency health impacts
- From consumer use of products made with or sterilized with EtO



Over your lifetime

Breathing in EtO over
many years can cause
breast cancer and
lymphoid cancer.



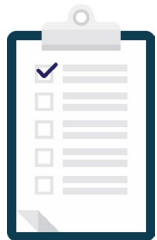
Special Considerations about Risk



Workers may be exposed at higher levels.



Children and babies may be at higher risk.



This risk assessment and the rule it supports are focused on community risk not worker risk.

**Reducing EtO coming
out of facility is
the best way
to reduce risk.**



Details about this analysis

- EtO Uses
- Facility Processes
- Facility Equipment
- Community Details
- Weather

Analysis

**Mapped
Location of Risk
Caused by EtO
from a Facility**



Recent Steps Taken to Learn about Risk and Reduce It:

- July 2022: Complete analysis showing where, in which specific communities, risk is highest for people who live nearby.
- Continue to seek more immediate reductions of EtO coming out of facilities.

Previous work:

- 2016: Learn EtO is more dangerous when people breathe it in.
- 2018: Initial analysis showing that EtO might be causing risk near certain types of facilities.
- 2020-2022: Collect and verify data and complete analysis to understand more exactly where there is risk and why.

CUSTOMED Fajardo, Puerto Rico

Maximum Risk Level: 1000/Million:

Blue: Estimated lifetime cancer risks of 100 in a million or greater.

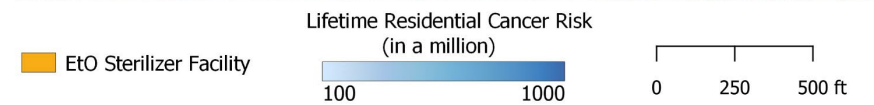
Lifetime cancer risk - breathe air containing EtO at the level estimated at that location for 24 hours a day, every day for 70 years.

This estimated risk is in addition to cancer risk from other causes.

For more information and to view this map online: <https://www.epa.gov/eto/>



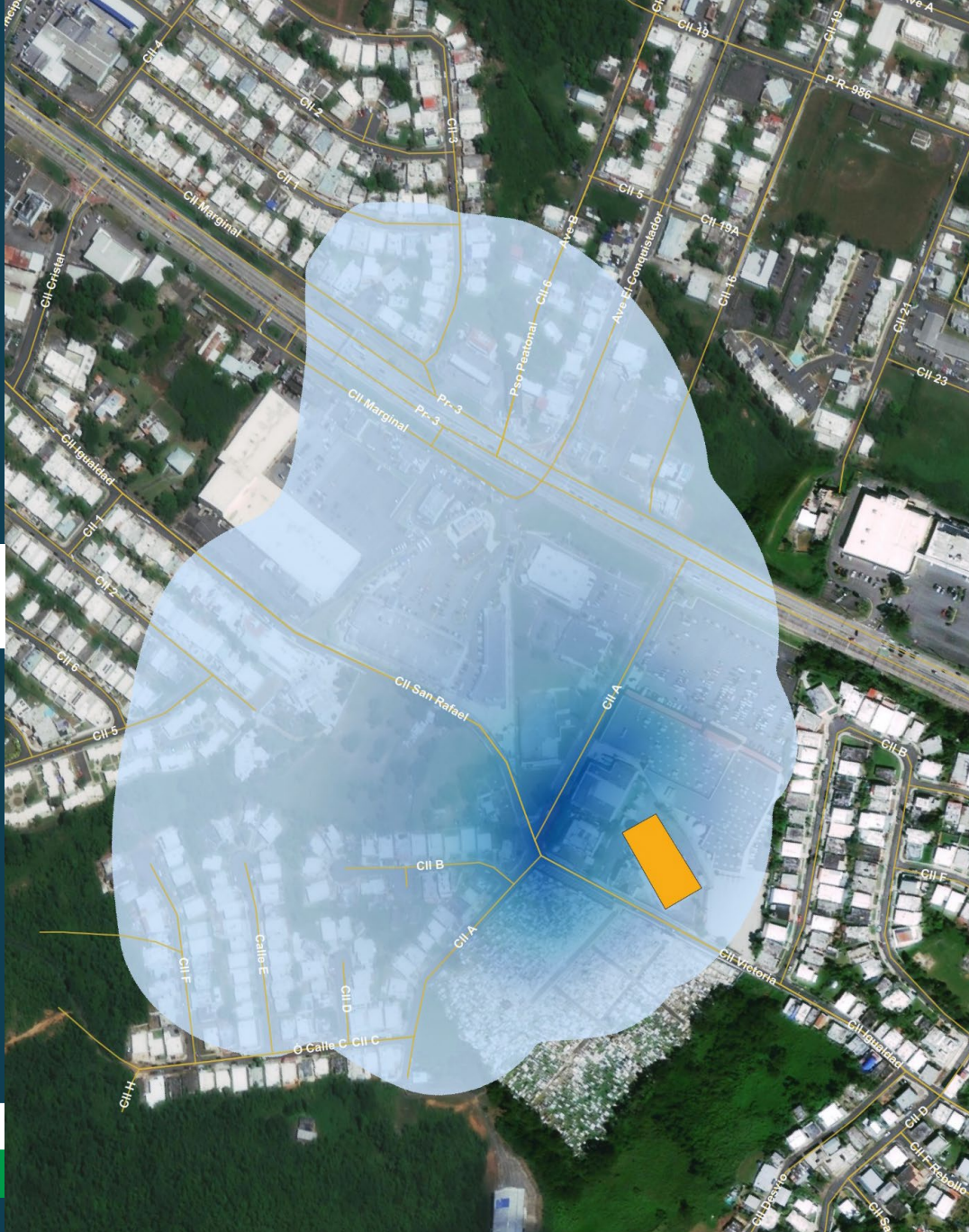
Risk and distance scales are different and specific to each community. You cannot easily compare one map to another.



This map shows EPA's estimates of lifetime cancer risks from EtO near Customed, Inc. in Fajardo, Puerto Rico. Risk decreases with distance from the facility. The area in blue shows estimated lifetime cancer risks of 100 in a million or greater from breathing air containing EtO emitted from the facility. A lifetime cancer risk of 100 in a million means that, if 1 million people were exposed to this level of EtO in the air 24 hours a day for 70 years, 100 people would be expected to develop cancer from that exposure.

The area in dark blue on the map shows that EtO exposure could contribute to a maximum increased risk level of 10 cancer cases if 10,000 people were exposed for 70 years. EPA cannot predict whether an individual person will develop cancer.

Lifetime Residential Cancer Risks - EtO Sterilization Customed, Fajardo, PR

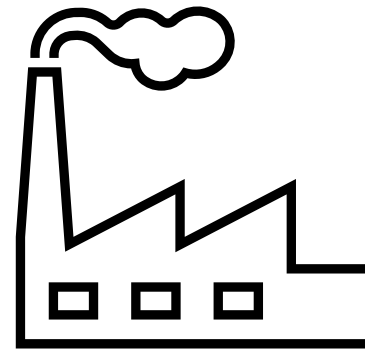


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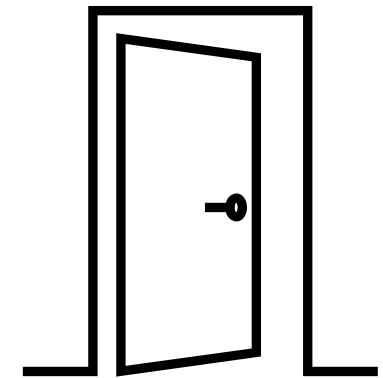
Where EtO Comes from at the Facility

There are two types of EtO emissions from facilities:

Controlled Emissions



Fugitive Emissions



In this community, the majority of the risk is being caused by fugitive emissions

Understanding Risk

How close?

How much?

How long?



For Updates and to Learn More

<https://www.epa.gov/eto/>



Source: https://commons.wikimedia.org/wiki/File:Fajardo_Las_Croabas_3.jpg

Location of Customed Inc.



Sterilization Process

- **Conditioning** – Temperature and humidity adjustment in accordance with product sterilization recipe (product validation regulated by FDA).
- **Sterilization** – A sterilization cycle consists of 5 phases (conditioning, EtO gas injection, exposure, evacuation, and air washes). A sterilization cycle and each of these phases depend on the type of product.
- **Aeration** – Once the sterilization cycle is completed the product is placed in an aeration room where any residual EtO retained in the product is removed.
- **Storage** – Staging area where sterilized product is placed until it is picked up by clients for shipping.

Customed's Operations

- Started operations in 1989. However, sterilization activities using EtO first started in 2005.
- Manufactures and sterilizes custom made surgical kits (packs and trays) for +50 hospitals and clinics in PR.
- 130 to 140 cycles per year.
- Consumes an average of 8,000 lbs. (4 tons) of EtO in a yearly basis. Allowable emission of EtO is 5 tons/yr.
- Uses 62 lbs. of EtO per cycle.
- 100% of product is sterilized using ethylene oxide. Not all the product sterilized
- Each component and surgical kits sterilized uses a special package that has special porosity the allows EtO to enter to the product, then to be removed and guratnee the sterilization and integrity of the product.
- Uses a sterilization chamber capacity of 9 pallets and aeration room. Each with their own decie of control.

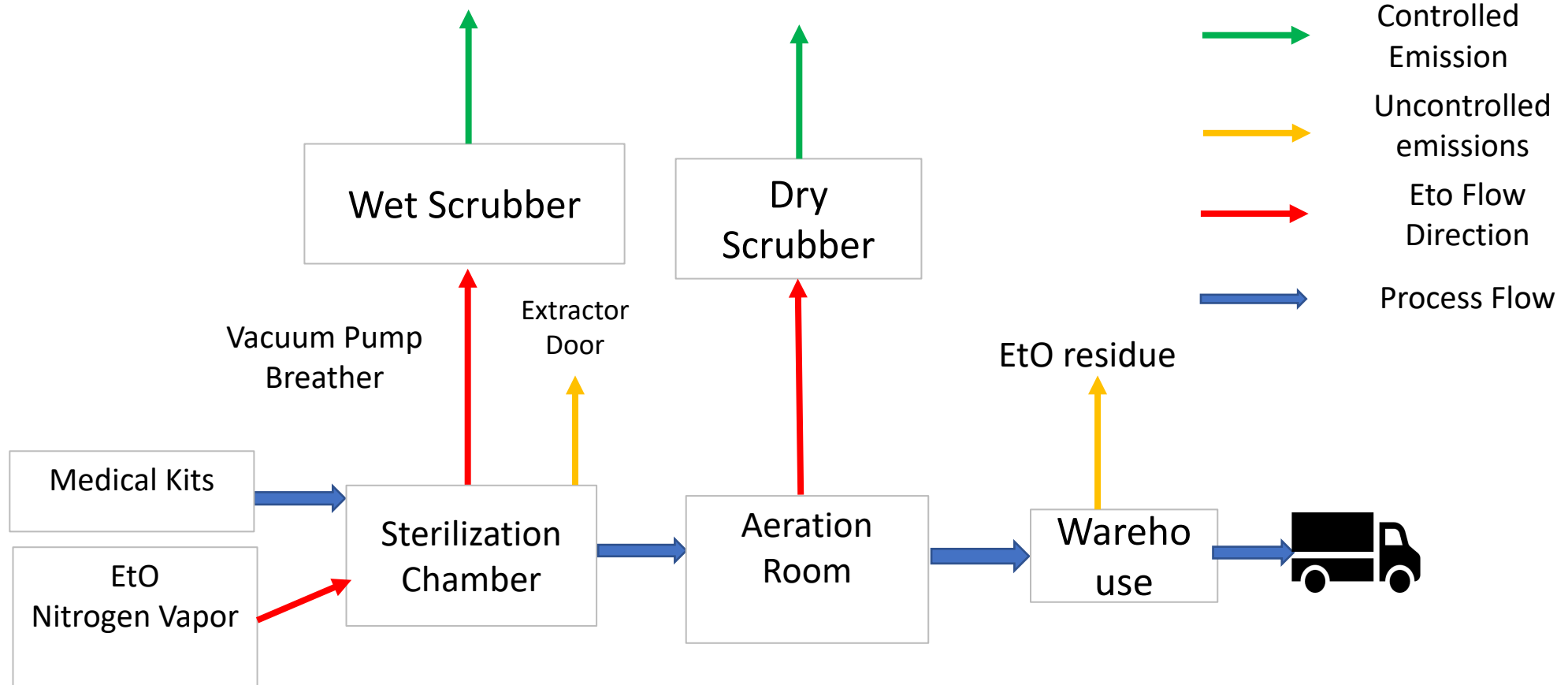
Customized Sterilization Process Continue

- Operates 5 days a week. Operation and office working hours are from 7 am to 5 pm. For the sterilization area the hours of operation varies when a sterilization cycle is processed. On days when sterilization cycles are processed, working hours are from 5:00 AM to 3:30 PM, and when no sterilization is active from 5:00 AM to 1:30 PM.
- As of 2022, the facility reported having 48 full time employees, 4 of them work in the Eto process and 2 in the post-sterilization (quality control). Those 4 employees use SCBA PPE.
- Ethylene oxide sterilization process is regulated and approved by the US Food and Drug Administration (FDA).
- Subject to 40 CFR Part 63 Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities.
- Air emissions operating permit issued by the Department of Natural and Environmental Resources establishes the facility conditions and requirements to comply with federal and state regulation.

Customized Sterilization Process Continue

- The product to be sterilized is processed in a pre-conditioning room with high temperature and humidity.
- The conditioned product is loaded into a sterilization chamber to expose it to EtO, nitrogen, and moisture.
- Vacuum pumps from the sterilization chamber vents remove EtO from the chambers to a wet scrubber where the EtO is exposed to a liquid solution that converts the gas to ethyl glycol in its liquid state.
- The product is then transferred to an aeration room to remove residual EtO retained in the product packaging. Air from aeration rooms is also treated through a dry resin scrubber.

Customed Process Flow



Sterilization Processes

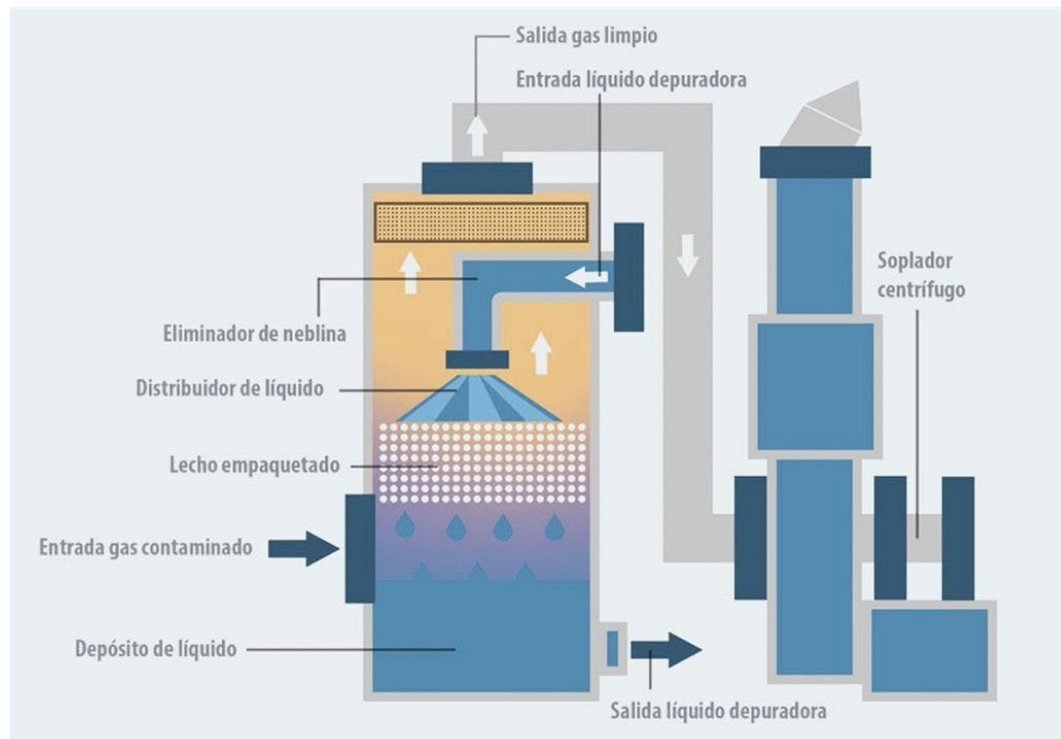


Examples of a sterilization chamber and aeration room

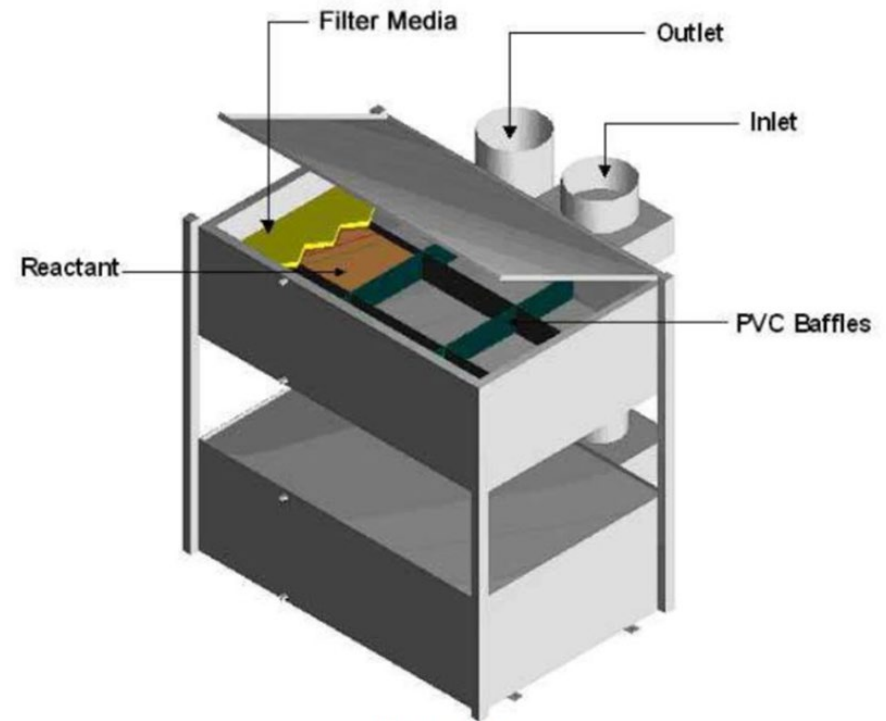
Source: <https://www.rsd-engineering.com/es/esterilizacion-oxido-de-etileno/autoclave-oxido-de-etileno>
<http://www.lesni.com/media/1040/preconditioning-degassing.pdf>

Examples of EtO Control Devices

Wet Scrubber



Dry Bed Reactor



Customed's EtO Control Devices

Wet Scrubber



Customed's EtO Control Devices

Dry Scrubber



Work in Progress

- EPA has been working with Customed Inc. on the possibility of installing control devices to address emissions from the sterilization chamber exhaust, which are currently being released to the atmosphere, and those from their warehouse.
- On January 17, 2023, the EPA conducted an inspection to assess compliance with applicable federal regulations and follow up on discussions about projects to reduce its EtO emissions. The company reported that they are evaluating a proposal to install dry gas scrubbers to treat the emissions from the sterilization chamber extractor.



NESHAP Subpart O

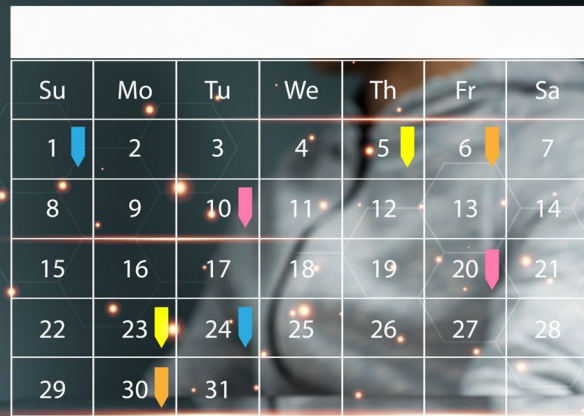
- Current Regulatory Requirement (40 CFR Part 63 Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities)
 - 99% reduction in EtO emissions from sterilization chambers.
 - Maximum concentration of 1 ppm or 99% reduction of EtO emissions from aeration rooms.
 - Ventilation emissions from sterilization chambers and warehouses do not require control equipment.
- Compliance with the current regulation does not guarantee a low risk.
- New regulation to be proposed later this year.
- There are many examples of facilities that have upgraded their EtO treatment configurations to address the issue before a new regulation is proposed and finalized.

EtO emissions control technology upgrades

- Edwards Lifesciences (Añasco, Puerto Rico) – Voluntary improvements to increase their EtO removal efficiency by replacing control devices with new technology and adding further controls to achieve 99.99% EtO removal efficiency. Sterilization building under negative pressure. Improvement project also contemplates conveying warehouse emissions to a control device. All emissions conveyed to a single stack from which emissions will be continuously monitored.
- Medline Industries (Waukegan, Illinois) – Agreed with the State of Illinois on installing new emission controls, placed building under 100% capture (negative air pressure) and routed all emissions through control devices. Measures set forth in the facility operations permit go beyond the measures under the current NESHAP Subpart O.
- Sterigenics (Atlanta, Georgia) – In addition to improvements to increase their EtO removal efficiency from their regulated emission sources, the Facility agreed with the State of Georgia to install a negative pressure system to collect and control fugitive emissions within non-process areas where sterilized product is transported or stored prior to shipment.

Timeline

- New regulation to be proposed this year.
- The public comment period will last 60 days.
- Final rule is expected in 2023.
- Once the rule is final, facilities typically have 3 years to comply with new requirements.
- Additional resources on the comment process are available here:
<https://www.epa.gov/eto/comment>



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22	23	24	25	26	27	28
29	30	31				

Timeline (continued)

Additional actions this year on EtO:

- New risk information for workers at EtO facilities and people who work or attend school nearby
- Proposed changes to EtO use inside facilities expected in 2022
- Public comment period.
- Once changes are final, it typically takes several years for changes to take effect
- Learn more about EPA's review of EtO use as a pesticide: <https://www.epa.gov/ingredients-used-pesticide-products/ethylene-oxide-eto>

Key Points




EPA has learned that EtO is causing health risk in some American communities.

We are working to reduce this risk by:

1. Working across government and industry to reduce EtO coming from sterilization facilities.
2. We are updating air pollution regulations to be more protective of your health.
3. We are sharing these risk results with you, so you have the same information we have.

Next Steps

- 
- New regulation proposed by end of the year.
 - EPA continuing to work with Customed and PRDNER to reduce EtO emissions from facility.
 - Submit questions to EPA via eto@epa.gov or Brenda Reyes at reyes.brenda@epa.gov or 787-977-5865

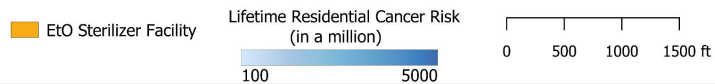
Thank You!



Are there Other Sterilizers in Puerto Rico?

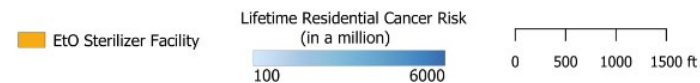
Añasco

Lifetime Residential Cancer Risks - EtO Sterilization
 Edwards Lifesciences, Añasco, PR
 Risk information current as of July 27, 2022.



Salinas

Lifetime Residential Cancer Risks - EtO Sterilization
 Steri-Tech, Inc, Salinas, PR
 Risk information current as of July 27, 2022.



Villalba

Lifetime Residential Cancer Risks - EtO Sterilization
 Medtronic, Villalba, PR
 Risk information current as of July 27, 2022.

