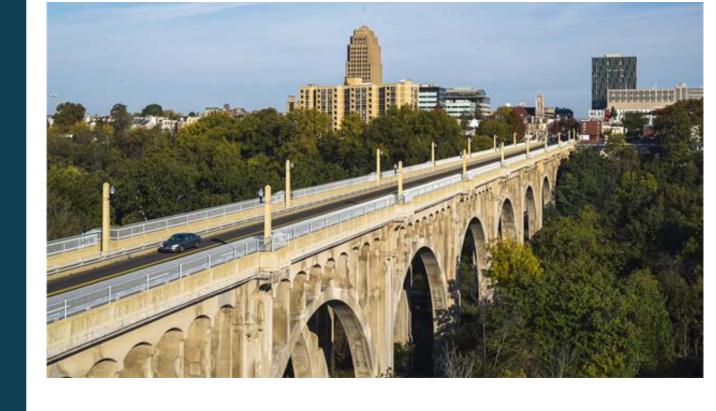
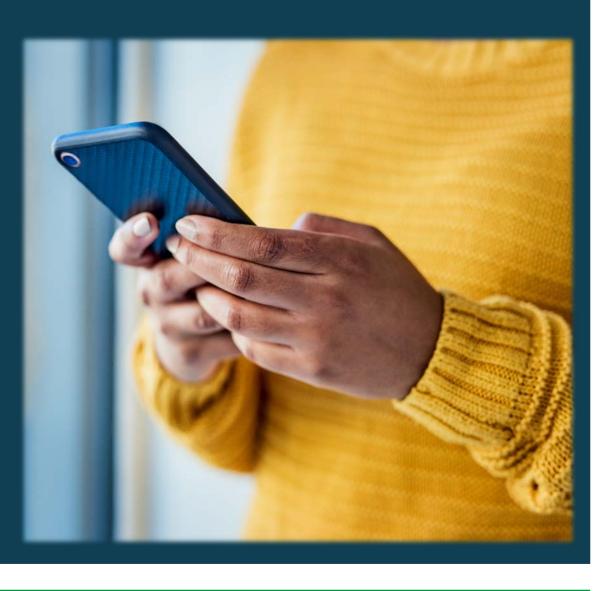
Ethylene Oxide in the Allentown, PA Community







Use the Q and A module to ask questions or ask for technical help.

Adam Ortiz

Mid-Atlantic Regional Administrator U.S. EPA Region 3

To contact us, please visit EPA's website at:

https://www.epa.gov/eto

Click the "Contact Us" link to leave a question or comment.

Why we are here today

B. Braun Medical is using ethylene oxide in Allentown.

We are working to reduce risk from this chemical.

We want to hear from you.



Madeline Beal

Senior Risk Communications Specialist
Office of the Administrator
U.S. EPA Headquarters

Website:

https://www.epa.gov/eto



What is Ethylene Oxide?

Gas, Colorless,
 Flammable, Odorless

(in concentrations we see in communities)

B. Braun in Allentown
 Uses EtO to Sterilize
 Medical Devices







Current knowledge suggests these risks are not a concern

No indication of non-cancer 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 lymph cancer.



Special Considerations about Risk



Workers at sterilizer facilities 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.





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.

Understanding Risk

How close?
How much?
How long?



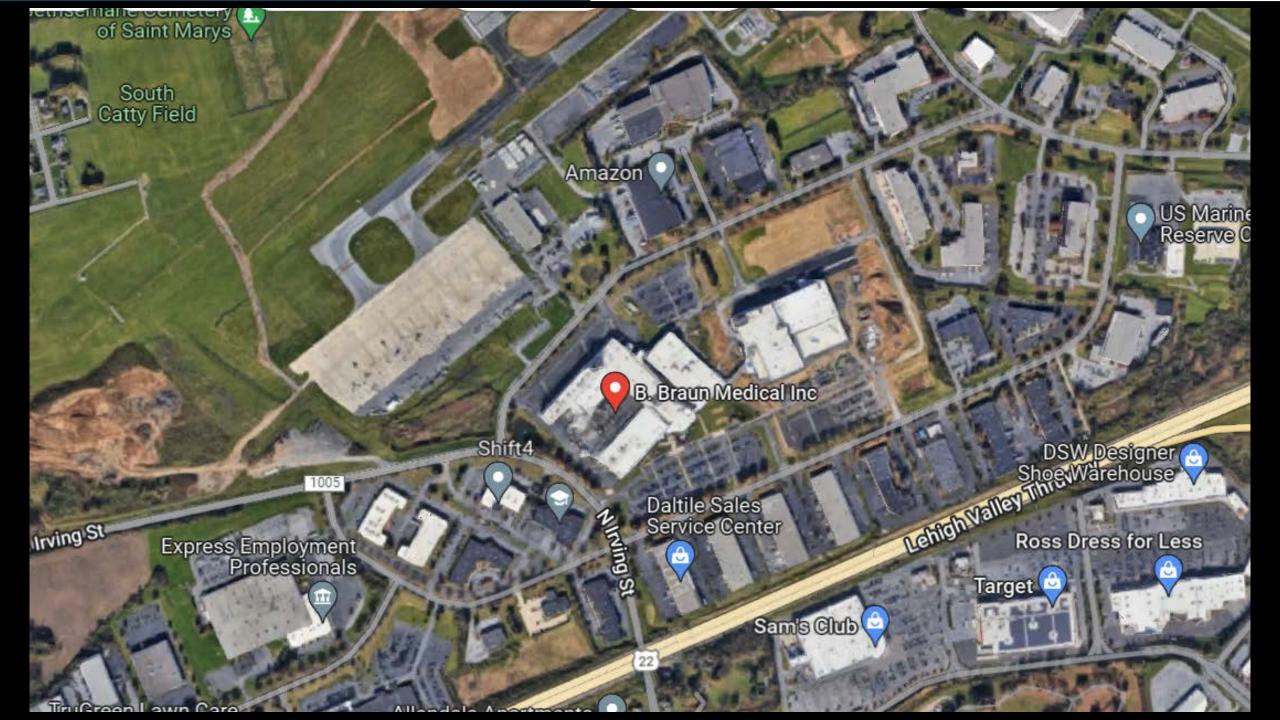
Cristina Fernandez

Air Division Director Mid-Atlantic Region U.S. EPA Region 3 Website:

https://www.epa.gov/eto

https://www.epa.gov/eto/allentown





Details about this analysis

EtO Uses
Facility Processes
Facility Equipment
Community Details
Weather

Analysis

Location of Risk from EtO Emitted from Sterilizers like B. Braun Reducing EtO coming out of facility is the best way to reduce risk.



Actions to Reduce Risk:

Update rules on:

- How much EtO can come out of facilities.
- How EtO can be used in facilities.

Work with Pennsylvania, local authorities, and B. Braun to reduce risk.





Timeline

- These two new regulations will be proposed in the coming weeks.
- The public comment period will last 60 days.
- How long facilities have to meet the new requirements may be up to 3 years but could be shorter.
- Additional resources on the comment process are available here:

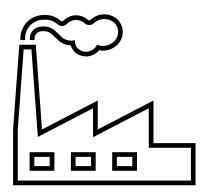
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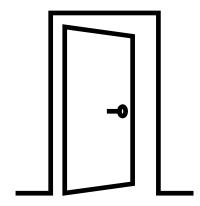
Where EtO Comes from at the Facility

There are two types of EtO emissions from facilities:

Controlled Emissions

Fugitive **Emissions**





Work in Progress

- B. Braun installed a new control system in 2020 which reduced EtO emissions over 90% from 2018 to 2021.
- Pennsylvania Department of Environmental Protection inspected the facility in November 2022.
- PADEP will continue to conduct routine inspections to verify compliance with air quality operating conditions.





Ethylene Oxide (EtO) Public Outreach

PADEP Northeast Region December 1, 2022

Air Quality Permit

B Braun holds Air Quality Permit 39-00055

- Current EtO controlled sources
 - sterilizers (8)
 - aeration room
- B. Braun has installed new and updated controls



Previous Controls

- DEOXX Scrubber
 - Designed to control 99% EtO
 - Required as best available technology
- Catalytic Oxidizer
 - Designed to control 99% EtO
 - Required by 40 CFR Subpart O of the National Emission Standards for Hazardous Air Pollutants for Sterilization Facilities



New Controls

- Dry Bed System installed in 2019
 - Voluntarily installed by B. Braun
 - Controls EtO from previously uncontrolled rear sterilizer vent
 - Designed for 99% EtO control
 - Significant reduction in overall EtO emissions

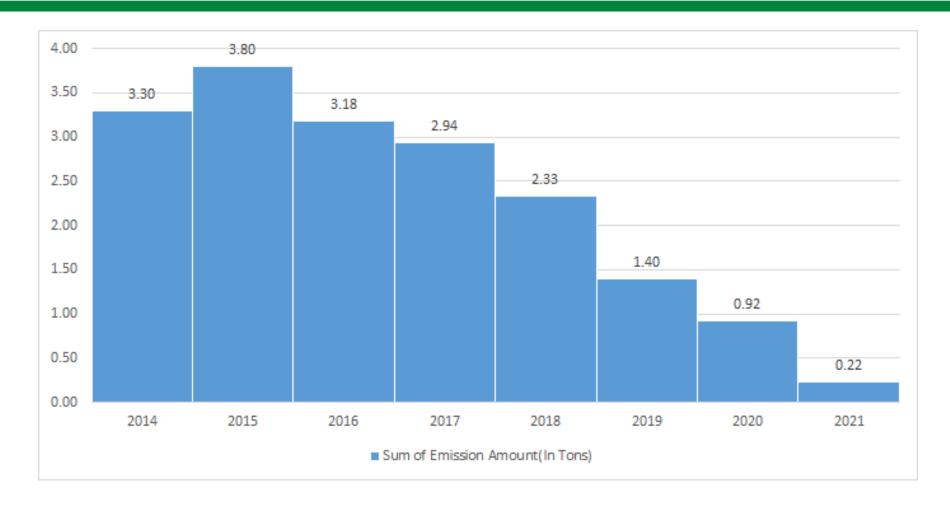


Updated Controls

- Catalytic Oxidizer with Peak Shaver 2020
 - Voluntarily upgraded by B. Braun replacing existing DEOXX scrubber and catalytic oxidizer
 - Previous equipment designed for 99% EtO control
 - New system is designed to achieve 99.9% EtO control
 - Demonstrated EtO destruction of 99.98%
 - Significant reduction in overall EtO emissions



B Braun EtO Emission Trend





EtO Emission Reductions

- 10TPY EtO emission limit
- Current EtO emissions at 2.2% of limit
- More than 90% EtO emission reduction since 2018



PADEP Inspections

- PADEP conducts periodic unannounced inspections
- Full Compliance Evaluations (FCE)
- Last FCE November 2022
- No violations identified



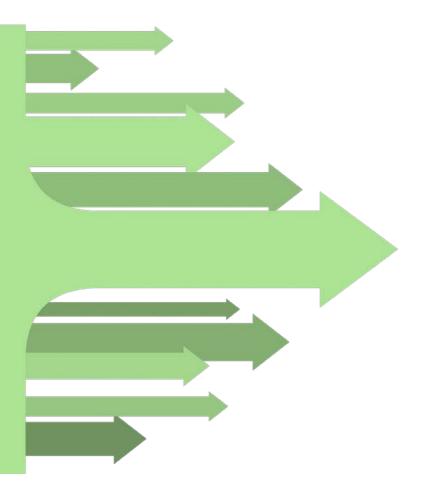


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Next Steps



- New regulations to be proposed in the coming weeks.
- Go to <u>https://www.epa.gov/eto/allentown</u> to learn more and to sign up to receive updates.

Use Q and A Module to type a question.

