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

Image Source: https://www.usgs.gov/media/images/aerial-photography-lago-toa-vaca-puerto-rico

Website:

https://www.epa.gov/eto

Email:

eto@epa.gov

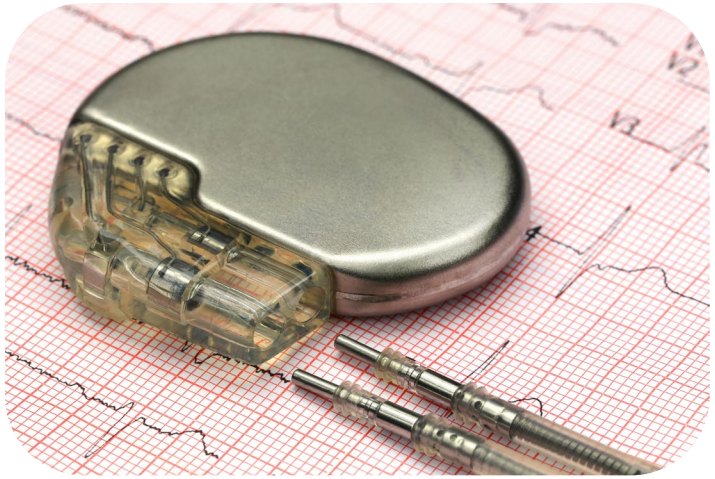
Why we are here today

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 concentrations we see in communities)



EtO Uses

- Used to Makes Other Products
- Sterilizes

National Context

- Approximately **100** commercial sterilizers in the United States
- Medtronic Villaba 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**

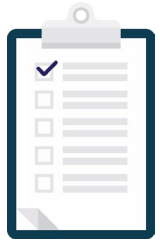
Over your lifetime

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

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.

Medtronic's Villalba, Puerto Rico

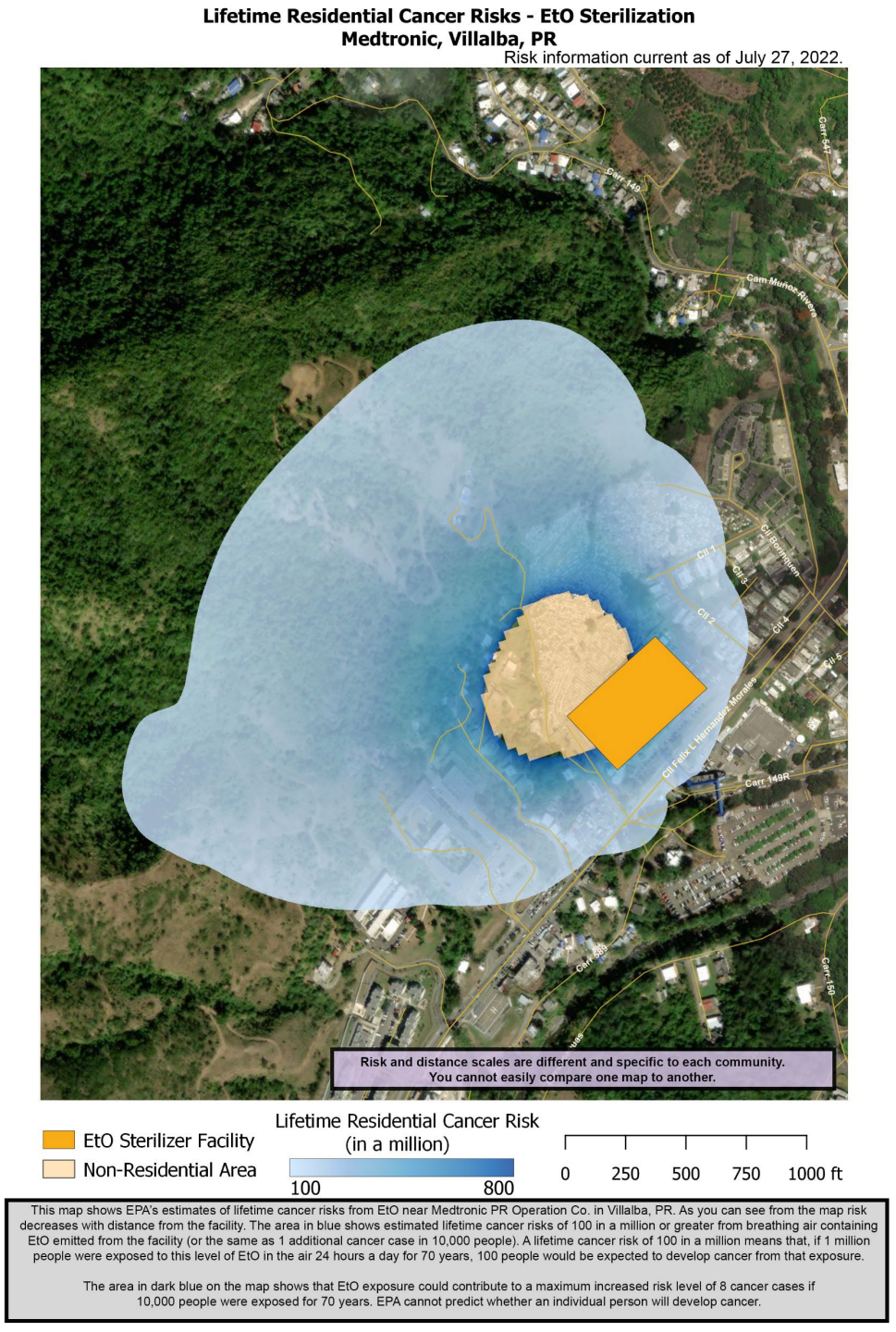
Maximum Risk Level: 800/Million:

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/



Understanding Risk

How close?

How much?

How long?

For Updates and to Learn More

https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/villalba-puerto-rico-medtronic-pr-operation-co

Image Source: https://www.discoverpuertorico.com/profile/plaza-publica-de-villalba/8434

Location of Medtronic Villalba

Medtronic's Operations

- Started operations in 1974. First sterilization with EtO started around 1997 with the installation of 7 sterilizers. Gradually installed additional sterilizers. Since 2003, the Facility uses 23 sterilizers.
- Operate in two different buildings, North and South Buildings and three (3) different rooms that are designated as either high-voltage or low-voltage chambers and neuromodulation.
- The high- and low-voltage designations refer to the type of device being sterilized.
- Consumes between 1-3 tons of EtO in a yearly basis. Consumed 2.58 tons of EtO in 2020 and 1.25 tons in 2021.
- The 23 sterilizers are operated 5 days per week. Not all sterilizers operate at the same time.
- 100% of product is sterilized using ethylene oxide. Not all product managed requires sterilization at the facility.
- Complete around 4-5 sterilization cycles per day.
- As of 2022, the facility has around 1,600 employees.
- 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.

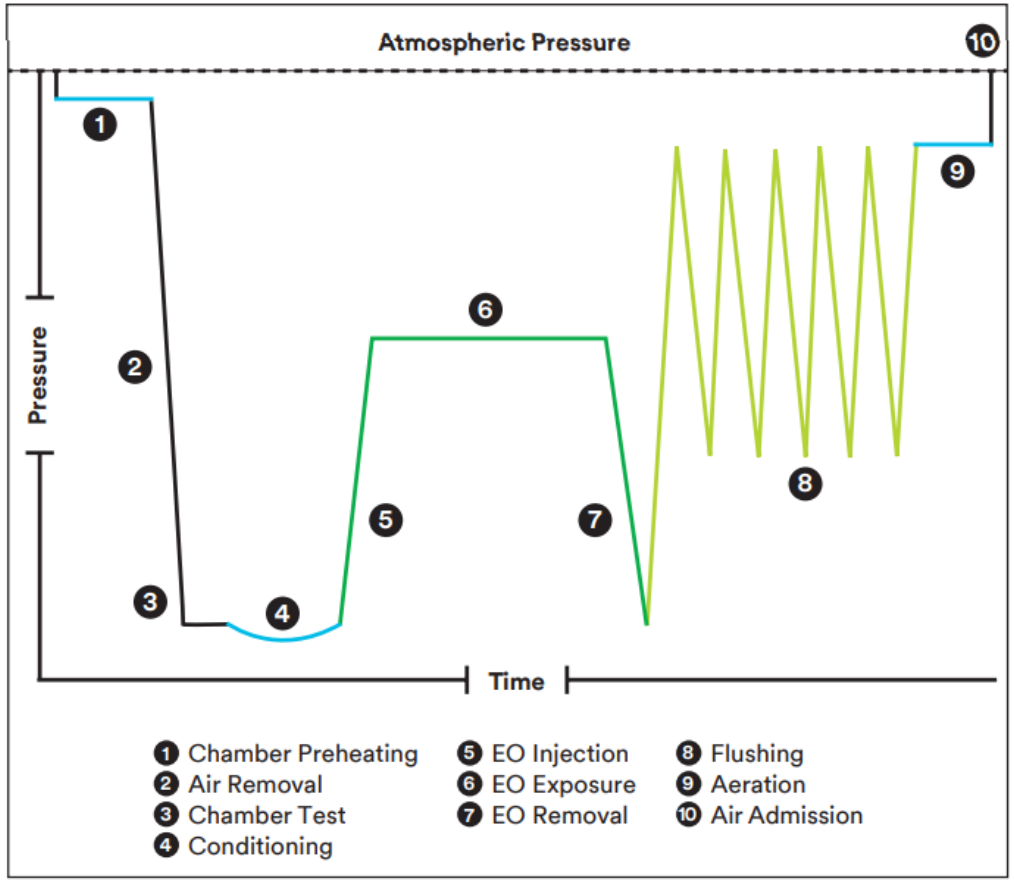
Cont. Medtronic's Operations

- As of 2022, the facility has around 1,600 employees.
- 10 employees work at the sterilization areas (2 shifts of 8 hours). The facility offers annual training and medical surveillance. Only personnel on these training and medical surveillance program can access the sterilization areas.
- The sterilization areas are equipped with EtO monitoring equipment and alarm system.
- 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.

General 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 area 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.

Medtronic's 3M™ Sterilization Process



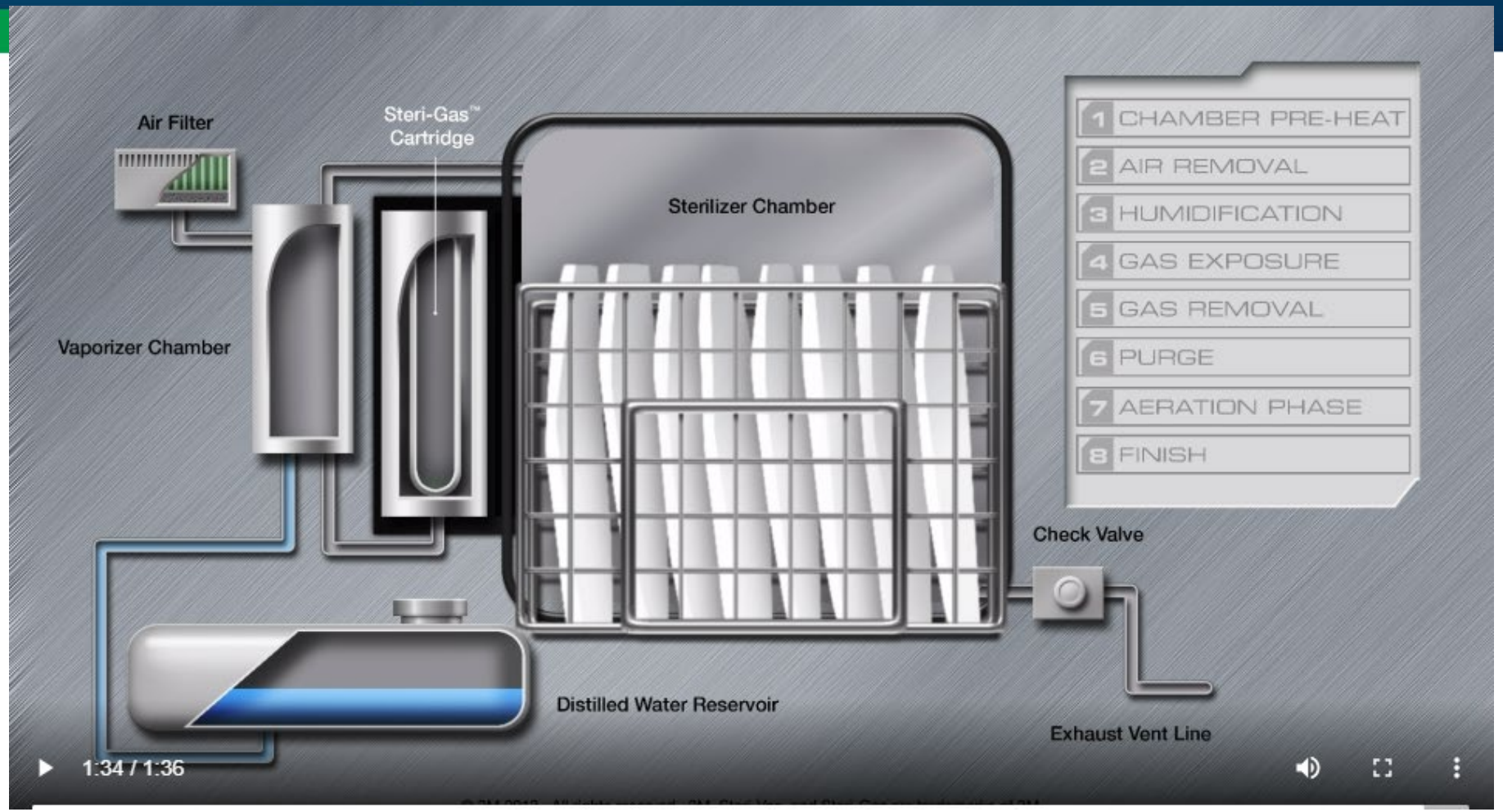
- The product basket is loaded to the sterilizer and walls are heated to the selected temperature, placed under negative pressure to remove air from the chamber, and water is vaporized to humidify the load.
- EtO is injected and product exposed in accordance to its sterilization recipe. The chamber remains under negative pressure (vacuum) throughout the gas exposure.
- After completion of the gas exposure phase, the chamber is cleared of gas with a vacuum and conveyed to an abator system.
- The chamber is repeatedly flushed and filled with filtered air and cleared by a vacuum and conveyed to an abator system.
- Temperature, air flow and vacuum is maintained to complete the aeration phase.
- The product basket is removed and placed on the sterilizer aerator for further time established by its recipe. Emissions from the aerator are not required to be controlled and are currently emitted to the atmosphere.

Source: https://multimedia.3m.com/mws/media/1427940O/3m-steri-vac-sterilizer-gs-series-safety-summary.pdf

Cont. Medtronic's 3M™ Sterilization Process

3M™ Process Animation

https://multimedia.3m.com/mws/media/880149O/3m-steri-vac-sterilizer-animation.mp4



Medtronic's Inc. Process Description

- 23 3M™ Steri-Vac Sterilizer/Aerator units in three different areas. Two (2) areas in the North Building (total of 17 sterilizers) and one (1) in the South Building (6 sterilizers).
- EtO emissions from sterilizer are treated by abatement equipment with +99% removal efficiency known as Abator System. Each sterilizer has its own abator to treat its EtO emissions. The abator system uses a catalytic material and a heat producing reaction to convert EtO to carbon dioxide and water.
- Precise usage of EtO using single dose cartridge of 127 grams per cycle. No EtO fugitive emissions related to EtO vaporization and other components such as valves and fittings.
- Each sterilizer has an aerator chamber where product basket is loaded to complete the aeration requirements of the product. The emissions from the sterilization chamber are conveyed to the abator system and the aerator emissions are emitted to the atmosphere, as currently allowed by the applicable federal regulation.

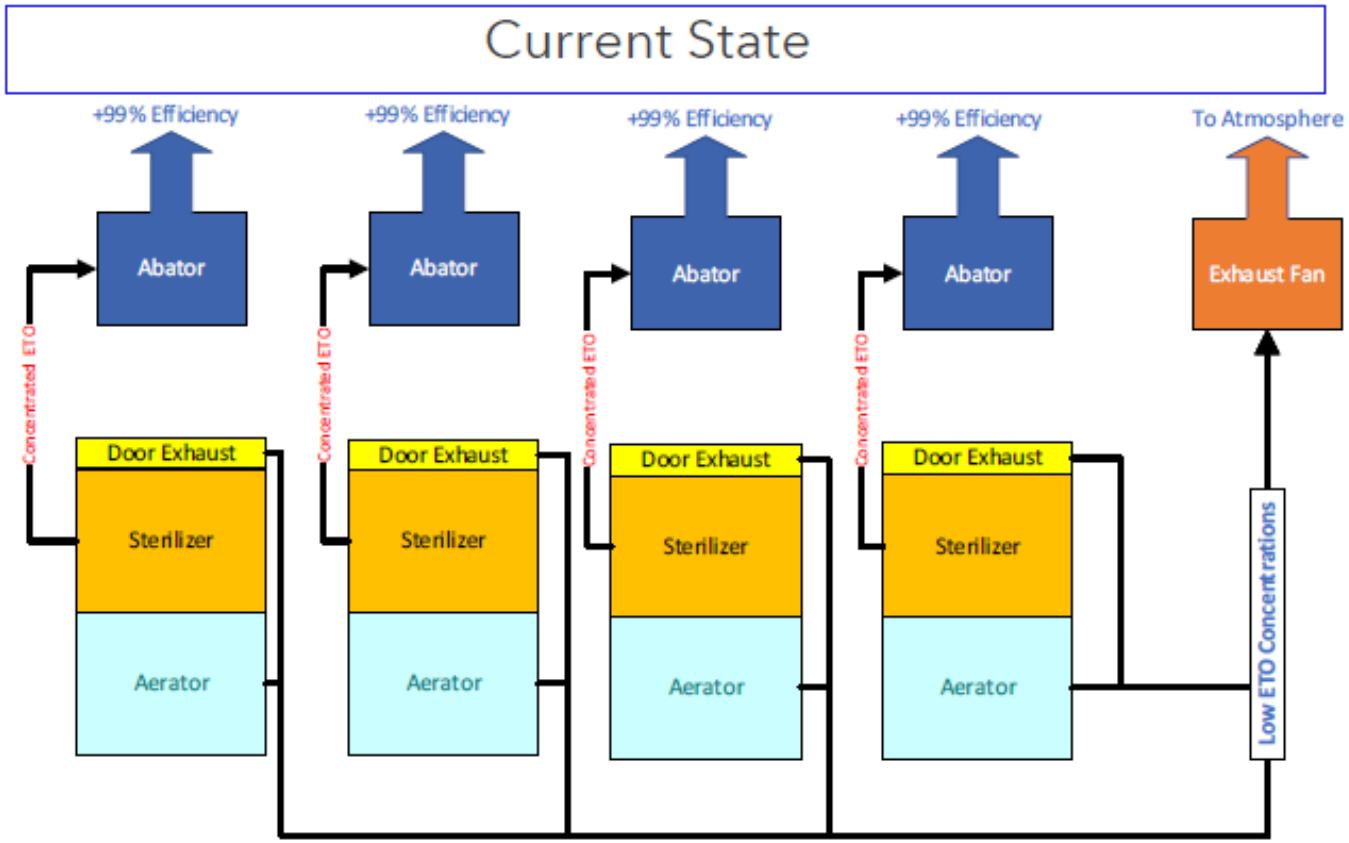
Medtronic's Sterilization Processes

3M(TM) Steri-Gas(TM) Gas Cartridges

3M(TM) Steri-Vac(TM) Sterilizer/Aerator GSX Series, Model GS8X

Sources: Steri-Vac™ - https://multimedia.3m.com/mws/media/1057877O/3m-steri-vac-ethylene-oxide-sterilization-systems.pdf
Abator System - https://multimedia.3m.com/mws/media/630760O/eo-abator-model-50-system-brochure.pdf
Steri-Gas™ - https://www.3m.com/3M/en_US/p/d/v000212377/

Medtronic's EtO Treatment

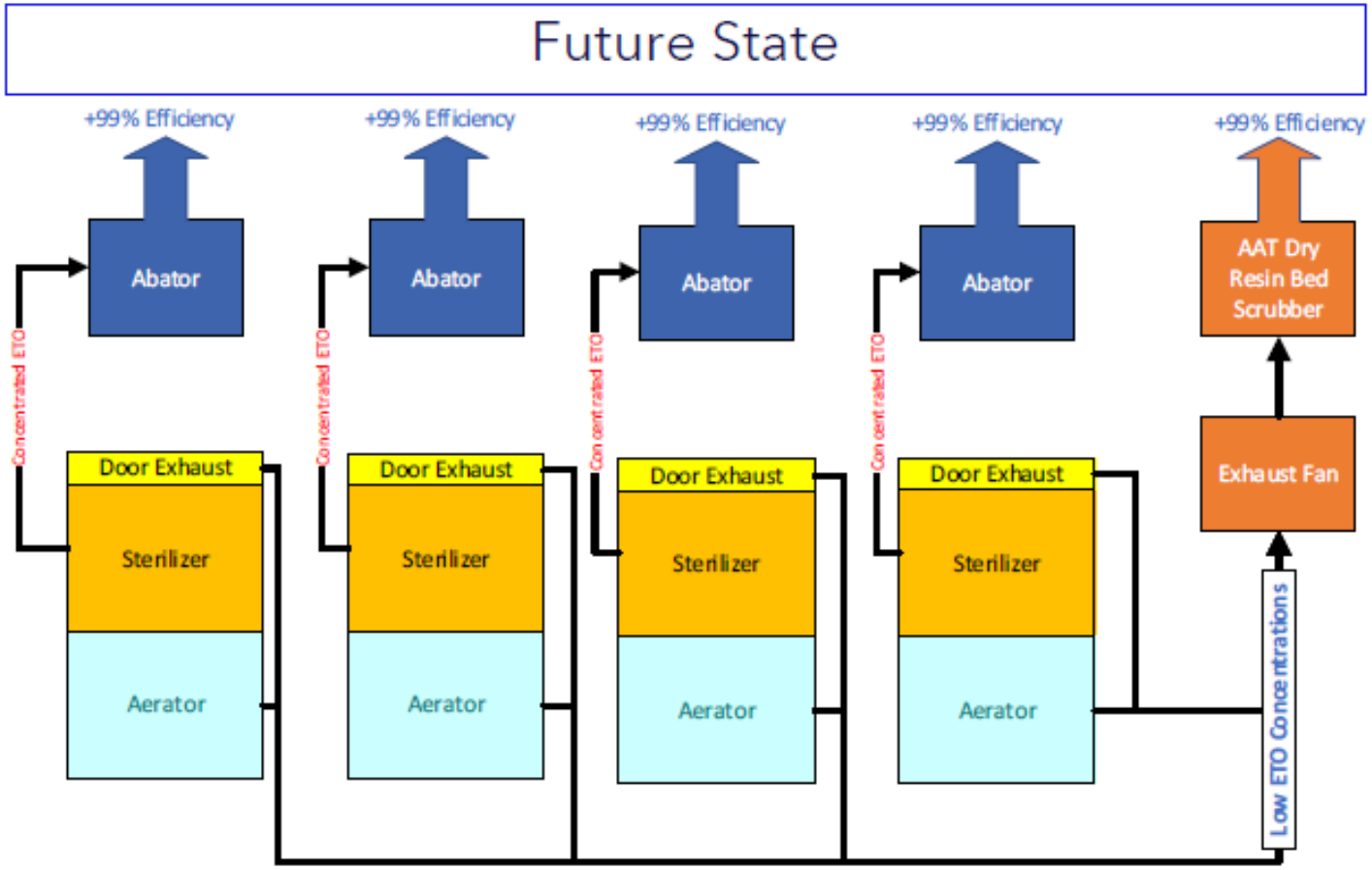


Source: Medtronic Inc.

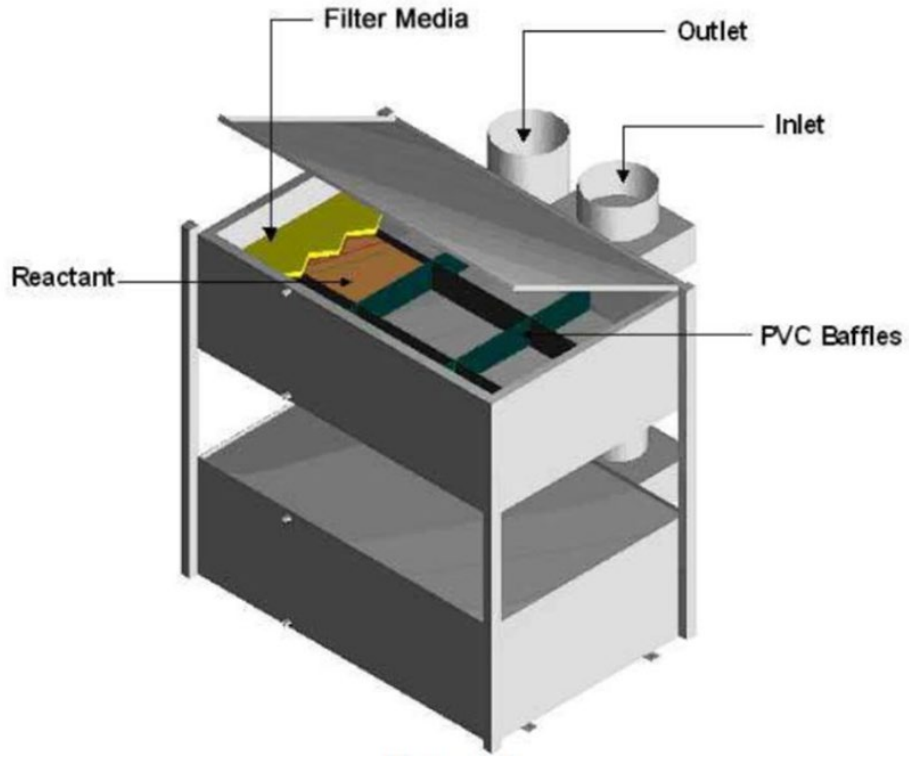
Work in Progress

- The company applied for an air emission source construction and operating permit to install control devices to treat the EtO emissions from the aeration phase of their sterilization cycle. A total of 23 control devices (dry bed reactors) will be installed, one per each sterilizer/aerator unit.
- DNER issued an operating permit for the project on December 14, 2022.
- The company already started the construction phase of the project, and the **target completion date is May 2023.**

Proposed EtO Control Configuration

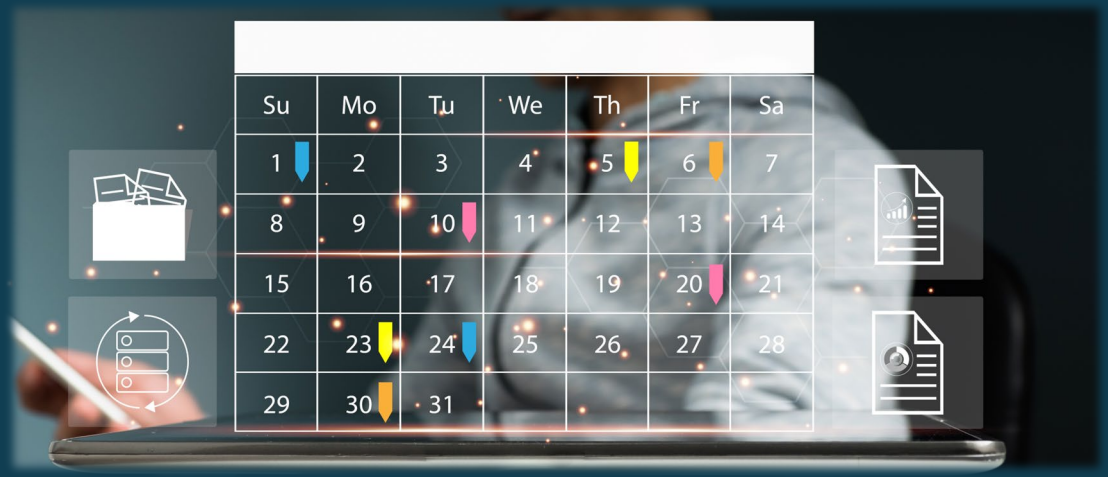


Dry Resin Bed Scrubber



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 examples of facilities that have upgraded their EtO treatment configurations to address the issue before a new regulation is proposed and finalized.



Timeline

- New regulation to be proposed in the upcoming months.
- 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

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 2023
- 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.

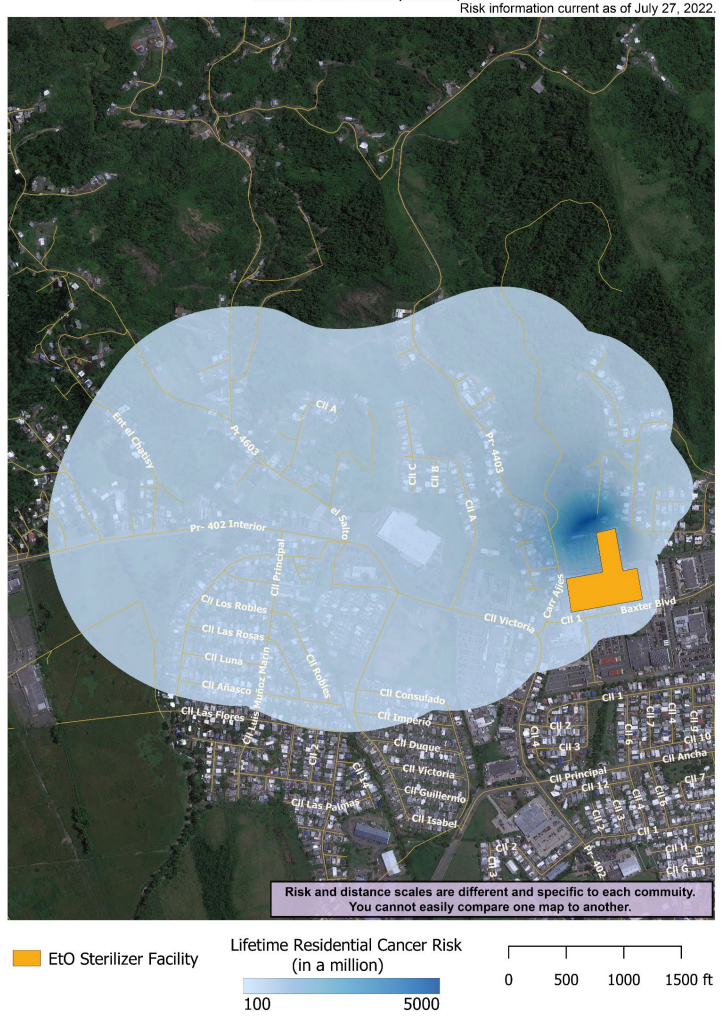
Next Steps

- New regulation proposal.
- EPA continuing to work with Medtronic 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

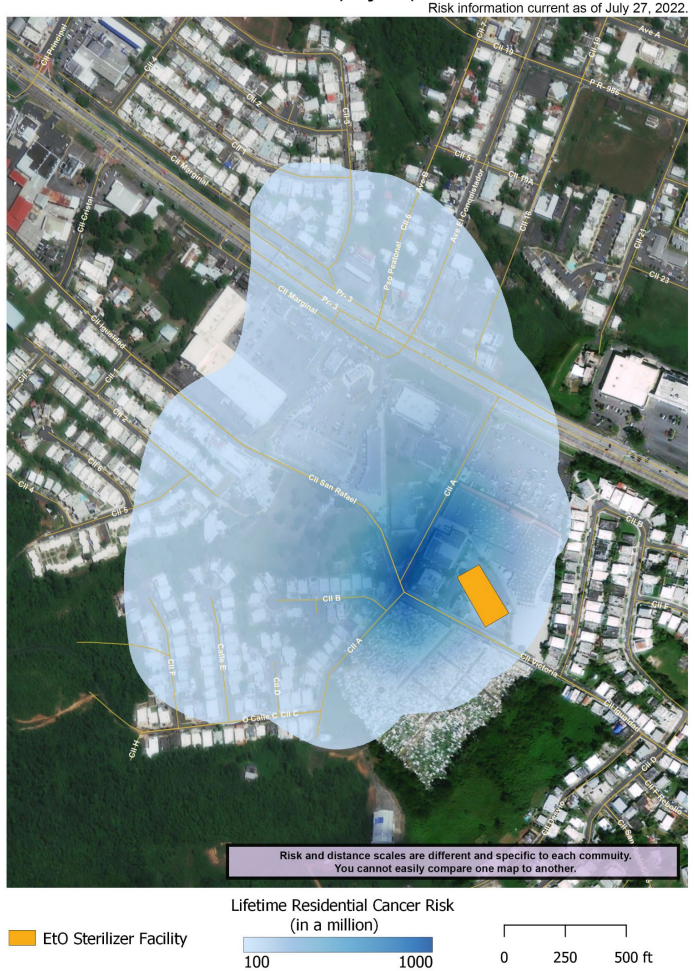
Thank You!

Are there Other Sterilizers in Puerto Rico?

Añasco



Fajardo



Salinas