

Introduction to Sterigenics

ATLANTA, GA

OCTOBER 2019

Sterigenics provides outsourced sterilization and decontamination services to safeguard patients and consumers



22 Facilities

18 Facilities

6 Facilities

Through 46 facilities in 13 countries we ensure medical devices, pharmaceutical products, and food are safe for people to use and consume

The method of sterilization is determined by the customer based on the materials and design of the product being sterilized and FDA Sterility requirements, NOT by Sterigenics



30 Employees Dedicated to Safely Sterilizing Vital Medical Products

Performing sterilization operations at current location since the early 1970s Ethylene Oxide (EO) sterilization services primarily to medical customers

Operates in compliance with and outperforms permits and regulations

More than 1 Million Devices Sterilized Each Day









15,000 Drapes /gowns

10,000 Trocar Devices









"...we see that in residential areas surrounding the facility, the emissions from Sterigenics are within the range that the Clean Air Act directs us to when evaluating safety." Mary Walker, EPA Region 4 (August 19, 2019) "...when we looked at zip codes...adjacent to the facility...we actually did not see...any evidence of increased incidents of cancers ...that have known to be associated with ethylene oxide."
Cherie Drenzek, Georgia Department of Public Health (August 19, 2019)



- <u>Complex Regulatory Landscape</u>. Regulatory requirements impact all aspects of our business.
- <u>Significant Regulatory Oversight</u>. Sterigenics must operate "audit ready" at all times.
- <u>Regulatory Requirements Are Constantly Changing</u>. Existing regulations are continuing to tighten and new regulatory requirements are introduced regularly.







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Medicines & Healthcare products Regulatory Agency







ENVIRONMENTAL PROTECTION DIVISION



Typical EO Facility



Products remain on the pallets they were delivered on and in the manufacturer's original boxes and packaging throughout the sterilization process.



Control Systems Go Beyond Regulatory Requirements for EO Emissions



Sterigenics Atlanta facility outperforms regulatory requirements and is poised to do even more



- Agreed to install the best available technology to further reduce EO emissions beyond already safe levels
 - Agreement followed months of discussions with the Georgia EPD
- Sterigenics suspended operations in order to expedite the installation of the new technology.
 - 1. Connecting the vacuum pump emissions to a second existing emission control system (for a double scrub)
 - 2. Installing a negative pressure system that captures all fugitive emissions
 - 3. Sealing off existing ventilation points within the facility
- Construction is near completion and the facility is near ready to begin the testing protocol developed by EPD.
- The project remains on hold currently as we attempt to resolve issues with Cobb County.

With these improvements, the facility will be state-of-the-art among all other sterilization facilities in the U.S. capturing > 99.99% of EO emissions, including 100% of indoor fugitive emissions.



Building On a Record of Continuous Improvement in Georgia

• Sterigenics Atlanta has consistently outperformed regulatory standards, and voluntarily reduced emissions by 90%, one year prior to the risk assessment from the EPA



* Considers additional emissions from voluntary backvent controls



• EO is primarily used in industrial manufacturing operations to make other chemicals. Ethylene oxide and its derivatives help make a variety of products we use every day:



- EO exists naturally in the air all around us
 - Natural sources of EO include the human body's normal metabolic process, plants and microbes
 - Everyday sources of EO include vehicle exhaust, natural gas combustion, home furnaces, gas grills and agricultural chemicals

Less than one half of one percent of the EO used in the U.S. is in the sterilization of medical products



 A range of sources contribute to background levels of EO in communities across the country



Detection levels based on initial air monitoring samples in Cobb County "did not reveal anything unusual."

(1) Samples collected 12-October to 23-October, 2018 and 12-November to 20-November, 2018.

(2) Based on testing conducted by the Colorado Department of Public Health & Environment, December 2018.

(3) Based on data from the American Chemistry Council.

(4) Georgia EPD data released on August 16, 2019 based on June 14, 2019 test.



Summary

- Sterigenics operates safely and our facility does not pose a risk to public health.
- The Company has consistently outperformed regulatory requirements and the current enhancements go even further.
 - The EPD's recent investigation reaffirms compliance with applicable rules.
 - EO releases for past five years have been less than the reporting level for a single release.
- Enhancements are state-of-the-art and will capture >99.99% of emissions, including 100% of indoor fugitive emissions, representing the highest control standard in the country.
- Sterigenics has shown cooperation and good faith while working through this matter in Georgia.
 - Proactively worked with EPD to develop emission control enhancements in advance of any federal or state requirement to do so.
 - Entered into consent order with State to implement improvements.
 - Reported potential releases to EPD even when below reportable limit and will share with local and state officials going forward.
 - Expedited installation of new controls by temporarily suspending operations.
- The Atlanta facility plays a vital role in the U.S. healthcare system; further delay in resuming operations places patients and businesses at risk.

Sterigenics is committed to the safety of our employees, the communities in which we operate and the patients we serve.

