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Attorneys for Respondent
STERIGENICS US, LLC

BEFORE THE BOARD OF THE

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT, Petitioner, v. STERIGENICS US, LLC [Facility ID Nos. 126197 and 126191], Respondent.	Case No. 6225-1 **NOTICE OF INTENT TO INTRODUCE DOCUMENTS AS EHXIBITS** Date: August 9, 2022 Time: 9:00 a.m. Place: 21865 Copley Drive Diamond Bar, CA 91765

RESPONDENT hereby offers notice of intent to introduce witness declarations, copies of which are attached, as exhibits on the hearing of the Petition for Order for Abatement [Stipulated] in the above-captioned matter. The declarants are expected to be additionally available to be called as witnesses and examined or cross-examined on any matter relevant to the issues. This voluntary filing merely provides courtesy notice and the possibility of advance review of written materials that Petitioner intends to introduce as evidence at hearing.

Dated: August 4, 2022

MAYA LOPEZ GRASSE
ALSTON & BIRD LLP

Maya Lopez Grasse
Attorney for Respondent
STERIGENICS US, LLC

CERTIFICATE OF SERVICE

I hereby certify that on August 4, 2022, I emailed Respondent's Notice of Intent to Introduce Documents as Exhibits in Case No.6225-1 to the Clerk of the South Coast AQMD Hearing Board with accompanying electronic service by email on counsel for Petitioner, Mr. Nicholas A. Sanchez at nsanchez@aqmd.gov, Mr. Brian Tomasovic at btomasovic@aqmd.gov and Ms. Josephine Lee at jlee@aqmd.gov. Petitioner has agreed to accept electronic service by email of documents as acknowledged in an email by Petitioner's counsel to the Clerk of the Board dated July 15, 2022.

Dated: August 4, 2022

Maya Lopez Grasse

DECLARATION OF AARON DEMENT

I, Aaron DeMent, declare:

1. I am Aaron DeMent, Vice President of Technological Services at Sterigenics U.S., LLC ("Sterigenics"). Prior to this current role I spent four years as the Vice President of Global Quality Assurance at Sterigenics. The matters set forth below are within my personal knowledge and if called upon as a witness, I could and would testify competently as to each of them.

2. In my role as Vice President of Technological Services, I am responsible for managing applied sterilization technologies for sterilization globally.

3. I am familiar with the Petition for Order for Abatement and the conditions which have been stipulated to as part of the proposed Order in this proceeding. As Vice President of Technological Services, I will be overseeing compliance with FDA regulations as it relates to the validation of medical device sterilization and change control.

4. The Food and Drug Administration ("FDA") regularly inspects Sterigenics' facilities, including the Vernon Facilities, given the importance of sterilization as a final step in the production and preparation of medical and surgical products in the United States.

5. Ethylene oxide ("EtO"), a gas, can come from naturally occurring sources, such as plants, microbes and ripening fruits. EtO can also come from other common sources, such as gas cooktops, barbecue grills, and ordinary combustion engines found in vehicles and household equipment like lawn mowers. Additionally, ethylene oxide is internally produced by the human body as part of its normal metabolic process.

6. Ethylene oxide is also a heavily regulated chemical. As a chemical, EtO is critical to the healthcare industry, as it sterilizes over 50% of the sterilized medical devices and the vast majority of the surgical kits used in patient procedures in the United States. According to the FDA, ethylene oxide sterilizes over 20 billion medical devices each year in the United States alone. (See FDA statement included here as **Attachment Dement-1**.)

7. For the majority of single-use medical devices, complex implantable devices, and surgical kits, ethylene oxide sterilization is widely used because it is the only practical, FDA-approved sterilization method available. While heat and radiation can sometimes be used for

sterilization, those processes degrade plastics and other synthetic materials that are common components of many medical devices and surgical kits, including hypodermic needles, catheters and many other common hospital and operating room equipment. For heat- and irradiation-sensitive devices, no currently available sterilization method which can penetrate the product to the extent EtO can has been accepted and approved as a practical replacement for ethylene oxide. The other commonly available gas sterilization methods such as VHP and NO2 are essentially surface sterilants and cannot penetrate most product packaging or products requiring sterilization beyond the outer surfaces. A statement just issued by the FDA on August 3, 2022 states that "other methods of sterilization cannot currently replace the use of EtO for many devices. To that end, we are equally concerned about the potential impact of shortages of sterilized medical devices that would result from disruptions in commercial sterilizer facility operations." (See full statement included here as **Attachment Dement-1**.)

8. The FDA regulates the sterilization processes that are employed to sterilize a product so that it is safe for use in patients, including those processes that use EtO. Because EtO can be absorbed by many medical products, all sterilized products must undergo aeration to remove residual ethylene oxide from the products at the end of the sterilization process.

9. The FDA recognizes a voluntary consensus standard, ISO 10993-7:2008(R)2012 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm) regarding allowable limits for residual EtO on devices after sterilization, depending on how the device is used, how often, and how long to pose a minimal risk to patients in normal product use. To remain compliant with the consensus standard an appropriate amount of aeration is validated to ensure sterilized products remain safe for use in clinical procedures or for implantation into the human body.

10. Among the many aspects of the sterilization process that the FDA reviews for medical devices sterilized by EtO is the maximum levels of sterilant residuals that remain on the device after sterilization. The maximum amount of sterilant residuals allowed are based on risk assessments. Sterile product can contain small amounts of EtO even after it has met its residual requirements after the process and after the validated amount of aeration has been completed. This is consistent with health-protective FDA requirements standards. Per the FDA, two voluntary

consensus standards (ISO 11135:2014 and ISO 10993-7:2008(R)2012) describe how to develop, validate, and control EtO sterilization processes for medical devices and the acceptable levels of residual EtO left on a device after it has undergone EtO sterilization. Note that while these are called "voluntary" consensus standards, in practice they are almost always conformed with by manufacturers and used by regulators as the current Good Manufacturing Practice. As FDA has explained, "these standards help ensure levels of ethylene oxide on medical devices [post-sterilization]are within safe limits . . . ." See FDA Website, Ethylene Oxide Sterilization for Medical Devices, https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxidesterilization-medical-devices#epa, at 1–2; and FDA Guidance, Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices labeled as Sterile (Jan. 21, 2016), at 3, available at https://www.fda.gov/media /74445/download.

11. Medical device manufacturers are responsible for and dictate the sterilization process to be utilized for their medical devices. As a contract sterilizer for those manufacturers, Sterigenics must comply with the validated sterilization process set forth in its customer contracts and cannot deviate from that process under federal law. The validation testing, compliant with the FDA recognized consensus standards, is required to support the sterilization process and is reviewed either upon submission for product approval, or can be reviewed as part of routine FDA inspections of either Sterigenics or its customer. As required by regulations, the sterilization process for a particular medical device is an aspect of the sterile device's overall design and validated manufacturing process which only the medical device manufacturer has the authority to change. The FDA's review of the sterilization validation protocol for EtO includes the configuration of the product on the pallet, as well as the product and pallet packaging designs. When the medical device manufacturer changes the sterilization method for a particular device, the FDA cautions that changes to an EtO sterilization process may leave increased residuals on the device surface or unintentionally affect device performance and will require a new 510(k) submission. (See FDA Guidance, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, https://www.fda.gov/media/99812/download, at 9, 27.)

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12. Once validated, every part of the process is subject to change control under quality system regulations. Changes must be assessed for risk, a determination of the extent of validation required completed, and testing executed as required. All change notifications must be submitted to the FDA which is then able to review the associated change control and validation work either as part of the notification or during customer or Sterigenics audits.

13. The Vernon Facilities are subject to stringent FDA requirements including compliance to Good Manufacturing Practices per the Quality System Regulation (QSR – 21 CFR Part 820). The QSR describes the quality system requirements that must be followed to ensure the product is manufactured in a controlled way, with all changes and nonconformances to the validated process detected and addressed. As part of its Good Manufacturing Practices regulations, the FDA requires that medical devices and equipment be sterilized pursuant to exacting protocols that must first be rigorously tested and validated.

14. These FDA-required validation processes are expensive and can take anywhere from four to nine months to complete. The cost of that validation process is borne by the customer, and the process validation is specific to the particular sterilization facility that will perform the sterilization processing, and the specific sterilization chamber within that facility that will be used.

15. Once validation activities are completed, a change notice must be submitted to the FDA and any other appropriate global regulator. Due to regulatory review times, our current estimate of time for a full cycle of validation and regulatory review is approximately 18 months on average. It should be noted that while FDA review times can be relatively fast, most customers provide products on a global basis and review times in jurisdictions like the EU and China are quite long compared to the FDA. Customers cannot easily split their processing for US bound and "Rest of World" bound products, and in our experience have not typically done that. This results in the longest regulatory review time being the gating factor in how quickly a new sterilization process can be brought into use.

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16. Validation, once complete, cannot be transferred to another facility, or even to another sterilization chamber at the same facility without further validation work. If a customer wants to move its sterilization processing to a different facility, the four-to-nine-month validation process (and potentially months-longer regulatory review component) must be performed all over again or an equivalency demonstration must be made.

17. Because the contract sterilization industry is capacity constrained and transferring sterilization processing of a particular process is not a simple matter, even a temporary shutdown of the Vernon Facilities could contribute to a significant shortage in sterilized medical equipment in California and throughout the country.

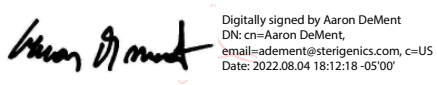
18. Changes to Sterigenics' processes can implicate FDA patient safety concerns, and those changes cannot be made if they would threaten patient safety.

19. The sterilization market has little to no surge capacity due to ongoing constraints on facilities. Any available sterilization capacity that does exist is typically available in small increments in second or third tier contract sterilization facilities and that limited availability may be insufficient if Sterigenics had to reduce its capacity.

20. The FDA maintains a webpage that provides updates and closely monitors the supply chain effects of closures and potential closures of certain facilities in the US and beyond that use ethylene oxide to sterilize medical devices prior to their use. (https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates .) The FDA has been and remains concerned about the future availability of sterile medical devices and the potential for medical device shortages that might impact patient care. This is because without ETO sterilization, infection risk associated with surgical procedures and other forms of medical care could be meaningfully increased. Included here as attachment **Dement-2** is a true and correct copy of an FDA presentation, published on the FDA website, illustrating the issues surrounding shortages with EtO-sterilized equipment in particular. One example used in this presentation is a shortage in recent years of sterilized pediatric tracheostomy tubes, resulting in potential infections at the insertion point.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct to my personal knowledge.

Executed this 4th day of August, 2022, in Oakbrook, Illinois.



Aaron DeMent

Dement-1

FDA STATEMENT

FDA Continues Efforts to Support Innovation in Medical Device Sterilization

For Immediate Release:

August 03, 2022

Statement From:

Jeffrey E. Shuren, MD, JD
Director - CDRH Offices: Office of the Center Director

The sterilization of medical devices is a vital process for helping to prevent serious infections. The U.S. Food and Drug Administration continually works to oversee sterilization methods for these devices to ensure they are effective and used in amounts that are safe for the patients and health care professionals who use them.

Ethylene oxide, or EtO, is a gas used during manufacturing processes to sterilize a variety of both medical and non-medical products. Use of ethylene oxide is a well-established and scientifically-proven method of preventing harmful microorganisms from reproducing and causing infections without degrading the product, unlike some other sterilization methods. It is currently the most commonly used method in the U.S. to sterilize medical devices and is widely used by medical device manufacturers and contract sterilizers worldwide.

In fact, more than 20 billion devices sold in the U.S. every year are sterilized with ethylene oxide, accounting for approximately 50% of devices that require sterilization. These devices range from wound dressings to more specialized devices, such as stents, as well as kits used in routine hospital procedures or surgeries that include multiple components made from different materials. Inadequate sterilization can lead to life-threatening infections in patients undergoing a wide range of medical procedures.

Today, the Environmental Protection Agency, which regulates industrial facilities to ensure unsafe emissions levels are not released into the environment, announced plans (https://www.epa.gov/newsreleases/epa-launches-community-engagement-efforts-new-ethylene-oxide-risk-information) to propose an air pollution rule later this year to address emissions of ethylene oxide at commercial sterilizers. As part of its proposal, the EPA has conducted a risk assessment which identified 23 commercial sterilizers in several states that were found to emit high levels of ethylene oxide.

The FDA shares concerns about the release of ethylene oxide at unsafe levels into the environment. We have been proactively working with medical device sterilizers to reduce the amount of EtO they use while still effectively sterilizing products to help ensure they meet the EPA's standards for ethylene oxide emission levels. In addition, we have been working with companies on the development of novel sterilization methods to replace the use of ethylene oxide.

Over the past few years, we have prioritized reducing the use of ethylene oxide and several actions to develop programs and initiatives to support innovation in medical device sterilization.

For example, we launched the EtO Sterilization Master File Pilot Program for premarket approval (PMA) holders of high-risk devices that enables certain changes between sterilization processes and facilities that reduces the amount of ethylene oxide concentrations used to sterilize medical devices without compromising safety and effectiveness. To date, 11 sites and 28 class III devices are included in the pilot. Multiple organizations have also expressed interest in our recently announced 510(k) master file pilot program, which exponentially expands the number of medical devices that are eligible for pilot participation.

The Innovation Challenges we launched have also shown encouraging progress with new strategies to reduce EtO emissions. Early observations suggest that some facilities have cut emissions ranging from 20-35%, with the potential to impact millions of devices. In general, manufacturers are targeting an ethylene oxide cycle concentration that is 11-66% less than the typical ethylene oxide concentration range. In addition to reducing emissions by lowering the EtO cycle concentration, Challenge participants are also exploring the potential for using alternative sterilization methods, such as vaporized hydrogen peroxide, supercritical carbon dioxide and nitrogen dioxide for certain types of medical devices. In some cases, device manufacturers are working collaboratively with contract sterilizers to validate new or different sterilization methods as well as the feasibility for scale up.

Collectively, these programs encourage new ways to sterilize medical devices that reduce the potential impact of ethylene oxide on the environment and public health, and we are committed to continuing to prioritize these efforts.

While signs of innovation are promising, other methods of sterilization cannot currently replace the use of EtO for many devices. To that end, we are equally concerned about the potential impact of shortages of sterilized medical devices that would result from disruptions in commercial sterilizer facility operations. Our supply chain program is ready to work with industry to help prevent and mitigate potential shortages due to reduced supply of certain ethylene oxide sterilized medical devices.

The FDA remains focused in our commitment to encourage novel ways to sterilize medical devices while reducing adverse impacts on the environment and public health and developing solutions to avoid potential shortages of devices that the American public relies upon.

Related Information

- Sterilization for Medical Devices (https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#MasterFile)
- Resilient Supply Chain Program for Medical Devices (https://www.fda.gov/about-fda/cdrh-offices/resilient-supply-chain-program-medical-devices)
- FDA Innovation Challenge 1: Identify New Sterilization Methods and Technologies (https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies)
- FDA Innovation Challenge 2: Reduce Ethylene Oxide Emissions (https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions)

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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888-INFO-FDA

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U.S. FOOD & DRUG ADMINISTRATION

Shortage of Ethylene Oxide Sterilized Medical Devices: CDRH's Role

Adam E. Saltman, M.D., Ph.D.

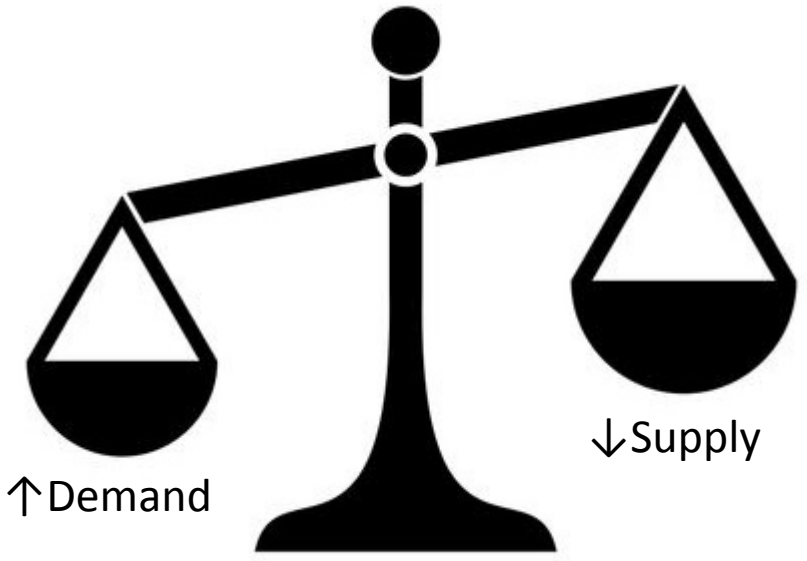
CDRH Medical Officer and OPEQ Shortages Lead

Topics

- Shortages 101: How and why shortages happen
- CDRH considerations and capabilities
  - Considerations and definitions
    - Shortage assessment
    - Medical necessity
    - Management plan
  - Capabilities and tools
    - Regulatory
    - Communication

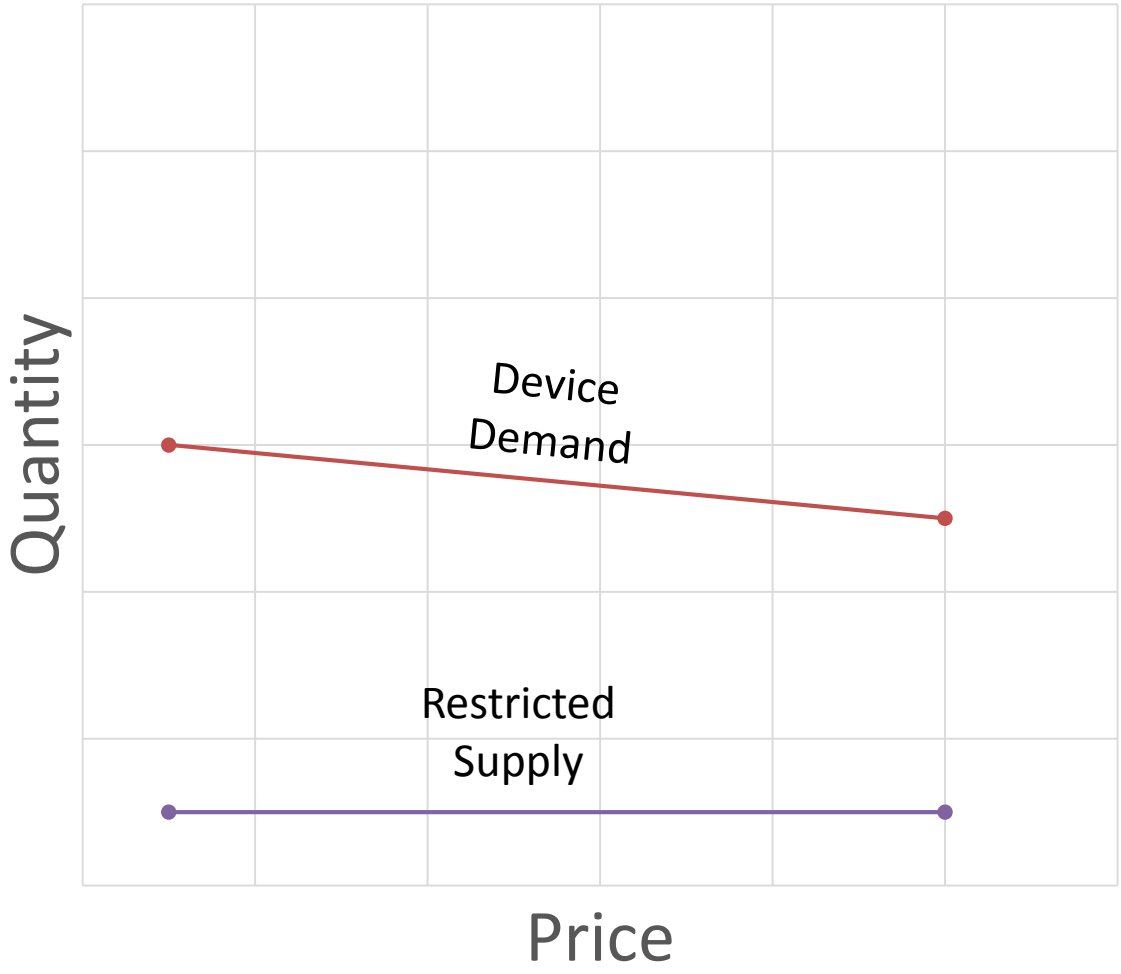
How and Why Shortages Happen

- There is no formal regulatory definition of a device shortage
- CDRH working definition
  - A *device shortage* is the period of time for which the demand or projected demand for a medical device within the United States will exceed the supply or projected supply of t



When Demand Exceeds Supply
The Medical Device Market Under Duress

Ideal Conditions



Medical Devices in Shortage

How and Why Shortages Happen

Increased Demand

- Expansion of user population
- Expansion of indications for use
- Expanded coverage determinations
- Evolving practice patterns

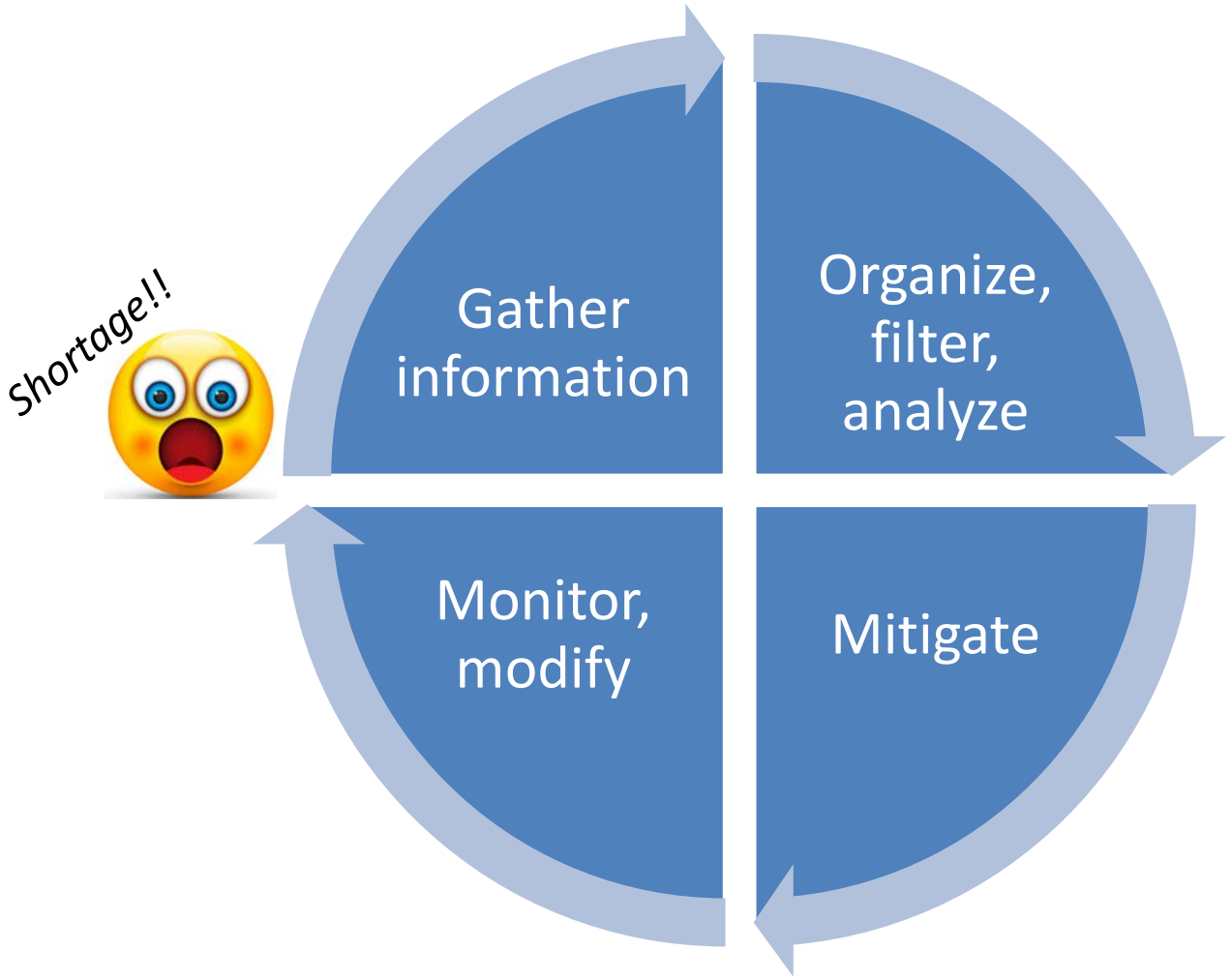
Decreased Supply

- Market removal (recall)
- Voluntary market departure
- Supply chain interruption
  - Loss of raw materials, sterilization
- Manufacturing interruption
  - Natural or man-made disasters

Shortage is usually temporary, as manufacturers increase production and new firms enter the market

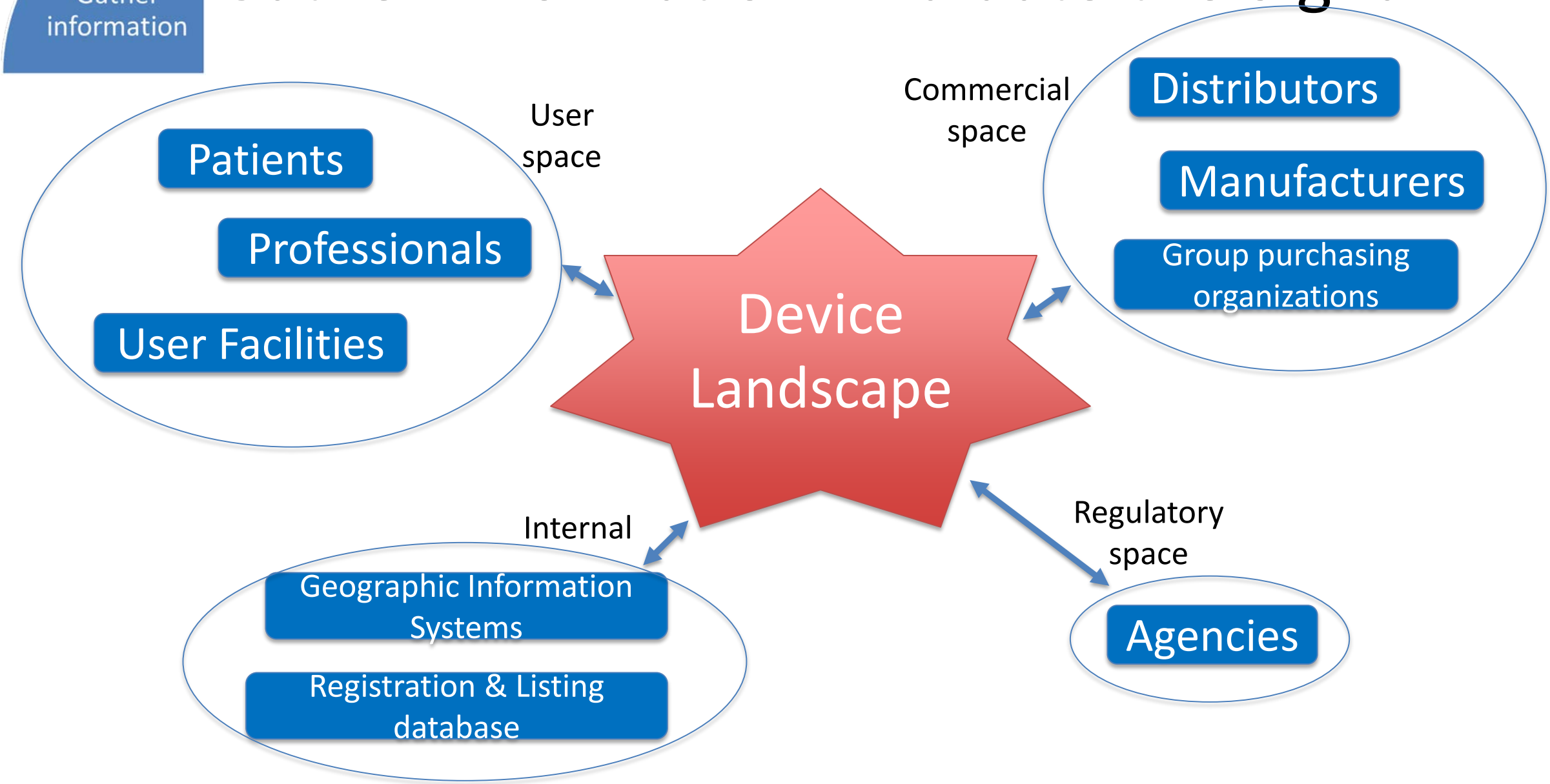
Shortage may or may not be permanent, depending upon economic, regulatory, and other factors

How Does CDRH Approach (Potential) Shortages?



Gather information

Gather Information: Evaluate the Signal



Organize, filter, analyze

Organize, Filter, Analyze

- Tools
  - Shortage assessment
  - Medical necessity determination
  - Shortage management plan

Organize, filter, analyze

Shortage Assessment Tool

- A formal evaluation of the likelihood that a medical device cannot be **obtained in sufficient amounts** should there be a market removal, withdrawal, or cessation in distribution.

- Mainly economic and logistical, not clinical

Organize, filter, analyze

Medical Necessity Determination Tool

- Any medical device used to diagnose, treat, or prevent a serious disease or medical condition **for which there is no other adequately available device or treatment** that CDRH clinical staff judge to be **an appropriate substitute**. Off-label uses and investigational devices can be considered essential. Patient inconvenience alone is an insufficient reason to classify a device product as essential.

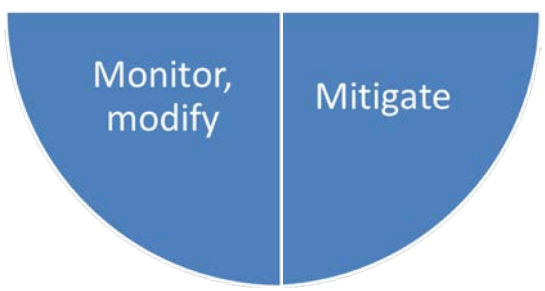
Organize, filter, analyze

The Medical Necessity of a Medical Device

- Are the devices within the product code used to diagnose, treat or prevent a **serious disease or medical condition**?
- If these devices do not have a diagnosis or treatment indication, is/are it/they used as **a tool** (e.g., core medical equipment) for **life sustaining conditions or patient care**?
- Are there **alternatives available** to diagnose, treat or prevent a serious disease or medical condition?
- Are these devices made by **one or a few manufacturers**?

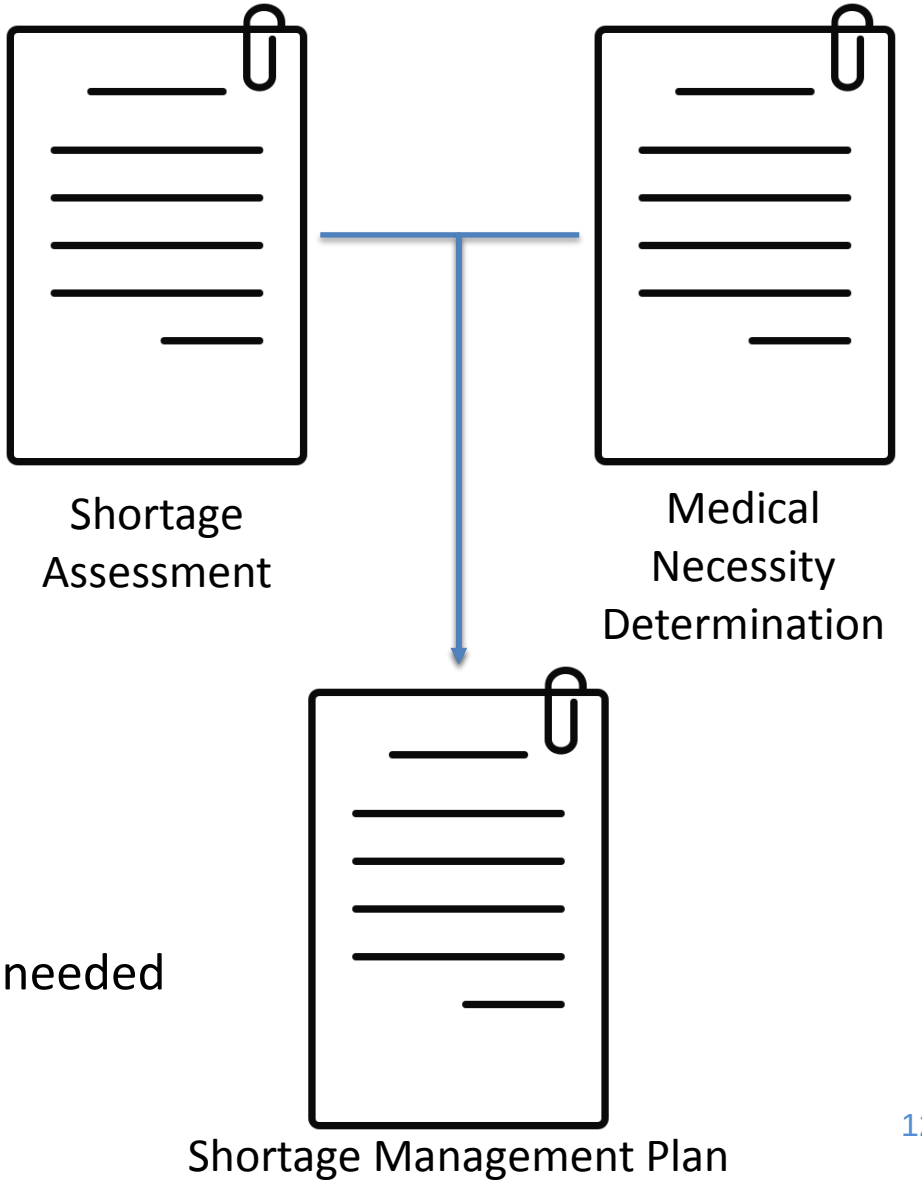
Not a linear process

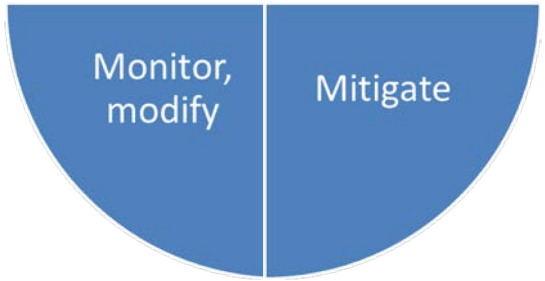
Not mutually exclusive



The Shortage Management Plan

- Background
  - Situational details
  - Previous experience
- Action details
  - Why the device is essential
  - Why access is being denied/allowed
    - Qualifications and conditions for continuing access/denial
  - Roles and responsibilities
    - FDA, manufacturer, other stakeholders
  - Mitigation plan
  - Monitoring and termination plan
    - Time, frequency, contact, other sources of information needed
  - Conditions for terminating the shortage state





Potential FDA Shortage Mitigation Actions

Regulatory tools

- Expedited reviews
  - Change requests for manufacturing sites, suppliers, etc.
  - Marketing applications for new, substitute products
- Discretion
  - Importation of unapproved/uncleared devices
  - Extension of expiration dates

Communication

- Direction and updates
  - Webpages
  - Public notifications
- Information exchange and messaging collaboration, involving
  - State and federal governmental agencies
  - Manufacturer/trade associations

  Health professional associations

Thank You!

Adam E. Saltman, M.D., Ph.D.
CDRH Medical Officer and OPEQ Shortages Lead

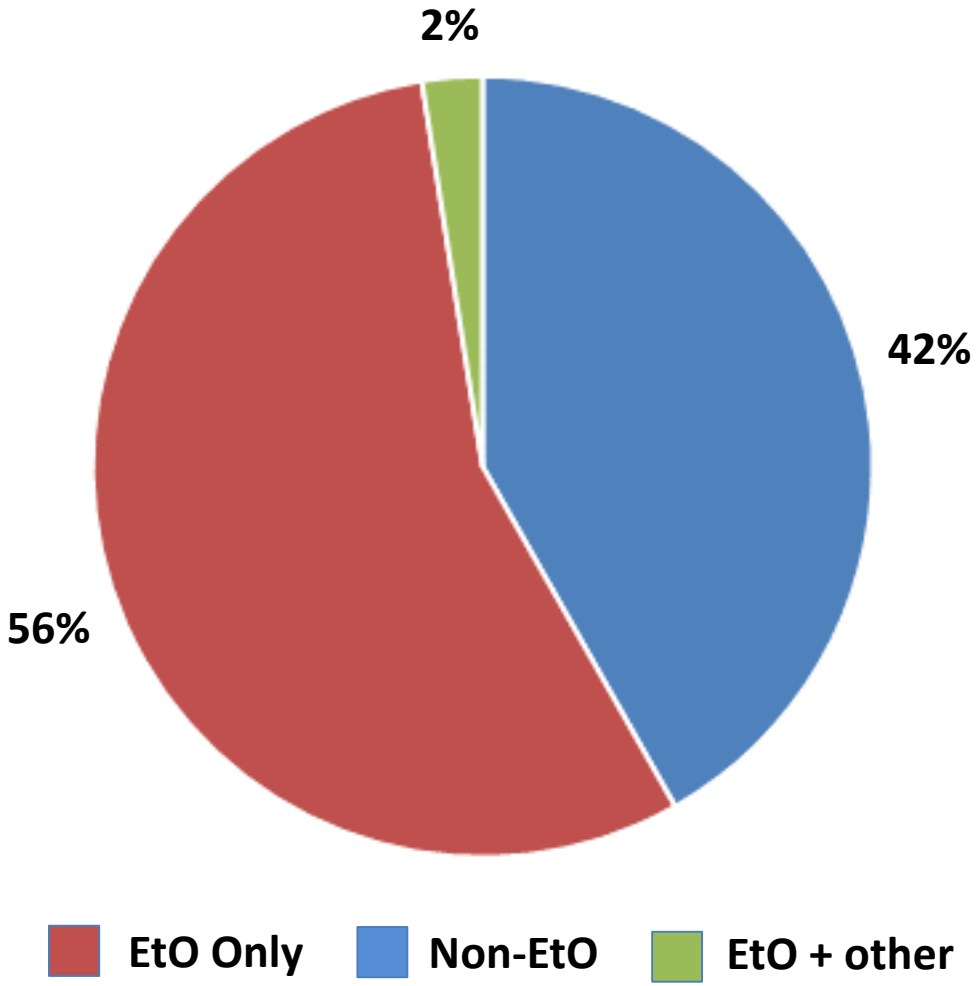
Shortage of Industrial Ethylene Oxide Sterilized Medical Devices: Clinical Impact

Karoll J. Cortez, MD., MHS., FACP

Office of Surgical and Infection Control Devices
Center for Devices and Radiological Health

Shortage of Industrial Ethylene Oxide Sterilized Medical Devices: Clinical Impact

Sterilization Modality for Devices Provided Sterile to the End User



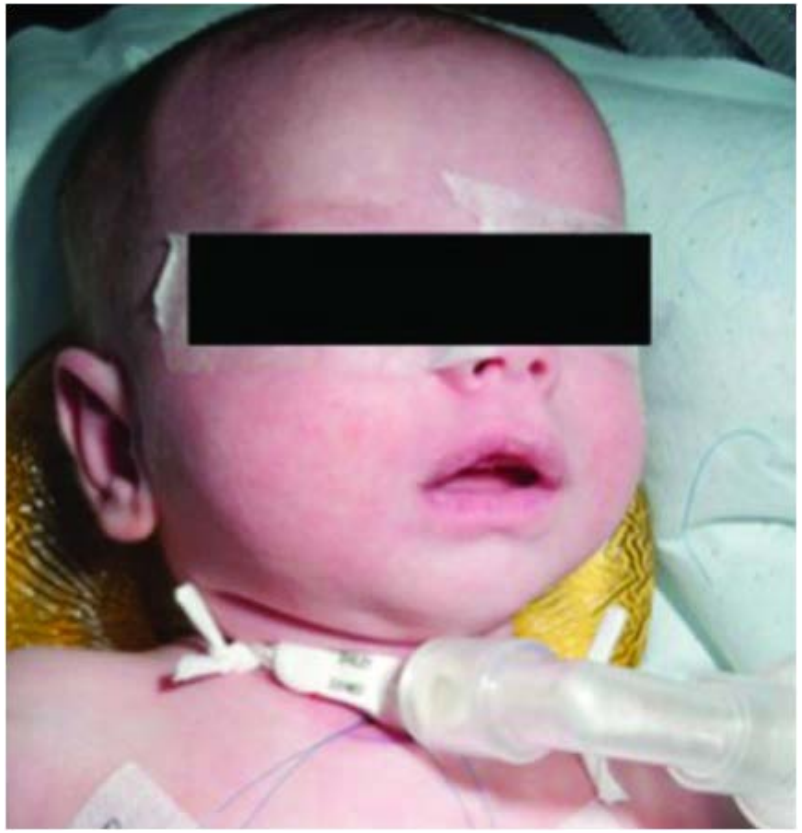
Life Saving / Sustaining Devices
Examples:

- Drug eluting stents
- Catheters
- Shunts
- Deep brain stimulator – components and accessories
- Intravascular infusion ports
- Pacemakers
- Renal hemodialysis sets
- Anesthesia masks and circuits
- Left ventricular assist devices

Daily Use Devices
Examples:

- Surgical kits
- Syringes
- Tubing sets/bloodlines
- Respirators
- Sutures

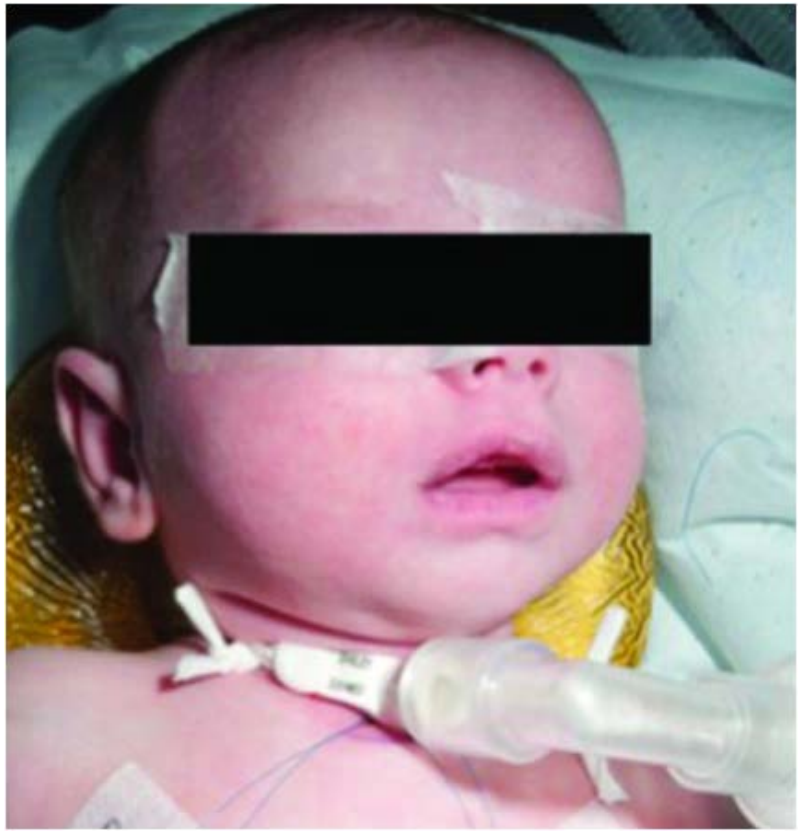
Shortage of Industrial Ethylene Oxide Sterilized Medical Devices: Clinical Impact



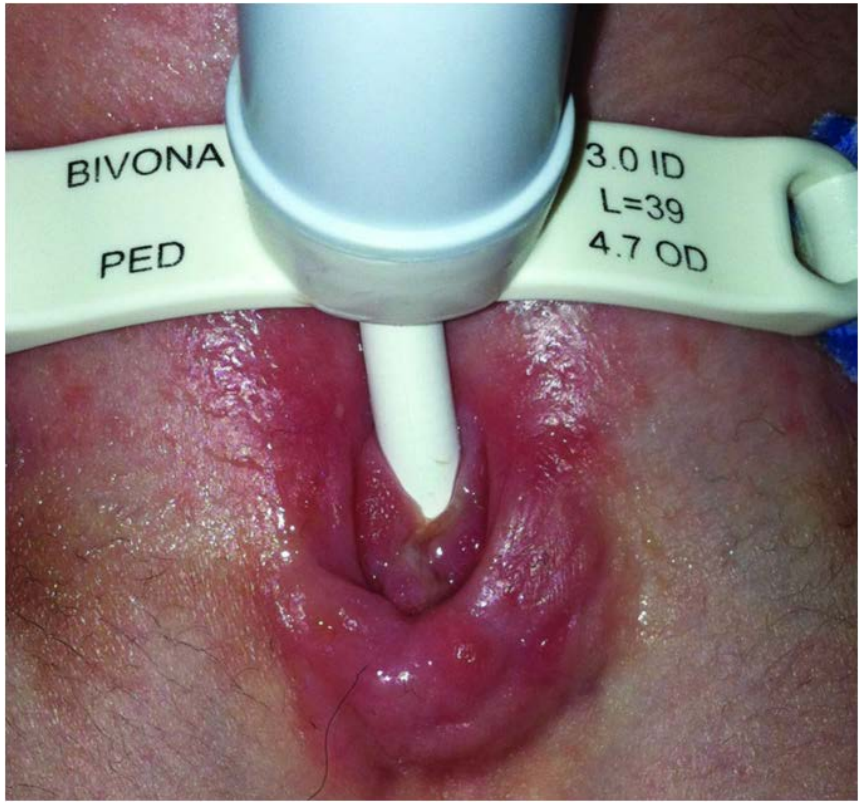
Flexible materials resist kinking and crushing ensuring safe ventilation and preventing damage to endotracheal tissue

Shortage of Industrial Ethylene Oxide Sterilized Medical Devices: Clinical Impact

Affected population



Tracheostomy tube in situ



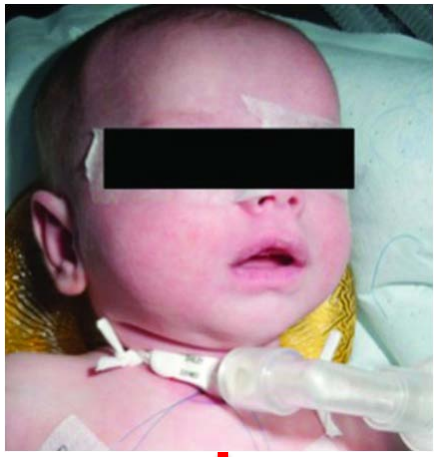
Peristomal granulation tissue in a 5-y-old child with chronic tracheostomy dependence.

Karen F Watters Respir Care 2017;62:799-825

Shortage of Industrial Ethylene Oxide Sterilized Medical Devices: Clinical Impact

FDA:
-Works with firm. Real-time review to expedite move sterilization to new EtO facility
-Public communication with frequent updates

Supply = Demand



Manufacturer:
-Works with FDA: generates data at new EtO facility for real-time review
-Communicates with FDA of status and plans

Hospital-Provider:
Shortage management Working groups
Safety of patient at risk
Planning to be prepared: Inventory, triaging,
Concerns: Delays in diagnosis and treatment->increase in morbimortality.

Shortage of Industrial Ethylene Oxide Sterilized Medical Devices: Clinical Impact

- Medical devices shortages can impact patient care.
- The severity varies depending on:
  - Device type and intended use.
  - Population impacted
  - Device misallocation and hoarding
  - Effectiveness of mitigation measures
- Prompt action can reduce or prevent adverse consequences
- However, if essential, and irreplaceable devices are unavailable, physicians can't make a diagnosis or provide life-saving therapeutic interventions.

Thank You!

Karoll J. Cortez, M.D., M.H.S.
CDRH Medical Officer

Overview of Industrial Ethylene Oxide Sterilization

Steve Elliott MSc., Scientific Reviewer, Biochemist
Sterility Devices Team
Office of Surgical and Infection Control Devices
Center for Devices and Radiological Health

Presentation Objectives

- Discussion of Industrial Ethylene Oxide (EtO) sterilization
  - Characteristics of EtO cycle
  - EtO sterilization cycle validation

Why EtO is used to sterilize Medical Devices?

- Broad material and device compatibility
  - Delicate devices sensitive to moisture or high temperatures
- Process flexibility
  - Adjustable parameters for load and device challenges
- Penetration through multiple layers of packaging.
  - Cartons and pallets vs. individual packages
- Large capacity facilities.
  - Small to very large (multiple pallet)
- Understood regulatory expectations
  - Long history of use and regulatory familiarity

Ethylene Oxide Sterilization Process Validation

- **Creation, definition and control of a Process that can provide sterile product.**
  - **Define Product:**
    - **What is it?**
    - **How is it packaged and arranged?**
    - **How contaminated is it?**
- Characterize Equipment & Define Sterilization Process
  - The equipment that will be used to sterilize the product and how will the process work
  - Explanation of the sterilization process and the equipment used to carry out the process.
  - Needs to be compatible with the intended product – device + packaging
- Validation:
  - Show the sterilization process works – can yield sterile product (process meets acceptable sterility assurance level)
  - Qualify sterilization site, equipment and process
    - Site, equipment and sterilization process all meet defined specification/tolerances.
    - Process can deliver acceptable lethality (kill/ destruction/deactivation of microorganisms)

Ethylene Oxide Sterilization Process Validation

- Creation, definition and control of a Process that can provide sterile product.
  - Define Product:
    - What is it?
    - How is it packaged and arranged?
    - How contaminated is it?
- **Characterize Equipment & Define Sterilization Process**
  - **The equipment that will be used to sterilize the product and how will the process work**
  - **Explanation of the sterilization process and the equipment used to carry out the process.**
  - **Needs to be compatible with the intended product – device + packaging**
- Validation:
  - Show the sterilization process works – can yield sterile product (process meets acceptable sterility assurance level)
  - Qualify sterilization site, equipment and process
    - Site, equipment and sterilization process all meet defined specification/tolerances.
    - Process can deliver acceptable lethality (kill/ destruction/deactivation of microorganisms)

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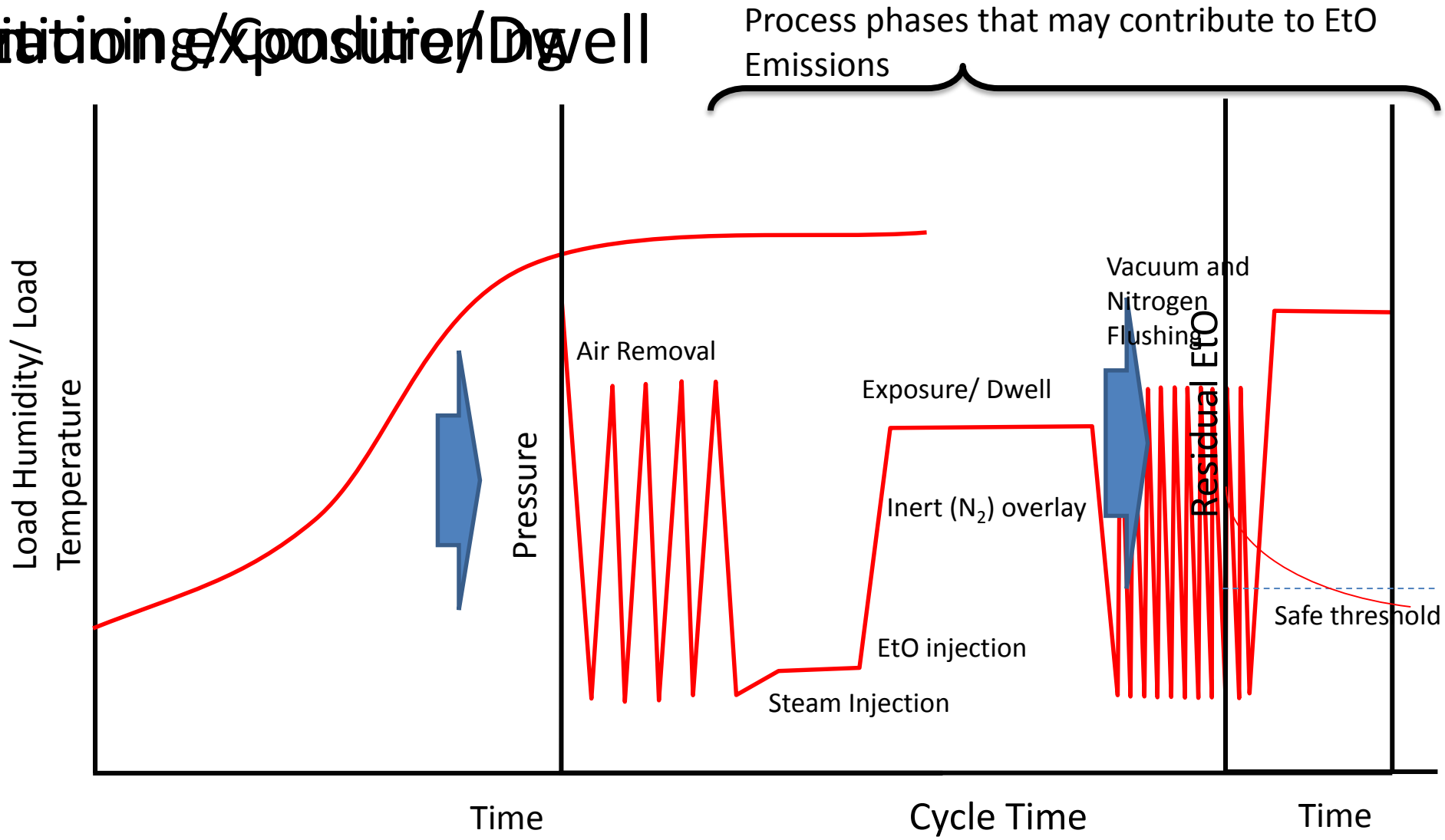
  - **Qualify sterilization site, equipment and process**
    - **Site, equipment and sterilization process all meet defined specification/tolerances.**
    - **Process can deliver acceptable lethality (kill/ destruction/deactivation of microorganisms)**

Ethylene Oxide Sterilization Process

- Pre-conditioning/Conditioning
- Sterilization/Exposure/Dwell
- Aeration/Degassing



Ethylene Oxide Process Validation Cont.

- Performance qualifications:
  - Microbiological – show sufficient lethality to extrapolate sterility assurance level for the process (10^{-6}, or probability of less than 1 in 1000000 positives after exposure to the intended sterilization cycle)
    - May be as high as conditions suitable to kill 1 million more spores after complete kill of organisms on validation loads.
    - Theoretical kill of up to 1 000 000 000 000 spores in worst case locations for a sterilization process.
  - Physical – show that the process parameters established to achieve sterilization in routine processing can consistently and reproducibly be met.

Ethylene Oxide Process Validation Cont.

- Routine monitoring and control
  - Systems to verify efficacy of routine processes
    - Parameter measurements
    - Biological indicators/ biological process challenge devices
    - Chemical indicators
  - Product Release
    - Decision making based on results from routine monitoring and control systems.
  - Maintaining Process effectiveness

Ethylene Oxide Process Validation Cont.

- Additional tests:
  - Sterilant residuals:
    - Ethylene Oxide and Ethylene Chlorohydrin residuals
  - Endotoxin/Pyrogen tests
  - Packaging
    - Transport/handling
    - Microbial barrier

Thank You!

Steve Elliott, Scientific Reviewer

Sterility Devices Team

Office of Surgical and Infection Control Devices

Center for Devices and Radiological Health

How FDA reviews sterilization information in premarket regulatory submissions for medical devices

Chris Dugard, Scientific Reviewer
Sterility Devices Team
Office of Surgical and Infection Control Devices
Center for Devices and Radiological Health

Industrial vs. Healthcare Sterilization

- Industrial sterilization
  - Typically used for terminally sterilized product
  - FDA regulates the process, not the sterilization facility
  - Inspections are conducted to ensure that process controls are in place and endpoints are reliably met
- Healthcare sterilization
  - Used for end-user sterilized or reusable devices in a healthcare setting
  - A healthcare sterilizer is considered a medical device

Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile

Guidance for Industry and Food and Drug Administration Staff

- 3 categories
  - Established Category A (Steam, EO, radiation, dry heat, etc.)
    - Well-established methods with a long history of safe and effective use
    - FDA-recognized consensus standards can be used in review
  - Established Category B (H_2O_2, ozone, flexible chamber systems, etc.)
    - No recognized consensus standards, but have been previously evaluated
  - Non-traditional/alternative Sterilization methods
    - Little to no published information or history with FDA

Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled

Review of Sterilization in a Premarket Submission

- Terminal sterilization is considered part of the “manufacturing process”
  - Manufacturing is not reviewed in a 510(k), summary level sterility information only
  - Manufacturing controls reviewed for Class III devices, full validation reports required
- Healthcare sterilization utilizes FDA-cleared sterilizers
  - Requires review of full test reports
  - Additional requirements in “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff” for reusable devices

Required Sterilization Information in a 510(k) for a Terminal Process

- Established A/B:
  - Description of the method
  - Description of sterilization chamber (if not rigid)
  - Sterilization site
  - Sterilant concentration and residuals (for chemical sterilants)
  - Sterilization dose (for radiation-based methods)
  - Validation method (e.g. half-cycle method) and standards followed
  - Sterility Assurance Level
  - Pyrogens (if applicable)
  - Description of sterile barrier and a summary of the methods used to support package integrity
- Non-traditional:
  - Full validation reports needed for review in addition to the information needed for established category A/B methods

Required Sterilization Information for Other Premarket Submissions

- IDE:
  - Validation data supporting device sterility throughout the investigational period needed
- PMA:
  - Manufacturing controls reviewed for Class III devices
  - Full validation reports required for review

Thank You!

Chris Dugard, Scientific Reviewer

Sterility Devices Team

Office of Surgical and Infection Control Devices

Center for Devices and Radiological Health

DECLARATION OF MICHAEL BRUNNER

I, Michael Brunner, declare as follows:

1. I am Michael Brunner, Vice President of Operations, Americas Ethylene Oxide, at Sterigenics U.S., LLC ("Sterigenics"). The matters set forth below are within my personal knowledge and if called upon as a witness, I could and would testify competently as to each of them.

2. In my role as Vice President of Operations, I am responsible for managing operations, safety, quality, maintenance, and customer service for eleven facilities.

3. Sterigenics is a leading global provider of sterilization and irradiation services and has provided sterilization services for over 90 years. Sterigenics operates 48 facilities in 13 countries to ensure medical devices, pharmaceutical products, and food are safe for people to use and consume. Sterigenics has deep expertise across all major modalities of sterilization including Gamma radiation ("Gamma"), Ethylene Oxide ("EtO"), Electron Beam ("E-beam") and X-Ray sterilization.

4. Ethylene oxide is critical to the healthcare industry, as it sterilizes over 50% of sterilized medical devices and a vast majority of the surgical kits used in patient procedures in the U.S. According to an August 3, 2022 statement by the United Stated Food and Drug Administration ("FDA"), ethylene oxide sterilizes over 20 billion medical devices each year in the United States alone. Additionally, for many types of devices, other methods of sterilization cannot currently replace ethylene oxide, as the FDA recently stated on August 3, 2022. (Please see the Declaration of Aaron DeMent for a more detailed discussion of medical sterilization pursuant to FDA requirements, including attachment Dement-1 which is FDA's recent statement.)

5. The Vernon Facilities are subject to stringent FDA requirements that must be followed to ensure that Sterigenics' customers' products are manufactured in a controlled way, with all changes and nonconformances to our customers' validated sterilization processes detected and addressed. As described in more detail in the Declaration of Aaron DeMent, the FDA requires that medical devices and equipment be sterilized pursuant to exacting protocols that must be rigorously tested and validated.

6. Sterigenics provides contract sterilization services to approximately 2,800 medical

device manufacturers that come to Sterigenics for EtO sterilization of a wide variety of medical products, including including surgical kits; delivery systems (stents, blood management, drug, needles, pumps, syringe); implants; surgical drapes & barriers; ophthalmic products; tubing systems (like catheters and feeding tubes); dialyzers; wound management (burns, sutures, tape); and reusable equipment for hospitals.

7. The Vernon Facilities provide a critical service to the medical industry in southern California. The Vernon Facilities sterilize between 3.5 to 4 million medical devices each month. Many of those products, including surgical kits, delivery systems and COVID test swabs, have been critically needed by the health care industry to respond to the COVID pandemic.

8. The Vernon Facilities are distinct in a number of ways from Sterigenics' other facilities due to factors as simple as their location in an urban-industrial area and the ages and configurations of the building. The Vernon Facilities have a substantial number of customers who are small-volume capacity. This could be because there are many small medical devices manufacturers in southern California.

9. Sterigenics follows exacting validation procedures dictated by its customers to determine the optimal sterilization method for each product, and to validate that the chosen method will achieve the sterility requirement for that product. (Please refer to the Declaration of Aaron DeMent for a more in-depth discussion of the Food and Drug Administration ["FDA"] requirements for EtO sterilization.)

10. Sterigenics adheres to customers' process specifications to treat their product. For many products, customers are required to include in the FDA product registration the specific sterilization facility used to validate the product's listing, and are typically required to re-register if they switch facilities, making switching locations for a particular product a difficult and expensive process our customers.

11. These FDA-required validation processes are expensive and can take four to nine months to complete. (Incorporating the necessary regulatory review times, our current estimate of time for a full cycle of validation and regulatory review is in the vicinity of 18 months on average; please refer to the Declaration of Aaron DeMent for more discussion on this topic.) The cost of that

validation process is borne by the device manufacturer, and the process is specific to the particular facility and specific sterilization chamber at the facility. That validation, once complete, cannot be transferred to another facility, or even to another sterilization chamber at the same facility. If a customer wants to move to a different facility, the months-long validation process must be performed all over again or an equivalency demonstration must be made. Because of industry sterilization and capacity constraints and the fact that shifting sterilization activities is not a simple matter of substitution, even a temporary shutdown of the Vernon Facilities could result in significant shortages in sterilized medical equipment in California and throughout the country.

12. I am familiar with the Petition for Order for Abatement and the conditions which have been stipulated to as part of the proposed Order in this proceeding.

13. Although the proposed conditions impose some substantial new requirements on the Vernon Facilities, they also serve to set specific deadlines on enhancements that were already underway at the facilities. These include interim solutions, including installation of drybeds and development of negative pressure, as well as the ultimate permanent total enclosure solution for both facilities: the 50th Street facility being completed by January 15, 2024, and the 49th Street facility completed by May 1, 2024. These are aggressive deadlines considering that these improvements require significant construction on older buildings, and the attendant third-party permitting from agencies other than the District. However, the Vernon Facilities enhancements are a priority for Sterigenics, and we are committed to meeting these obligations.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct to my personal knowledge.

Executed this 4th day of August, 2022, in Norfolk, Virginia.

Digitally signed by Michael Brunner
DN: cn=Michael Brunner, o=Sterigenics, ou, email=mbrunner@sterigenics.com, c=US
Date: 2022.08.04 21:41:53 -04'00'

Michael Brunner

DECLARATION OF KEVIN WAGNER

I, Kevin Wagner, declare as follows:

1. I am Vice President Global Environmental, Health & Safety ("EHS") at Sterigenics U.S., LLC ("Sterigenics"). The matters set forth below are within my personal knowledge and if called upon as a witness, I could and would testify competently as to each of them.

2. In my role as Vice President of EHS, I am responsible for managing EHS matters and assisting all of Sterigenics' facilities in implementing the company's EHS programs. I am familiar with the EHS programs and the legal/regulatory compliance status of Sterigenics' facilities at 49th Street and 50th Street in Vernon, CA (the "Vernon Facilities") that are the subject of this proceeding for an Order for Abatement.

3. The Food and Drug Administration ("FDA") regularly inspects Sterigenics' facilities, including the Vernon facilities, given the importance of sterilization as a final step in the production and preparation of medical and surgical products in the United States.

4. I am familiar with the Petition for Order for Abatement and the conditions which have been stipulated to as part of the proposed Order in this proceeding. I have been – and continue to be – actively involved in Sterigenics' efforts to work cooperatively with the South Coast AQMD (the "District") in identifying and implementing emissions reduction enhancements, and have regularly communicated directly with the District regarding various matters, including the enhancements required by the proposed conditions.

5. I am also familiar with the equipment at the Vernon Facilities that has received permits to operate from the District.

6. All ethylene oxide process emissions from Sterigenics' sterilization operations at the Vernon Facilities are routed to permitted emissions controls. Sterigenics' emissions controls for direct process emissions effect more stringent control than is required by the current rules and regulations. See **Attachment Wagner-1** showing the three process emissions flows to control equipment at each facility. Source tests on both facilities' scrubber emissions stacks on June 3, 2022 and both facilities' abator emissions stacks April 14, 2022 confirmed the permitted equipment is operating at greater efficiency than required.

7. The use of ethylene oxide ("EtO") at any medical sterilization facility, including the Vernon Facilities, can result in fugitive emissions of EtO (in addition to the controlled process emissions). Sources of such fugitive emissions can include in-process product, sterilization equipment and processed product. Sterile product can contain small amounts of EtO even after it has met its residual requirements during and after aeration. (The fugitive emissions from processed product is contemplated by the FDA sterilization regulations and guidance, as described more detail in the Declaration of Aaron Dement). Throughout the years of operations at the Vernon Facilities, such fugitive emissions have been minimized by customer sterilization cycle design modifications, equipment changes and enhanced emission controls. Fugitive emissions indoors are measured by the gas chromatograph ("GC") system.

8. The GC system is made up of ports that conduct a cycle of air sampling for EtO, and are connected to a visual and aural alarm system. The ports are generally strategically placed in areas where EtO could tend to accumulate first. The system's lights signal solid green when the ports detect zero or de minimis amounts of EtO; if the port detects EtO in a concentration of equal to or greater than 1ppm, the green light begins flashing. If the port detects that indoor levels rise to 3ppm, the light turns to amber. And if levels rise to 5ppm or greater, the amber light will flash. Employees are trained in safety protocols, including that when the GC system lights change, the purported EtO concentration should be checked with the more accurate handheld instrument in the vicinity of the port in order to more accurately assess whether fugitive EtO emissions are present. Typically, the handheld instrument's more accurate reading demonstrates that the GC system has triggered a false alarm. Because Sterigenics has protocols in place to require verification, the false alarms merely serve to be highly protective. (If the handheld instrument does detect elevated EtO, employees follow Cal/OSHA requirements, including donning personal protective equipment and limiting exposure time, as warranted.)

9. However, the GC system should be considered a voluntary safety tool and a potentially useful tool to learn from, not an accurate proxy for fugitive emissions. In the course of providing the District with information it requested, including as related to the GC system, Sterigenics has reviewed the GC data from the Vernon Facilities and confirmed that while it is

valuable as an employee safety tool, it is not an appropriate system for calculating EtO fugitive emission factors. Some supporting reasons are as follows:

- As part of the employee safety program, the fixed gas-chromatograph ports are strategically located in specific areas of the facility where higher potential EtO concentrations can be expected. The ports are not located in positions that would allow one to estimate the EtO concentration in the rooms/spaces within the facility.
- The Sterigenics GC system is not under a standardized validation routine, and the data have shown that this often results in very conservative readings, which can be acceptable for industry approaches to indoor air quality monitoring but not representative for estimating precise concentrations in air. For example, our past review of GC data reveals that the sampling valve and port cross contamination, port location and other system features may yield questionably high GC results that can be immediately invalidated by a handheld instrument. Indeed, it is not uncommon for a facility to get a high GC EtO concentration reading and then get a 0-ppm concentration reading with the handheld instrument. However, given the configuration of the system, we have rarely (if ever) seen GC readings that are lower than the reading of a handheld instrument.
- Depending on the location of the GC ports, there are sometimes various reasons for higher EtO concentrations that may not be indicative of area EtO concentrations. Most commonly, if the sample is being taken from a GC port at a time when processed product being transferred to aeration is directly adjacent to the port, the EtO concentration will be drawing a sample of the EtO concentrations from a pallet of processed product and not necessarily indicative of either employee exposure or fugitive concentrations.
- Because there is no applicable validation protocol, the historic data, including any inconsistencies, has been for informational use only. Sometimes GC ports are also used for other ad-hoc EtO measurements and such use is not noted on historic GC data.
- The GC data is not representative of average EtO concentrations for an entire, large-volume room such as those at the Vernon Facilities. For example, some GC ports may be located in an area with stagnant air or near areas that are under negative pressures routed to control

devices by design, in order to effect the earliest possible reading and generate the most conservative employee safety alert for any increases of EtO concentration in the room.

10. The GC system has a tendency to trigger false positives; please refer to the Declaration of Al Lopez for some examples of recent occurrences. However, Sterigenics has and will continue to use the GC system because its tendency to trigger false positives for EtO concentration is very protective of employees, and Sterigenics takes employee safety very seriously.

11. Sterigenics provides extensive training for its employees in a number of areas, often going beyond training imposed by regulatory requirements. This includes training on compliance with permit requirements, proper handling of ethylene oxide and maintenance of all equipment associated with processing, ventilation, and emissions controls. Sterigenics also conducts chemical storage, personal protective equipment, and ethylene oxide exposure trainings (among many others), all of which discuss how to safely work with ethylene oxide. Supervisors also make sure that employees are trained to recognize and prevent potential hazards in their work areas. Sterigenics also conducts ongoing and adaptive training on a regular basis to ensure employees and supervisors work safely and stay current on government-imposed requirements, and Sterigenics' own requirements, which often exceed government requirements. And, as stated previously, employees follow Cal/OSHA requirements for workplace safety.

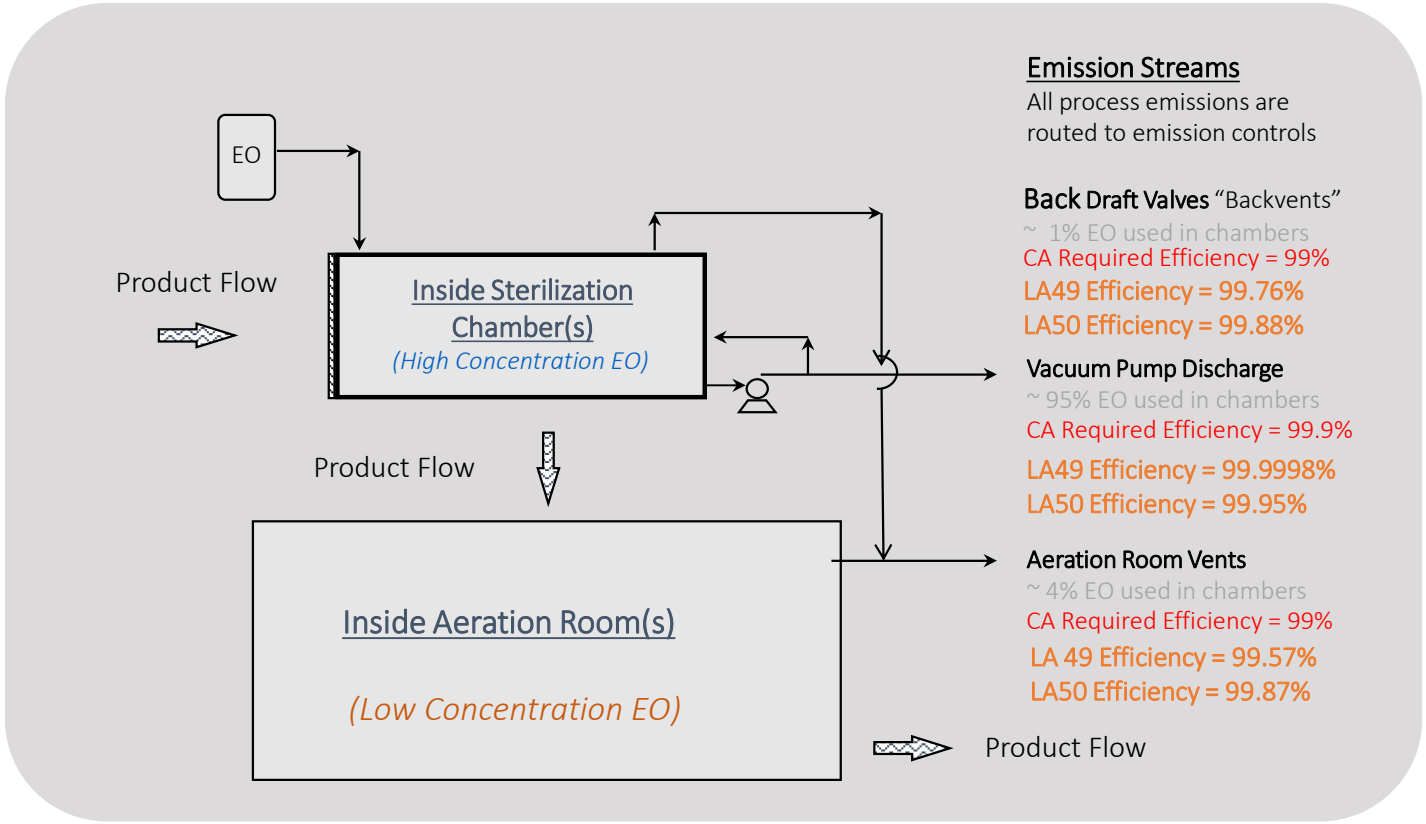
12. Cal/OSHA is aware of the District's investigation, and has visited the facility several times over the past few months. However, I am not aware of any issues identified by Cal/OSHA regarding employee safety at the facility.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct to my personal knowledge.

Executed this 4th day of August, 2022, in Oak Brook, Illinois

Kevin Wagner

Wagner-1: EtO Process Emissions – Vernon Facilities



DECLARATION OF ABDEL LOPEZ

I, Abdel Lopez, declare as follows:

1. My name is Abdel Lopez, and I go by Al Lopez. I am the General Manager of Sterigenics' facilities located on 49th Street and 50th Street in Vernon, California (the "Vernon Facilities"). The matters set forth below are within my personal knowledge and, if called upon as a witness, I could and would testify competently as to each of them.

2. In my role as General Manager of the Vernon Facilities, I am responsible for managing all operations at the facilities, as well as ensuring compliance with applicable rules, regulations and directives from Sterigenics' environmental, health and safety ("EHS") group.

3. I am familiar with the Petition for Order for Abatement and the conditions which have been stipulated to as part of the proposed Order in this proceeding. As General Manager, I will be primarily responsible for ensuring compliance with the conditions at the operational level. The proposed conditions would impose substantial new obligations for monitoring, reporting, and taking various other actions as specified, along with posing some technological challenges and I believe that, as stipulated, compliance with the conditions is achievable.

4. The Vernon Facilities employ up to 43 people and sterilize, using ethylene oxide ("EtO") a variety of medical products, including custom surgical kits (pulmonary, obstetric, cardiac, vascular); delivery systems (stents, blood management, drug, needles, pumps, syringe); implants (artificial hearts, cochlear, defibrillators, heart valves, prosthetics); surgical drapes & barriers; ophthalmic (hydrophobic lens/case, coated lens, corneal inlay); tubing systems (catheters, feeding, drainage); dialyzers; wound management (burns, sutures, tape); and reusable equipment for hospitals.

5. The Vernon facilities offer both small and larger chambers to sterilize a wide variety of products for 96 active customers, including 53 that are based in California. These customers range from large global medical device/pharmaceutical companies to small niche, start-up companies as well as local hospitals and medical centers. The Vernon Facilities count among their customers a significant number of small-volume capacity customers from the southern California region. These customers could be particularly hard-pressed to secure alternative locations for their

medical product sterilization requirements. All customers of the Vernon Facilities are dependent on us to get their products sterilized prior to distribution to their customers.

6. Our operations are subject to stringent regulation by federal, state and local agencies charged with oversight of, among other things, process safety and quality assurance, employee safety, and environmental controls. Our practice is to operate "audit ready," as we are audited over 30 times per year by federal and local regulatory bodies as well as by our customers.

7. The sterilization product flow at the Vernon Facilities is as follows: Customer products are received usually by semi-truck (sometimes smaller trucks). The trucks back to a loading dock and Sterigenics' employees unload the customer's packaged product, already stacked on pallets, in the receiving area. (Sterigenics does not alter the packaging or configuration of the customer's pallet structure because they are part of the customer's FDA validation protocol.) Products then enter a Pre-Conditioning room, where elevated temperature and humidity conditions the palletized products for sterilization processing. Thereafter, the palletized products are loaded into sterilization chambers, specific to the customer-specified validation protocol for the particular products. The chambers themselves are in their own section of the facility, with partitioned access. Once the chamber is loaded, sterilization is performed following a validated Cycle Specification Agreement that contains specific parameters for processing the load. Thereafter, the sterilized, palletized product is taken to heated aeration rooms. The product specifications set forth minimum and sometimes maximum heated aeration times. When the palletized product has completed aeration, it is moved to the shipping area, and ultimately loaded into trucks at the loading docks. This process flow is illustrated on **Attachment Lopez-1** which is representative of the various stages of product movement that occurs at the Vernon Facilities**.** (Please refer to the Declaration of Aaron DeMent for a more specific discussion of the relevant Food and Drug Administration ["FDA"] regulations, standards and validation processes.)

8. While we are referencing the Vernon Facilities together for convenience and for purposes of the Order for Abatement proceedings, they are actually two distinct facilities with different building configurations, different operational considerations, different customer products processed, and slightly different process flows. For example, the 50th Street facility is made up of

two different buildings. One of those buildings (address 4863 E. 50th Street) does not use or store EtO at all; the building is comprised of a receiving area, a preconditioning room, and some office space and is not available or configured for storage or use of EtO. Additionally, the two Vernon Facilities are separated by an active railway which is not a public right-of-way. Additionally, our customers' FDA validated sterilization cycles are specific to particular chambers, generally either at the 50th Street facility or the 49th Street facility. The chambers at the 50th Street facility are larger and can accommodate larger loads (approximately 13 pallets), while the 49th Street facility's chambers are smaller, accommodating 3- or 6-pallet loads.

9. The process flow of customer product is constrained by several variables, including (1) the permitted throughput of EtO; (2) the FDA protocols for sterilization (including aeration minimum and maximums); (3) customer specifications (including aeration maximums); (4) physical capacity of the aeration room and shipping areas; and (5) shipping logistics, including customer pickup requirements. These factors are further influenced by the general availability – or lack thereof – of EtO sterilization capacity nationwide. Ultimately, if there are reductions in capacity at other EtO facilities for any reason, the few customers who have been validated at more than one facility, i.e. a back-up facility, may seek to have product sterilized at this back-up facility, which could influence the capacity at the back-up facility.

10. Given those variables, it is critical that I, as the General Manager, maintain the operational flexibility necessary to adjust to the changing variables while complying with the new requirements imposed by the proposed conditions. For example, Sterigenics has already been in the process of increasing the time product spends in aeration (without exceeding specifications from customers or FDA. However, it is a newly implemented process flow, and requires constant adjustments to address the variables mentioned above. The proposed Order's conditions, as currently drafted, balance this critical flexibility.

11. As General Manager, I am also responsible for ensuring employee safety regulations and protocols are followed. One of the employee safety tools that we have voluntarily deployed for many years is the gas chromatograph ("GC") system inside the Vernon Facilities. To understand the usefulness – and limits – of this technology, which also features in the proposed conditions, it is

necessary to provide some additional context.

12. The GC system is not a continuous measurement system; rather it is a single GC system with multiple monitoring ports. The system samples each port separately and sequences the sampling through set sampling patterns. The process of collecting and analyzing a sample from all of the ports combined takes about 30 minutes. Once the sampling pattern is completed, the system immediately restarts the sequence. The GC system is connected to a lighting and alarm system designed to notify employees of potentially higher EtO concentrations in various facility areas. The GC system is voluntary.

13. The GC system is not required by any regulatory agency and is not used for Cal/OSHA compliance. Sterigenics achieves compliance with the employee exposure monitoring aspects of the OSHA EtO standard through periodic badge sampling of its employees to measure the 8-hour exposures and compare them to the OSHA Permissible Exposure Limits ("PELs"). In addition, Sterigenics has identified various activities that might result in higher EtO employee exposures and requires respirator protection for these activities. The GC system is a tool Sterigenics uses to measure EtO concentration in certain facility areas, to identify areas of potentially higher EtO employee exposure, and to ensure that employees review and don respirator protection if needed in these specific potentially-higher concentration areas.

14. The Declaration of Kevin Wagner describes in more detail some of the specific limitations of the GC system, particularly for use as a proxy for actual ambient concentrations of EtO. Given the conservative bias and frequently inaccurate readings of the GC system, it is Sterigenics' long-standing policy at the Vernon Facilities to immediately note when the GC system registers an ostensibly elevated EtO concentration, but also to immediately verify whether the reading is accurate by using a handheld instrument in close proximity to the relevant GC port.

15. The handheld instruments used at the facility are Honeywell MiniRAE 3000s and are accurate to within 0.1 parts per million in measuring EtO and provide far more accurate readings of EtO concentrations in a given area than the GC system is designed or able to provide. However, the GC system is always biased towards alerting to potential EtO increases, even if that yields "false positives" and that is precisely why it is in use as a conservative and overly protective tool to

promote employee safety.

16. To provide a recent example of some of the limitations of the GC system and its tendency towards over-alerting, an Air District inspector was at the facility on July 26, 2022 when the GC system went from a steady green light to a flashing green light, indicating that one of the ports had registered potentially elevated levels of EtO. Following the routine safety protocols that have long been in place at the facility, a Sterigenics employee immediately used a handheld instrument in close proximity to the GC port that had registered the potentially elevated levels to confirm whether the GC system had accurately registered an increase. The handheld verifying reading was 0.0 parts per million. The reading was also 0.0 at other points within that space.

17. In another example that occurred on August 3, 2022, the GC system's warning light in the administration office alerted at the yellow level. The administration office is the point in the 50th Street facility farthest from EtO operational areas, under positive air flow. We immediately checked the EtO concentration with the handheld instrument, which read 0.0 ppb. (Included here as **Attachment Lopez-2** is a true and correct copy of a photograph taken August 3, 2022, during the false positive occurrence described). So, the false positives from the system are not limited to falsely alerting to potentially low levels of EtO, but also potentially alerting to high levels – which, in both cases, proved to be erroneous upon investigation with the more accurate handheld instrument reading 0.0.

18. The GC system can also be triggered to alert for EtO concentrations by registering commonly found sources, such as certain cleaning supplies, fragrances, and aerosol sprays. This has been noted particularly at those GC ports in the vicinity of the administration room, where those types of products are more commonly used (though they are used with caution to avoid unnecessarily triggering the GC system). For all of the reasons described here (and in the Declaration of Kevin Wagner), the GC system should not be used as a reliable indicator of actual EtO concentrations – it is an early first alert system only.

19. Despite the limitations and inaccuracy of the GC system for purposes of estimating fugitive emissions, there may be useful information to glean from a closer or more methodical examination of the GC data alongside other tools and measurements.

20. It should be noted, too, that as some of the proposed conditions are implemented (and, indeed, with the measures Sterigenics has already implemented), we expect to see EtO concentrations increase for indoor air at the Vernon Facilities from time to time. This means that there may be instances where the GC system registers 1 ppm more frequently, which will have to be checked with a handheld instrument. It may also trigger Cal/OSHA requirements to don appropriate personal protective equipment ("PPE"). I also expect that some of these interior EtO levels will be increasingly lowered as we implement more of the interim measures in the proposed conditions, such as the installation of the dry beds and additional Timilon filters. In any case, throughout the implementation of the measures, we will continue to ensure the safety of our workers by continuing to go above and beyond Cal/OSHA requirements in the continued use of the GC system and appropriate use of PPE when required.

21. Cal/OSHA is aware of the District's investigations at the Vernon Facilities and of the interim measures that have occurred already. Cal/OSHA has visited the Vernon Facilities in recent months. As of today's date, there have been no indications of any conditions that would create Cal/OSHA concerns to workers.

22. Over the past 3-4 months, Sterigenics has been implementing enhancements designed to reduce the potential for fugitive emissions. These include the following measures that did not require SCAQMD permits: installation of heavy-duty plastic curtains within the facility and at the truck loading docks; changing fan operation and adjusting indoor air circulation; increasing the time product spends in aeration (without exceeding specifications from customers or FDA); and implementation of strict door protocols. Sterigenics has also already submitted permit applications for several interim improvements, as described further in the Declaration of Joseph W. Hower. These measures also include installation of Timilon filters, which have been shown to be effective in reducing fugitive emissions indoors (and thus reducing the potential indoor fugitive emissions that could escape outdoors).

23. With respect to the ongoing and proposed ambient air monitoring, I would like to share some additional context regarding the monitoring locations. The existing Air District monitor referred to as "Site No. 1" (see Decl. of Joseph W. Hower, "Air Monitoring Efforts") is located in

an industrial, private parking lot that abuts the 49th Street facility and is immediately adjacent to the railroad tracks that separate the 49th Street facility from 50th Street facility. I have visited the area immediately adjacent to the parking lot and also viewed the parking lot from the roof of the Sterigenics building and observed that the monitor associated with SCAQMD's van is located at the rear of the parking lot, close to the fenceline and across the railway from the 50th Street Facility. Sterigenics also has an exterior security camera with a view of this section of the parking lot and the adjacent railway. Included here as **Attachment Lopez-3** are true and correct screen captures of security camera footage of the parking lot to illustrate the location of the monitor at Site No. 1 (which will be similar to the proposed location of monitor M2 under the proposed conditions). Between my physical viewing of that section of the parking lot and review of video camera footage showing the area of the lot where the District's monitor is located, I have observed that there are no workers regularly present for more than a few minutes at a time at that part of the parking lot where the monitor is located, and not every day, in that section of the parking lot.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct to my personal knowledge.

Executed this 4th day of August, 2022, in VERNON, California.

Digitally signed by Abdel I Lopez
DN: cn=Abdel I Lopez, o=Sterigenics, ou, email=alopez5@sterigenics.com, c=US
Date: 2022.08.04 17:22:05 -07'00'

Abdel Lopez

Lopez-1: EO Sterilization Product Flow

Receiving
Inbound Trucks with Product

Pre-Conditioning
Elevated Temperature & Humidity

Load
Into Chambers

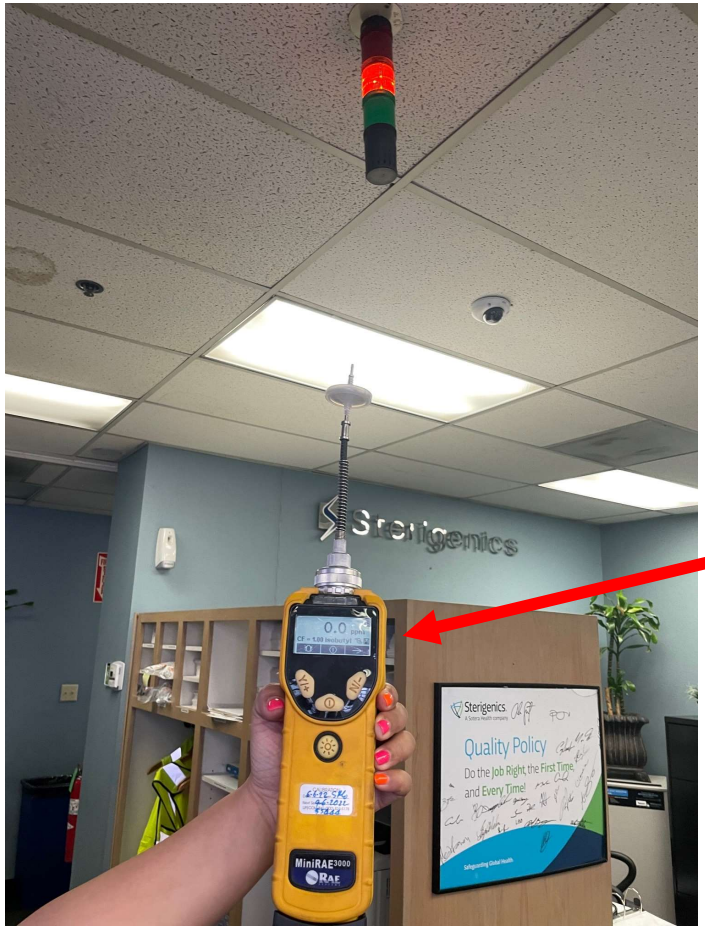
Product Aerates
In Controlled Area

Processed
Product is Stored

Shipping
Customer Picks Up Processed Product

Note: Facility is representative of process flow at Vernon Facilities, but are not the Vernon Facilities.

Lopez-2: False positive from GC system



Lopez-3: SCAQMD monitoring Site No. 1

SCAQMD monitoring van at Site No. 1

Sterigenics' 50th Street Facility

Lopez-3: SCAQMD monitoring Site No. 1

DECLARATION OF JOSEPH W. HOWER

I, Joseph W. Hower, declare as follows:

1. I am a Project Officer and Vice President of Mechanical Engineering at Ramboll, a global consulting firm. I am a District approved Certified Permitting Professional (CPP), a licensed Professional Engineer in nine States including California, and a Board Certified Air Pollution Engineer by the American Academy of Environmental Engineers and Scientists. I have been working with the District since 1978, and served on its Advisory Council for nearly five years. I have been previously designated as an expert by the Hearing Board.

2. I have personal knowledge of the facts set forth in this declaration and if called as a witness, I could and would testify competently to them.

3. I am a consultant to sterilization facilities, including Sterigenics, on air quality matters, including, but not limited to, compliance with District rules and permits. I am familiar with the equipment and operations at the Vernon Facilities.

4. I am familiar with the Petition for Order for Abatement and the conditions which have been stipulated to as part of the proposed Order in this proceeding.

5. Since April 2022, I have been advising Sterigenics in connection with permitting for new and modified equipment at the Vernon Facilities for enhancements that have been installed and will be installed pursuant to the proposed conditions. In fact, Ramboll has, on behalf of Sterigenics, already proactively submitted permit applications for most of the enhancements in the proposed conditions, as detailed more specifically in the chart included here as **Table 1. Sterigenics Permitting Plan**.

6. Sterigenics has already implemented a number of interim measures in an effort to reduce fugitive emissions from the Vernon facilities, as described more specifically in the Declaration of Abdel Lopez. These measures have had a notable impact on reducing the ethylene oxide ("EtO") concentrations measured by the District, shown in the attached **Air Monitoring Efforts**, which is a true and correct copy of the portion of the District's Sterigenics website describing the air monitoring as of August 3, 2022.

7. Separate from this Order for Abatement proceeding, but relevant to understanding the

context of those interim measures, Ramboll is also engaged by Sterigenics to assist in preparation of an updated Health Risk Assessment and development and implementation of a Risk Reduction Plan pursuant to District Rule 1402. Ramboll and Sterigenics have already timely complied with the initial deadlines in that process.

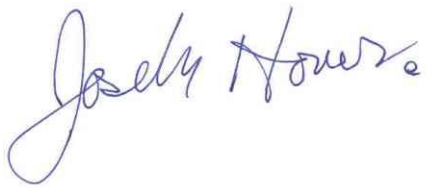
8. I am familiar with the Office of Health Hazard Assessment ("OEHHA") regulations and guidelines regarding the assessment of health risks from toxic air contaminants, as well as the District's rules implementing the air toxics program. I am also familiar with the ambient air monitoring conducted by the District in the vicinity of the Vernon Facilities. Specifically, I have reviewed the publicly available data posted on the District's website, and have also reviewed the sites where the monitors are located. The District has relied on the OEHHA methodology in determining that a substantial health risk exists to off-site workers, relying in large part on data collected from the monitor located at the site labeled by SCAQMD as Site No. 1, which has consistently shown higher concentrations of ethylene oxide in sampling results when compared with other locations where monitoring around the Vernon Facilities has been occurring. "Site No. 1" is also roughly equivalent to the proposed site of monitor "M2" in Fig. 1 of Appendix A (Fenceline Air Monitoring Plan) to the proposed conditions. Some additional context regarding location of "Site No. 1" and proposed "M2" is relevant when considering the sampling results from the District's monitoring.

9. "Site No. 1" is located in an industrial, private parking lot that abuts the 49th Street facility and is immediately adjacent to the Union Pacific railroad tracks that separate the 49th Street facility from 50th Street facility. (See the Declaration of Abdel Lopez, Attachment Lopez-2, for photographs of the site). While the Site No. 1 monitoring location can be selected as a receptor location under the OEHHA program, which requires selecting sites for maximum impact, such a receptor location is conservative and not reflective of potential risks to actual workers, only hypothetical ones. Under OEHHA, the risk from a particular concentration of a toxic air contaminant like EtO, is based on the assumption that a worker is exposed - in that exact receptor location – for 8 hours per day, 5 days per week, over 25 years. Here, there is no person who will spend anything close to that amount of time at the Site No. 1/M2 location.

10. Because EtO dissipates rapidly, concentrations (and the calculated health risk) is dramatically reduced with any distance from EtO sources, as demonstrated by the data collected at SCAQMD's "Site No. 4," which has recorded background levels of EtO at a residential area close to the Vernon Facilities, and as acknowledged by the District on their website, where they state that their monitoring results "show that EtO levels and off-site worker cancer risk drops off substantially (about 50 times lower) a short distance away (about 150 feet), from the facility." (See **Air Monitoring Efforts.)** However, Site No. 1 represents an off-site worker receptor location that is very close to the Vernon Facilities (while being immediately adjacent to the railroad tracks), and so while not a realistic reflection of an actual off-site worker location, it is a conservative receptor location consistent with OEHHA guidance.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct to my personal knowledge.

Executed this 4th day of August, 2022, in Long Beach, California.



Joseph W. Hower

Table 1. Sterigenics Permitting Plan
Sterigenics US, LLC.
SCAQMD Facility IDs 126191, 126197

Facility ID	Permit No.	Description	Date Submitted to AQMD
126191 (50th St)	G-2974	Connected pressure drop gauge to stack and ensured equipment is maintained in good operating condition.	5/12/2022
		Added pH meter to comply with SCAQMD request	N/A
		Submitted permit application to modify equipment description to reflect that scrubber vents to Timilon filters.	5/16/2022
		Submitted permit application to modify equipment description to reflect installed equipment dimensions.	5/16/2022
	--	Submitted application for permits to construct two dry bed adsorption systems at 50th Street Facility	6/6/2022
	--	Submitted application for a permit to construct on one coalescing filter and one polishing dry bed.	6/6/2022
	--	Submitted application for a permanent total enclosure to reduce fugitive emissions.	6/6/2022
	--	Application to be submitted for AQMD permit to operate on portable Timilon filter systems.	Pending: August 2022
	--	Application to be submitted for AQMD permit to operate on rerouted scrubber exhaust. Scrubber exhaust will be routed through abator stack, resulting in increased dispersion	Pending: August 2022
126197 (49th St.)	R-G43812	Submitted permit application to modify equipment description to reflect tank dimensions and capacity.	5/16/2022
		Submitted permit application to modify equipment description to reflect that scrubber vents to Timilon filters.	5/16/2022
		Submitted permit application to modify equipment description for the packed absorption tower pump to reflect actual operation.	5/16/2022
	--	Submitted application for permit to construct one dry bed adsorption system at the 49th Street Facility.	6/6/2022
	--	Submitted application for a permit to construct on one coalescing filter and one polishing dry bed.	6/6/2022
	--	Submitted application for a permanent total enclosure to reduce fugitive emissions.	6/6/2022
	--	Application to be submitted for AQMD permit to operate on portable Timilon filter systems.	Pending: August 2022
	--	Application to be submitted for AQMD permit to operate on rerouted scrubber exhaust. Scrubber exhaust will be routed through abator stack, resulting in increased dispersion	Pending: August 2022

Air Monitoring Efforts

South Coast AQMD is conducting local air sampling to determine levels of EtO in the surrounding community and evaluate potential sources of emissions coming from the Sterigenics buildings. Individual grab samples (an air sample collected at one location at one point in time) were taken near the facilities (Figure 1), and two monitors were placed nearby on 50th Street and 49th Street (Figure 3) to collect 24-hour samples (Figure 4).

Grab samples were also collected near the surrounding community and closest school and a monitor has been placed in the community to collect 24-hour samples. The data collected so far shows levels of EtO in the community to be within background levels (Figure 2).

Additionally, mobile monitoring was conducted to collect data on volatile organic compounds (VOCs) around the facilities and the surrounding community. VOC signals associated with EtO were elevated near the facilities; however, levels in the community were within typical background levels.

Grab Samples

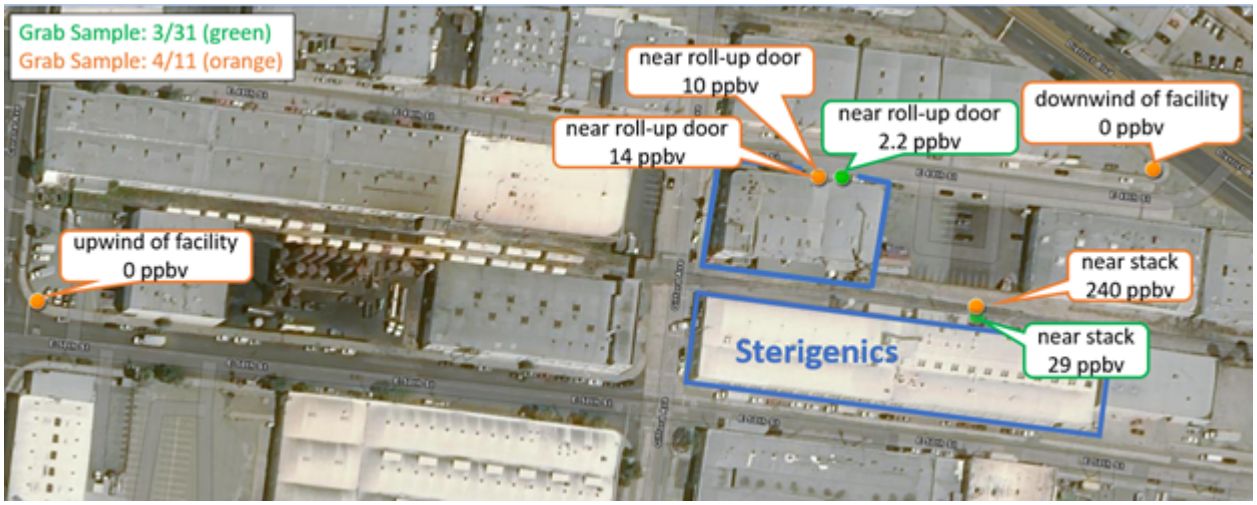


Figure 1. Map of grab samples. Concentrations are in parts per billion volume (ppbv).

Community Grab Samples

Figure 2. Map of community grab samples. Concentrations are in parts per billion volume (ppbv).

24-Hour Integrated Sample Locations

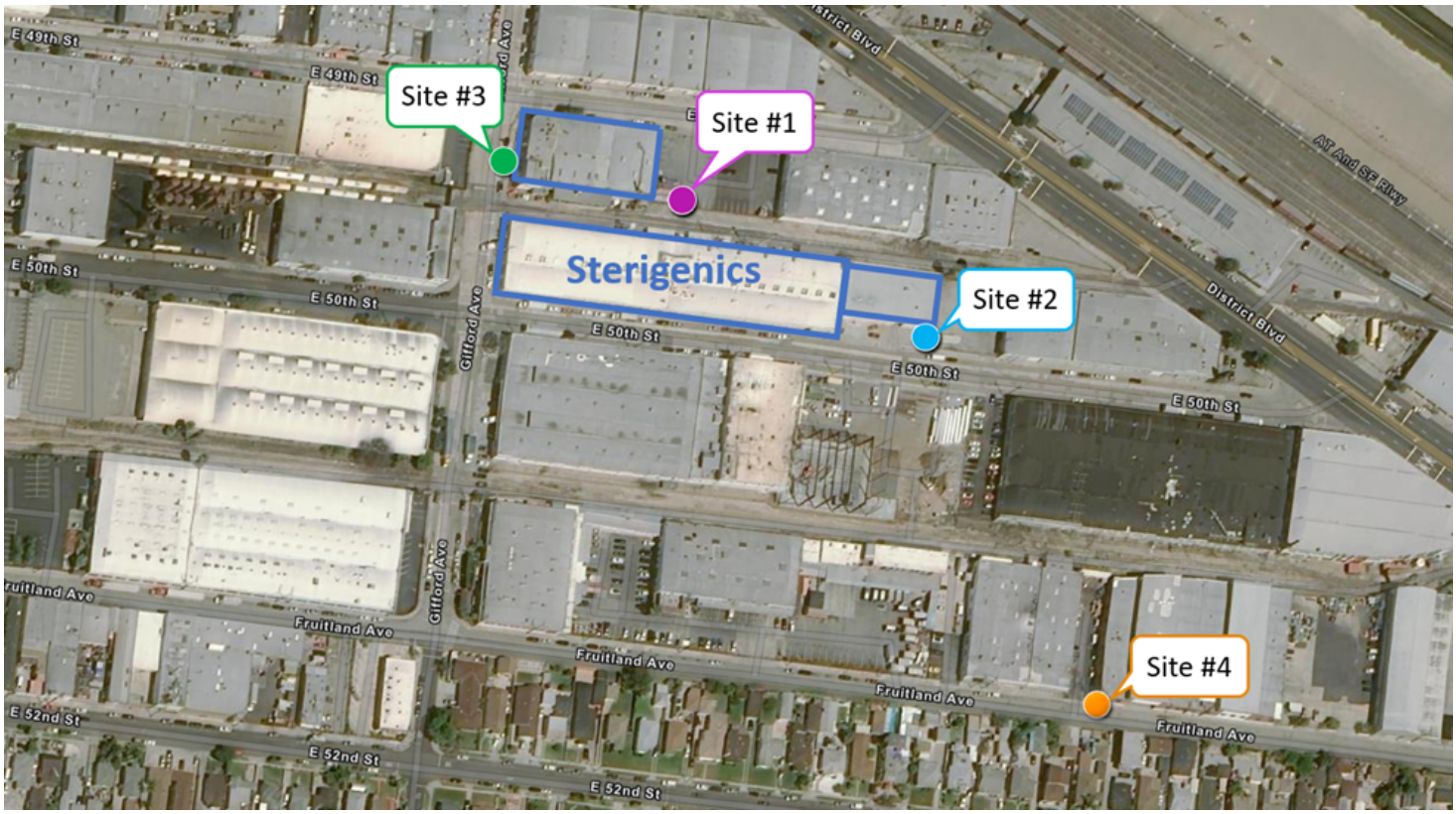


Figure 3. Map of 24-hour sampling locations.

24-Hour Samples

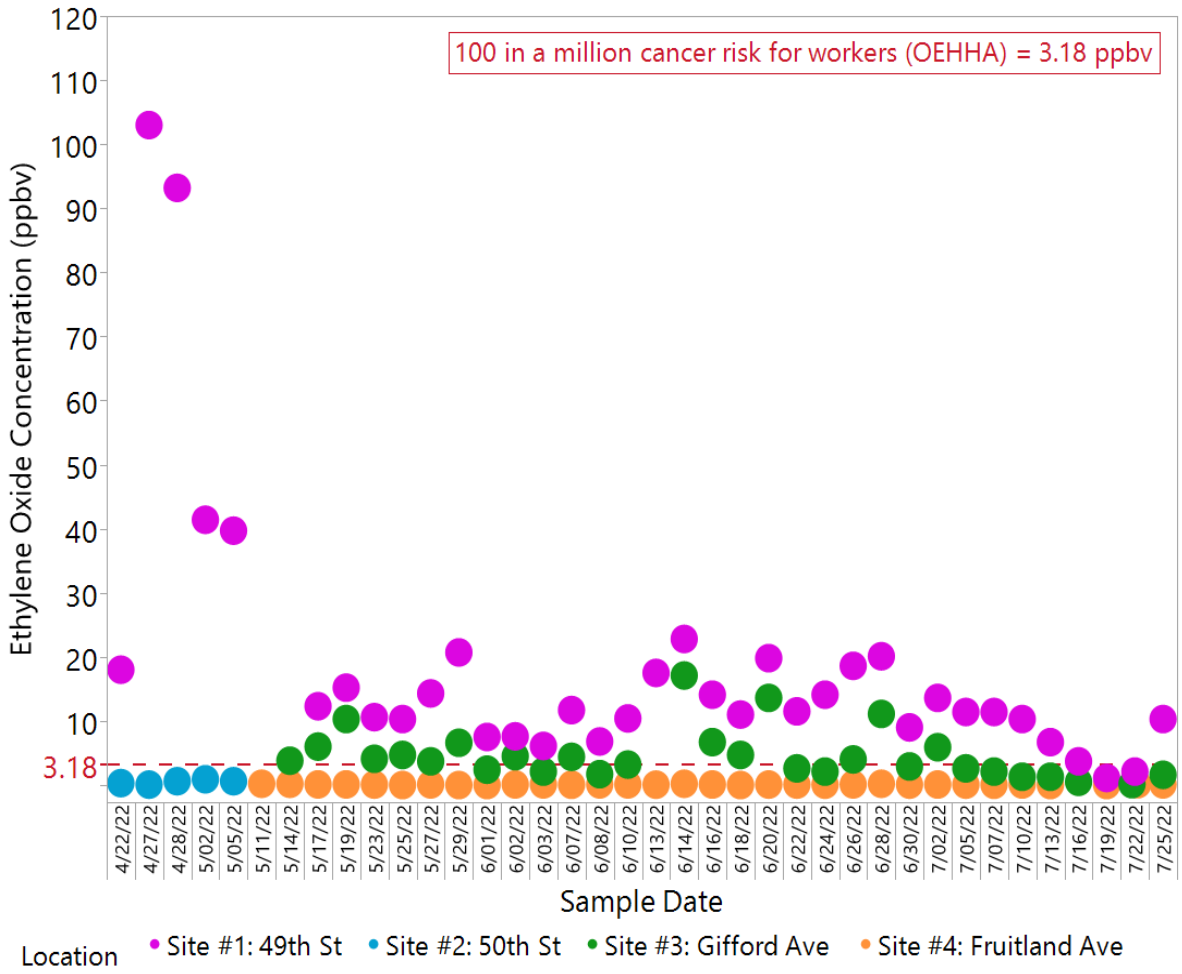


Figure 4. Plot of 24-hour time integrated sample concentrations.

24-hour Time-integrated Sample data (concentrations in ppbv)

Sample Begin Time	Site #1 (49th St.)	Site #2 (50th St.)*	Site #3 (Gifford Ave.)	Site #4 (Fruitland Ave.)
04/22/2022 12:00	18	0.3		
04/27/2022 00:00	103	0.07		
04/28/2022 12:00	93.2	0.6		
05/02/2022 00:00	41.4	0.9		
05/05/2022 00:01	39.7	0.6		
05/11/2022 00:01	Invalid		Invalid	0.2
05/14/2022 00:00	Invalid		3.8	0.2
05/17/2022 00:00	12.3		6.0	0.1
05/19/2022 00:00	15.2		10.3	0.1
05/23/2022 00:00	10.6		4.1	0.08

05/25/2022 00:00	10.3		4.7	ND
05/27/2022 00:00	14.3		3.7	0.1
05/29/2022 00:00	20.7		6.6	ND
06/01/2022 00:00	7.5		2.4	ND
06/02/2022 00:00	7.6		4.5	0.1
06/03/2022 00:00	6.1		2.1	0.1
06/07/2022 00:00	11.7		4.4	0.05
06/08/2022 00:00	6.8		1.7	0.1
06/10/2022 12:00	10.4		3.2	0.1
06/13/2022 12:00	17.5		Not Sampled	0.06
06/14/2022 12:00	22.8		17.1	0.2
06/16/2022 12:00	14.1		6.7	0.09
06/18/2022 12:00	11.0		4.7	ND
06/20/2022 12:00	19.8		13.6	0.08
06/22/2022 12:00	11.5		2.6	0.08
06/24/2022 12:00	14.1		2.1	0.06
06/26/2022 12:00	18.6		4.0	0.1
06/28/2022 12:00	20.1		11.1	0.2
06/30/2022 12:00	9.0		2.9	0.07
07/02/2022 12:00	13.6		5.9	0.09
07/05/2022 12:00	11.4		2.6	0.07
07/07/2022 12:00	11.4		2.1	0.05
07/10/2022 12:00	10.3		1.3	0.09
07/13/2022 12:00	6.7		1.3	ND
07/16/2022 12:00	3.7		0.5	Invalid
07/19/2022 12:00	1.1		Invalid	ND
07/22/2022 12:00	2.1		0.2	0.08
07/25/2022 12:00	10.3		1.6	0.1

**Discontinued sampling at Site 2*
ND = Not Detected
Figure 5: 24-hour Time-integrated Sample data (concentations in ppbv)

Health Impacts

South Coast AQMD is required to use methodologies developed by OEHHA in its health risk programs. Based on preliminary monitoring data, the primary concern is off-site worker exposure. This data indicates that workers at facilities adjacent to the Sterigenics facilities could be experiencing cancer risks as high as about 750 in a million, if they are or have been exposed for long periods (i.e., a 25-year worker exposure). This risk level is more than one and a half times higher than the average lifetime cancer risk throughout the region according to South Coast AQMD's Multiple Air Toxics Exposure Study V. The preliminary air monitoring results also show that EtO levels and off-site worker cancer risk drops off substantially (about 50 times lower) a short distance away (about 150 feet), from the facility.

DECLARATION OF MICHAEL RUTZ

I, Michael Rutz, declare as follows:

1. I am Michael Rutz, and I am the President of Sterigenics U.S., LLC ("Sterigenics"). The matters set forth below are within my personal knowledge and if called upon as a witness, I could and would testify competently as to each of them.

2. In my role as President of Sterigenics, I am responsible for overseeing Sterigenics' facilities throughout the United States, including the Vernon Facilities. This includes general oversight of compliance, customer relations, and capital planning, working closely with Sterigenics' specialized teams including Environmental Health and Safety, Engineering, and Customer Interactions and Contracts.

3. I have been actively involved in Sterigenics' efforts to work cooperatively with the District over the past several months, and have communicated directly with the District on Sterigenics' behalf.

4. I am familiar with the Petition for Order for Abatement and the conditions which have been stipulated to as part of the proposed Order in this proceeding. I confirm, as President of Sterigenics, that Sterigenics has stipulated to these proposed conditions and has authority to do so.

5. While some of the proposed conditions put enforceable deadlines and requirements on measures Sterigenics had already intended to implement as part of its planned enhancements for the Vernon Facilities, other conditions impose new and potentially challenging requirements for Sterigenics. However, these proposed conditions reflect many hours of careful consideration by both the District and Sterigenics, and I am confident Sterigenics will be able to comply with them.

6. Sterigenics takes very seriously its commitment to its employees, its customers and the medical patients who are the ultimate beneficiaries of our services, the community (including off-site workers and residents), and the environment, and we look forward implementing the facility enhancements laid out in the proposed conditions.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct to my personal knowledge.

Executed this _4th_ day of August, 2022, in Oak Brook, Illinois.

Michael Rutz