



GEORGIA
DEPARTMENT OF NATURAL RESOURCES

ENVIRONMENTAL PROTECTION DIVISION

Richard E. Dunn, Director

Air Protection Branch
4244 International Parkway
Suite 120
Atlanta, Georgia 30354
404-363-7000

OCT 31 2019

Ms. Kathleen Hoffman
Senior Vice President – Global Environmental, Health & Safety and Technical Services
Sterigenics U.S. LLC
2015 Spring Road, Suite 650
Oak Brook, IL 60523

RE: **Consent Order No. EPD-AQC-6980**
Sterigenics, U.S. LLC, Atlanta, Georgia

Dear Ms. Hoffman:

On October 22, 2019, the Division received the revised Work Practice Plan for the Sterigenics Atlanta facility required by Consent Order No. EPD-AQC-6980. The Work Practice Plan originally received on September 9, 2019 was updated to reflect the Division's requested changes. The revised Work Practice Plan meets the requirements of Condition No. 3 of the Consent Order.

Sterigenics must update the Work Practice Plan to be consistent with the amended air quality permit, when issued. Additional changes may be needed to the plan at that time and, if amended, should also be submitted to the Division for approval within fifteen days of such date.

Thank you for your cooperation. If you have any questions concerning this correspondence, please feel free to contact Sherry Waldron at 404-362-4569 or Sherry.Waldron@dnr.ga.gov.

Sincerely,

Sean Taylor
Program Manager
Stationary Source Compliance Program

SMT:sgw

c: Daryl Mosby, Sterigenics

AIRS No. 067-00093



October 21, 2019

Mr. Sean Taylor, Program Manager
Georgia EPD – Air Protection Branch
Stationary Source Compliance Program
4244 International Parkway, Suite 120
Atlanta, Georgia 30354

Subject: **Sterigenics Atlanta facility Work Practice Plan – Requested Revisions**

Dear Mr. Taylor

In response to your request, Sterigenics is providing an updated work practice plan for the Sterigenics Atlanta facility located at 2971 Olympic Industrial Drive, Suite 116, in Atlanta, Georgia.

Sterigenics reviewed your requested changes to the work practice plan and is submitting an updated work practice plan to address those items that are applicable to the negative pressure system. Two proposed changes refer to the entire facility; however, the proposed negative pressure system includes areas within the facility where ethylene oxide could be present. Specifically, as stated in the permit application, the negative pressure system is proposed to capture air internally from chamber rooms, work aisles, processed product storage, and shipping areas. Therefore the following two comments are only relevant to the negative pressure area and not the facility.

Letter states *“Addition of daily negative pressure verifications along all outside walls of the facility, either by airflow observations using a smoke test or similar visual method or using permanently installed differential pressure gauges.”*

Letter states *“Addition of specifying the protocol for the sequence of using dock door seals and opening rollup doors during offloading/loading operations and associated training of affected employees.”*

Please contact me at lhartman@sterigenics.com or 630-928-1700 for questions or additional information.

Regards,

Laura Hartman
Manager, Environmental Health and Safety

Attachment: Work Practice Plan

CC: General Manager, Sterigenics Atlanta Facility

I. PURPOSE

This work instruction describes the practices taken to help limit fugitive emissions from the EO sterilization process

II. SCOPE

Covers the routine sterilization processing as well as non-routine tasks which could generate leaks, releases, or fugitive emissions of EO.

III. PROCESS OWNER

Atlanta EO facility management

IV. APPLICATION

This procedure applies to operations and areas of the facility where EO is used or contains sources which could emit EO including Chamber room, work aisle, emission control areas, aeration room, and the processed storage/shipping warehouse.

V. IMPLEMENTATION REQUIREMENTS

All requirements of this procedure will be implemented on the effective date

VI. PROCEDURE

REQUIREMENTS

- A. Employees will ensure work practices are followed to minimize generation of EO fugitive emissions.
- B. Emission control systems will be utilized to capture and control EO fugitive emissions to the extent practical.
- C. The Advanced Air Technologies (AAT) scrubber/dry bed system will be inspected and tested frequently to ensure required efficiency is maintained.
- D. Enhanced reporting of confirmed Lower Explosive Limit (LEL) or Gas Chromatograph (GC) alarms which show a released amount of EO to the environment to local agencies will be followed.
- E. Initial and refresher training is required.
- F. The facility will implement practices to ensure 100% of emissions in accordance with EPA procedures are captured and all dry bed systems reduce emissions to an acceptable level:
 - 1. Outlet reading of AAT dry beds will not exceed 1ppm
 - 2. Outlet reading of the Negative pressure system dry beds will not exceed 1ppm.

PROCEDURE

- A. Minimizing EO Fugitives
 - 1. Upon receipt of EO drums from the supplier, employees will use existing work practices (as described in G-WI-EO-OPS-013, EO Drums: Safe Storage and Handling) to ensure drums are leak free

DRAFT

and in good condition prior to being brought into the facility.

2. The monitoring devices in the EO drum storage area will be operational to monitor for leaks.
3. The setting for Chamber Door Interlock/VAPORS will be set to 5% or less.
4. At the end of the sterilization cycle, the chamber door will be opened slightly and the operator must allow the backvents to run for a minimum of 15-minutes prior to unloading the sterile product.
5. When unloading sterilization chambers of product, remove and immediately transport pallets directly to the aeration room, and do not stage pallets in the aisle before transporting to aeration.
6. Maximize, to the extent practicable, the duration that a product remains in aeration before removal, consistent with customer approvals and customer shipping demands for each particular product
7. The Shipping warehouse doors will remain closed unless in use for loading trailers.
8. Maintenance personnel will ensure safe practices for isolating EO lines and inspecting equipment are followed to prevent leaks/releases.
9. Enhance the current capture and control equipment:
 - i. The AAT drybed unit will be tested weekly using current sample bags and analysis with GC. The measured level cannot exceed 1ppm.
 - ii. The barometric dampers in the sterilization chamber room exhaust to the AAT. The dampers will be used to the extent possible to capture any fugitive emissions in the area.
 - iii. Maintenance to ensure any deviations to scrubber or dry bed operation are reported immediately to Corporate EH&S (scrubber tank level, pH, flow, EO concentration)

B. Reporting of EO Leaks and Releases

1. In addition to current procedures for detecting and assessing leaks or releases, the facility will immediately notify corporate EH&S of any high level EO alarms so a joint investigation can be completed to determine quantity of the leak.
2. The affected part of the process will be stopped until the investigation is complete to ensure safety.
3. If the leaked amount of EO is determined to be > 10 lbs. or unknown within 15-minutes then an immediate notification to the National Response Center, Georgia EPD, the LEPC (Cobb County Fire Department) will be made.
4. When safe to do so, a complete investigation for each incident will be conducted to determine root cause with corrective actions
5. Follow-up reporting with each respective agency will be completed to report the final investigation report.

C. Training

1. Training is to be provided to all employees on this work instruction within 30 days.
2. Annual training is required.

D. Operation and Maintenance of Negative Pressure System and Dry Beds

1. Negative pressure system:

- i. Upon startup of the negative pressure system, demonstrate capture within the negative pressure area. The demonstration will determine the number of rollup doors that can be opened in the negative pressure area. See *Appendix 1* for diagram of the negative pressure enclosure.
- ii. On a daily basis, verify and record the pressure within the negative pressure area.
- iii. Calibrate pressure measuring device(s) for the negative pressure area annually.

2. All facility dry beds:

- i. Dry bed media will be tracked to predict end of useful life in accordance with manufacturers recommendations based on EO usage.
- ii. In addition to the above, each dry bed system will be monitored weekly by taking an outlet sample with a Tedlar bag for 15-minutes. The sample will be analyzed with the GC and shall not exceed 1ppm
- iii. If a sample exceeds 1ppm a notification will be made to Corporate EH&S. A plan will be implemented to resample the system. If two consecutive samples are > 1ppm then the dry bed media will be changed out.
- iv. When dry bed media is changed out, each dry bed cell will be isolated from the system via damper valves. This will ensure the system can still operate with expected efficiency. The changeout of each bed will continue until all are complete.

3. Facility doors

- i. Doors located in the negative pressure area will remain closed when not in use to ensure the negative pressure system is effective.
- ii. The facility will limit the number of dock doors that can be opened at a time within the negative pressure area based on the demonstration per D1. Dock seals will be installed to limit any openings around the docks while trailers are actively being loaded.
- iii. Prior to opening a dock door, operators will ensure the trailer is aligned correctly with the dock door seals.
- iv. Dock door seals will be visually inspected weekly to check the integrity and these inspections will be recorded.

4. Special emission control work practices in case of breakdown
 - i. If the sterilization chamber emission control system unexpectedly fails the chamber cycles will be suspended.
 - ii. If the negative dry bed system fan fails the secondary blower fan will be put online to ensure continued operation of the system.
 - iii. Verifications of negative pressure within the affected operational areas will be conducted while any portion of those systems affecting air flow are inoperable.
 - iv. If the facility loses power, then *EOP-001 Power Outages* will be followed and handheld monitors will be used throughout the facility to measure any EO levels.
 - v. All doors and openings in the negative pressure area will remain closed during power outages.

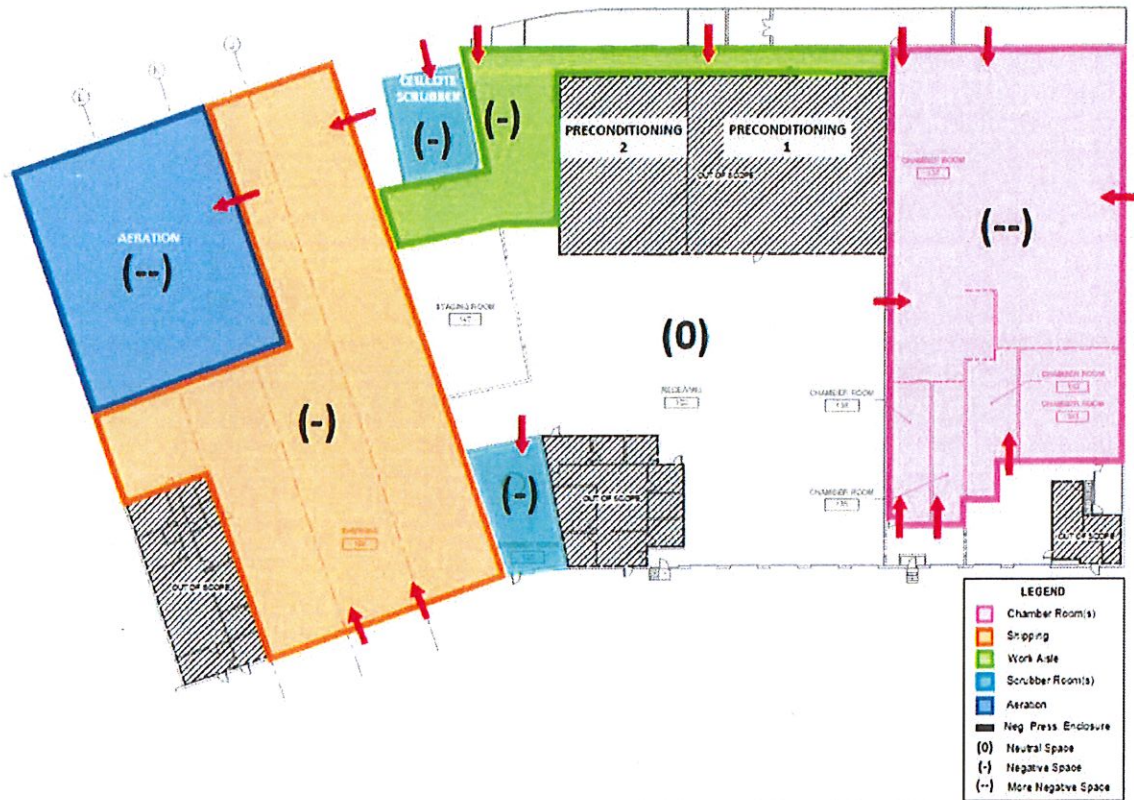
VII. DEFINITIONS/ABBREVIATIONS

N/A

VIII. REVISION HISTORY

| Revision | Section | Description of Change |
|----------|---------|-----------------------|
| 1 | ALL | New work instruction |

OVERALL PRESSURE PLAN
 STERIGENICS ATLANTA





RECEIVED

SEP 09 2019

Air Protection
Branch

September 6, 2019

Mr. Sean Taylor, Program Manager
Georgia EPD – Air Protection Branch
Stationary Source Compliance Program
4244 International Parkway, Suite 120
Atlanta, Georgia 30354

Subject: **Sterigenics Atlanta facility Work Practice Plan**

Dear Mr. Taylor

In accordance with Order Number EPD-AQC-6980, Sterigenics is providing a work practice plan for the Sterigenics Atlanta facility located at 2971 Olympic Industrial Drive, Suite 116, in Atlanta, Georgia.

Please contact me at kwagner@sterigenics.com or 630-928-1771 for questions or additional information.

Regards,

Kevin Wagner
Director, Environmental Health and Safety

Attachment: Work Practice Plan

CC: General Manager, Sterigenics Atlanta Facility

06700093

I. PURPOSE

This work instruction describes the practices taken to help limit fugitive emissions from the EO sterilization process

II. SCOPE

Covers the routine sterilization processing as well as non-routine tasks which could generate leaks, releases, or fugitive emissions of EO.

III. PROCESS OWNER

Atlanta EO facility management

IV. APPLICATION

This procedure applies to operations and areas of the facility where EO is used or contains sources which could emit EO including Chamber room, work aisle, emission control areas, aeration room, and the processed storage/shipping warehouse.

V. IMPLEMENTATION REQUIREMENTS

All requirements of this procedure will be implemented on the effective date

VI. PROCEDURE

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| REQUIREMENTS | <p>The Work Practice Plan is divided into two phases for implementation according to construction of the negative air system.</p> <ul style="list-style-type: none">A. Prior to final construction of the negative air system employees will ensure work practices are followed to minimize generation of EO fugitive emissions.B. Emission control systems will be utilized to the extent practical to capture and control EO fugitive emissions.C. The Advanced Air Technologies (AAT) scrubber/dry bed system will be inspected and tested frequently to ensure required efficiency is maintained.D. Enhanced reporting of confirmed Lower Explosive Limit (LEL) or Gas Chromatograph (GC) alarms which show a released amount of EO to the environment to local agencies.E. Initial and refresher training is required.F. Once new emission controls and negative pressure systems are installed, the facility will implement practices to ensure 100% of emissions are captured and all dry bed systems reduce emissions to an acceptable level:<ul style="list-style-type: none">1. AAT dry beds will not exceed an outlet reading of 1ppm2. Negative pressure system dry beds will not exceed an outlet reading of 1ppm. |
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| PROCEDURE | <p>A. Prior to installation of negative pressure system and dry beds:</p> <ol style="list-style-type: none">1. Upon receipt of EO drums from supplier, employees will use work practices already in place (as described in G-WI-EO-OPS-013, EO Drums: Safe Storage and Handling) to ensure drums are in good condition with no leaks prior to being brought into the facility.2. The monitoring devices in the EO drum storage area will be operational to monitor for leaks.3. Program the setting for Chamber Door Interlock/VAPORS to lowest levels (5% LEL/3% Release levels)4. At the end of the sterilization cycle, the chamber door will be opened slightly and the operator must allow the backvents to run for a minimum of 15-minutes prior to unloading the sterile product.5. During unloading of the sterile product and transfer to aeration pallets will not be staged and will be taken directly from chamber to aeration through the facility additional personnel will be used to decrease the time taken to move the product through uncontrolled areas.6. When unloading sterilization chambers of product, remove and immediately transport pallets directly to the aeration room, and do not stage pallets in the aisle before transporting to aeration.7. Maximize, to the extent practicable, the duration that a product remains in aeration before removal, consistent with customer approvals and customer shipping demands for each particular product8. The Shipping warehouse doors will be kept closed unless in use for loading trailers. Only one dock door can be opened at a time.9. Maintenance personnel will ensure safe practices for isolating EO lines, inspection of equipment, are followed to prevent leaks/releases.10. Enhance the current capture and control equipment:<ol style="list-style-type: none">i. The AAT drybed unit will be tested weekly using current sample bags and analysis with GC. The measured level cannot exceed 1ppm.ii. The barometric dampers in the sterilization chamber room exhaust to the AAT. The dampers will be used to the extent possible to capture any fugitive emissions in the area.iii. Maintenance to ensure any deviations to scrubber or dry bed operation are reported immediately to Corporate EH&S (scrubber tank level, pH, flow, EO concentration) <p>B. Reporting of EO Leaks and Releases</p> <ol style="list-style-type: none">1. In addition to current procedures for detecting and assessing leaks or releases, the facility will immediately notify corporate EH&S of any high |
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| | <p>level EO alarms so a joint investigation can be completed to determine quantity of the leak.</p> <ol style="list-style-type: none">2. The affected part of the process will be stopped until the investigation is complete to ensure safety.3. If the leaked amount of EO is determined to be > 10 lbs. or unknown within 15-minutes then an immediate notification to the National Response Center, Georgia EPD, the LEPC (Cobb County Fire Department) will be made.<ol style="list-style-type: none">a. Until the negative pressure system is installed, leaks will be reported to the LEPC and Georgia EPD regardless of amount.4. When safe to do so, a complete investigation for each incident will be conducted to determine root cause with corrective actions5. Follow-up reporting with each respective agency will be completed to report the final investigation report. <p>C. Training</p> <ol style="list-style-type: none">1. Training to be provided to all employees on this work instruction within 30 days.2. Annual training is required. <p>D. Operation and Maintenance of Negative Pressure System and Dry Beds</p> <ol style="list-style-type: none">1. All facility dry beds:<ol style="list-style-type: none">i. Dry bed media will be tracked to predict end of useful life in accordance with manufacturers recommendations based on EO usage.ii. In addition to the above, each dry bed system will be monitored weekly by taking an outlet sample with a Tedlar bag for 15-minutes. The sample will be analyzed with the GC and shall not exceed 1ppmiii. If a sample exceeds 1ppm a notification will be made to Corporate EH&S. A plan will be implemented to resample the system. If two consecutive samples are > 1ppm then the dry bed media will be changed out.iv. When dry bed media is changed out, each dry bed cell will be isolated from the system via damper valves. This will ensure the system can still operate with expected efficiency. The changeout of each bed will continue until all are complete.2. Facility doors<ol style="list-style-type: none">i. Doors to the facility will remain closed to ensure the negative pressure system is effective.ii. The facility will limit one dock door to be opened at a time. Dock seals will be installed to limit any openings around the docks while trailers are actively being loaded or unloaded. |
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Sterigenics Atlanta
EO Fugitives – Work Practice Plan

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| | <p>3. Special emission control work practices in case of breakdown</p> <ul style="list-style-type: none">i. If an emission control system unexpectedly fails the process will be cycle stoped.ii. If the negative dry bed system fan fails the secondary blower fan will be put online to ensure continued operation of the system.iii. If the facility loses power, then EOP-001 Power Outages will be followed and handheld monitors will be used throughout the facility to measure any EO levels. |
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VII. DEFINITIONS/ABBREVIATIONS

N/A

VIII. REVISION HISTORY

| Revision | Section | Description of Change |
|----------|---------|-----------------------|
| 1 | ALL | New work instruction |