

February 24, 2022

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

Sterigenics Atlanta facility Work Practice Plan Update Subject:

Dear Mr. Taylor

In accordance with the GA EPD permit, Sterigenics is providing an updated work practice plan for the Sterigenics Atlanta facility located at 2971 Olympic Industrial Drive, Suite 116, in Atlanta, Georgia.

Permit Number 7389-067-0093-S-06-0 condition 5.8 requires Sterigenics to submit an updated Work Practice Plan for the Atlanta facility within 60 days after issuance of this permit to ensure consistency with the permit and include a protocol to minimize ethylene oxide emissions from on-site trucks containing sterilized product.

On October 28, 2021, Sterigenics submitted a revised Work Practice Plan to reflect the indoor air system as well as add language regarding shipping practices which Georgia EPD approved on December 16, 2021. Sterigenics believes the updates previously submitted and approved meet the work practice requirements in the permit issued January 6, 2022. In addition to these revisions, the document format was updated in accordance with new internal template requirements during the document management system process. Please find attached the updated Work Practice Plan to satisfy the requirement to submit an updated Work Practice Plan within 60 days of permit issuance.

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

Regards,

Laura Hartman

Laura Hartin

Manager, Environmental Health and Safety

Attachment: Work Practice Plan

CC: General Manager, Sterigenics Atlanta Facility

Document No: AT-WI-046

Revision N°: 4.0 Effective Date:14-Mar-2022

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 in 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.

III. PROCESS OWNER

Atlanta EO facility management

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IV. IMPLEMENTATION REQUIREMENTS

All requirements of this procedure will be implemented on the effective date. (1)

V. PROCEDURE

A. REQUIREMENTS

All Atlanta facility employees

- 1. Employees will ensure work practices are followed to minimize generation of EO fugitive emissions.
- 2. Emission control systems will be utilized to the extent practical to capture and control EO fugitive emissions.
- The Advanced Air Technologies (AAT) scrubber/dry bed system will be inspected and bag tested weekly to ensure required performance is maintained.
- 4. 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.
- 5. Initial and annual refresher training is required.
- 5. 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. AAT dry beds will not exceed an outlet reading of 1ppm
 - 2. Negative pressure system dry beds will not exceed an outlet reading of 1ppm.

B. OPERATIONAL REQUIREMENTS

Atlanta Facility personnel trained to perform task

- Upon receipt of EO drums from supplier, employees will use work practices already in place (as described in <u>EO Drums: Safe Storage</u> <u>and Handling</u>) 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

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operational to monitor for leaks.

- 3. The (|) Chamber Door Interlock/VAPORS system will be utilized for each sterilization cycle to help reduce EO levels at the end of each cycle prior to opening the chamber door.
- 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, efforts will be taken to minimize product transfer time from the chambers to aeration.
- 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 be kept closed unless in use for loading trailers. Only two dock doors can be opened at a time.
- 8. Once trailers are loaded with processed product, the truck driver(s) will be advised to close the trailer doors and depart the site.
- Maintenance personnel will ensure safe practices for isolating EO lines and inspection of equipment are followed to prevent leaks/releases.
- 10. 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. (|) 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).

C. REPORTING OF EO LEAKS AND RELEASES

Atlanta Facility personnel trained to perform task

- 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.
- If the released 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.

D. TRAINING

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Atlanta Facility personnel trained to perform task

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

E. OPERATION AND MAINTENANCE OF NEGATIVE PRESSURE SYSTEM AND DRY BEDS

Atlanta Facility personnel trained to perform task

- 1. Negative pressure system:
 - i. Upon startup of the negative pressure system, verify by measurement or smoke testing while at least one rollup door is open, a trailer is backed up to the dock doors, and dock door seals are in place. Verification should include a measurement or smoke test along each outside wall of the negative pressure system, as well as the facility roof, where operational areas are located and there is a wall/roof penetration or opening. See *Appendix 1* for diagram of the negative pressure enclosure.
 - ii. On a daily basis, verify and record for informational purposes the negative pressure from the pressure gauges identified for the negative pressure system.
 - iii. Calibrate negative system pressure gauges annually.
- 2. All facility dry beds:
 - 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 air pressure areas will remain closed, except when in use, to ensure the negative pressure system is effective.
 - ii. The facility will limit two dock doors to be opened at a time in shipping. Dock seals are installed to limit any openings around the docks while trailers are actively being loaded or unloaded.
 - 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 for informational purposes.

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- 4. Special emission control work practices in case of breakdown
 - i. If an emission control system unexpectedly fails the process will be cycle stopped.
 - 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 <u>Electrical Power Outages</u> will be followed and handheld monitors will be used throughout the facility to measure any <u>EO levels</u>.

All doors and openings will remain closed during power outages except when in use for personnel ingress and egress.

VI. DEFINITIONS/ABBREVIATIONS

There are no definitions/abbreviations required in this revision

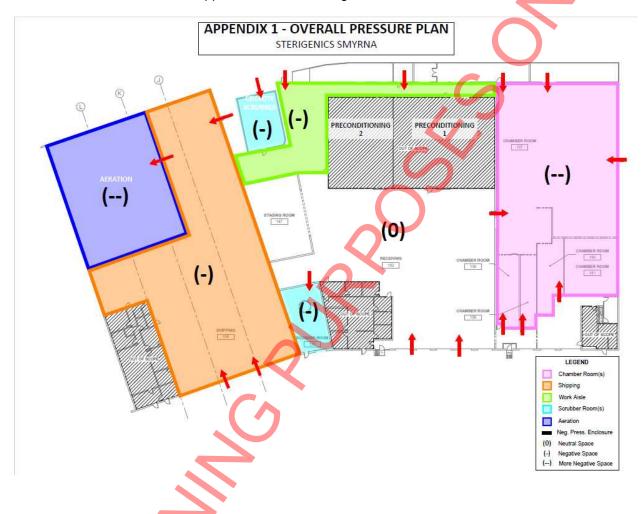
VII. REVISION HISTORY			
Revision	Section	Description of Change	
4	II	Added pertinent information from previous Application section	
	IV	Deleted Application section as per current work instruction template in MERLIN. Subsequent section numbers adjusted.	
	V.B.3	Clarified that VAPORS will be used on every run	
	V.B.5.	Clarified that transfer time to aeration will be minimized	
	V.B.8.	Added instruction for Shipping to advise truck drivers to close truck doors and depart site after processed product loading is complete.	
	V.B.10.ii	Deleted section no longer applicable	
	V.E.3.i V.E.4	Clarified except when in use	
3	N/A	No training required as revision was made to capture missing revision history from Revision 2 not included in distributed document.	
2	VI.A.3 VI.B.7 VI.C.3 VI.E.3.ii	Minor verbiage updates and changes in sections outlined.	
1	ALL	New work instruction	

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Appendix 1 – Atlanta Negative Air Overview



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Approvers:	
Mosby, Daryl	2022-02-09 21:07:48 GMT
Gaitor, Kenneth	2022-02-10 19:55:17 GMT
Hartman, Laura	2022-02-09 21:16:03 GMT