## IN THE SUPERIOR COURT OF NEWTON COUNTY STATE OF GEORGIA

RICHARD E. DUNN, DIRECTOR,	)
ENVIRONMENTAL PROTECTION DIVISION,	)
GEORGIA DEPARTMENT OF NATURAL	)
RESOURCES,	)
Plaintiff,	) ) )
$\mathbf{v}_{\star_{\mathbf{u}}}$	) Civil Action File Number:
BECTON, DICKINSON and COMPANY,	)
Defendant.	) )
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## DIRECTOR'S VERIFIED COMPLAINT TO ENJOIN THE UNLAWFUL OPERATION OF A MEDICAL DEVICE STERILIZATION FACILITY

COMES NOW Richard E. Dunn, Director (Director) of the Environmental Protection Division of the Georgia Department of Natural Resources (EPD) and brings this action to enjoin Becton, Dickinson and Company (BD) from continuing to operate a medical device sterilization facility in Covington, Georgia in violation of the requirements of the Georgia Air Quality Act, O.C.G.A. §§ 12-9-1 through 12-9-25 (the Act) and the Rules for Air Quality Control promulgated thereunder, Ga. Comp. R. & Regs. 391-3-1-.01 through 391-3-1-.15 (the Rules). Injunctive relief is authorized under O.C.G.A. § 12-9-12 based on: (1) BD's failure to report to EPD that it released 54.5 pounds of ethylene oxide into the atmosphere and (2) BD's failure to take all reasonable precautions to prevent fugitive emissions of ethylene oxide in a timely manner as required by its Air Quality Permit and the Rules.

## PARTIES, JURISDICTION, AND VENUE

1.

The Director is the Plaintiff in this action and seeks to enforce the requirements of the Act and the Rules by enjoining BD in order to protect the public health, safety, and welfare.

2.

BD, a New Jersey corporation, is the Defendant in this action and is subject to the jurisdiction of this Court. BD may be served through its registered agent CT Corporation System, at 289 S. Culver St., Lawrenceville, Georgia, 30046-4805.

3.

BD owns and operates a medical device sterilization facility located at 8195 Industrial Boulevard in Covington, Newton County, Georgia (the Facility). All acts and failures to act complained of herein occurred in Newton County.

4.

This Court, upon hearing and for cause shown, has jurisdiction to grant a temporary or permanent injunction, restraining or other order enjoining any person from violating the Act. See O.C.G.A. § 12-9-12.

5.

Pursuant to O.C.G.A. § 12-9-12 jurisdiction and venue are proper in the Superior Court of Newton County where the unlawful acts have and continue to occur.

## STATUTORY AND REGULATORY FRAMEWORK

6.

EPD regulates air quality in the State of Georgia under the Georgia Air Quality Act and also implements the federal Clean Air Act 42 U.S.C. §§ 7401 to 7671q pursuant to a delegation of authority from the United States Environmental Protection Agency (USEPA).

7.

In the course of regulating air quality, EPD coordinates with USEPA in the adoption of rules and relies upon information and studies done by USEPA.

8.

BD is required to operate the facility in compliance with the Act, the Rules, and the Air Quality Permit Number 3841-217-0021-S-04-0 (the Permit) that the Director issued to BD on December 27, 2018. See the Permit attached as Exhibit A.

9.

Under O.C.G.A. § 12-9-12, the Director may apply for injunctive relief when any person has engaged in or is about to engage in any act or practice which constitutes an unlawful action under the Act.

#### FACTUAL BACKGROUND

10.

In 2016, the United States Environmental Protection Agency (USEPA) characterized ethylene oxide as a known carcinogen and produced a "total cancer unit risk" that estimated the possible increased cancer risk from continuously

inhaling a specified concentration of ethylene oxide over a lifetime. See https://www.epa.gov/iris/iris-recent-additions (last visited October 21, 2019) (containing the Integrated Risk Information System risk assessment characterizing ethylene oxide as carcinogenic to humans by the inhalation route of exposure for the first time in 2016).

11.

BD uses ethylene oxide to sterilize medical devices. According to the U.S. Food and Drug Administration (FDA) ethylene oxide is often used by manufacturers because, unlike other sterilization methods such as moist heat (steam), dry heat, radiation or vaporized hydrogen peroxide, ethylene oxide does not damage medical devices during the sterilization process. The FDA states that, "medical devices made from certain polymers (plastic or resin), metals, or glass, or that have multiple layers of packaging or hard-to-reach places (for example, catheters) are likely to be sterilized with ethylene oxide." See <a href="https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices#why">https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices#why</a> (last visited October 21, 2019).

12.

In August 2018, USEPA published the National Air Toxics Assessment (NATA) which is periodically updated, based on source data collected beginning in 2014 and including 2014 ethylene oxide emissions data from BD's Facility. See <a href="https://www.epa.gov/national-air-toxics-assessment">https://www.epa.gov/national-air-toxics-assessment</a> (last visited October 21, 2019).

The results of the NATA showed that a census tract located near the Facility warranted further study.

13.

As a result of the NATA, EPD contacted BD to request information regarding its emissions of ethylene oxide. EPD used the updated data from BD to conduct computer air modeling regarding the risks to the public in the area of the Facility as a result of ethylene oxide emissions. On June 7, 2019, EPD completed its report memo: Modeling Analysis for Ethylene Oxide Becton Dickinson (formerly C. R. Bard), Covington, Newton County, GA memo (the Modeling Memo). See the Modeling Memo attached as Exhibit B.

14.

The Clean Air Act standard for an acceptable risk of potential excess cancers over a seventy-year lifetime if exposed to that concentration continuously (24 hours per day seven days per week) is 100 in one million. Anything above 100 in one million is an unacceptable risk. See <a href="https://www.epa.gov/national-air-toxics-assessment/nata-frequent-questions#risk1">https://www.epa.gov/national-air-toxics-assessment/nata-frequent-questions#risk1</a> (last visited October 21, 2019). Although the Modeling Memo indicates that the modeled concentrations of ethylene oxide at the closest residences to BD were at or below 100 in one million, the concentration modeled at some residences was found to be above the Acceptable Ambient Concentration (AAC) for ethylene oxide in Appendix A of EPD's Guideline for Ambient Impact Assessment of Toxic Air Pollutant Emissions. See

https://epd.georgia.gov/air-protection-branch-technical-guidance-0/toxic-impact-assessment-guideline (last visited October 21, 2019).

15.

If the modeled concentration of a toxic air pollutant is above the AAC, EPD requires that the company either: (1) reduce emissions of that air toxic, or (2) take other steps to ensure that the concentrations at nearby residences and businesses are below the AAC for that pollutant, or (3) demonstrate that they reduced emissions of that pollutant to the maximum extent possible. EPD shared the Modeling Memo with BD in June of 2019 and in August of 2019 requested that BD take steps to reduce its emissions of the toxic air pollutant ethylene oxide as soon as possible with an emphasis on reducing fugitive emissions.

16.

EPD has worked diligently to encourage BD to reduce its ethylene oxide emissions at the Facility as soon as possible. But, EPD's efforts have been to no avail. Despite public statements of being cooperative, BD has not been a cooperative partner with EPD. To date, BD has not submitted a permit modification application or any other substantive document to EPD indicating that it has made progress toward reducing ethylene oxide emissions at the Facility. In sum, based upon information that has come to EPD's attention, it appears that BD has taken few, if any, demonstrable steps to reduce emissions of ethylene oxide at the Facility.

BD's lack of progress toward achieving a reduction of ethylene oxide emissions is in stark contrast to the response that EPD has gotten from other similar commercial sterilizers in Georgia. EPD asked two other commercial sterilizers to submit permit modifications and reduce their ethylene oxide emissions. Those facilities complied with EPD's request and are progressing in their efforts to reduce ethylene oxide emissions.

18.

BD's sterilization process at the Facility involves placing the medical devices in a vented sterilization chamber and introducing ethylene oxide gas to the sterilizer chamber to accomplish sterilization. Once sterilization is complete, a vacuum process pulls ethylene oxide from the sterilization chamber through the sterilizer chamber vent to the emission control device. Finally, the medical devices are aerated following sterilization.

19.

On September 23, 2019, BD discovered that, due to operator error, the exhaust valve on the chamber vent that is part of the vacuum process for sterilizer chamber 5 was not fully closed. That valve, while opened vented ethylene oxide into the atmosphere. See the Incident Report at Exhibit C.

20.

Upon investigating further, BD determined that the Facility had intermittently released ethylene oxide into the atmosphere from September 15,

2019 through September 22, 2019 as a result of the partially open valve. The release was in violation of the Permit. See the Incident Report at Exhibit C.

21.

EPD has been conducting weekly phone calls with BD since August 2019 for the purpose of seeking updates on BD's activities toward accomplishing a reduction in the ethylene oxide emissions at the Facility. On September 24, 2019, during a routine weekly call, BD first notified EPD that a release of ethylene oxide had occurred. During the call with EPD, which occurred the day after BD had discovered the release; BD failed to recognize or disclose the duration and extent of the release to EPD representing initially that it lasted one day and involved the release of only two pounds of ethylene oxide. EPD requested additional information.

22.

Three days later, on September 27, 2019, BD provided additional information to EPD in an Incident Report indicating a much longer and more significant event. Specifically, on page 3 of its Incident Report BD calculates that 54.5 pounds of ethylene oxide were released into the atmosphere over the course of eight days as a result of operator error. See the Incident Report at Exhibit C.

23.

BD's Incident Report indicates that between September 15, 2019 and September 22, 2019, BD used a total of 2,050 pounds of ethylene oxide in

sterilization chamber number five with the valve partially open. See the Incident Report at Exhibit C, p. 3.

24.

The release of 54.5 pounds of ethylene oxide during the eight day period when 2,050 pounds of ethylene oxide was used in sterilization chamber number five indicates a 97.3% reduction of ethylene oxide emissions to the atmosphere from that sterilization chamber vent. Permit Condition 2.3 requires that, "the ethylene oxide emissions to the atmosphere from each sterilizer chamber vent shall be reduced by at least 99%." Thus, the release constitutes a violation of the Permit. See the Permit, p. 2 at Exhibit A.

25.

BD represented in its Incident Report that by September 30, 2019 it would ensure all technicians were trained on operation of the style of valve that was left partially open. To date, BD has not presented EPD with evidence that the training has taken place. See the Incident Report at Exhibit C, p. 2.

26.

BD's Incident Report also indicates it will install blanks on the outlet to the vacuum exhaust valve to prevent flow regardless of valve position or condition.

BD's target date for completion of the installation is October 25, 2019. With knowledge of the possibility of unintended release of ethylene oxide, BD is continuing normal operations despite the risk of another negligent release during the interim period.

As a result of public concern regarding the emissions of ethylene oxide at the Facility, the City of Covington (the City) contracted for seven days of ambient air monitoring in the area surrounding the Facility. The City notified BD, EPD, and the public of its plan before the air monitoring commenced. The City worked with BD and requested that a BD official certify daily that the company was conducting normal operations during the period of air monitoring. BD agreed to do so. The City's contractor conducted the air monitoring from September 17, 2019 through September 23, 2019.

28.

From September 17, 2019 through September 23, 2019, BD provided the City of Covington with the requested Affidavits thereby certifying that the Facility was operating normally during the seven day test period. Specifically, BD certified that it was conducting its usual operations in accordance with its 2019 Standard Operating Procedures. See the Affidavits attached as Exhibit D.

29.

The Affidavits were provided to the City by BD even though, during the monitoring period, BD was intermittently releasing ethylene oxide into the atmosphere starting on September 15, 2019 - two days before the air monitoring commenced, through almost the entire monitoring period which ended on September 23, 2019 - the day BD discovered the release. BD either acted in bad faith in providing the Affidavits to the City or BD acted negligently because BD

either knew that it was experiencing an unauthorized release in violation of the Permit or it should have known.

30.

The City of Covington's contractor conducted air testing in 11 locations in Newton County and other counties and on October 16, 2019, the City shared its ambient air testing results with EPD. While the measured concentrations varied widely and include ethylene oxide emitted from other sources, the average<sup>1</sup> concentration measured was 1.97 micrograms per cubic meter, which is well above 0.02 micrograms per cubic meter, the concentration that USEPA considers as posing an acceptable risk, if exposed to that concentration continuously over a lifetime.

31.

Of greatest concern to EPD are the average concentrations measured in two neighborhoods close to BD: (1) the average concentration in Settler's Grove Area was 4.08 micrograms per cubic meter and (2) the average concentration in the Covington Mill Area was 6.45 micrograms per cubic meter. EPD submits that the higher concentrations measured in the neighborhoods close to BD during the monitoring period indicated that BD's emissions of ethylene oxide increased the ethylene oxide concentrations in the ambient air in those two areas. The City of Covington's air monitoring results are attached as Exhibit E.

<sup>&</sup>lt;sup>1</sup> Average does not include duplicate samples or samples analyzed at the second laboratory.

Permit Condition 3.1 requires BD to, "take all reasonable precautions with any operation, handling, transportation, or storage facilities to prevent fugitive emissions of air contaminants." See the Permit, p. 2 at Exhibit A.

33.

USEPA defines "fugitive emissions" in the regulations promulgated under Title V of the Clean Air Act as "those emissions which could not reasonably pass through a stack, chimney, vent, or other functionally-equivalent opening." 40 CFR § 70.2.

34.

Ga. Comp. R. & Regs. 391-3-1-.02(2)(a)(1) provides:

No person owning, leasing or controlling the operation of any air contaminant sources shall willfully, negligently or through failure to provide necessary equipment or facilities or to take necessary precautions, cause, permit, or allow the emission from said air contamination source or sources of such quantities of air contaminants as will cause, or tend to cause, by themselves or in conjunction with other air contaminants a condition of air pollution in quantities or characteristics or of a duration which is injurious or which unreasonably interferes with the enjoyment of life or use of property in such area of the State as is affected thereby. Complying with any of the other paragraphs of these rules and regulations or any subparagraphs thereof, shall in no way exempt a person from this provision.

35.

Given USEPA's determination that ethylene oxide is a known carcinogen and EPA's "total cancer unit risk" discussed in paragraph 10, *above*, whereby EPA estimates a possible increased cancer risk from continuously inhaling a specified

concentration of ethylene oxide over a lifetime, EPD is working to reduce ethylene oxide emissions in Georgia. Based on information provided to EPD by BD, EPD estimates that BD is allowing 555.7 pounds per year of fugitive emissions of ethylene oxide into the atmosphere in the immediate vicinity of the Facility. See the Modeling Memo at Exhibit B.

36.

BD has the ability to control the fugitive emissions but is not acting expeditiously to accomplish reductions. In short, BD has failed or refused to recognize the urgency EPD believes is necessary to accomplish a reduction of ethylene oxide in a timely manner and to act accordingly. The quantity and duration of the fugitive emissions from the Facility violate Ga. Comp. R. & Regs. 391-3-1-.02(2)(a)(1) because they are injurious and unreasonably interfere with the enjoyment of life or use of property in the immediate vicinity of the Facility in Covington, Georgia.

## COUNT I (Violation of Permit Condition 2.3)

37.

EPD hereby incorporates the foregoing paragraphs numbered 1 through 36, as if fully set forth herein.

38.

Between September 15, 2019 and September 22, 2019, BD negligently allowed the release of 54.5 pounds of ethylene oxide to the atmosphere as a result of its operator's error in violation of Condition 2.3 of the Permit as well as O.C.G.A.

§12-9-7(a) and Ga. Comp. R. & Regs. 391-3-1-.03(2)(g) which require BD to operate in compliance with the Permit. BD has not taken the necessary corrective actions to ensure that a negligent release will not recur. BD acted negligently or in bad faith in certifying normal operations to the City of Covington during the period when it was intermittently releasing ethylene oxide.

39.

Based on the foregoing, injunctive relief against BD is necessary to protect the health and welfare of the public, residents, and visitors to the State of Georgia.

O.C.G.A. § 12-9-12.

## COUNT II (Violation of Permit Condition 3.1)

40.

The Director hereby incorporates the foregoing paragraphs numbered 1 through 39, as if fully set forth herein.

41.

BD is operating in violation of Permit Condition 3.1 relating to the release of fugitive emissions. BD has not taken "reasonable precautions...to prevent fugitive emissions of air contaminants."

42.

BD has failed to submit a permit modification application or any other substantive document to EPD indicating that it has made progress toward reducing ethylene oxide emissions at the Facility.

BD is willfully or negligently allowing 555.7 pounds per year of fugitive emissions of ethylene oxide into the atmosphere surrounding the Facility in violation of Condition 3.1 of the Permit as well as O.C.G.A. § 12-9-7 and Ga. Comp. R. & Regs. 391-3-1-.03(2)(g) which require BD to operate in compliance with the Permit.

44.

The quantity and duration of the fugitive emissions is injurious and unreasonably interferes with the enjoyment of life or use of property in Covington, Georgia in violation of Ga. Comp. R. & Regs. 391-3-1-.02(2)(a)(1).

## NO REQUIREMENT TO SHOW LACK OF ADEQUATE REMEDY AT LAW

45.

The Director is authorized to apply to the Superior Court for an injunction, without the necessity of showing lack of an adequate remedy at law in accordance with O.C.G.A. § 12-9-12.

WHEREFORE, the Director respectfully requests the following:

- (a) That the Court take jurisdiction over the parties and of the subject matter of this action;
- (b) That the Court issue a temporary restraining order and preliminary and permanent injunctive relief against BD prohibiting it from operating the Facility and conducting any sterilization of medical

devices at the Facility until it has demonstrated to the Court that it has:

- Trained all technicians on the proper operation of all valves in the Facility,
- (2) Completed corrective action to prevent a future release from all vacuum exhaust valves at the Facility by installing blanks on the outlets to all vacuum exhaust valves to prevent flow regardless of valve position or condition, and
- (3) Install necessary pollution control equipment to capture fugitive emissions of ethylene oxide at the Facility and route them to a control device with at least 99% efficiency.
- (c) That the Court schedule a hearing on this matter;
- (d) That the Director have such other and further relief as the Court deems just, proper, and equitable; and
- (e) That BD bear all costs in this matter.

Respectfully submitted,

CHRISTOPHER M. CARR

112505

Attorney General

ISAAC BYRD

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## PLEASE SERVE:

MARGARET KEMMERLY ECKROTE Senior Assistant Attorney General 40 Capitol Square SW Atlanta, Georgia 30334-1300 Telephone: (404) 656-7540

## **VERIFICATION**

I, Richard E. Dunn, personally appearing before the undersigned officer duly authorized by law to administer oaths, come now, on behalf of the Environmental Protection Division of the Georgia Department of Natural Resources, after being duly sworn, under penalty of perjury, and depose and say that I have read the foregoing Verified Complaint to Enjoin Becton, Dickinson and Company (BD) from operating a medical device sterilization facility in an unlawful manner and the facts stated therein are true and correct to the best of my knowledge and belief.

This 21st day of October 2019.

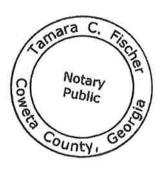
Richard E. Dunn, Director (Environmental Protection Division

SWORN TO AND SUBSCRIBED BEFORE ME THIS  $21^{\text{ST}}$  day of October, 2019.

Tamara C. Fischer

NOTARY PUBLIC

My Commission Expires: 1-27-2022



PERMIT NO. 3841-217-0021-S-04-0 ISSUANCE DATE: December 27, 2018



## ENVIRONMENTAL PROTECTION DIVISION

## **Air Quality Permit**

In accordance with the provisions of the Georgia Air Quality Act, O.C.G.A. Section 12-9-1, et seq and the Rules, Chapter 391-3-1, adopted pursuant to and in effect under that Act,

**Facility Name:** 

BD (Becton, Dickinson and Company)

Facility Address:

8195 Industrial Boulevard

Covington, Georgia 30014, Newton County

**Mailing Address:** 

8195 Industrial Boulevard

Covington, Georgia 30014

**Facility AIRS Number:** 

04-13-217-00021

is issued a Permit for the following:

The operation of an ethylene oxide sterilization facility.

This Permit is issued for the purpose of establishing practically enforceable emission limitations such that the facility will not be considered a major source with respect to Title V of the Clean Air Act Amendments of 1990.

This Permit is conditioned upon compliance with all provisions of The Georgia Air Quality Act, O.C.G.A. Section 12-9-1, et seq, the Rules, Chapter 391-3-1, adopted and in effect under that Act, or any other condition of this Permit.

This Permit may be subject to revocation, suspension, modification or amendment by the Director for cause including evidence of noncompliance with any of the above; or for any misrepresentation made in Application No. 26803 dated October 29, 2018; any other applications upon which this Permit is based; supporting data entered therein or attached thereto; or any subsequent submittals or supporting data; or for any alterations affecting the emissions from this source.

This Permit is further subject to and conditioned upon the terms, conditions, limitations, standards, or schedules contained in or specified on the attached 7 pages.



[Signed]

Richard E. Dunn, Director Environmental Protection Division



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## 1. General Requirements

- 1.1 At all times, including periods of startup, shutdown, and malfunction, the Permittee shall maintain and operate this source, including associated air pollution control equipment, in a manner consistent with good air pollution control practice for minimizing emissions. Determination of whether acceptable operating and maintenance procedures are being used will be based on information available to the Division which may include, but is not limited to, monitoring results, opacity observations, review of operating and maintenance procedures, and inspection or surveillance of the source.
- 1.2 The Permittee shall not build, erect, install or use any article, machine, equipment or process the use of which conceals an emission which would otherwise constitute a violation of an applicable emission standard. Such concealment includes, but is not limited to, the use of gaseous diluents to achieve compliance with an opacity standard or with a standard that is based on the concentration of a pollutant in the gases discharged into the atmosphere.
- 1.3 The Permittee shall submit a Georgia Air Quality Permit application to the Division prior to the commencement of any modification, as defined in 391-3-1-.01(pp), which may result in air pollution and which is not exempt under 391-3-1-.03(6). Such application shall be submitted sufficiently in advance of any critical date involved to allow adequate time for review, discussion, or revision of plans, if necessary. The application shall include, but not be limited to, information describing the precise nature of the change, modifications to any emission control system, production capacity and pollutant emission rates of the plant before and after the change, and the anticipated completion date of the change.
- 1.4 Unless otherwise specified, all records required to be maintained by this Permit shall be recorded in a permanent form suitable for inspection and submission to the Division and shall be retained for at least five (5) years following the date of entry.
- 1.5 In cases where conditions of this Permit conflict with each other for any particular source or operation, the most stringent condition shall prevail.

#### 2. Allowable Emissions

- 2.1 The Permittee shall comply with all applicable provisions of the National Emission Standard for Hazardous Air Pollutants (NESHAP) as found in 40 CFR Part 63 Subpart O, "Ethylene Oxide Emission Standards from Sterilization Facilities" for the operation of the ethylene oxide sterilization equipment.

  [40 CFR 63 Subpart O: 40 CFR 63 360]
  - [40 CFR 63 Subpart O; 40 CFR 63.360]
- 2.2 The Permittee shall comply with all applicable provisions of 40 CFR Part 63 Subpart A "General Provisions" as specified in Table 1 of 40 CFR 63 Subpart O. [40 CFR 63 Subpart A; 40 CFR 63.360]

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- 2.3 The ethylene oxide emissions to the atmosphere from each sterilizer chamber vent shall be reduced by at least 99%.

  [40 CFR 63 Subpart O; 40 CFR 63.362(c); 40 CFR 70 Avoidance for HAP and VOC]
- 2.4 The Permittee shall either reduce ethylene oxide emissions from each aeration room vent to 1 ppm by volume or less or by at least 99%.

  [40 CFR 63 Subpart O; 40 CFR 63.362(d); 40 CFR 70 Avoidance for HAP and VOC]
- 2.5 The emission limitations of Condition Nos. 2.3. and 2.4 apply during sterilization operation. The emission limits do not apply during periods of malfunction.

  [40 CFR 63 Subpart O; 40 CFR 63.362(b)]
- 2.6 The Permittee shall comply with the emissions limitations of 40 CFR Part 63, Subpart O as follows:

  [40 CFR 63 Subpart O; 40 CFR 63.360(g)]
  - a. All sterilization chamber vents with an initial startup date after December 6, 1998 shall comply immediately upon initial startup of the source.
  - b. All aeration room vents with an initial startup date on or after December 6, 2000, shall comply immediately upon initial startup of the source.

#### 3. Fugitive Emissions

3.1 The Permittee shall take all reasonable precautions with any operation, process, handling, transportation, or storage facilities to prevent fugitive emissions of air contaminants.

## 4. Process & Control Equipment

- 4.1 The Permittee shall operate the Regenerative Thermal Oxidizer (RTO-1) at or above 1447 degrees Fahrenheit (or a new minimum oxidation temperature approved in writing by the Division), except during periods of startup, shutdown, or malfunction. An operating parameter deviation is defined as any 24-hour average of the oxidation temperature for the Regenerative Thermal Oxidizer (RTO-1) that is below 1447 degrees Fahrenheit (or a new minimum oxidation temperature approved in writing by the Division). The Permittee may establish a new minimum oxidation temperature based on performance testing and that is at least equal to or higher than the recommended minimum oxidation temperature provided by the Regenerative Thermal Oxidizer (RTO-1) manufacturer.

  [40 CFR 63 Subpart O; 40 CFR 63.363(b)(3), 40 CFR 63.363(f)]
- 4.2 Routine maintenance shall be performed on all air pollution control equipment. Maintenance records shall be recorded in a permanent form suitable and available for inspection by the Division. The records shall be retained for at least five years following the date of such

maintenance.

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- 4.3 A spare parts inventory for control equipment shall be maintained by the Permittee.
- 4.4 Malfunctioning components of air pollution control systems shall be repaired as expeditiously as possible.

#### 5. Monitoring

- 5.1 The Permittee shall either continuously monitor and record the oxidation temperature using the temperature monitor(s) described in Condition No. 5.2 or measure and record the ethylene oxide concentration in accordance with 40 CFR 63.364(e). Monitoring is required only when the Regenerative Thermal Oxidizer (RTO-1) is operated.

  [40 CFR 63 Subpart O; 40 CFR 63.364(c)]
- 5.2 The Permittee shall install, calibrate, maintain, and operate a system to continuously monitor and record the oxidation temperature as determined from the average reading of the three combustion chamber temperature sensors on the Regenerative Thermal Oxidizer (RTO-1). Monitoring is required only when Regenerative Thermal Oxidizer (RTO-1 is operated. The temperature monitor shall be accurate within ±5.6 degrees Celsius (± 10 degrees Fahrenheit). Where such performance specification(s) exist, each system shall meet the applicable performance specification(s) of the Division's monitoring requirements. [40 CFR 63 Subpart O; 40 CFR 63.364(c)]
- 5.3 The Permittee shall verify the accuracy of the temperature monitor required by Condition No. 5.2 twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards)

  [40 CFR 63 Subpart O; 40 CFR 63.364(c)(4)]
- 5.4 Any monitoring system installed by the Permittee shall be in continuous operation except during calibration checks, zero and span adjustments or periods of repair. Maintenance or repair shall be conducted in the most expedient manner to minimize the period during which the system is out of service.
- 5.5 The Permittee shall provide and maintain a spare parts inventory for any monitoring system installed. A list of parts to be kept in inventory shall be kept in a form suitable for inspection by the Division for no less than five years.

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## 6. Performance Testing

- 6.1 The Permittee shall cause to be conducted a performance test at any specified emission point when so directed by the Division. The following provisions shall apply with regard to such tests:
  - a. All tests shall be conducted and data reduced in accordance with applicable procedures and methods specified in the Division's Procedures for Testing and Monitoring Sources of Air Pollutants.
  - b. All test results shall be submitted to the Division within sixty (60) days of the completion of testing.
  - c. The Permittee shall provide the Division thirty (30) days prior written notice of the date of any performance test(s) to afford the Division the opportunity to witness and/or audit the test, and shall provide with the notification a test plan in accordance with Division guidelines.
  - d. All monitoring systems and/or monitoring devices required by the Division shall be installed, calibrated and operational prior to conducting any performance test(s). For any performance test, the Permittee shall, using the monitoring systems and/or monitoring devices, acquire data during each performance test run. All monitoring system and/or monitoring device data acquired during the performance testing shall be submitted with the performance test results.
- 6.2 In accordance with 40 CFR 63.7(b) and 63.9(e), the Permittee shall notify the Division of intent to conduct a performance test at least 60 calendar days before the performance test is scheduled to begin. If the test must be rescheduled due to unforeseeable circumstances beyond his control, the Permittee shall notify the Division within five (5) days prior to the scheduled date of the test and shall specify the date when the test is rescheduled.
- 6.3 In accordance with 40 CFR 63.7(c)(4), the Permittee shall analyze performance audit samples during each performance test.
- 6.4 The Permittee shall provide performance testing facilities as specified in 40 CFR 63.7(d). Performance tests shall be conducted under conditions based on representative performance of the source and as otherwise specified in 40 CFR 63.7(e).
- 6.5 In accordance with 40 CFR 63.7(c)(2), the Permittee shall submit a site-specific test plan along with the Notification of Intent to conduct a performance test.
- 6.6 In accordance with 40 CFR 63.7(g), 63.9(h), 63.10(d), and 63.366(a), the Permittee shall submit the results of a performance test within 60 days following completion of the test.

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## 7. Notification, Reporting and Record Keeping Requirements

- 7.1 The Permittee shall maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, any malfunction of the air pollution control equipment or any periods during which a continuous monitoring system or monitoring device is inoperative. The Permittee shall retain these records for a period of at least five (5) years after the date of any such startup, shutdown, or malfunction.
- 7.2 The Permittee shall maintain a file of all measurements, including continuous monitoring system, monitoring device, and performance testing measurements; all continuous monitoring system performance evaluations; all continuous monitoring system or monitoring device calibration checks; adjustments and maintenance performed on these systems or devices; and all other information required by this Permit. The information shall be recorded in a permanent form suitable and available for inspection and shall be retained for at least five (5) years following the date of such measurements maintenance, reports, and records.
- 7.3 The data acquisition system for the temperature monitors required by Condition No. 5.2 shall compute and record a daily average oxidation temperature from the 15-minute or shorter period temperature values. Strip chart data shall be converted to record a daily average oxidation temperature for each day any instantaneous temperature recording falls below the minimum temperature.

[40 CFR 63 Subpart O; 40 CFR 63.364(c)]

- 7.4 The Permittee shall maintain files of all information required by this permit or by 40 CFR 63 in a form suitable and available for expeditious inspection and review for at least five years following date of entry in accordance with 40 CFR 63.10(b)(1).
- 7.5 The Permittee shall maintain General records and CMS records as specified by 40 CFR 63.10(b)(2) and (c), respectively, and Table 1 of 40 CFR 63 Subpart O.
- 7.6 In accordance with 40 CFR 63.10, 63.366(a), and Table 1 of 40 CFR 63 Subpart O, the Permittee shall submit the following reports:
  - a. Deviation reports; and
  - b. Continuous Monitoring System performance and summary reports

Contents and submittal dates for Deviation and Continuous Monitoring System Performance Reports shall be as specified in 40 CFR 63.366(a)(3).

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- 7.7 The Permittee shall submit a written report containing any excess emissions, exceedances, and/or excursions as described in this permit and any monitor malfunctions for each semiannual period ending June 30<sup>th</sup> and December 31<sup>st</sup> of each year. All reports shall be postmarked by the 30<sup>th</sup> day following the end of each reporting period, July 30<sup>th</sup> and January 30<sup>th</sup>. In the event that there have not been any excess emissions, exceedances, excursions, or malfunctions during a reporting period, the report should so state. Otherwise, the contents of each report shall be as specified by the Division's Procedures for Testing and Monitoring Sources of Air Pollutants and shall contain the following:

  [391-3-1-.02(6)(b)1, 40 CFR 63.10(e)]
  - a. A summary report of excess emissions, exceedances and excursions, and monitor downtime, in accordance with Section 1.5(c) and (d) of the above referenced document, including any failure to follow required work practice procedures.
  - b. Total process operating time during each reporting period.
  - c. The magnitude of all excess emissions, exceedances and excursions computed in accordance with the applicable definitions as determined by the Director, and any conversion factors used, and the date and time of the commencement and completion of each time period of occurrence.
  - d. Specific identification of each period of such excess emissions, exceedances, and excursions that occur during startups, shutdowns, or malfunctions of the affected facility. Include the nature and cause of any malfunction (if known), the corrective action taken or preventive measures adopted.
  - e. The date and time identifying each period during which any required monitoring system or device was inoperative (including periods of malfunction) except for zero and span checks, and the nature of the repairs, adjustments, or replacement. When the monitoring system or device has not been inoperative, repaired, or adjusted, such information shall be stated in the report.
  - f. Certification by a Responsible Official that based on information and belief formed after reasonable inquiry, the statements and information in the report are true, accurate, and complete.

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## 8. Special Conditions

- 8.1 At any time that the Division determines that additional control of emissions from the facility may reasonably be needed to provide for the continued protection of public health, safety and welfare, the Division reserves the right to amend the provisions of this Permit pursuant to the Division's authority as established in the Georgia Air Quality Act and the rules adopted pursuant to that Act.
- 8.2 The Permittee shall calculate and pay an annual Permit fee to the Division. The amount of the fee shall be determined each year in accordance with the "Procedures for Calculating Air Permit Fees."
- 8.3 Georgia Air Quality Permit No. 3841-217-0021-S-03-0, is hereby revoked in its entirety.



#### Richard E. Dunn, Director

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

### **MEMORANDUM**

June 7, 2019

To: James Boylan
Thru: Byeong-Uk Kim
From: Yan Huang

**Subject: Modeling Analysis for Ethylene Oxide** 

Becton Dickinson (formerly, C. R. Bard), Covington, Newton County, GA

## **GENERAL INFORMATION**

As part of a review on the EPA 2014 National Air Toxics Assessment (NATA), air dispersion modeling of ethylene oxide was conducted by the Georgia Environmental Protection Division (GA EPD) to assess the impacts of ethylene oxide emissions from Becton Dickinson (AIRS# 21700021) on ambient air surrounding the facility. Although this modeling analysis is not for issuance of a permit, GA EPD adopted procedures described in GA EPD's Guideline for Ambient Impact Assessment of Toxic Air Pollutant Emissions<sup>1</sup>.

This memo discusses modeling results including the procedures used to develop the dispersion modeling. Becton Dickinson sterilizes packaged medical equipment shipped from other locations using ethylene oxide. After sterilization, the ethylene oxide is displaced with air and vented to a regenerative thermal oxidizer (RTO) and 14 exhaust fans. The air toxic impacts from ethylene oxide emissions was below its Acceptable Ambient Concentration (AAC) at the 15-min averaging period, but exceeded its annual AAC. Site-specific risk assessments were performed at five nearby residential areas and the modeled ground-level concentrations exceeded the annual AAC at all five residential areas. The results are summarized in the following sections of this memorandum.

## **INPUT DATA**

- 1. Meteorological Data Hourly meteorological data (2014 to 2018) used in this review were generated by GA EPD (<a href="http://epd.georgia.gov/air/georgia-aermet-meteorological-data">http://epd.georgia.gov/air/georgia-aermet-meteorological-data</a>). Surface measurement obtained from the Hartsfield-Jackson Atlanta Airport at Atlanta, GA. Upper air observations were obtained from the Atlanta Regional Airport Falcon Field at Peachtree City, GA. These measurements were processed using the AERSURFACE (v13016), AERMINUTE (v15272), and AERMET (v18081) with the adjusted surface friction velocity option (ADJ\_U\*).
- 2. Source Data Emission release parameters and emission rates were provided by the company and reviewed by the GA EPD Stationary Source Permitting Program. The point source emissions are exhausted from the facility's stack connected to an RTO, and the non-point fugitive emissions are exhausted from a total of 14 exhaust fans. Based on Becton Dickinson's submittal, the ethylene oxide

<sup>1</sup> https://epd.georgia.gov/air/documents/toxics-impact-assessment-guideline



- annual emissions in 2017 were 101.7 lbs from the RTO and 555.7 lbs from the 14 exhaust fans (see Appendix A for details).
- 3. Receptor Locations Discrete receptors with 25-meter intervals were placed on a Cartesian grid along the fence-line. Receptors extend outwards from the fence-line at 100-meter intervals to approximately 2 kilometers, at 250-meter intervals to approximately 5 kilometers, and at 500-meter to approximately 12.5 kilometers. This domain (25 km by 25 km) is sufficient to capture the maximum impact. Additional receptors were placed at five nearby residential areas. The nearest residence is located approximately 270 meters east of the facility. All receptor locations are represented in the Universal Transverse Mercator (UTM) projections, Zone 17, North American Datum 1983.
- 4. **Terrain Elevation** Topography was found to be generally flat in the site vicinity. Terrain data from USGS 1-sec National Elevation Dataset (NED) were extracted to obtain the elevations of all sources and receptors by the AERMAP terrain processor (v18081).
- 5. Building Downwash The potential effect for building downwash was evaluated via the "Good Engineering Practice (GEP)" stack height analysis and was based on the scaled site plan submitted by the facility using the BPIPPRM program (version 04274). The BPIPPRM model was used to derive building dimensions for downwash assessment and the assessment of cavity-region concentrations appropriate for the AERMOD model.

## **AIR TOXICS ASSESSMENT**

The impacts of facility-wide ethylene oxide emissions were evaluated according to the Georgia Air Toxics Guideline available at <a href="https://epd.georgia.gov/air/documents/toxics-impact-assessment-guideline">https://epd.georgia.gov/air/documents/toxics-impact-assessment-guideline</a>. The annual and 15-minute AACs were reviewed based on U.S. EPA Integrated Risk Information System (IRIS) Risk Based Air Concentration (RBAC) and OSHA Permissible Exposure Limit (PEL) according to the Georgia Air Toxics Guideline (see Appendix B for details). The EPA NATA used a different annual AAC value (see Appendix C for details). For this assessment, GA EPD used the annual AAC derived according to the Georgia Air Toxics Guideline and took two approaches to evaluate the impacts. The first approach (described in the Georgia Air Toxics Guideline) selects the year with the highest annual modeled maximum ground-level concentrations (MGLC) from the 5-year modeling period and uses this year in the assessment. The second approach calculates the maximum annual modeled concentrations averaged over the 5-year modeling period. The modeled 1-hour and annual ground-level concentrations were calculated using the AERMOD dispersion model (v18081).

#### Analysis with the Highest 5-Year MGLCs

Table 1 summarizes the AAC levels and the MGLCs from the year with the highest value. The 15-min MGLC is based on the 1-hour MGLC multiplied by a factor of 1.32. The 15-min MGLC was below its corresponding 15-min AAC. However, the annual MGLC exceeded the annual AAC. Figure 1 shows the spatial distributions of ground level concentrations with the 2015 meteorological data (the year with the highest MGLC). Figure 2 shows a close-up look of modeled concentrations centered at the facility with the five nearby residential areas labeled. The MGLCs of the five closest residences are shown in Table 2. The areas inside the green lines indicate that the MGLC exceeds the ethylene oxide AAC annual level.

Table 1. Modeled highest 5-year MGLCs and the Respective AACs.

Averaging period	MGLC (μg/m³)*	AAC (μg/m³)
Annual	0.163	0.00033
15-min	3.688	900

<sup>\*</sup> The highest concentration over all averaging periods was modeled in 2015.



**Figure 1.** Contours of annual average ground-level concentrations overlaid on a Google Earth map for 2015 (the year with the highest modeled MGLC).



Figure 2. A close-up look of Figure 1 with the closest residential areas labeled.

Table 2. Risk Analysis for Residential Areas with Modeled highest 5-year MGLCs.

	Receptor UT	M Zone:17	MGLC	Averaging	AAC	Ratio of MGLC (µg/m³) to AAC
Residential Areas	Easting (meter)	Northing (meter)	(μg/m³)*	Period	(μg/m³)	(µg/m³)
R1	236,932.5	3,722,361.2	0.032	Annual	0.00033	97
R2	236,137.9	3,721,995.0	0.011	Annual	0.00033	34
R3	236,163.0	3,721,885.6	0.008	Annual	0.00033	23
R4	237,343.8	3,721,603.8	0.012	Annual	0.00033	38
R5	235,611.0	3,722,319.2	0.014	Annual	0.00033	42

<sup>\*</sup> The highest concentration over all averaging periods was modeled in 2015.

## Analysis with 5-Year Average Ground-level Concentrations

To further assess the impact over longer period, maximum values from the 5-year averaged ground-level concentrations are summarized in Table 3. Contours of modeled annual ground-level concentrations averaged over the 5-year period are shown in Figure 3. Figure 4 shows a close-up look centered at the facility with the five nearby residential areas labeled. The 5-year averaged modeled ground-level concentrations of the five nearby residential areas are shown in Table 4.

Table 3. Modeled Maximum 5-year Annual Average Ground-level Concentrations and the Respective AAC.

Averaging period	MGLC (μg/m³)*	AAC (μg/m³)
Annual	0.144	0.00033

<sup>\*</sup> The maximum of ground-level concentration averaged over 5 years.



**Figure 3.** Contours of 5-year annual average ground-level concentrations modeled overlaid on a Google Earth map.



Figure 4. A close-up look of Figure 3 with the closest residential areas labeled.

Table 4. Risk Analysis for Residential Areas with 5-year Average Ground-level Concentrations.

	Receptor UT	M Zone:17	MGLC	Averaging	AAC	Ratio of Ground-level
Residential Areas	Easting (meter)	Northing (meter)	(μg/m³)*	Period	(μg/m³)	Concentration (µg/m³) to AAC (µg/m³)
R1	236,932.5	3,722,361.2	0.028	Annual	0.00033	84
R2	236,137.9	3,721,995.0	0.009	Annual	0.00033	27
R3	236,163.0	3,721,885.6	0.006	Annual	0.00033	17
R4	237,343.8	3,721,603.8	0.010	Annual	0.00033	32
R5	235,611.0	3,722,319.2	0.012	Annual	0.00033	35

## **CONCLUSIONS**

The dispersion modeling analysis for ethylene oxide shows exceedances at the annual AAC level with the revised 2017 emissions submitted by the facility. The risk assessment indicates that the ethylene oxide concentrations at the nearby residential areas are well above the AAC level (17-97 times).

## Appendix A

Revised Emissions for Year 2017 and Model Input Parameters

Ethylene Oxide (EtO) Emissions

	2017 EtO
Emission Source	Emissions
	(Ib/yr)
RTO	101.7
Fugitives	555.7

# Model Input Parameters for EtO Emissions Sources

(m)	Œ	Stack		UTM E	UTM N <sup>4</sup>		Modeled EtD	Steck	Stack Height	Stack Temperature	perature	Exhaust Gas	Exit Vi	Exit Velocity	Stack Diameter	ameter
Exhaust Fan         POINT         256,488-7         3,722,382.1         4%         3,197E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaust Fan         POINT         236,488-0         3,722,382.1         4%         3,197E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaust Fan         POINT         236,488-7         3,722,302.2         4%         3,197E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaust Fan         POINT         236,488-7         3,722,302.2         10%         7,593E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaust Fan         POINT         236,488-1         3,722,345-4         10%         7,993E-04         25.0         7,620         70         294,26         24,000         34.0         11,034           Exhaust Fan         POINT         236,488-8         3,722,348-7         10%         7,993E-04         25.0         7,620         24,000         34.0         11,034           Exhaust Fan         POINT         236,498-8	Modelin	Description	Source Type	(m)		Emils %	Emissions			2000		How Rate				
Exhaust Fan         PONYT         236,448.9         3,722,282.1         4%         3,197E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaust Fan         PONYT         236,452.0         3,722,304.2         4%         3,197E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaust Fan         PONYT         236,452.0         3,722,302.2         10%         7,997E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaust Fan         PONYT         236,487.8         3,722,302.2         10%         7,993E-04         25.0         7.62.0         70         294,26         24,000         34.0         10,363           Exhaust Fan         PONYT         236,487.8         3,722,347.3         10%         7,993E-04         25.0         7.62.0         70         294,26         24,000         36.2         11,034           Exhaust Fan         PONYT         236,492.8         3,722,347.0         10%         7,993E-04         25.0         762.0         70         294,26         24,000         36.2         11,034           Exhaust Fan							ts/3	(m)	(m)	(44)	(10)	(clm)	(t/\s)	(s/w)	(luch)	(m)
Exhaust Fan         PONNT         236,450.5         3,722,304.2         4%         3,197E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaust Fan         PONNT         236,452.0         3,722,380.9         4%         3,197E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaust Fan         PONNT         236,485.7         3,722,302.2         10%         7,993E-04         36.0         10,973         70         294,26         10,000         34.0         10,363           Exhaust Fan         PONNT         236,485.7         3,722,345.4         10%         7,993E-04         25.0         762.0         70         294,26         24,000         36.2         11,034           Exhaust Fan         PONNT         236,495.8         3,722,345.4         10%         7,993E-04         25.0         762.0         70         294,26         24,000         36.2         11,034           Exhaust Fan         PONNT         236,495.8         3,722,348.7         10%         7,993E-04         25.0         7.620         70         294,26         24,000         36.2         11,034           Exhaust Fan	EF17	Exhaust Fan	POINT	235,448.9	3,722,282.1	4%	3.197E-04	30.0	9.144	70	294.26	10,000	34.0	10.363	30.0	0.762
Exhaus Fan         PONYT         236,452.0         3,722,280.9         4%         3,197E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaus Fan         PONYT         236,473.6         3,722,380.3         4%         3,197E-04         30.0         9,144         70         294,26         10,000         34.0         10,363           Exhaus Fan         PONYT         236,485.7         3,722,345.3         10%         7,993E-04         25.0         70         294,26         24,000         37.9         11,552           Exhaus Fan         PONYT         236,485.8         3,722,345.3         10%         7,993E-04         25.0         762.0         70         294,26         24,000         36.2         11,034           Exhaus Fan         PONYT         236,487.8         3,722,347.0         10%         7,993E-04         25.0         762.0         70         294,26         24,000         36.2         11,034           Exhaus Fan         PONYT         236,492.8         3,722,348.7         10%         7,993E-04         25.0         762.0         70         294,26         24,000         36.2         11,034           Exhaus Fan         PONYT <th< td=""><td>EF18</td><td>Exhaust Fan</td><td>POINT</td><td>236,450.5</td><td>3,722,304.2</td><td>4%</td><td>3.197E-04</td><td>30.0</td><td>9.144</td><td>70</td><td>294.26</td><td>10,000</td><td>34.0</td><td>10.353</td><td>30.0</td><td>0.762</td></th<>	EF18	Exhaust Fan	POINT	236,450.5	3,722,304.2	4%	3.197E-04	30.0	9.144	70	294.26	10,000	34.0	10.353	30.0	0.762
Exhaust Fan         POINT         236,473.6         3,722,300.3         4%         3.197E-04         30.0         9.144         70         294.26         10,000         34.0         10.353           Exhaust Fan         POINT         236,485.7         3,722,302.2         10%         7.993E-04         25.0         7.620         70         294.26         24,000         37.9         11.034           Exhaust Fan         POINT         236,485.1         3,722,345.4         10%         7.993E-04         25.0         7.620         70         294.26         24,000         36.2         11.034           Exhaust Fan         POINT         236,487.8         3,722,347.9         10%         7.993E-04         25.0         7.620         70         294.26         24,000         36.2         11.034           Exhaust Fan         POINT         236,498.8         3,722,347.9         10%         7.993E-04         25.0         7.620         70         294.26         24,000         36.2         11.034           Exhaust Fan         POINT         236,498.2         3,722,348.7         5%         3,996E-04         25.0         7.620         70         294.26         24,000         36.2         10.211           Exhaust Fan	EF20	Exhaust Fan	POWT	236,452.0	3,722,280.9	4%	3.197E-04	30.0	9.144	70	294.26	10,000	34.0	10.363	30.0	0.762
Exhaustfan         POINT         236,485.7         3,722,302.2         10%         7.993E-04         36.0         10.973         70         294.26         24,000         37.9         11.552           Exhaustfan         POINT         236,489.1         3,722,343.3         10%         7.993E-04         25.0         7.620         70         294.26         24,000         36.2         11.034           Exhaustfan         POINT         236,492.8         3,722,345.4         10%         7.993E-04         25.0         7.620         70         294.26         24,000         36.2         11.034           Exhaustfan         POINT         236,449.8         3,722,348.7         10%         7.993E-04         25.0         7.620         70         294.26         24,000         36.2         11.034           Exhaustfan         POINT         236,449.8         3,722,348.7         10%         7.993E-04         25.0         7.620         70         294.26         24,000         36.2         11.034           Exhaustfan         POINT         236,429.5         3,722,30.3         8%         6,394E-04         25.0         7.620         70         294.26         24,000         35.5         10.211           Exhaustfan <t< td=""><td>EF21</td><td>Exhaust Fan</td><td>POINT</td><td>236,473.6</td><td>3,722,300.3</td><td>24</td><td>3.197E-04</td><td>30.0</td><td>9.144</td><td>70</td><td>294.26</td><td>10,000</td><td>34.0</td><td>10.363</td><td>30.0</td><td>0.762</td></t<>	EF21	Exhaust Fan	POINT	236,473.6	3,722,300.3	24	3.197E-04	30.0	9.144	70	294.26	10,000	34.0	10.363	30.0	0.762
Exhaust Fan         POINT         236,489.1         3,722,324.3         10%         7.993E-04         25.0         7.62         70         294,26         24,000         36.2         11.034           Exhaust Fan         POINT         236,487.8         3,722,345.4         10%         7.993E-04         25.0         7.62         70         294,26         24,000         36.2         11.034           Exhaust Fan         POINT         236,449.8         3,722,348.7         10%         7.993E-04         25.0         7.62         70         294,26         24,000         36.2         11.034           Exhaust Fan         POINT         236,449.8         3,722,377.0         5%         3.996E-04         25.0         7.62         70         294,26         24,000         36.2         11.034           Exhaust Fan         POINT         236,432.1         3,722,301.4         5%         3.996E-04         25.0         7.62         70         294,26         13,200         40.0         12.192           Exhaust Fan         POINT         236,425.5         3,722,301.4         5%         6,394E-04         25.0         7.62         70         294,26         21,200         33.5         10.211           Exhaust Fan <td< td=""><td>EF22</td><td>Exhaust Fan</td><td>POINT</td><td>236,485.7</td><td>3,722,302.2</td><td>10%</td><td>7.993E-04</td><td>36.0</td><td>10.979</td><td>70</td><td>294.26</td><td>24,000</td><td>37.9</td><td>11.552</td><td>44.D</td><td>1.118</td></td<>	EF22	Exhaust Fan	POINT	236,485.7	3,722,302.2	10%	7.993E-04	36.0	10.979	70	294.26	24,000	37.9	11.552	44.D	1.118
Exhaust Fan         POINT         236,487.8         3,722,345.4         10%         7.993e-04         25.0         7.62 0         70         294,26         24,000         36.2         11.034         11.034           Exhaust Fan         POINT         236,470.2         3,722,347.0         10%         7.993e-04         25.0         7.62 0         70         294,26         24,000         36.2         11.034         11.034           Exhaust Fan         POINT         236,449.8         3,722,377.0         5%         3.996e-04         25.0         7.62 0         70         294,26         24,000         36.2         11.034         11.034           Exhaust Fan         POINT         236,432.1         3,722,377.0         5%         3.996e-04         25.0         7.62 0         70         294,26         13,200         40.0         12.192           Exhaust Fan         POINT         236,429.5         3,722,320.3         8%         6,394e-04         25.0         7.62 0         70         294,26         21,200         33.5         10.211           Exhaust Fan         POINT         236,445.2         3,722,348.8         8%         6,394e-04         25.0         7.62 0         70         294,26         21,200         33.5	EF23	Exhaust Fan	POINT	236,489.1	3,722,324.3	10%	7.993E-04	25.0	7.620	70	294.26	24,000	36.2	11.034	45.0	1.143
Exhaust Fan         POINT         136,470.2         3,722,342.0         10%         7.993E-04         25.0         7.62 0         70         294,26         24,000         36.2         11.034           Exhaust Fan         POINT         136,449.8         3,722,348.7         10%         7.993E-04         25.0         7.62 0         70         294,26         24,000         36.2         11.034           Exhaust Fan         POINT         236,432.1         3,722,377.0         5%         3.996E-04         28.0         8.534         70         294,26         13,200         40.0         12.192           Exhaust Fan         POINT         236,429.5         3,722,301.4         5%         3.996E-04         25.0         7.62 0         70         294,26         13,200         40.0         12.192           Exhaust Fan         POINT         236,429.5         3,722,320.3         8%         6,394E-04         25.0         7.62 0         70         294,26         21,200         33.5         10.211           Exhaust Fan         POINT         236,445.2         3,722,348.8         8%         6,394E-04         25.0         7.62 0         70         294,26         21,200         33.5         10.211           Information	EF24	Exhaust Fan	POINT	236,487.8	8,722,345.4	10%	7.993E-04	25.0	7.620	70	294.26	24,000	36.2	11.034	45.0	1.143
Exhaust Fan         PONT         136,449.8         3,722,348.7         10%         7.993E-04         25.0         7.62 0         7.6 24,26         24,00         36.2         11.034           Exhaust Fan         PONT         236,432.1         3,722,377.0         5%         3.996E-04         28.0         6.534         70         294,26         13,200         40.0         12.192           Exhaust Fan         PONT         236,423.5         3,722,301.4         5%         3.996E-04         28.0         6.534         70         294,26         13,200         40.0         12.192           Exhaust Fan         PONT         236,429.5         3,722,320.3         8%         6,394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Exhaust Fan         PONT         236,435.1         3,722,348.8         8%         6,394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Exhaust Fan         PONT         236,445.2         3,722,348.8         8%         6,394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Intermal         Axidizer	EF25	Exhaust Fan	POINT	236,470.2	3,722,347.0	10%	7.993E-04	25.0	7.620	70	294.26	24,000	36.2	11.034	45.0	1.143
Exhaust Fan         PONT         136,432.1         3,722,377.0         5%         9.996 E-04         28.0         8.534         70         294,26         13,200         40.0         12.192           Exhaust Fan         PONT         236,433.7         3,722,301.4         5%         3.996 E-04         28.0         6.534         70         294,26         13,200         40.0         12.192           Exhaust Fan         PONT         236,429.5         3,722,320.3         8%         6.394 E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Exhaust Fan         PONT         236,435.1         3,722,342.5         8%         6.394 E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Exhaust Fan         PONT         236,445.2         3,722,348.8         8%         6.394 E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Informalia         Accessed and a state of a state o	EF26	Exhaust Fan	POINT	236,449.8		10%	7.993E-04	25.0	7.620	70	294.26	24,000	36.2	11.034	45.0	1.143
Exhaust Fan         PONT         136,433.7         3,722,301.4         5%         3.996E-04         28.0         8.534         70         294,26         13,200         40.0         12.192           Exhaust Fan         PONT         136,435.1         3,722,320.3         8%         6,394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Exhaust Fan         PONT         136,445.2         3,722,342.8         8%         6,394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Exhaust Fan         PONT         136,445.2         3,722,348.8         8%         6,394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           thermal         PONT         136,445.2         3,722,348.8         8%         6,394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           thermal         oxidizer         PONT         236,445.2         3,722,395.0         N/A         1,463E-03         50.0         15,240         250         294,26         23,00         30.5         30.5         30.5	EF44*	Exhaust Fan	POINT	236,432.1	3,722,277.0	288	3.996E-04	28.0	8.534	7.0	294.26	13,200	40.0	12.192	31.8	0.808
Exhaust Fan         POINT         236,429.5         3,722,320.3         8%         6.394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Exhaust Fan         POINT         236,445.2         3,722,342.5         8%         6.394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Exhaust Fan         POINT         236,445.2         3,722,348.8         8%         6.394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           regenerative         regenerative         remail         N/A         1.463E-03         50.0         15.240         250         394,26         23,000         30.5         9.296	EF45*	Exhaust Fan	TNFOd	236,433.7	3,722,301.4	2%	3.996E-04	28.0	8.534	7.0	294.26	13,200	40.0	12.192	31.8	0.808
Exhaust Fan         POINT         136,445.2         3,722,342.5         8%         6,394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           Exhaust Fan         POINT         236,445.2         3,722,348.8         8%         6,394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           regenerative thermal oxidizer         1         236,424.2         3,722,295.0         N/A         1.463E-03         50.0         15,240         250         394,26         23,000         30.5         9.296	EF47	Exhaust Fan	POINT	236,429.5	3,722,320,3	368	6.394E-04	25.0	7.620	70	294.26	21,200	33.5	10,211	44.0	1.118
Exhaust Fan         POINT         236,445.2         3,722,348.8         8%         6.394E-04         25.0         7.620         70         294,26         21,200         33.5         10.211           regenerative thermal oxidizer         POINT         236,424.2         3,722,295.0         N/A         1.463E-03         50.0         15,240         250         394,26         23,000         30.5         9.296	EF48	Exhaust Fan	POINT	236,431.1		83%	6,394E-04	25.0	7,620	70	294,26	21,200	33.5	10,211	44.0	1.118
regenerative	EF49	Exhaust Fan	POINT	236,445.2	3,722,348.8	8%	6.394E-04	25.0	7.620	70	294.26	21,200	33.5	10.211	44.0	1,118
thermal cxidizer POINT 236,424.2 3,722,295.0 N/A 1.463E-03 50.0 15,240 250 394.26 23,000 30.5 9,296		regenerative														
oxidizer PONT 236,424.2 3,722,295.0 N/A 1.463E-03 50.0 15.240 250 394.26 23,000 30.5 9.296		thermal														
	ato	oxidizer	POINT	236,424.2	3,722,295.0	N/A	1.463E-03	50.0	15.240	250	394.26	23,000	30.5	9.296	48.0	1.219

Coordinates reflect UTM NADBS, Zone 17, EF20 coordinates were revised based on site plan.

ERLA BROEFLS - Roof mounted uplant type fan, modeled diameters were derived from flow rate and exitive bothy
 EF22725 - Rectargular Duct shows as the found equivalent

## Appendix B

GA EPD Calculation of the Annual and 15-min AAC for Ethylene Oxide

## GA EPD Calculation of the Annual and 15-min AAC for Ethylene Oxide

According to the GA EPD's Guideline for Ambient Impact Assessment of Toxic Air Pollutant Emissions, the annual and 15-min AAC for ethylene oxide are calculated as following:

## **Annual AAC**

In the EPA Integrated Risk Information System (IRIS), the Inhalation Unit Risk (IUR) for ethylene oxide is  $3\times10^{-3} \,\mu\text{g/m}^3$ . Since ethylene oxide is carcinogenic to humans, it belongs to Group A<sup>2</sup> with a cancer risk of 1/1,000,000. Therefore, the annual AAC is calculated as:

Annual AAC = cancer risk / IUR =  $(1/1,000,000)/(0.003 \mu g/m^3) = 0.00033 \mu g/m^3$ 

## 15-min AAC

The OSHA permissible exposure limit (PEL) for ethylene oxide is 5 ppm. To convert the PEL from ppm to mg/m³, use the following conversion formula from the guidance:

$$(5 \text{ ppm} \times 44.05 \text{ g/mol}) / (24.45 \text{ L/mol}) = 9 \text{ mg/m}^3$$

where, 44.05 is the molecular weight for ethylene oxide and 24.45 is the molar volume at 25°C and 760 mmHg. After applying a safety factor of 10 for acute sensory irritants, the 15-min AAC is calculated as:

15-min AAC = 9 mg/m<sup>3</sup> × 1000 (convert mg to  $\mu$ g) / 10 (safety factor) = 900  $\mu$ g/m<sup>3</sup>

<sup>2</sup>https://www.epa.gov/fera/risk-assessment-carcinogenic-effects

# Appendix C

EPA Calculation of the Annual AAC for Ethylene Oxide

# EPA Calculation of the Annual AAC for Ethylene Oxide

According to EPA's IRIS, inhalation unit risk (IUR) for ethylene oxide (EtO) is  $3x10^{-3}$  per  $\mu g/m^3$  (as discussed in Appendix C). However, because of the elevated risk due to the mutagenic mode of action through early-life exposures, EPA multiplied the IUR by 1.6:

Modified IUR for EtO =  $3x10^{-3}$  per  $\mu g/m^3 x 1.6 = 0.005/\mu g/m^3$ 

EPA's NATA used (100/1,000,000) individual risk for the purpose of determining "acceptable risk" (AR) in their national assessment.

AR Exposure Concentration = Cancer Risk /  $IUR = (100/1,000,000)/(0.005/\mu g/m^3) = 0.02 \mu g/m^3$ 

However, EPA uses (1/1,000,000) individual risk to incorporate an "ample margin of safety" (AMS) for setting emission standards<sup>3</sup> (e.g., benzene NESHAP).

AMS Exposure Concentration = Cancer Risk /  $IUR = (1/1,000,000)/(0.005/\mu g/m^3) = 0.0002 \mu g/m^3$ 

<sup>3</sup>https://www3.epa.gov/ttn/atw/rrisk/risk rep.pdf

## Incident Report

Completed by:

John LaMontagne

Date:

27 September 2019

**Location of Incident:** 

BD

8195 Industrial Blvd. Covington GA 30014

Release Point:

Vessel 5 vacuum pump exhaust stack.

~ 10 ft. above roof.

Date of Incident:

15-23 September 2019

## Description of Incident:

Starting on 15 September 2019 the Covington sterilization operation began experiencing intermittent elevated Ethylene Oxide (EO) levels as reported on the Indoor Ambient Air Monitoring System (Baseline). All elevated instances were investigated and with no root cause initially found, after area inspections and system checks.

On 23 September 2019 it was discovered that the Vacuum Exhaust Valve for the Covington Line 5 Sterilizer was not in the fully closed position. It is believed that the elevated levels were a result of the valve not being fully closed.

The valve was put in the fully closed position and tested to verify it was completely closed. All other vessels were checked, and the correct valve position was verified.

#### Background:

- 06 September 2019 a Change Control Request (CCR14-19) was initiated to route all vacuum pump exhaust to the Emission Control Device. The current configuration was to route vacuum pump exhaust from the Nitrogen Dilution phases of the cycle to atmosphere via a pipe that extended above the roof. The change involved removing the automated actuator and was made to simplify the system and eliminate a potential point of failure.
- The change was implemented on all Covington Sterilizers on 13 September 2019 via Work Order CV19-168. After the change routine operation resumed on 14 September 19.

On 15 September 2019 the facility started experiencing elevated Baseline readings. Levels were in the 1 to 32 ppm range at various locations inside the building. Elevated levels were intermittent in nature.



 On 23 September the investigation determined that the Vacuum Exhaust Valve was not fully closed. The valve was 180 degrees counterclockwise from the fully closed position. The valve position was immediately corrected.

## Root Cause Investigation:

Investigation has determined that elevated levels were a result of the valve not being in the fully closed position. EO was exhausting from the vacuum pump exhaust stack and entering the building through roof mounted ventilation intakes.

The valve actuator had been removed and the technician manually operated the valve to what he believed was the closed position. This valve has no indication to visually determine if it is in the fully closed position. The technician turned the valve so that the flat part of the stem was perpendicular to the pipe. This would typically indicate a closed position. This particular valve design requires that the stem be rotated in the clockwise direction to close. This valve style is unique to Vessel #5. The butterfly valves on the other Covington Vessels can be rotated in either direction to fully closed.

Following correction of the valve position, EO levels inside the facility returned to historical normal levels.

# **Corrective Action:**

The following steps were taken as corrective action:

The valve was put in the fully closed position and tested to verify on 23 Sept.

The following preventive actions are planned:

All technicians will be trained on operation of this style valve.
 Target date: 30 Sept 19

 Blanks will be installed on the outlet to the Vacuum Exhaust Valve (on all vessels) to prevent flow regardless of valve position or condition.

Target date: 25 Oct 19

## **Impact of Incident:**

#### Environmental:

Based on the information it is concluded that EO was released to the atmosphere. An estimate of the quantity of EO released, per load, is included below. The data confirms that the release is below the reportable quantity of 10 pounds per 24-hour period. The estimate is based on the technical information from the valve manufacturer and engineering principals. The values expressed are not exact due to the dynamic conditions of the process but are believed to represent worst case.

The following are to support that the actual release was likely less than the calculated values:

- The Scrubber Inlet line is maintained at a negative pressure relative to atmosphere (by the function of the RTO) and therefore the gas would tend to flow to the Scrubber inlet line and be conveyed to the RTO for destruction.
- Line 5 had been experiencing High Separator Pressure warnings just prior to the incident. This indicates that the flame arrester at the outlet of the Vacuum Exhaust line was restricted. This would further indicate the path of least resistance as the line to the RTO.
- Inspection of the subject valve after removal showed a considerable buildup of debris in the area between the valve disc and valve seat which would further restrict flow to the Vacuum Exhaust line/atmosphere.

Tracking Number	Site	Vessel	Total EO Used (lbs.)	EO removed by Vac Pump (lbs.)	To atmosphere (lbs.)	Emission Start	Emission Finish
194822	CV	5	113	112.5			9/15/19 7:05 PM
194766	CV	5	142	141.4	3.8	9/16/19 12:30 AM	9/16/19 4:58 AM
194850	CV	5	112	111.5	3.0	9/16/19 11:35 AM	9/16/19 4:03 PM
194774	CV	5	129	128.5	3.4	9/17/19 12:50 AM	9/17/19 5:18 AM
194864	CV	5	121	120.5	3.2	9/17/19 11:12 AM	9/17/19 3:40 PM
194827	cv	5	126	125.5	3.4	9/17/19 8:18 PM	9/18/19 12:47 AM
194702	CV	5	114	113.5	3.0	9/18/19 7:34 AM	9/18/19 12:02 PM
194838	CV	5	123	122.5	3.3	9/18/19 4:58 PM	9/18/19 9:26 PM
194887	CV	5	121	120.5	3.2	9/19/19 3:45 AM	9/19/19 8:13 AM
194699		5	120	119.5	3.2	9/19/19 4:07 PM	9/19/19 8:35 PM
194803	CV	5	117	116.5	3.1	9/20/19 3:27 AM	9/20/19 7:55 AM
194902	-	5	122	121.5		9/20/19 1:23 PM	9/20/19 5:51 PM
194882	CV	5	119	118.5	3.2	9/21/19 12:26 AM	9/21/19 4:54 AM
194918	-	5	113	112.5	3.0	9/21/19 10:12 AM	9/21/19 2:40 PM
194909		5	122	121.5		9/21/19 8:03 PM	9/22/19 12:32 AM
194890	-	5	121	120.5			9/22/19 10:26 AM
194814		5	115				9/22/19 8:34 PM
		Total	2050		54.5		

#### STATE OF GEORGIA

- 1. My name is Ron Pasdon and I am a resident of Walton County, Georgia. I am over 19 years of age, have personal knowledge of the facts set forth below and am competent and authorized to make this Affidavit.
- 2. I am employed by Becton, Dickinson and Company ("BD") as Sr. Manager, Sterilization Operations at BD's Covington, Georgia facility ("Covington facility"). I have been employed at the Covington facility since May 2011. I am fully familiar with the sterilization operations conducted at the Covington facility, and with the facts set forth below.
- 3. On September 17, 2019, the Covington facility conducted its usual, regularly scheduled sterilization processes, in accordance with its documented standard operating procedures, and consistent with its usual and anticipated level of sterilization activity conducted throughout 2019.
- 4. On September 17, 2019, sterilization operations were conducted for 24 hours, using our usual complement of employees [over the course of three shifts].
- 5. More particularly, on September 17, 2019, the Covington facility processed 11 sterilization load cycles in a 24-hour period. The load tracking numbers for the loads sterilized during that period are set forth on Attachment A to this affidavit. The amount of EtO used in the sterilization process for those cycles was 1,099 lbs. The Regenerative Thermal Oxidizer ("RTO") was operating normally during this time period and destroyed the EtO used in the sterilization process.



6. The number of sterilization load cycles processed on September 17, 2019 and the quantity of EtO used is consistent with the customary number of load cycles processed and EtO used over the past 12 months at the Covington facility.

Ron Pasdon

Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this \_\_\_\_\_ day of September 2019.

Signature of Noar Public - State of Georgia

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Personally Known (C. Product dentification

Type of Identificate

Tracking Load Number	Date	EO Used LB
194596	9/17/2019	34
194701	9/17/2019	32
194710	9/17/2019	34
194724	9/17/2019	110
194774	9/17/2019	129
194776	9/17/2019	124
194791	9/17/2019	128
194793	9/17/2019	132
194799	9/17/2019	119
194821	9/17/2019	136
194864	9/17/2019	121
11	Daily Total	1099

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- 3. On September 18, 2019, the Covington facility conducted its usual, regularly scheduled sterilization processes, in accordance with its documented standard operating procedures, and consistent with its usual and anticipated level of sterilization activity conducted throughout 2019.
- 4. On September 18, 2019, sterilization operations were conducted for 24 hours, using our usual complement of employees [over the course of three shifts].
- 5. More particularly, on September 18, 2019, the Covington facility processed 12 sterilization load cycles in a 24-hour period. The load tracking numbers for the loads sterilized during that period are set forth on Attachment A to this affidavit. The amount of EtO used in the sterilization process for those cycles was 1287 lbs. The Regenerative Thermal Oxidizer ("RTO") was operating normally during this time period and destroyed the EtO used in the sterilization process.

6. The number of sterilization load cycles processed on September 18, 2019 and the quantity of EtO used is consistent with the customary number of load cycles processed and EtO used over the past 12 months at the Covington facility.

Randon 19 Sept. 2019

Ron Pasdon

Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this \_\_\_\_\_\_\_ day of September 2019.

PUBLIC PU

Signature of Notary Public – State of Georgia

Print, type, or stamp commissioned name of Notary

Personally Known OR Produced Identification

Tracking Load Number	Date	EO Used LB
194620	9/18/2019	118
194623	9/18/2019	121
194702	9/18/2019	114
194719	9/18/2019	35
194771	9/18/2019	116
194820	9/18/2019	128
194827	9/18/2019	126
194838	9/18/2019	125
194843	9/18/2019	123
194860	9/18/2019	34
194867	9/18/2019	125
194885	9/18/2019	122
12	Daily Total	1287

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- 3. On September 19, 2019, the Covington facility conducted its usual, regularly scheduled sterilization processes, in accordance with its documented standard operating procedures, and consistent with its usual and anticipated level of sterilization activity conducted throughout 2019.
- 4. On September 19, 2019, sterilization operations were conducted for 24 hours, using our usual complement of employees [over the course of three shifts].
- 5. More particularly, on September 19, 2019, the Covington facility processed 11 sterilization load cycles in a 24-hour period. The load tracking numbers for the loads sterilized during that period are set forth on Attachment A to this affidavit. The amount of EtO used in the sterilization process for those cycles was 1160 lbs. The Regenerative Thermal Oxidizer ("RTO") was operating normally during this time period and destroyed the EtO used in the sterilization process.

The number of sterilization load cycles processed on September 19, 2019 and the 6. quantity of EtO used is consistent with the customary number of load cycles processed and EtO used over the past 12 months at the Covington facility.

Ron Pasdon

Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this \_\_\_\_\_ day of September 2019.



Signature of Notary Public - State of Georgia

Print, type, or stamp commissioned name of Notary Personally Known / OR Produced Identification

Tracking Load Number	Date	EO Used LB
194551	9/19/2019	123
194624	9/19/2019	120
194699	9/19/2019	119
194722	9/19/2019	32
194811	9/19/2019	123
194830	9/19/2019	108
194862	9/19/2019	128
194863	9/19/2019	129
1 <del>94</del> 874	9/19/2019	121
194887	9/19/2019	121
194893	9/19/2019	36
11	Daily Total	1160

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- 3. On September 20, 2019, the Covington facility conducted its usual, regularly scheduled sterilization processes, in accordance with its documented standard operating procedures, and consistent with its usual and anticipated level of sterilization activity conducted throughout 2019.
- 4. On September 20, 2019, sterilization operations were conducted for 24 hours, using our usual complement of employees [over the course of three shifts].
- 5. More particularly, on September 20, 2019, the Covington facility processed 10 sterilization load cycles in a 24-hour period. The load tracking numbers for the loads sterilized during that period are set forth on Attachment A to this affidavit. The amount of EtO used in the sterilization process for those cycles was 1024 lbs. The Regenerative Thermal Oxidizer ("RTO") was operating normally during this time period and destroyed the EtO used in the sterilization process.

6. The number of sterilization load cycles processed on September 20, 2019 and the quantity of EtO used is consistent with the customary number of load cycles processed and EtO used over the past 12 months at the Covington facility.

Ron Pasdon

Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this day of September 2019.

Signature of Notary Public - State of Georgia

Print, type, or stamp commissioned name of Notary Personally Known OR Produced Identification

Tracking Load Number	Date	<b>EO Used LB</b>
194735	9/20/2019	36
1 <b>94851</b>	9/20/2019	104
194803	9/20/2019	117
194769	9/20/2019	123
194878	9/20/2019	125
194906	9/20/2019	34
194902	9/20/2019	122
194817	9/20/2019	106
194815	9/20/2019	120
194881	9/20/2019	137
10	Daily Total	1024

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- 1. My name is Ron Pasdon and I am a resident of Walton County, Georgia. I am over 19 years of age, have personal knowledge of the facts set forth below and am competent and authorized to make this Affidavit.
- 2. I am employed by Becton, Dickinson and Company ("BD") as Sr. Manager, Sterilization Operations at BD's Covington, Georgia facility ("Covington facility"). I have been employed at the Covington facility since May 2011. I am fully familiar with the sterilization operations conducted at the Covington facility, and with the facts set forth below.
- 3. On September 21, 2019, the Covington facility conducted its usual, regularly scheduled sterilization processes, in accordance with its documented standard operating procedures, and consistent with its usual and anticipated level of sterilization activity conducted throughout 2019.
- 4. On September 21, 2019, sterilization operations were conducted for 24 hours, using our usual complement of employees [over the course of three shifts].
- 5. More particularly, on September 21, 2019, the Covington facility processed 11 sterilization load cycles in a 24-hour period. The load tracking numbers for the loads sterilized during that period are set forth on Attachment A to this affidavit. The amount of EtO used in the sterilization process for those cycles was 1052 lbs. The Regenerative Thermal Oxidizer ("RTO") was operating normally during this time period and destroyed the EtO used in the sterilization process.

6. The number of sterilization load cycles processed on September 21, 2019 and the quantity of EtO used is consistent with the customary number of load cycles processed and EtO used over the past 12 months at the Covington facility.

235g

Ron Pasdon

Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this 23 day of September 2019.

Signature of Notary Public - State of Georgia

Print, type, or stamp commissioned name of Notary Personally Known OR Produced Identification

Tracking Load Number	Date	<b>EO Used LB</b>
194768	9/21/2019	34
194882	9/21/2019	119
194795	9/21/2019	119
194854	9/21/2019	107
194802	9/21/2019	121
194896	9/21/2019	35
194918	9/21/2019	113
194891	9/21/2019	133
1 <del>94</del> 910	9/21/2019	128
194877	9/21/2019	109
1 <b>94</b> 895	9/21/2019	34
11	Daily Total	1052

## STATE OF GEORGIA

- 1. My name is Ron Pasdon and I am a resident of Walton County, Georgia. I am over 19 years of age, have personal knowledge of the facts set forth below and am competent and authorized to make this Affidavit.
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- 3. On September 22, 2019, the Covington facility conducted its usual, regularly scheduled sterilization processes, in accordance with its documented standard operating procedures, and consistent with its usual and anticipated level of sterilization activity conducted throughout 2019.
- 4. On September 22, 2019, sterilization operations were conducted for 24 hours, using our usual complement of employees [over the course of three shifts].
- 5. More particularly, on September 22, 2019, the Covington facility processed 12 sterilization load cycles in a 24-hour period. The load tracking numbers for the loads sterilized during that period are set forth on Attachment A to this affidavit. The amount of EtO used in the sterilization process for those cycles was 1327 lbs. The Regenerative Thermal Oxidizer ("RTO") was operating normally during this time period and destroyed the EtO used in the sterilization process.

6. The number of sterilization load cycles processed on September 22, 2019 and the quantity of EtO used is consistent with the customary number of load cycles processed and EtO used over the past 12 months at the Covington facility.

Ron Pasdon

Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this \_\_\_\_\_\_ day of September 2019.

Signature of Notary Public - State of Georgia

Print, type, or stamp commissioned name of Notary Personally Known OR Produced Identification

Tracking Load Number	Date	EO Used LB
194909	9/22/2019	122
194892	9/22/2019	122
194907	9/22/2019	133
194933	9/22/2019	34
194816	9/22/2019	117
194890	9/22/2019	121
194935	9/22/2019	126
194809	9/22/2019	125
194945	9/22/2019	38
1 <b>94</b> 925	9/22/2019	123
194814	9/22/2019	115
194915	9/22/2019	151
12	Daily Total	1327

#### STATE OF GEORGIA

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- 3. On September 23, 2019, the Covington facility conducted its usual, regularly scheduled sterilization processes, in accordance with its documented standard operating procedures, and consistent with its usual and anticipated level of sterilization activity conducted throughout 2019.
- 4. On September 23, 2019, sterilization operations were conducted for 24 hours, using our usual complement of employees [over the course of three shifts].
- 5. More particularly, on September 23, 2019, the Covington facility processed 11 sterilization load cycles in a 24-hour period. The load tracking numbers for the loads sterilized during that period are set forth on Attachment A to this affidavit. The amount of EtO used in the sterilization process for those cycles was 1102 lbs. The Regenerative Thermal Oxidizer ("RTO") was operating normally during this time period and destroyed the EtO used in the sterilization process.

6. The number of sterilization load cycles processed on September 23, 2019 and the quantity of EtO used is consistent with the customary number of load cycles processed and EtO used over the past 12 months at the Covington facility.

Ron Pasdon

Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this day of September 2019.

Signature of Notary Public - State of Georgia

Print, type, or stand communication in an e of Notary Personally Known OP Product Centification

Tracking Load Number	Date	EO Used LB
194921	9/23/2019	30
194926	9/23/2019	126
194922	9/23/2019	127
194927	9/23/2019	129
194920	9/23/2019	123
194970	9/23/2019	37
194952	9/23/2019	123
194939	9/23/2019	135
194961	9/23/2019	115
194835	9/23/2019	125
194975	9/23/2019	32
11	Daily Total	1102

## STATE OF GEORGIA

- 1. My name is Ron Pasdon and I am a resident of Walton County, Georgia. I am over 19 years of age, have personal knowledge of the facts set forth below and am competent and authorized to make this Affidavit.
- 2. I am employed by Becton, Dickinson and Company ("BD") as Sr. Manager, Sterilization Operations at BD's Covington, Georgia facility ("Covington facility"). I have been employed at the Covington facility since May 2011. I am fully familiar with the sterilization operations conducted at the Covington facility, and with the facts set forth below.
- 3. On September 24, 2019, the Covington facility conducted its usual, regularly scheduled sterilization processes, in accordance with its documented standard operating procedures, and consistent with its usual and anticipated level of sterilization activity conducted throughout 2019.
- 4. On September 24, 2019, sterilization operations were conducted for 24 hours, using our usual complement of employees [over the course of three shifts].
- 5. More particularly, on September 24, 2019, the Covington facility processed 11 sterilization load cycles in a 24-hour period. The load tracking numbers for the loads sterilized during that period are set forth on Attachment A to this affidavit. The amount of EtO used in the sterilization process for those cycles was 1205 lbs. The Regenerative Thermal Oxidizer ("RTO") was operating normally during this time period and destroyed the EtO used in the sterilization process.

The number of sterilization load cycles processed on September 24, 2019 and the 6. quantity of EtO used is consistent with the customary number of load cycles processed and EtO used over the past 12 months at the Covington facility.

Ron Pasdon

Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this \_\_\_\_\_\_\_ day of September 2019.

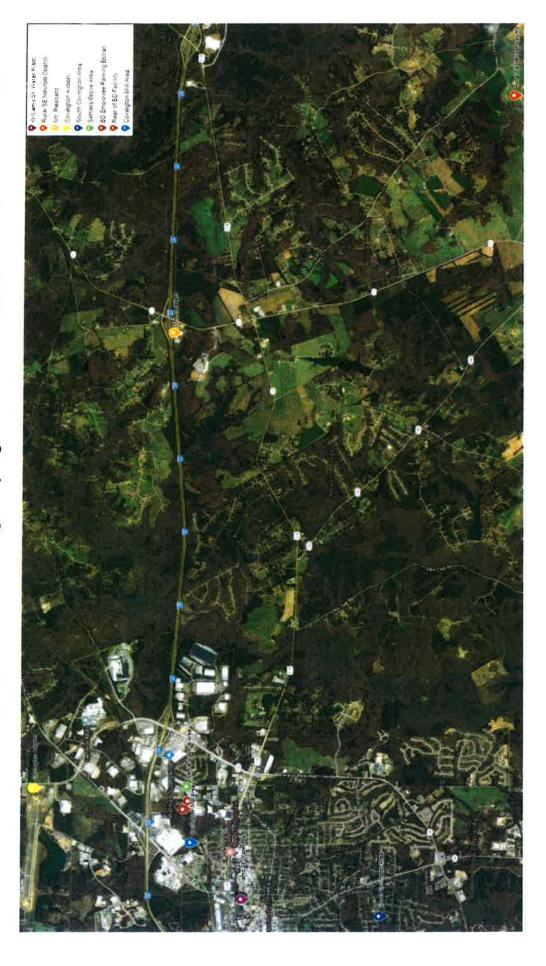
Signature of Novary Public - State of Georgia

Print, type, or stamp tom Personally Known

Tracking Load Number	Date	EO Used LB
194801	9/24/2019	118
194940	9/24/2019	153
194954	9/24/2019	121
194836	9/24/2019	119
194946	9/24/2019	35
194950	9/24/2019	132
194951	9/24/2019	127
194978	9/24/2019	127
194999	9/24/2019	35
194962	9/24/2019	120
194948	9/24/2019	118
11	Daily Total	1205











Summary of Ethylene Oxide Ambient Monitoring Data - City of Covington, Georgia Collected from 9/17/2019 through 9/24/2019

The second second	alloo	Collected Holli 9/1/12019 Inrough 9/24/2019	24/2019			
Location ID	Sample Location	Montrose Sample ID	Sample Start	Sample Fnd	Result	
		- 4			nddd	ng/m3
_	_	641120-1-P-20190917	9/17/2019	9/18/2019	0.715	1.29
£.		641120-1-P-20190918	9/18/2019	9/19/2019	0.220	0.396
<del>-</del>		641120-1-P-20190919	9/19/2019	9/20/2019	0.168	0.302
τ-		641120-1-P-20190920	9/20/2019	9/21/2019	0.604	1.09
_	Rear of BD Facility	641120-1-P-20190921	9/21/2019	9/22/2019	1.87	3.37
_	Rear of BD Facility	641120-1-P-20190922	9/22/2019	9/23/2019	6.85	12.3
~	Rear of BD Facility	641120-1-P-20190923	9/23/2019	9/24/2019	1.61	2.90
ν-	Rear of BD Facility (ERG)	641120-1-P-20190923	9/23/2019	9/24/2019	0.851	1.54
2	Employee Parking Entrance	641120-2-P-20190917	9/17/2019	9/18/2019	5.51	9.92
2	BD Employee Parking Entrance (ERG)	641120-2-E-20190917	9/17/2019	9/18/2019	3.53	6.39
2	<b>Employee Parking</b>	641120-2-P-20190918	9/18/2019	9/19/2019	0.122	0.220
2	<b>Employee Parking</b>	641120-2-P-20190919	9/19/2019	9/20/2019	0.0885	0.160
2	<b>Employee Parking</b>	641120-2-P-20190920	9/20/2019	9/21/2019	0.109	0.197
2	BD Employee Parking Entrance	641120-2-P-20190921	9/21/2019	9/22/2019	0.305	0.549
2	BD Employee Parking Entrance	641120-2-P-20190922	9/22/2019	9/23/2019	6.68	12.0
2	BD Employee Parking Entrance	641120-2-P-20190923	9/23/2019	9/24/2019	3.06	5.51
က	Settlers Grove Area	641120-3-P-20190917	9/17/2019	9/18/2019	7.65	13.8
က	Settlers Grove Area (Duplicate)	641120-3-D-20190917	9/17/2019	9/18/2019	6.94	12.5
3	Settlers Grove Area	641120-3-P-20190918	9/18/2019	9/19/2019	<0.0172	<0.0310
က	Settlers Grove Area (ERG)	641120-3-P-20190918	9/18/2019	9/19/2019	0.194	0.351
က	Settlers Grove Area	641120-3-P-20190919	9/19/2019	9/20/2019	0.105	0.189
က	Settlers Grove Area	641120-3-P-20190920	9/20/2019	9/21/2019	0.103	0.186
င	Settlers Grove Area	641120-3-P-20190921	9/21/2019	9/22/2019	0.321	0.578
က	Settlers Grove Area	641120-3-P-20190922	9/22/2019	9/23/2019	4.69	8.45
က	Settlers Grove Area	641120-3-P-20190923	9/23/2019	9/24/2019	2.95	5.31
4	Covington Mill Area	641120-4-P-20190917	9/17/2019	9/18/2019	3.05	5.50
4	Covington Mill Area	641120-4-P-20190918	9/18/2019	9/19/2019	0.649	1.17
4	Covington Mill Area	641120-4-P-20190919	9/19/2019	9/20/2019	0.328	0.592
4	Covington Mill Area (ERG)	641120-4-P-20190919	9/19/2019	9/20/2019	0.0567	1.03
4	Covington Mill Area	641120-4-P-20190920	9/20/2019	9/21/2019	5.35	9.64
4	Covington Mill Area (Duplicate)	641120-4-D-20190920	9/20/2019	9/21/2019	5.30	9.54
4	Covington Mill Area	641120-4-P-20190921	9/21/2019	9/22/2019	7.06	12.7
4	Covington Mill Area	641120-4-P-20190922	9/22/2019	9/23/2019	8.51	15.3
4	Covington Mill Area (ERG)	641120-4-P-20190922	9/22/2019	9/23/2019	5.66	10.2



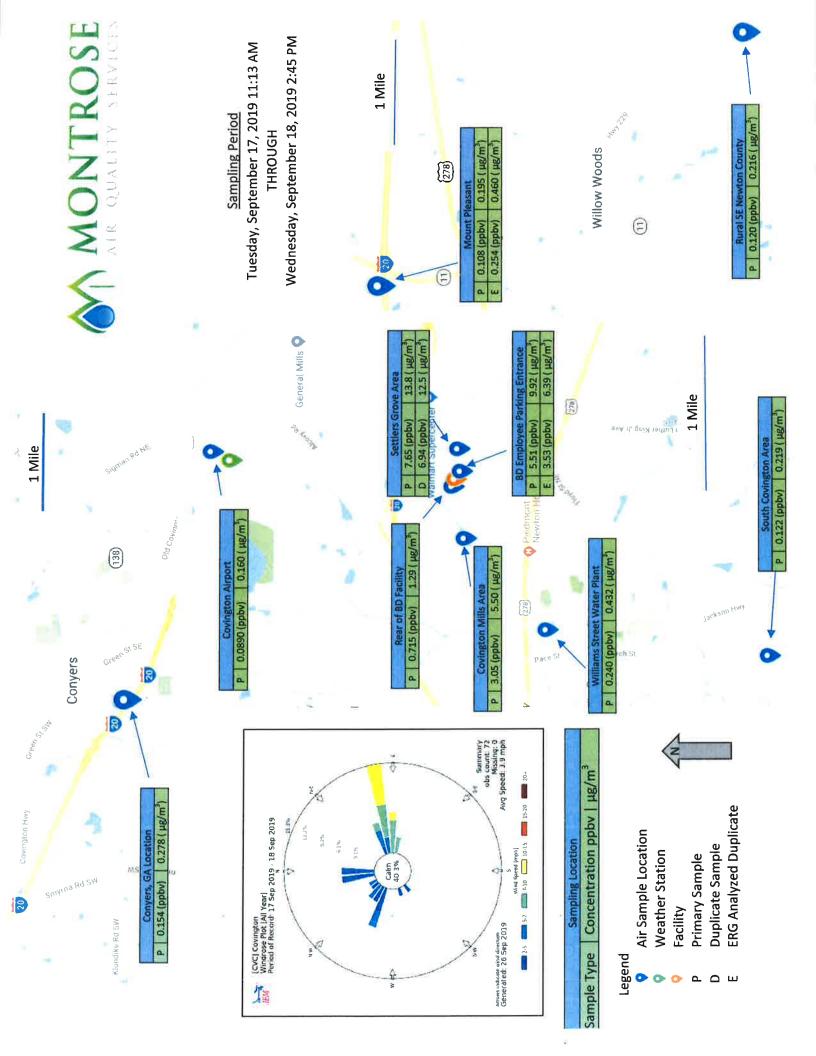
Summary of Ethylene Oxide Ambient Monitoring Data - City of Covington, Georgia Collected from 9/17/2019 through 9/24/2019

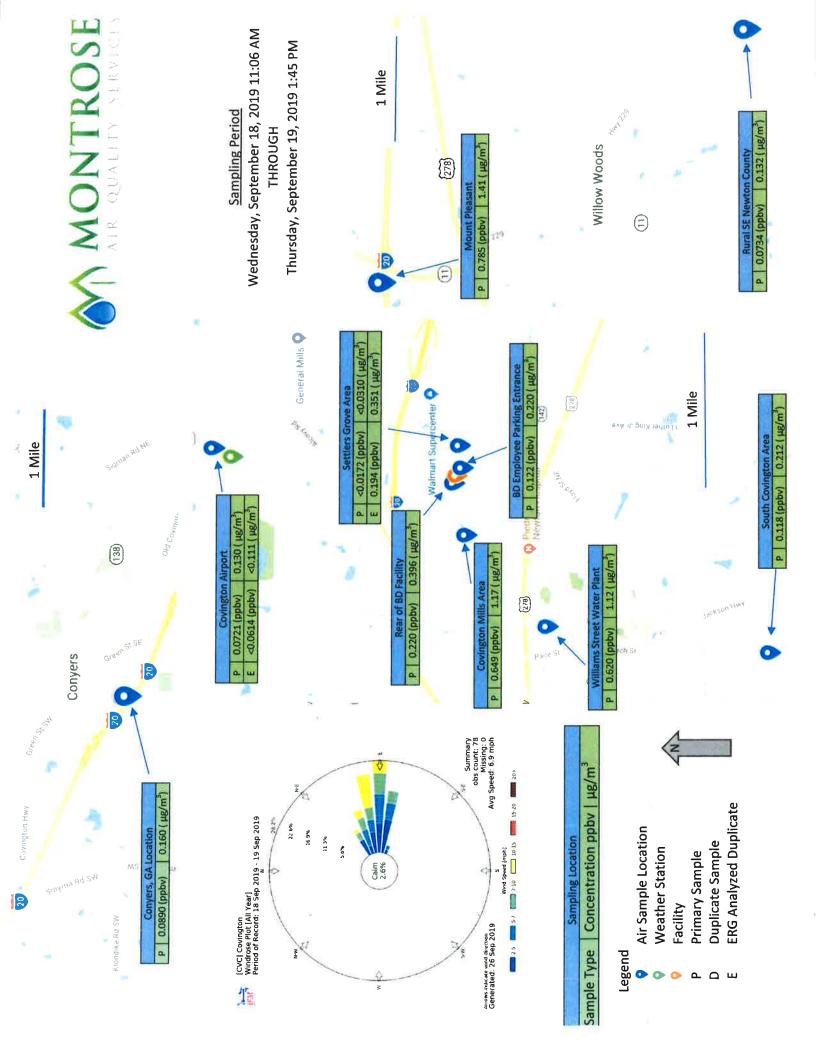
			24/2019			
Location ID	Sample Location	Montrose Sample ID	Sample Start	Sample End	Result	
4	Covington Mill Area	641120-4-P-20190923	9/23/2019	9/24/2019	0 142	ug/m3 0 255
2	Williams Street Water Plant	641120-5-P-20190917	9/17/2019	9/18/2019	0.240	0.432
വ	Williams Street Water Plant	641120-5-P-20190918	9/18/2019	9/19/2019	0.620	1.12
2	Williams Street Water Plant	641120-5-P-20190919	9/19/2019	9/20/2019	1.01	1.83
2	Williams Street Water Plant	641120-5-P-20190920	9/20/2019	9/21/2019	0.623	1.12
2	Williams Street Water Plant	641120-5-P-20190921	9/21/2019	9/22/2019	1.23	2.21
2	Williams Street Water Plant	641120-5-P-20190922	9/22/2019	9/23/2019	0.825	1.49
2	Williams Street Water Plant	641120-5-P-20190923	9/23/2019	9/24/2019	0.162	0.291
9	Mount Pleasant	641120-6-P-20190917	9/17/2019	9/18/2019	0.108	0.195
တ	Mount Pleasant (ERG)	641120-6-P-20190917	9/17/2019	9/18/2019	0.254	0.460
9	Mount Pleasant	641120-6-P-20190918	9/18/2019	9/19/2019	0.785	1.41
9	Mount Pleasant	641120-6-P-20190919	9/19/2019	9/20/2019	0.0829	0.149
9	Mount Pleasant	641120-6-P-20190920	9/20/2019	9/21/2019	0.0654	0.118
9	Mount Pleasant	641120-6-P-20190921	9/21/2019	9/22/2019	0.0831	0.150
9	Mount Pleasant	641120-6-P-20190922	9/22/2019	9/23/2019	0.113	0.203
9	Mount Pleasant	641120-6-P-20190923	9/23/2019	9/24/2019	0.206	0.371
7	Covington Airport	641120-7-P-20190917	9/17/2019	9/18/2019	0.0890	0.160
7	Covington Airport	641120-7-P-20190918	9/18/2019	9/19/2019	0.0721	0.130
7	Covington Airport (ERG)	641120-7-P-20190918	9/18/2019	9/19/2019	<0.614	<0.111
7	Covington Airport	641120-7-P-20190919	9/19/2019	9/20/2019	0.0865	0.156
7	Covington Airport	641120-7-P-20190920	9/20/2019	9/21/2019	0.0680	0.123
7	Covington Airport	641120-7-P-20190921	9/21/2019	9/22/2019	0.151	0.273
7	Covington Airport	641120-7-P-20190922	9/22/2019	9/23/2019	0.138	0.248
7	Covington Airport	641120-7-P-20190923	9/23/2019	9/24/2019	0.0790	0.142
ω	Rural SE Newton County	641120-8-P-20190917	9/17/2019	9/18/2019	0.120	0.216
ω	Rural SE Newton County	641120-8-P-20190918	9/18/2019	9/19/2019	0.0734	0.132
ω	Rural SE Newton County	641120-38-P-20190919	9/19/2019	9/20/2019	0.0917	0.165
œ	Rural SE Newton County	641120-8-P-20190920	9/20/2019	9/21/2019	9060.0	0.163
ω	Rural SE Newton County	641120-8-P-20190921	9/21/2019	9/22/2019	0.0781	0.141
<b>ω</b>	Rural SE Newton County	641120-8-P-20190922	9/22/2019	9/23/2019	0.0653	0.118
æ	Rural SE Newton County	641120-8-P-20190923	9/23/2019	9/24/2019	0.346	0.624
<b>o</b>	South Covington Area	641120-9-P-20190917	9/17/2019	9/18/2019	0.122	0.219
o	South Covington Area	641120-9-P-20190918	9/18/2019	9/19/2019	0.118	0.212
တ	South Covington Area	641120-9-P-20190919	9/19/2019	9/20/2019	0.106	0.192

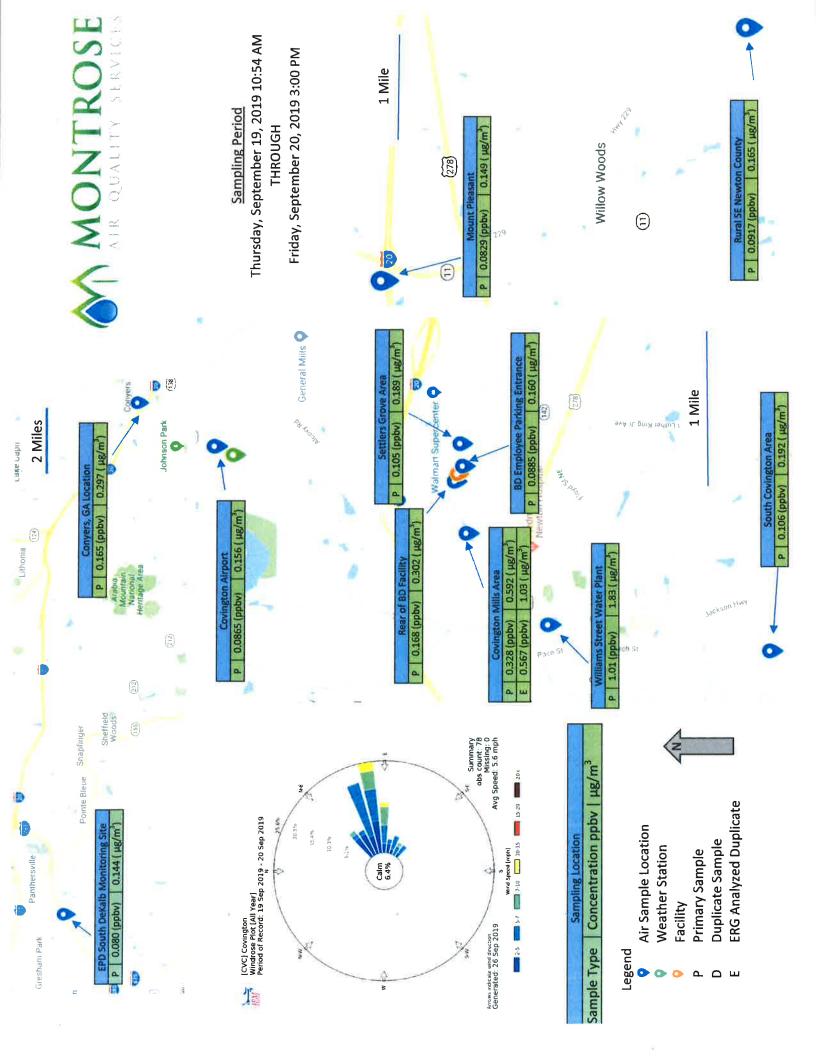


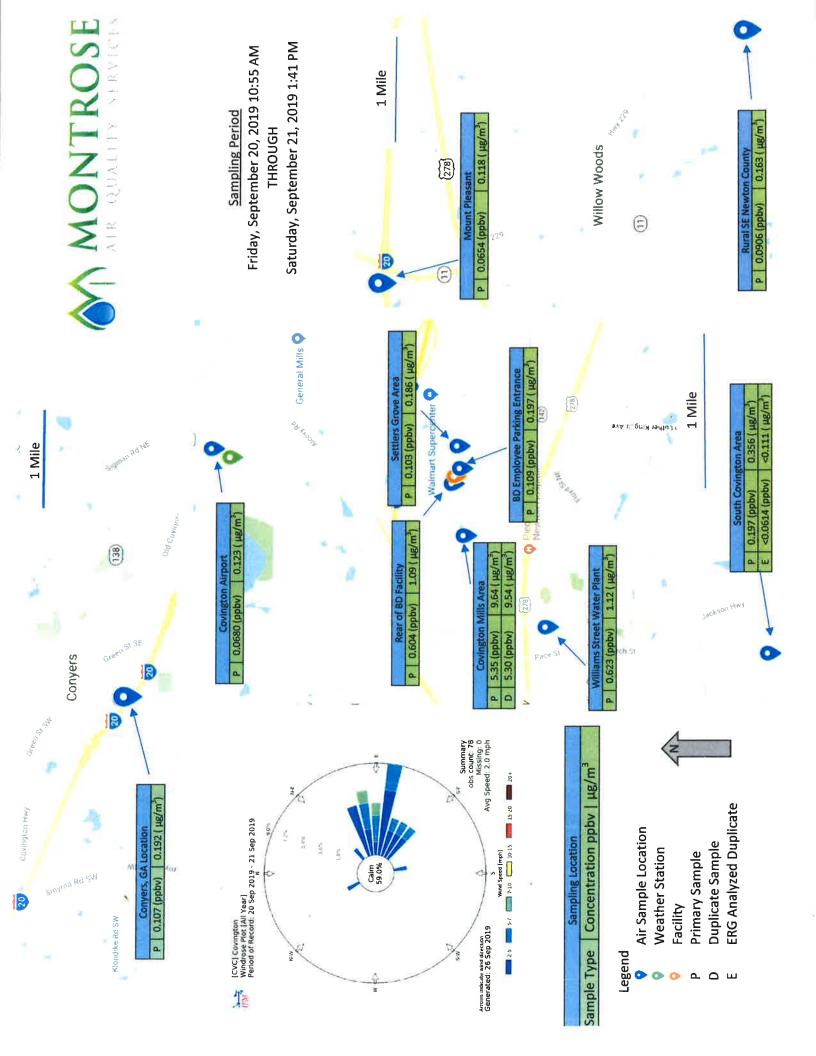
Summary of Ethylene Oxide Ambient Monitoring Data - City of Covington, Georgia Collected from 9/17/2019 through 9/24/2019

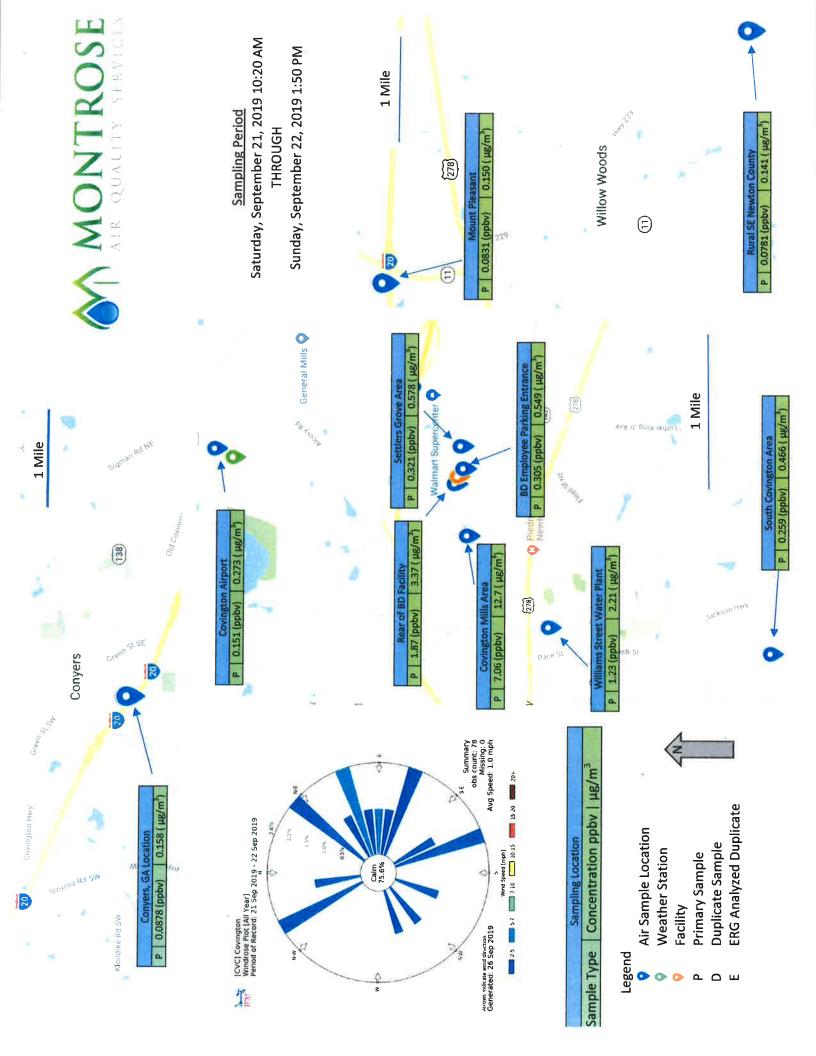
		20102/H2/6 H3/6 H1 17 20 10 H1 10 4/1 20 13	-4/4013			
Location ID	Location ID Sample Location	Montrose Sample ID	Sample Start	Sample Fnd	Result	
			Calliple Ordin	Carripie Lin	vada	ug/m3
ກ	South Covington Area	641120-9-P-20190920	9/20/2019	9/21/2019	0.197	0.356
O)	South Covington Area (ERG)	641120-9-P-20190920	9/20/2019	9/21/2019	<0.0614	<0.111
ത	South Covington Area	641120-9-P-20190921	9/21/2019	9/22/2019	0.259	0.466
0	South Covington Area	641120-9-P-20190922	9/22/2019	9/23/2019	0.199	0.359
0	South Covington Area	641120-9-P-20190923	9/23/2019	9/24/2019	0.0724	0.130
10	Conyers, GA Location	641120-10-P-20190917	9/17/2019	9/18/2019	0.154	0.278
10	Conyers, GA Location	641120-10-P-20190918	9/18/2019	9/19/2019	0.0890	0.160
10	Conyers, GA Location	641120-10-P-20190919	9/19/2019	9/20/2019	0.165	0.297
10	Conyers, GA Location	641120-10-P-20190920	9/20/2019	9/21/2019	0.107	0.192
10	Conyers, GA Location	641120-10-P-20190921	9/21/2019	9/22/2019	0.0878	0.158
10	Conyers, GA Location	641120-10-P-20190922	9/22/2019	9/23/2019	0.119	0.214
10	Conyers, GA Location	641120-10-P-20190922	9/22/2019	9/23/2019	0.117	0.212
10	Conyers, GA Location	641120-10-P-20190923	9/23/2019	9/24/2019	0.0908	0.164
11	EPD South DeKalb Monitoring Site	641120-11-P-20190919	9/19/2019	9/20/2019	0.0800	0.144

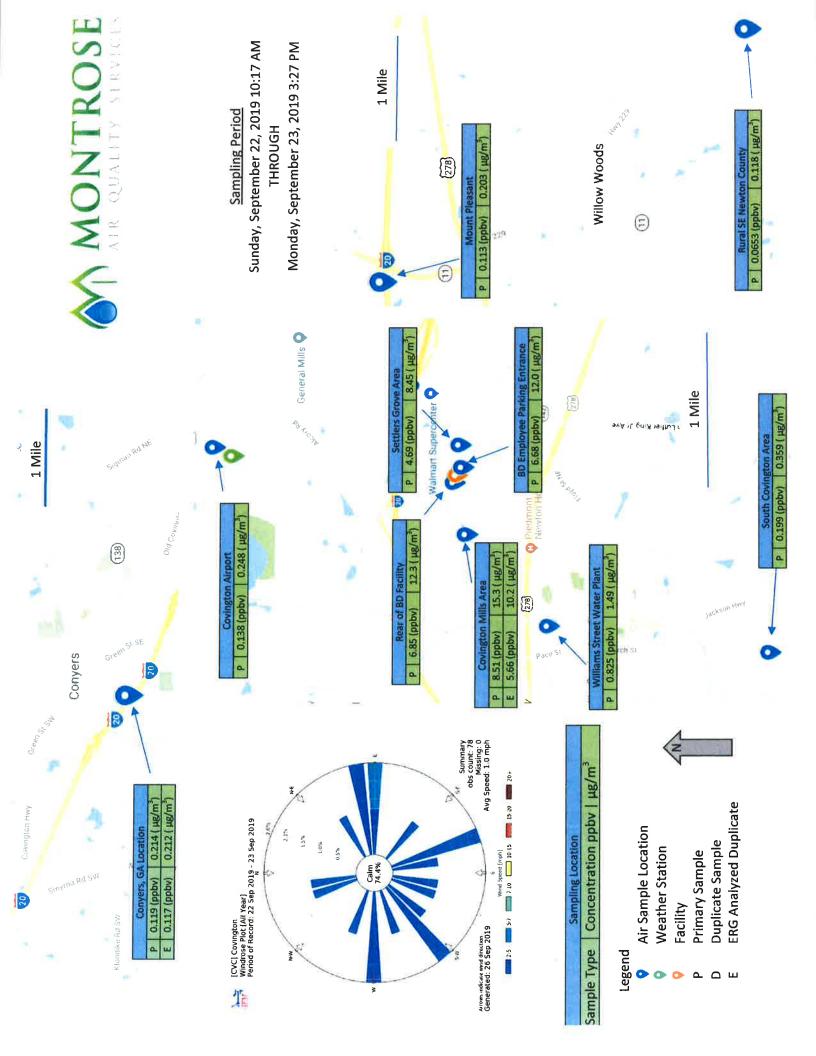


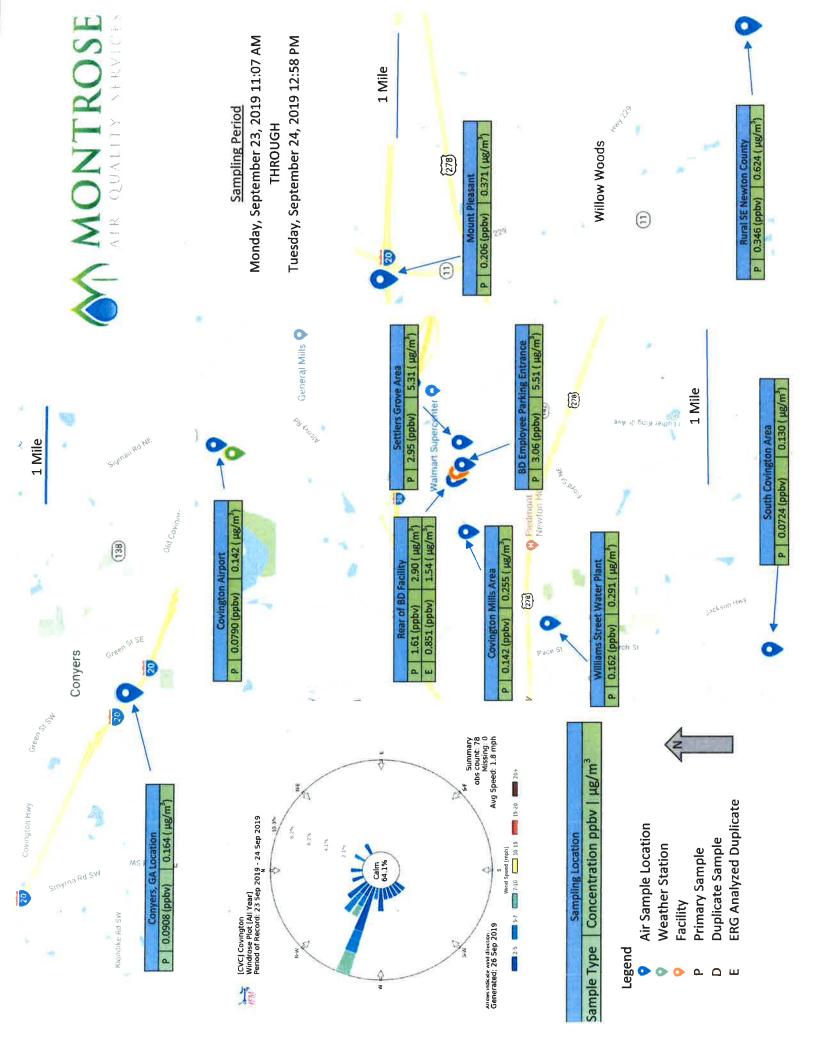






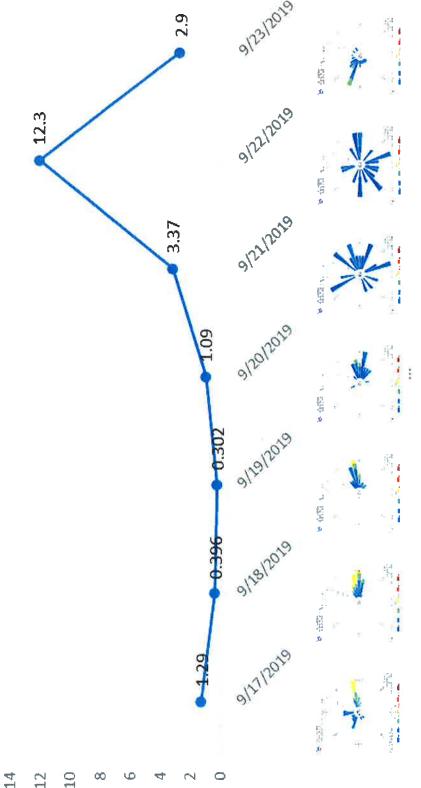








Site 1-Rear of BD Facility



- Enthalpy Result

EtO Concentration (ug/m3)

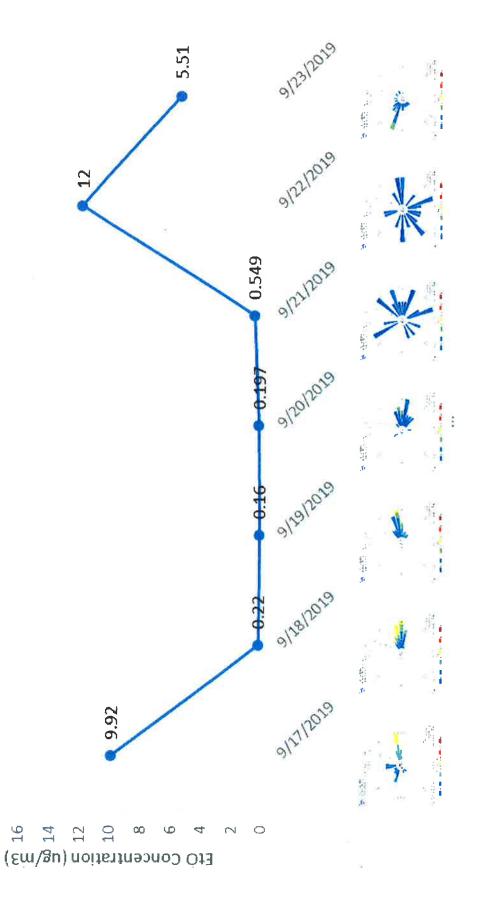
EtO Concentration (ug/m3)



Site 2-BD Employee Parking Entrance

20

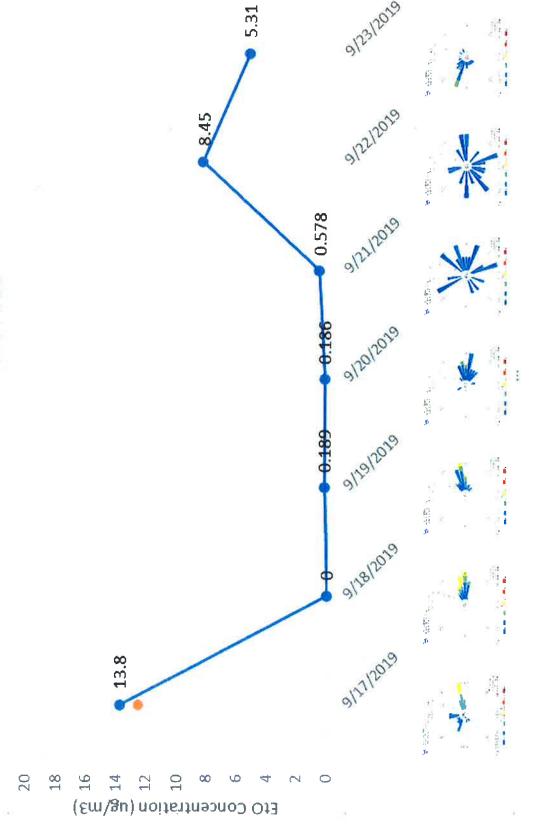
18



--- Enthalpy Result



Site 3-Settlers Grove Area

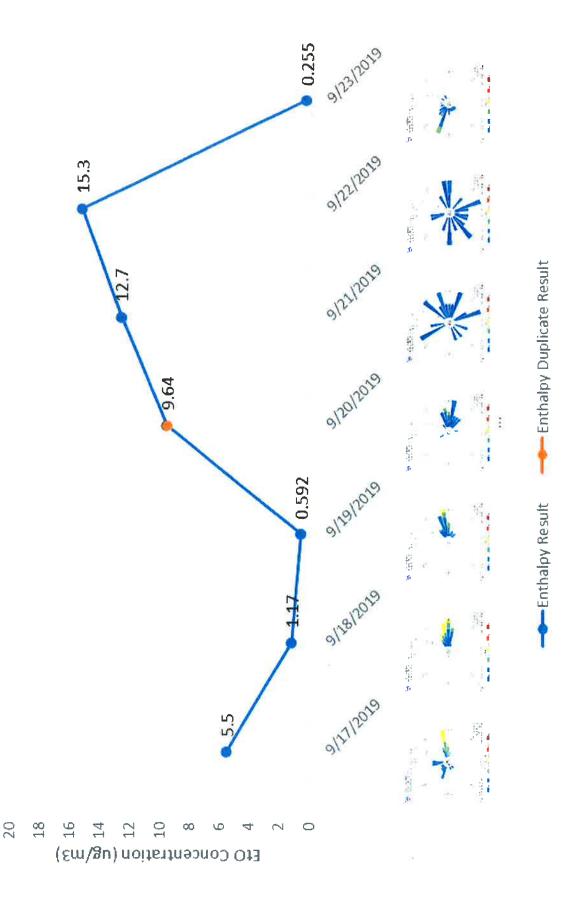


--- Enthalpy Duplicate Result

-- Enthalpy Result

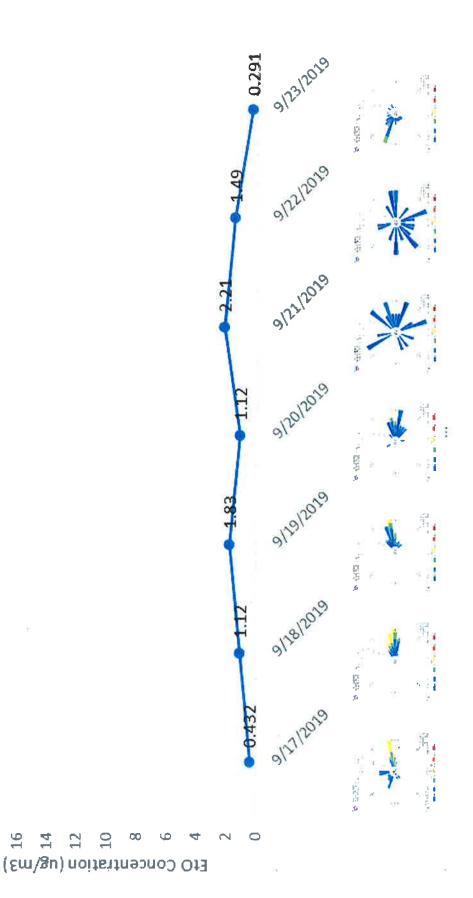


Site 4-Covington Mill Area





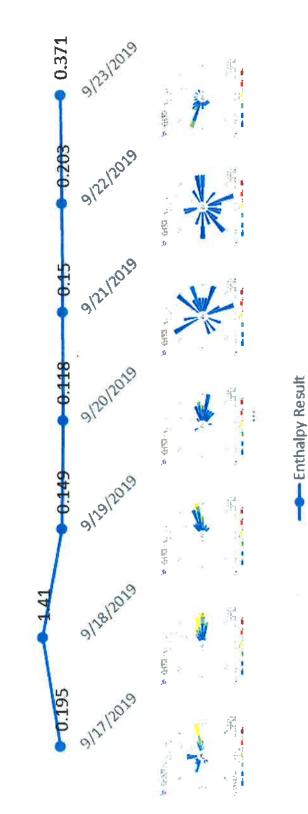
## Site 5-Williams Street Water Plant



-- Enthalpy Result



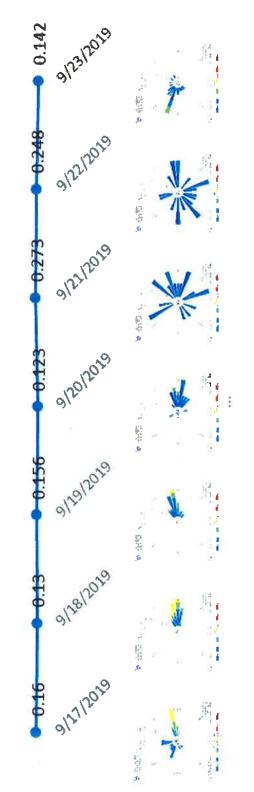
Site 6-Mount Pleasant



EtO Concentration (ug/m3)



## Site 7-Covington Airport

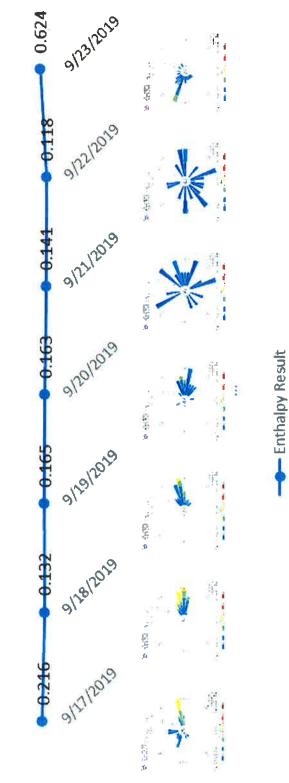


-- Enthalpy Result

EtO Concentration (ug/m3)



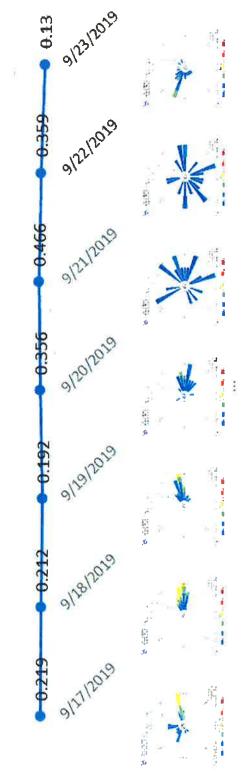
## Site 8-Rural SE Newton County



EtO Concentration (ug/m3)



Site 9-South Covington Area



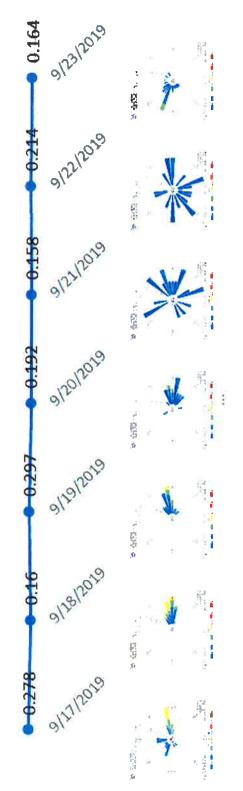
- Enthalpy Result

EtO Concentration (ug/m3)

EtO Concentration (ug/m3)



Site 10-Conyers, GA Location



- Enthalpy Result

EtO Concentration (ug/m3)

EtO Concentration (ug/m3)