IN THE STATE COURT OF GWINNETT COUNTY
STATE OF GEORGIA

TELIS JUSTICE as Surviving Next of Kin of BUIERELLA BENFORD, and as Administrator of the Estate of BUIERELLA BENFORD, Plaintiff,	)	
v.	)	Civil Action No. 21-C-05293-S5
BECTON, DICKINSON AND COMPANY; C. R. BARD, INC.; JOHN LAMONTAGNE; BOONE BROTHERS; RONALD PASDON; JAMES MCKINNON; WAYNE SANDBO; ELIZABETH BRUETTE; KIMBRELL DARNELL; KATHERINE MCFALLS; LEIGH TAYLOR; JEFFREY WILLIAMS; AND JOHN DOES NO. 1-10, Defendants.	)	**JURY TRIAL DEMANDED**

COMPLAINT FOR DAMAGES

TELIS JUSTICE, as Surviving Next of Kin of BUIERELLA BENFORD, and as Administrator of the Estate of BUIERELLA BENFORD ("Plaintiff") hereby files this Complaint for Damages against Defendants Becton, Dickinson and Company, C. R. BARD, Inc., John Lamontagne, Boone Brothers, Ronald Pasdon, James McKinnon, Wayne Sandbo, Elizabeth Bruette, Kimbrell Darnell, Katherine McFalls, Leigh Taylor, Jeffrey Williams, and John Does Nos. 1-10 (collectively referred to as the "Defendants"), showing this Court as follows:

INTRODUCTION

1. This action arises from the death of BUIERELLA BENFORD ("Decedent"), which occurred as a proximate result of exposure to ethylene oxide that was used on, stored on,

and emitted from the premises owned, operated, and/or controlled by Defendants. Defendants Becton, Dickinson and Company and C. R. BARD, Inc.'s unsafe practices using ethylene oxide for sterilizing medical products, by and through their employees and agents, resulted in the escape and emission of this toxic organic compound from the premises owned and/or controlled by these entities, and contaminated the air in the adjacent community where BUIERELLA BENFORD lived and/or worked. As a proximate result of Defendants' unsafe ethylene oxide emissions, BUIERELLA BENFORD contracted and was diagnosed with and ultimately died from Colon Cancer.

2. The State Court of Gwinnett County has original jurisdiction over this matter, and this action is not subject to federal jurisdiction or removal to federal court under the provisions of 28 U.S.C. § 1331 or 1332 because the claims asserted in this action relate to a tort committed in the State of Georgia, only Georgia state law claims are asserted, and one or more of the parties in interest properly joined and served as a defendant in this action is a citizen of and domiciled in the state in which the action has been brought. See, 28 U.S.C. § 1441(b).

PARTIES, JURISDICTION AND VENUE

3. TELIS JUSTICE, the Surviving Next of Kin of BUIERELLA BENFORD, and Administrator of the Estate of BUIERELLA BENFORD ("Plaintiff"), is a citizen, domicile, and resident of Georgia, residing at 1437 Cotton Trail, SW, Rockdale, GA 30094. Mr. Justice submits to the jurisdiction of this Court by filing this Complaint.

4. Defendant C. R. Bard, Inc. is a New Jersey corporation registered to do business in Georgia and can be served with legal process through its registered agent, CT Corporation System, at 289 S Culver St., Lawrenceville, Gwinnett County, Georgia, 30046-4805. Defendant

Bard is subject to the *in personam* jurisdiction of this Court as it transacts significant business in Georgia, including owning and operating the facility located at 8195 Industrial Blvd., Covington, Georgia 30014.

5. Defendant Becton, Dickinson and Company is a New Jersey corporation registered to do business in Georgia and can be served with legal process through its registered agent, CT Corporation System, at 289 S Culver St., Lawrenceville, Gwinnett County, Georgia, 30046-4805. Defendant Becton, Dickinson and Company is the corporate parent/stockholder of C. R. Bard, Inc. In December of 2017, Becton, Dickinson and Company completed its acquisition of C. R. Bard, Inc for approximately $25 billion, and as a result of their merger agreement, C. R. Bard, Inc is a wholly owned subsidiary of Becton, Dickinson and Company. Defendant Becton, Dickinson and Company is subject to the *in personam* jurisdiction of this Court as it transacts significant business in Georgia. Defendant Becton, Dickinson and Company, through its ownership, agency, joint venture, and as an alter ego of Defendant C. R. Bard, Inc., is responsible for its own negligence in the management and control of Bard and also vicariously liable for C. R. Bard, Inc.'s negligent conduct.[1]

6. Defendant John Lamontagne ("Lamontagne") is a resident, domiciliary, and citizen of Rockdale County, Georgia and can be served with legal process at 4820 Habersham Way NE, 89A, Conyers, Georgia 30094-4475. Defendant Lamontagne has worked as the Facilities Manager for BD at the Covington Facility since 1996. At all times relevant to this Complaint, Defendant Lamontagne acted in the course and scope of his employment and was an

[1] Defendants Becton, Dickinson and Company and C. R. Bard, Inc. shall hereinafter be referred to, collectively, as "BD."

agent of BD. Lamontagne is liable for his own tortious acts/inactions and BD is vicariously liable for the tortious acts of its employees and agents through the doctrine of respondeat superior

7. Defendant Boone Brothers ("Brothers") is a resident, domiciliary, and citizen of Gwinnett County, Georgia and can be served with legal process at 1162 Rising Moon Trail, Snellville, Georgia 30078-7394. At all times relevant to this Complaint, Brothers worked as the Environmental Health, Safety, and Sustainability Manager for BD at the Covington Facility. At all times relevant to this Complaint, Defendant Brothers acted in the course and scope of his employment and was an agent of BD. Brothers is liable for his own tortious acts/inactions and BD is vicariously liable for the tortious acts of its employees and agents through the doctrine of respondeat superior.

8. Defendant Ronald Pasdon ("Pasdon") is a resident, domiciliary, and citizen of Walton County, Georgia and can be served with legal process at 1515 Michael Rd NW, Monroe, Georgia 30656-4383. Defendant Pasdon is the Senior Manager of Sterilization and Operations for BD and has worked at the Covington Facility since 2011. At all times relevant to this Complaint, Defendant Pasdon acted in the course and scope of his employment and was an agent of BD. Pasdon is liable for his own tortious acts/inactions and BD is vicariously liable for their employees' and agents' tortious acts/inactions through the doctrine of respondeat superior.

9. Defendant James McKinnon ("McKinnon") is a resident, citizen, and domiciliary of Newton County, Georgia and can be served with legal process at 990 Cowan Rd, Covington GA 30016-8192. Defendant McKinnon is a Sterilization Coordinator and has worked at the Covington Facility for BD since 2011. At all times relevant to this Complaint, Defendant McKinnon acted in the course and scope of his employment and was an agent of BD. McKinnon

is liable for his own tortious acts/inactions and BD is vicariously liable for their employees' and agents' tortious acts/inactions through the doctrine of respondeat superior.

10. Defendant Wayne Sandbo ("Sandbo") is a resident, citizen, and domiciliary of Walton County, Georgia and can be served with legal process at 808 Oakridge Ter., Loganville, Georgia 30052-9030. Defendant Sandbo is a Senior Quality Assurance Manager over sterilization and has worked at the Covington Facility for BD since 2005. At all times relevant to this Complaint, Defendant Sandbo acted in the course and scope of his employment and was an agent of BD. Sandbo is liable for his own tortious acts/inactions and BD is vicariously liable for their employees' and agents' tortious acts/inactions through the doctrine of respondeat superior.

11. Defendant Elizabeth Bruette ("Bruette") is a resident and citizen of Walton County, Florida and can be served with legal process at 285 Turquoise Beach Drive, Santa Rosa Beach, Florida, 32459. Defendant Bruette is the Director of Sterilization Sciences for BD and has been in charge of ethylene oxide sterilization at the Covington Facility for BD since the late 1990s. At all times relevant to this Complaint, Defendant Bruette acted in the course and scope of her employment and was an agent of BD. Bruette is liable for her own tortious acts/inactions and BD is vicariously liable for their employees' and agents' tortious acts/inactions through the doctrine of respondeat superior.

12. Defendant Kimbrell Darnell ("Darnell") is a resident, citizen, and domiciliary of Gwinnett County, Georgia and can be served with legal process at 434 Willowwind Drive, Loganville, Georgia 30052-5640. Defendant Darnell is a Senior Quality Assurance Lab Manager specializing in sterilization and has worked at the Covington Facility for BD since 1997. At all times relevant to this Complaint, Defendant Darnell acted in the course and scope of his

employment and was an agent of BD. Darnell is liable for his own tortious acts/inactions and BD is vicariously liable for their employees' and agents' tortious acts/inactions through the doctrine of respondeat superior.

13. Defendant Katherine McFalls ("McFalls") is a resident, citizen, and domiciliary of Walton County, Georgia and can be served with legal process at 5590 Executive Drive, Loganville, Georgia 30052-2903. Defendant McFalls is a Quality Assurance Sterilization Engineer and has worked at the Covington Facility for BD since 2013. At all times relevant to this Complaint, Defendant McFalls acted in the course and scope of her employment and was an agent of BD. McFalls is liable for her own tortious acts/inactions and BD is vicariously liable for their employees' and agents' tortious acts/inactions through the doctrine of respondeat superior.

14. Defendant Leigh Taylor ("Taylor") is a resident, citizen, and domiciliary of Newton County, Georgia and can be served with legal process at 50 Inverleigh Row, Covington, Georgia 30014-8967. Defendant Taylor is a Principal Quality Global Sterilization Engineer and has worked at the Covington Facility for BD since 2015. At all times relevant to this Complaint, Defendant Taylor acted in the course and scope of her employment and was an agent of BD. Taylor is liable for her own tortious acts/inactions and BD is vicariously liable for their employees' and agents' tortious acts/inactions through the doctrine of respondeat superior.

15. Defendant Jeffrey Williams ("Williams") is a resident, citizen, and domiciliary of Newton County, Georgia and can be served with legal process at 5836 Highway 20 S 20, Covington, Georgia 30016-4965. Defendant Williams is a Quality Assurance Sterilization Engineer II and has worked at the Covington Facility for BD since 2014. At all times relevant to this Complaint, Defendant Williams acted in the course and scope of his employment and was an

agent of BD. Williams is liable for his own tortious acts/inactions and BD is vicariously liable for their employees' and agents' tortious acts/inactions through the doctrine of respondeat superior.

16. BD has, at all relevant times, operated a facility in Newton County, Georgia, that sterilizes medical equipment using the chemical Ethylene Oxide ("EtO"). The facility (the "Covington Facility") is located at 8195 Industrial Blvd., Covington, Georgia 30014 and was opened in 1967.

17. At all times relevant to this Complaint, Defendants Lamontagne, Brothers, Pasdon, McKinnon, Sandbo, Bruette, Darnell, McFalls, Taylor, and Williams were high-level supervisors, managers, and/or operators employed by BD at the Covington Facility (hereinafter referred to as the "Covington Managers"). At all times relevant to this Complaint, the Covington Managers were acting in the course and scope of their employment and were agents of BD (collectively, the "BD Defendants"). The Covington Managers were responsible for the operation, management, and/or control of the Covington Facility, including the Covington Facility's handling of EtO. BD is vicariously liable for the tortious acts and omissions of all of their employees and agents, including, but not limited to, the Covington Managers and any other individuals and agents who are determined to have contributed to Plaintiff's harm and damages.

18. Defendants John Does No. 1 through 10 are believed to be Georgia or foreign corporations, partnerships, associations, adult individuals, or other legal entities that have transacted business in the State of Georgia and are responsible for the injuries and damages incurred by Plaintiff. Once the identity and the whereabouts of the John Doe Defendants are established, said Defendant(s) will be served with a copy of summons and complaint as provided

by law. Defendants John Does No. 1 through 10 are subject to the jurisdiction and venue of this Court.

19. Jurisdiction is proper because all Defendants are residents of Georgia or are subject to the exercise of long-arm jurisdiction pursuant to O.C.G.A. § 9-10-91. Defendants have transacted substantial business in Georgia, created and continue to maintain a public nuisance in Georgia, and committed tortious acts and omissions in Georgia, including the tortious acts and omissions giving rise to this Complaint.

20. Venue is proper in this Court as one or more of the Defendants are citizens of and/or maintain a registered agent for service of process in Gwinnett County, Georgia and this suit is brought against Defendants as joint tortfeasors. G.A. Const. Art. I, § 2, ¶¶ III, IV & VI; O.C.G.A. §§ 9-10-31, 9-10-93, 14-2-510.

21. This Court has jurisdiction over the subject matter of this Complaint and the Defendants.

STATUTE OF LIMITATIONS

Misrepresentation and Concealment

22. Defendants negligently misrepresented and concealed the true nature and extent of EtO emissions from the Covington Facility, GDC, and/or Wheat Street Facility from government entities and the public in general, subjecting Decedent and those who live and work in the nearby community to an elevated cancer risk. These facts were not discovered until the publication of a July 19, 2019 WebMD article[2] which revealed that Georgia had three census tracts the EPA

[2] Goodman, Brenda, "Residents Unaware of Cancer-Causing Toxin in Air," available at: https://www.webmd.com/special-reports/ethylene-oxide/20190719/residents-unaware-of-cancer-causing-toxin-in-air (last visited July 15, 2021).

identified as having higher cancer risks due to EtO, including in Covington, where the EPA estimates the lifetime risk of developing cancer due to air toxics in the area surrounding BD's facilities is approximately ten times higher than the average national cancer risk across the U.S. population. Since this knowledge was not discovered until the publication date of the article, at the earliest, the statute of limitations did not begin to run against any action alleged by Plaintiff until July 19, 2019. Therefore, Plaintiff's claims are timely brought before the Court.

Georgia Supreme Court's March 14, 2020 Judicial Emergency Order

23. The Georgia Supreme Court's March 14, 2020 Judicial Emergency Order and subsequent extensions "suspend[ed], toll[ed], extended[ed], and otherwise grant[ed] relief from any deadlines or other time schedules or filing requirements imposed by otherwise applicable statutes, rules, regulations or court Orders," including statutes of limitation for civil cases.[3] The Emergency Order was extended 13 times, but the tolling provision contained in the March 14, 2020 Order terminated effective July 14, 2020, 122 days later.[4] Therefore, because the Emergency Order tolled the applicable statutes of limitations for causes of action arising prior to March 14, 2020 by 122 days, the statutes of limitations will not expire for any action alleged by Plaintiff until November 17, 2021 at the earliest. Plaintiff's claims are timely brought before the Court.

[3] *See* March 14, 2020, "Order Declaring Statewide Judicial Emergency," available at: https://www.gasupreme.us/wp-content/uploads/2020/03/CJ-Melton-amended-Statewide-Jud-Emergency-order.pdf (last visited July 15, 2021).
[4] *See* June 12, 2020, "Third Order Extending Declaration of Statewide Judicial Emergency," available at: https://www.gasupreme.us/wp-content/uploads/2020/06/THIRD_ORDER_EXTENDING_DECLARATION_OF_STATEWIDE_JUDICIAL_EMERGENCY_AS_ISSUED.pdf (last visited July 15, 2021).

Public Nuisance

24. Pursuant to Georgia law, "[t]he rule that the statute of limitations does not run in favor of a nuisance, only applies to public nuisances, and grows out of the impropriety of imputing laches to the public." *See Davis v. City of Forsyth*, 275 Ga. App. 747, 750 (2005) (citing *Anneberg v. Kurtz*, 197 Ga. 188, 194(2) (1944)). Plaintiff's public nuisance claims are timely brought before the court.

RICO

25. Pursuant to O.C.G.A. § 16-14-8, a plaintiff shall have five years from the last act to commence a civil lawsuit based upon the corrupt dealings of an organization. Therefore, Plaintiff's Rico claims are timely brought before the court.

RELEVANT FACTS

26. BUIERELLA BENFORD lived and/or worked in close proximity to Defendants' facilities.

27. BUIERELLA BENFORD was diagnosed with Stage 4 Colon Cancer as a result of his/her substantial chronic exposure to carcinogens emitted from Defendants' facilities. As a result of developing Colon Cancer, Ms. Benford died on March 27, 2021.

28. At the time of diagnosis, BUIERELLA BENFORD was unaware that his/her disease was caused by exposure to Ethylene Oxide.

<u>Ethylene Oxide</u>

29. Ethylene oxide ("EtO") is an industrial organic chemical compound made by reacting ethylene and oxygen.

30. At room temperature, EtO is a colorless gas with a sweet, ether-like odor that is rapidly absorbed after inhalation.[5]

31. Solutions of EtO can penetrate human skin. Most exposures to EtO occur by inhalation or skin contact.

32. In its gaseous form, EtO leaves no residue on the items it contacts.

33. EtO is heavier than air, and can cause asphyxiation if exposure occurs in enclosed, poorly ventilated, or low-lying areas.

34. EtO's sweet odor does not provide sufficient warning of hazardous concentrations, as EtO's odor is detected at 500 parts per million (ppm), while OSHA's (Occupational Health and Safety Administration) permissible exposure limit is 1 ppm averaged over eight hours.

35. EtO is a highly reactive and mutagenic agent that reacts with many constituents of body tissue causing cellular and tissue dysfunction and destruction.

36. Although EtO was first synthesized in 1859, it achieved industrial importance during World War I as a precursor to both the coolant ethylene glycol (anti-freeze) and the chemical weapon mustard gas.

37. Due to its flammability and extreme explosiveness, EtO is used as a main component of thermobaric weapons and must be handled and shipped as a refrigerated liquid to control its hazardous nature.

38. The half-life of EtO in the atmosphere, assuming ambient concentrations of 5×105 hydroxyl radicals/cm^3, is 211 days. EtO degrades by reaction with hydroxyl radicals that are

[5] Agency for Toxic Substances and Disease Registry, "Medical Management Guidelines for Ethylene Oxide" https://www.atsdr.cdc.gov/MMG/MMG.asp?id=730&tid=133

photochemically produced. Atmospheric EtO is not removed by rain or absorption into aqueous aerosols.[6]

39. Since the 1940's, EtO has been known to be mutagenic in many organisms, from viruses to mammals, by causing chromosomal damage.

40. Exposure to elevated levels of EtO has been shown to cause lymphoid cancers and tumors of the brain, lung, connective tissue, uterus, and mammary gland in animals exposed by inhalation, as well as an increase in mononuclear cell leukemia and brain tumors in rats.

41. In a 1977 article, the National Institute of Occupational Safety and Health ("NIOSH") concluded that occupational exposure to ethylene oxide may increase the frequency of genetic mutations in humans. The NIOSH report also raised concerns about the potential carcinogenicity of ethylene oxide.

42. In 1981, NIOSH released a subsequent report which recommended that EtO be regarded in the workplace as a potential occupational carcinogen. NIOSH based its recommendation on new evidence of EtO's carcinogenic, mutagenic, and reproductive hazards, including studies demonstrating that EtO induced cancer in experimental animals. Specifically, the studies showed an increase in instances of leukemia in line with increases of EtO concentrations, in addition to other adverse effects on reproductive health. An epidemiological investigation of Swedish workers exposed to EtO also revealed increased incidences of leukemia and other cancers.

43. In 1984, the Occupational Safety and Health Administration (OSHA) promulgated a stricter standard of permissible exposure limits for occupational exposure to EtO. The basis for this action was OSHA's determination, based on epidemiological and experimental evidence, that

[6] https://www.ncbi.nlm.nih.gov/books/NBK304417/

EtO "presents a carcinogenic, mutagenic, genotoxic, reproductive, neurologic and sensitization hazard to workers."[7]

44. In 1985, the U.S. Department of Health and Human Services published the Fourth Annual Report on Carcinogens and classified EtO as reasonably anticipated to be a human carcinogen.

45. In the early 1990s, NIOSH published the largest and most informative epidemiological study of ethylene oxide. The study analyzed over 18,000 employees working with EtO at fourteen different industrial facilities sterilizing medical equipment and food spices. The study found sufficient evidence to support a causal link between exposure to ethylene oxide and increased mortality from lymphatic and hematopoietic cancers. Follow-up studies have additionally demonstrated an association between EtO exposure and breast cancer.

46. In 1994, as a result of these findings, the World Health Organization ("WHO") listed EtO as a Group 1 human carcinogen—the agency's highest risk classification—finding ethylene oxide to be carcinogenic to humans.

47. In 2000, the U.S. National Institutes of Health ("NIH") revised EtO's designation as "reasonably anticipated to be a human carcinogen" to "known to be a human carcinogen" based on sufficient evidence of carcinogenicity from human epidemiological studies and studies on carcinogenetic mechanisms of EtO.[8]

[7] 49 FR 25734-01, 1984 WL 146443.
[8] https://ntp.niehs.nih.gov/ntp/roc/content/profiles/ethyleneoxide.pdf

48. In 2016, in its IRIS study, the U.S. Environmental Protection Agency ("EPA") changed its designation of EtO from "probably carcinogenic" to "carcinogenic." The IRIS study is incorporated by reference herein.[9]

49. The International Agency for Research on Cancer (IARC), in 2018, categorized EtO as carcinogenic to humans.

50. A large epidemiologic study performed by NIOSH, on sterilizer workers exposed to EtO, reported positive exposure-response trends to lymphohematopoietic cancer mortality, primarily in males and in particular for lymphoid cancer (i.e., non-Hodgkin lymphoma [NHL], myeloma, and lymphocytic leukemia), and for breast cancer mortality in females. The positive exposure-response trend for female breast cancer was confirmed in an incidence study based on the same worker cohort. (Steenland et al., 2003). There is further supporting evidence for an association between EtO and breast cancer from additional studies.

51. Non-occupational exposure to EtO may also come from tobacco, residues in spices, and other food products (Jensen, 1988; Fowles et al., 2001) and some skin-care products (Kreuzer, 1992). EtO is also formed during the combustion of fossil fuel, but the amount is expected to be negligible. Any non-occupational exposures to EtO are considered minor.[10]

[9] Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, published December 2016, accessed January 3, 2019.
https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf
[10] Ethylene Oxide, in Chemical Agents and Related Occupations
https://www.ncbi.nlm.nih.gov/books/NBK304417/

EtO's Regulatory Framework

52. Air pollutants are defined as either criteria air pollutants or hazardous air pollutants by the U.S. Environmental Protection Agency ("EPA"). EtO is classified and regulated as a Hazardous Air Pollutant ("HAP") by the EPA.

53. HAPs, or air toxics, are designated as such because they are either known or suspected carcinogens, or causative agents of other serious health problems such as neurological, reproductive, or respiratory problems.

54. The Clean Air Act ("CAA") identifies EtO as a HAP because it is carcinogenic in humans, is highly mutagenic and teratogenic (an agent or factor that causes malformation of an embryo) and has significant acute and sub-chronic exposure health effects.

55. Unlike criteria air pollutants, air toxics regulated by the EPA, like EtO, have no universal, predefined risk levels that clearly delineate acceptable or unacceptable thresholds.

56. Under Section 112 of the Clean Air Act (Air Toxics), the EPA is required to develop national emission standards for hazardous air pollutants ("NESHAP") for source categories that have been identified as major and area sources of HAPs.

57. The NESHAP requirement applies to sources that use at least 1 ton of EtO in sterilization operations in each 12-month period.

58. Despite stating that it has no predefined risk level for acceptable exposure levels, the EPA has implemented a two-step risk-based decision framework for the NESHAP program which first sets an upper limit of acceptable risk at 1-in-10,000, or 100-in-1 million, lifetime cancer risk for the most exposed person. A cancer risk of 1 in 10,000 means that if 10,000 people are exposed to the same concentration of a pollutant continuously over 70 years, one person would

likely contract cancer from this exposure. This risk is in addition to any risk borne by a person not exposed to the air toxic.

59. In order to protect as many people as possible, the NESHAP framework next sets a target of an individual lifetime risk level of no higher than 1-in-1 million. Other health and risk factors are considered in order to complete an overall judgement on acceptability.[11]

60. Georgia EPD regulates air quality in the State of Georgia under the Georgia Air Quality Act, and also implements regulations under the Clean Air Act pursuant to a delegation of authority from the EPA.

61. Georgia EPD's level of concern for EtO is 0.02 micrograms per cubic meter ($\mu g/m^3$) of air, which represents an additional cancer risk of 100 cases for every million people exposed over the course of their lifetime.[12]

62. In the course of regulating air quality, Georgia EPD coordinates with the EPA in the adoption of rules and relies upon information and studies done by the EPA. The Georgia EPD does not require any stricter testing, reporting, recording, or risk assessment than the EPA.

63. In 2006, the EPA began a 10-year study to better understand the risks of EtO to human health. The results prompted the agency to move EtO from the list of chemicals that could cause cancer to the list of those that definitively cause cancer. The EPA also updated a key risk number for the chemical to reflect that EtO was 30 times more likely to cause certain types of cancers than scientists had previously predicted.

[11] https://www.epa.gov/national-air-toxics-assessment/nata-frequent-questions#risk1
[12] https://www.epa.gov/il/ethylene-oxide-emissions-frequent-questions

64. In 2018, the EPA used that new risk value for a periodic report that assesses health risks from releases of airborne toxins in the U.S. That report, called the National Air Toxics Assessment ("NATA"), flagged 109 census tracts across the country where cancer risks were higher because of exposure to airborne toxins. Most of the risks were driven by EtO.

Cancer Cluster – Covington, GA

65. For the community surrounding the BD sterilization facility and warehouse in Covington, NATA lists a total cancer risk of 200-in-1 million, based on 2014 EtO modeling data.[13]

66. The highest risks were in 12 census tracts in Louisiana called "cancer alley," near facilities that make EtO or use it to make other chemicals. Other states with affected areas included Pennsylvania, Colorado, Texas, New Mexico, Delaware, New Jersey, Georgia, and Illinois.

67. Georgia has three affected census tracts, all in metro Atlanta - two in the Smyrna area, and one in Covington.

68. The EPA deems the cancer risk from pollution to be unacceptable when it exceeds 100 cases for every one million people who are exposed to a chemical over the course of their lifetime. In Covington, it is estimated EtO causes approximately 214 cases for every million people exposed. In other words, the EPA estimates the lifetime risk of developing cancer due to air toxics in the area surrounding BD's facility in Covington, Georgia is approximately *ten times higher* than the average national cancer risk across the U.S. population.

69. Importantly, the 2014 NATA is a model created on the assumed exposure of a facility's reported 2014 emissions. However, the emissions from BD's facility in Covington,

[13] https://gispub.epa.gov/NATA/

Georgia have historically been considerably higher than its reported emissions in 2014, which suggests the cancer risks surrounding BD's facility are understated.

70. People who live in the 30014 zip code, which covers the area around BD's sterilization and warehouse facilities, are diagnosed with cancer more frequently than residents in Newton County, and the state as a whole.

71. In the 30014 zip code, there were 527 cases of cancer diagnosed for every 100,000 people, compared with an average of 466 cases of cancer diagnosed for every 100,000 people statewide.[14] The difference between the cancer rate in 30014 and the state is statistically significant, meaning that the increase is not merely coincidental. As a comparative measure, the state with the highest cancer rate in the country (Kentucky) has a cancer rate of 521 new cases of cancer per 100,000 people.

72. Incidences of non-Hodgkin's lymphoma, a type of cancer linked to EtO exposure, as well as cancer rates in general, have recently tested higher in the 30014 zip code compared to the overall average in Georgia. For instance, non-Hodgkin's lymphoma rates have been rising an average of nearly 7% each year from 2007 to 2016 in this zip code. The increase is statistically significant, according to public health officials.

73. Rates of breast cancer, another type of cancer linked to EtO exposure, peaked in the 30014-zip code between 2010 and 2014, with 139 cases diagnosed for every 100,000 people.

BD's Operations

74. BD began operations in Georgia upon opening a Urological Division in Covington, Georgia in 1967.

[14] https://dph.georgia.gov/sites/dph.georgia.gov/files/Cancer_2016_Final.pdf

75. In 1967, BD began using, and continues to use, EtO to sterilize medical devices in Covington, Georgia.

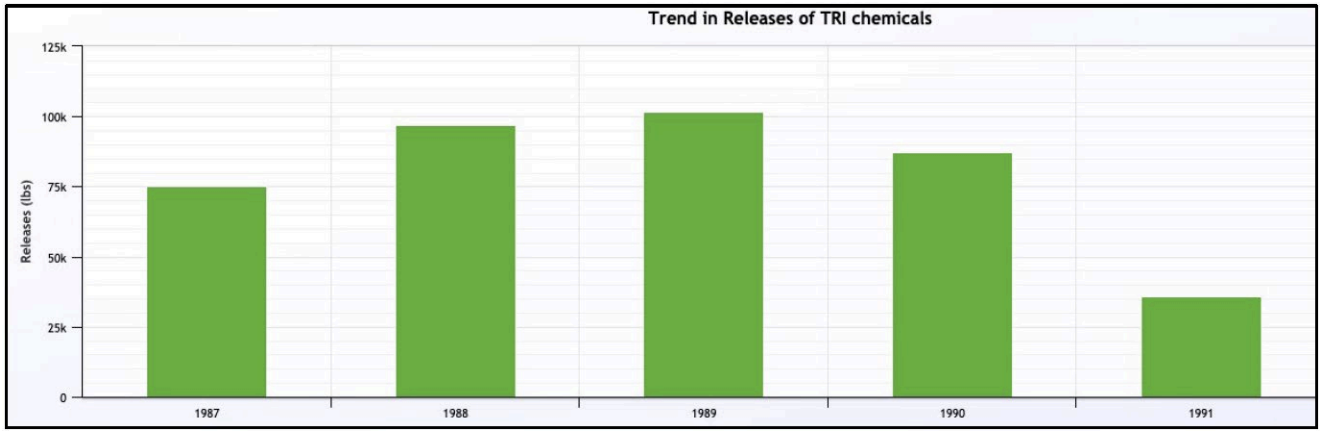
76. BD's Covington, Georgia facilities have continuously used EtO since opening without any known long-term periods of non-use. Through this process, BD emits EtO into the air, allowing it to disburse and be carried by wind throughout the area surrounding its facility.

77. Resultingly, local residents and workers have been exposed to carcinogenic EtO for decades, all while BD knew that EtO is dangerous, toxic, mutagenic, and carcinogenic.

78. Before 1987, BD did not report or provide measurements for the amount of EtO its sterilization facility regularly released into the atmosphere.

79. The EPA maintains a Toxic Release Inventory ("TRI") which includes annual self-reported emissions data from industrial facilities using EtO and other toxic chemicals that pose a threat to human health and the environment.

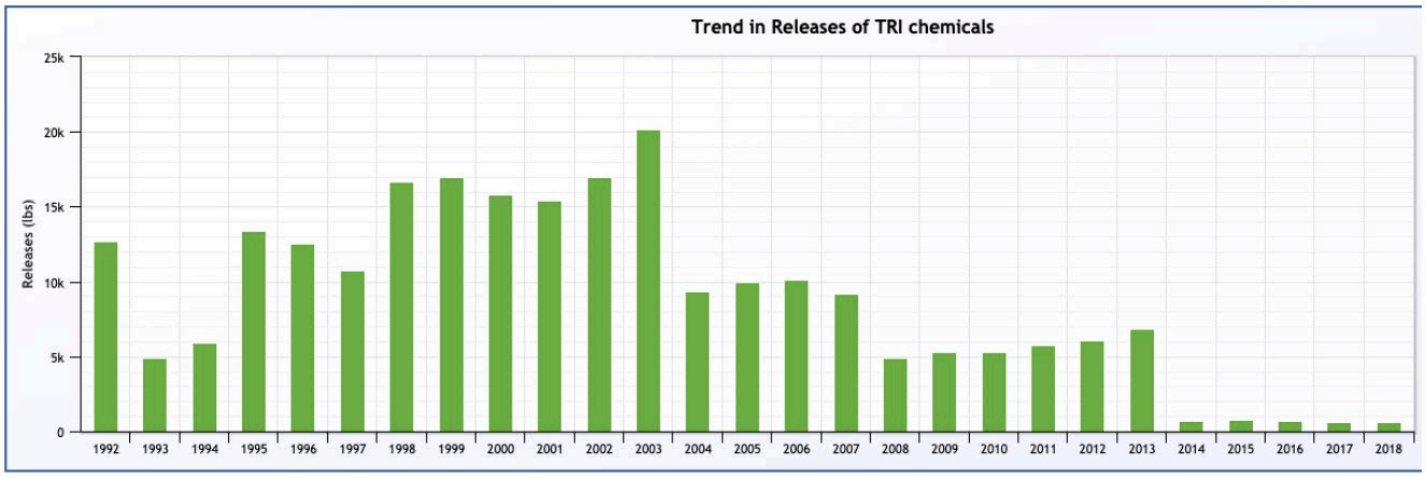
80. A review of TRI data shows EtO emissions from BD's Covington Facility over the course of more than twenty years. *See* Figures 1-3.



(Figure 1, showing EtO emissions from the Covington Facility between 1987 and 1991).

81. For the first time in its history, BD self-reported emissions in 1987 and admitted that 75,306 lbs. of EtO was released into the atmosphere that year. By 1989, BD's EtO emissions surged to 101,755 lbs.

82. While BD initially used a blend of EtO and freon in its sterilization process, BD switched to using 100 percent EtO in late 1992.



(**Figure 2**, showing EtO emissions from the Covington Facility between 1992-2018).

Year	Fugitive Emissions (in lbs)	Stack Emissions (in lbs)
1987	6,846	68,460
1988	10,233	86,630
1989	11,473	90,282
1990	13,066	73,971
1991	1,700	34,000
1992	103	12,558
1993	1,258	3,651
1994	1,521	4,415
1995	8,250	5,163
1996	8,745	3,823
1997	8,886	1,876
1998	14,024	2,619
1999	14,269	2,709
2000	13,395	2,390
2001	13,134	2,295
2002	14,710	2,274
2003	17,274	2,932
2004	6,164	3,218
2005	6,527	3,404
2006	6,637	3,455
2007	6,028	3,179
2008	2,009	2,933
2009	2,168	3,093
2010	2,224	3,093
2011	2,387	3,340
2012	2,536	3,533
2013	2,845	3,984
2014	580	111
2015	649	122
2016	612	114
2017	555	101
2018	555	100

(Figure 3) (*On 6/3/19, BD retroactively reduced its 2014-17 reported EtO emissions).

83. From 2004 to 2013, BD consistently emitted between approximately 4,900 to 10,000 lbs of carcinogenic EtO annually from the Covington Facility. From 1995 to 2003, BD

consistently emitted between 10,700 and 20,200 lbs of EtO annually. From 1987 to 1990, BD emitted between 75,300 and 101,700 lbs of EtO annually.

84. Between 2004 and 2018, BD reported using 5,212,188.5 lbs. of EtO at the Covington Facility.

85. The data and figures appear to show that EtO emissions from the Covington Facility drastically decreased after 2013. However, on June 3, 2019, Defendant Pasdon of BD retroactively revised the Covington Facility's 2014-2017 EtO emissions reported to the EPA, including reducing its 2014[15] emissions from 6,047 to 692 pounds, 2015[16] emissions from 6,725 to 771 pounds, 2016[17] emissions from 6,294 to 726 pounds, and 2017[18] emissions from 5,605 to 656 pounds. In total, BD reduced its 2014-2017 reported EtO emissions by 21,825 pounds.

86. On August 22, 2019, BD published a statement providing responses to an inquiry from The Atlanta Journal-Constitution ("AJC").[19] In this statement, BD answered a question from the AJC regarding its EtO emissions previously reported to the EPA in 2016 and 2017. BD responded as follows:

[15] https://enviro.epa.gov/enviro/tri_formr_partone_v2.get_thisone?rpt_year=2014&dcn_num=1314216792440&ban_flag=Y (last accessed March 25, 2021).
[16] https://enviro.epa.gov/enviro/tri_formr_partone_v2.get_thisone?rpt_year=2015&dcn_num=1315216792453&ban_flag=Y (last accessed March 25, 2021).
[17] https://enviro.epa.gov/enviro/tri_formr_partone_v2.get_thisone?rpt_year=2016&dcn_num=1316216792438&ban_flag=Y (last accessed March 25, 2021).
[18] https://enviro.epa.gov/enviro/tri_formr_partone_v2.get_thisone?rpt_year=2017&dcn_num=1317216792426&ban_flag=Y (last accessed March 25, 2021).
[19] https://etosafety.bd.com/wp-content/uploads/2019/08/AJC-Responses-20180822.pdf (last accessed March 25, 2021).

Follow Up Question: According to the EPA's Toxics Release Inventory, the Covington plant emitted 5,605 pounds in 2017 and 6,294 pounds in 2016.

A: As part of the modeling exercise for Georgia EPD, we reviewed our historic emission data in December 2018 and determined Bard's historical methodology to calculate emissions was based on our permit requirement (99% destruction efficiency) rather than the industry practice of using the actual DRE, which in this case, testing performed by a third party had determined to be greater than 99.95%. In December 2018, working with the Georgia EPD, we agreed to update our emission data by using the actual DRE and provide this more accurate data to the Georgia EPD for modeling purposes. We are providing emissions data on this basis to both the EPA and the Georgia EPD going forward, including the data filed by the Covington site for the 2018 TRI filing that was submitted on July 1, 2019. This brings reporting from Covington in line with industry practice and BD standards for emissions reporting. If you go beyond 2014, you will see numbers based on the historical methodology that are much higher than what the actual emissions were. We did not go back to update years prior to 2014, because they were outside of EPD's five-year modeling window.

Reported emissions from the past five years are below:

Year	Covington EtO Emissions
2018	656.3 pounds
2017	657.4 pounds
2016	726.9 pounds
2015	771.2 pounds
2014	692.6 pounds

87. In BD's response to the AJC's inquiry, BD represented that it updated its "emission data by using the actual [destruction efficiency of 99.95%] and provide this more accurate data to the Georgia EPD for modeling purposes." However, "destruction efficiency" only relates to stack emissions, not fugitive emissions. Yet, BD still retroactively reduced its reported fugitive emissions for 2014-2017 by thousands of pounds.

88. A significant portion of BD's EtO emissions include fugitive emissions from leaking valves and other equipment. Fugitive emissions occur when EtO escapes from anywhere other than the facility's stack and is not captured by pollution controls. These emissions are only based on estimates due to their elusive nature. Between 1997 and 2007, BD's fugitive emissions were greater that than the controlled emissions and in 2003 they reached 5.9 times the controlled emissions. *See* Figure 3.

89. Notably, in or around 1999, when BD's fugitive emissions from the Covington Facility far exceeded its stack emissions, BD openly acknowledged the toxic and carcinogenic nature of its EtO emissions. Specifically, Defendant Bruette, "the Operations Manager in charge of EtO sterilization at the Covington facility," testified under oath that EtO is "a toxic chemical and is possibly carcinogenic."[20]

90. On October 10, 2006, Defendant Lamontagne of BD reported that "due to values being in the wrong configuration, on a [sic] industrial sterilizer," 30 lbs of EtO had been leaked from its Madison facility into the surrounding community, prompting a response from EPD's Emergency Response Team. However, BD and Defendant Lamontagne failed to report the hazardous material spill to EPD until 11 days after the leak had occurred, claiming they were unaware it had even happened.[21] The leak was later blamed on negligent operation.

91. On January 20, 2016, Defendant Lamontagne of BD reported a "hazardous material spill" of 85 lbs of EtO, which had "accidently" been leaked from the Covington Facility into the surrounding community, prompting a response from EPD's Emergency Response Team.[22]

92. BD claims it sterilizes 250 million medical devices annually at its facilities in Covington and Madison.

93. BD's operation of its Covington Facility, and EtO sterilization, is regulated based on its Air Quality Permit ("Permit"), which GA EPD issued to BD in accordance with the provisions of the Georgia Air Quality Act, O.C.G.A. § 12-9-1, *et seq*. (GA EPD Air Quality Permit attached as Exhibit A).

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[20] *Muir v. C.R. Bard, Inc*., 519 S.E.2d 583, 587 (Ct. App. 1999).
[21] Georgia EPD Complaint ID 42277.
[22] Georgia EPD Complaint ID 78838.

94. In addition to its Covington Facility, BD operates a warehouse, referred to as a Global Distribution Center ("GDC"), which stores products previously sterilized at BD's Covington and Madison, Georgia facilities. The GDC is located at 14201 Lochridge Blvd, Covington, GA 30014, which is 1.6 miles from BD's Covington Facility.

95. BD claims it is in full compliance with laws and regulations surrounding the safe use of EtO, that all of its facilities have permits for EtO emissions, and that all facilities operate well below the threshold allowed by those permits.[23]

96. Despite these claims, BD has neither reported emissions from the GDC or any additional warehouses they maintained, nor did BD apply for a permit for those emissions until they received a violation letter from EPD after it was revealed that the GDC, where BD stores sterilized products, was releasing excessive levels of EtO.

97. In fact, the Covington Managers all personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

98. After Defendant Lamontagne began working at the Covington Facility in 1996, annual fugitive emissions of EtO began vastly exceeding stack emissions. Between the years of 1997-2003, the Covington Facility's fugitive emission of EtO were consistently 4 to 6 times higher than stack emissions. In 2003, stack emissions of EtO measured in at 2,932 lbs compared to 17,274 lbs of fugitive emissions. Since 1996, Defendant Lamontagne has had both control and discretion over the Covington Facility's EtO emissions.

[23] *EPD et. al. v. Becton, Dickinson and Company*; Defendants' Response in Opposition to Plaintiff's Motion for Temporary Restraining Order.

99. Since as early as 1996, Defendant Lamontagne has personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

100. Since as early as 2018, Defendant Brothers has personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

101. Since as early as 2011, Defendant Pasdon has personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

102. Since as early as 2011, Defendant McKinnon has personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

103. Since as early as 2005, Defendant Sandbo has personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

104. Since as early as the late 1990's, Defendant Bruette has personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

105. Since as early as 1997, Defendant Darnell has personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

106. Since as early as 2013, Defendant McFalls has personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

107. Since as early as 2015, Defendant Taylor has personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

108. Since as early as 2014, Defendant Williams has personally witnessed, directed, cooperated, controlled, and/or participated in the improper disposal and/or release of fugitive emissions of EtO from the GDC and/or the Covington Facility.

109. In August 2019, the Georgia EPD attempted to force BD to take additional measures to reduce their toxic EtO emissions as soon as possible, with an emphasis on reducing fugitive emissions.

110. BD claims, that since 1991, the Covington Facility has used a regenerative thermal oxidizer, which allegedly treats its exhaust air.

111. BD claims its Covington Facility achieves greater than 99.95% destruction of EtO in plant emissions. However, these numbers do not account for fugitive emissions. Rather, BD's figures are derived only from its stack testing, which is meant to measure the EtO emitted through the Facility's filtration system alone.

112. BD readily admits that stack testing and air monitoring are completely different. Stack testing uses a probe inserted in the stack to record the thermal oxidizer's destruction efficiency, while air monitoring measures EtO in the ambient air surrounding a facility.

113. EtO is released daily into the atmosphere from BD's Covington Facility, not only through the stack atop the Facility but also as unmonitored fugitive emissions.

114. Prior to a study performed by Montrose Environmental Group, Inc. ("Montrose Environmental") between September 17, 2019 to September 23, 2019, no independent air monitoring had ever been done to assess the EtO levels in the areas surrounding the Covington Facility. That is, no independent air monitoring had occurred at the Covington Facility since its opening in 1967.

115. Montrose Environmental's study analyzed air samples from 11 different locations, including several test sites at BD's sterilization facility, locations near Covington Square, the Covington Mill and Settlers Grove neighborhoods, south Covington, and the Covington Airport.

116. The EtO levels measured in Covington Mill, a neighborhood sitting just southwest of the Covington Facility, over seven days of testing, ranged from 0.6 to 15.3 micrograms per cubic meter of air ($\mu g/m^3$). The highest level, 15.3 $\mu g/m^3$, taken on September 22, 2019, is 765 times higher than the EPD's acceptable level of 0.02 $\mu g/m^3$.[24]

117. In Settlers Grove, the closest neighborhood to the east of BD, the levels ranged from nondetectable to 13.8 $\mu g/m^3$. 13.8 $\mu g/m^3$ is 690 times the EPD's level of concern for EtO.

118. BD's own testing results near its sterilization facility, analyzed by a company called Ramboll, or Ramboll Group A/S, revealed levels ranging from 0.3 to 10.5 $\mu g/m^3$ between September 17, 2019 through September 23, 2019.

119. Prior to the test results becoming public, BD reported an 8-day leak at its Covington facility, stemming from an improperly closed valve, spilling 54.5 lbs. of EtO into the community.

[24] https://www.epa.gov/il/ethylene-oxide-emissions-frequent-questions

However, BD represented that the leak likely had little to no effect on the test results. "Given the variability of the results, with many days seeing only background levels of EtO, BD does not believe the unintended release of EtO that BD voluntarily reported had any significant bearing on these results," BD stated in a media release.[25]

120. The overall design of the Covington Facility and the lack of training received by BD employees partially contributed to the facility's fugitive emissions. The City of Covington released an incident report stating that the valve at issue at the Covington Facility had "no indication to visually determine if it [was] in the fully closed position." It was not until after the incident that BD planned to institute training and education for its employees regarding the proper operation of the valve involved in the leak.

121. After receiving the preliminary air testing results, Covington officials requested that BD temporarily cease operations using EtO until further emissions control equipment could be put in place.

122. Georgia EPD described the results as "deeply troubling" and said it would double testing frequency at the plant in order to "determine what regulatory action may be necessary for the surrounding community's safety."[26]

123. Georgia Attorney General Chris Carr stated that BD "negligently allowed the release of 54.5 pounds of ethylene oxide into the atmosphere, which upon further investigation has

[25] https://etosafety.bd.com/wp-content/uploads/2019/10/BD_Statement_AirMonitoring_FINAL_20191016-latest-version.pdf

[26] Stanford, Larry. "Deeply Troubling: EPD investigates leak at BD after release of Covington's EtO air testing results," The Citizens. https://www.rockdalenewtoncitizen.com/news/deeply-troubling-epd-investigating-leak-at-bd-after-release-of-covington-eto-air-testing-results/article_244c5870-f0fe-11e9-8eac-af6cdc39633e.html

been determined to have been caused by a lack of diligence and prolonged operator error rather than an equipment malfunction. In addition, BD has failed to take all responsible precautions to prevent fugitive emissions of ethylene oxide…"[27]

124. In an October 2019 statement released by Governor Brian Kemp, the Governor stated, "After months of failed negotiations, empty promise, and misleading reports of ethylene oxide leaks, we have filed a Temporary Restraining Order to suspend operations at the BD facility in Covington. Our top priority is the health and well-being of Georgia families. This measure is necessary to ensure transparency and prevent behavior that threatens the safety of employees and the community."

125. On October 21, 2019, Attorney General Chris Carr, on behalf of Governor Kemp and Georgia EPD, filed an injunction based upon the following assertions:

a. 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 EtO emissions data from BD's Covington Facility.[28] The results of the NATA showed that a census tract located near the Facility warranted further study.

b. As a result of the NATA, EPD contacted BD to request information regarding its emissions of EtO. 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 EtO emissions. On June 7, 2019, EPD completed its report memo: Modeling

[27] https://law.georgia.gov/press-releases/2019-10-21/carr-epd-file-complaint-against-bd-violations-georgia-law-and-rules
[28] https://www.epa.gov/national-air-toxics-assessment

Analysis for EtO BD, Covington, Newton County, GA memo (the Modeling Memo). (Modeling Memo attached as Exhibit B).

c. The concentration modeled at some residences was above the Acceptable Ambient Concentration (AAC) for EtO in Appendix A of EPD's Guideline for Ambient Impact Assessment of Toxic Air Pollutant Emissions.

d. 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 EtO as soon as possible, with an emphasis on reducing fugitive emissions.

e. EPD has worked diligently to encourage BD to reduce its EtO emissions at the Facility. But, EPD's efforts have been to no avail. Despite public statements to the contrary, 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 they have made progress toward reducing EtO 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 EtO at the Facility.

f. BD's lack of progress toward achieving a reduction of EtO 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 acquire permits modifications and reduce their EtO emissions. Those facilities complied with EPD's request and are progressing in their efforts to reduce EtO emissions.

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

h. 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 EtO into the atmosphere. (Incident Report attached as Exhibit C).

i. Upon further investigation, BD determined that the Facility had intermittently released EtO 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* Exhibit C).

j. At all times while the Covington Facility intermittently released EtO into the atmosphere from September 15, 2019 through September 22, 2019 as a result of the partially open valve, the Covington Managers were responsible for the

operation, management, and/or control of the Covington Facility, including the Covington Facility's handling of EtO.

k. 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 EtO emissions at the Facility. On September 24, 2019, during a routine weekly call, BD first notified EPD that a release of EtO 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 the release lasted one day and involved the release of only 2 lbs of EtO. EPD requested additional information.

l. 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 calculated that 54.5 lbs of EtO were released into the atmosphere over the course of eight (8) days as a result of operator error. (*See* Exhibit C).

m. BD's Incident Report indicates that between September 15, 2019 and September 22, 2019, BD used a total of 2,050 lbs of EtO in sterilization chamber number five with the valve partially open. (*See* Exhibit C, p. 3).

n. The release of 54.5 lbs of EtO during the eight-day period when 2,050 lbs of EtO was used in sterilization chamber number five indicates a 97.3% reduction of EtO emissions to the atmosphere from that sterilization chamber vent. Permit Condition 2.3 requires that, "the EtO 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* Exhibit A, p. 2).

o. BD, through Defendant Lamontagne, 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 not provided EPD with concrete evidence that the training has taken place. (*See* Exhibit C, p. 2).

p. BD's Incident Report also indicated it would 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 was October 25, 2019. With knowledge of the possibility of unintended release of EtO, BD continued normal operations despite the risk of another negligent release during the interim period.

q. As a result of public concern regarding the emissions of EtO at the Facility, the City of Covington (the City) contracted for seven (7) 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.

r. From September 17, 2019 through September 23, 2019, BD provided the City of Covington with the requested Affidavits certifying that the Facility was operating normally during the seven-day test period. Specifically, Defendant Ronald Pasdon

repeatedly certified that BD was conducting its usual operations in accordance with their 2019 Standard Operating Procedures. (Affidavits attached as Exhibit D.)

s. Defendant Pasdon's Affidavits were provided to the City by BD even though the Covington Facility was intermittently releasing EtO 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 acted negligently because BD either knew that it was experiencing an unauthorized release in violation of the Permit or it should have known.

t. 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 EtO emitted from other sources, the average concentration measured was 1.97 $\mu g/m^3$, which is well above 0.02 $\mu g/m^3$, the concentration that USEPA considers as posing an acceptable risk, if exposed to that concentration continuously over a lifetime.

u. Of greatest concern to EPD are the average concentrations measured in two neighborhoods close to BD's facilities: (1) the average concentration in Settler's Grove Area was 4.08 $\mu g/m^3$ and (2) the average concentration in the Covington Mill Area was 6.45 $\mu g/m^3$. EPD submits that the higher concentrations measured in the neighborhoods close to BD's facilities during the monitoring period indicated that BD's emissions of EtO increased the EtO concentrations in the ambient air in

those two areas. (City of Covington's Air Monitoring Results attached as Exhibit E).

v. 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* Exhibit A, p. 2).

w. 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.

x. Ga. Comp. R. & Regs. 391-3-1-.02(2)(a)(l) 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."

y. Given USEPA's determination that EtO is a known carcinogen and EPA's "total cancer unit risk" discussed in paragraph 44, above, in which EPA estimated a possible increased cancer risk from continuously inhaling a specified concentration

of EtO over a lifetime, EPD is working to reduce EtO emissions in Georgia. Based on information provided to EPD by BD, EPD estimated that BD is allowing 555.7 lbs per year of fugitive emissions of EtO into the atmosphere in the immediate vicinity of the Facility. (*See* Exhibit B).

z. BD has had the ability to control the fugitive emissions but has not acted expeditiously to accomplish reductions. In short, BD has failed or refused to recognize the urgency EPD believed, and still believes, is necessary to accomplish a reduction of EtO in a timely manner and to act accordingly.

126. On October 28, 2019, BD's Covington Facility was ordered closed, from October 30 to November 6, 2019, pursuant to a Consent Order granting the EPD's requested injunction against BD.

127. Due to EPD's oversight as a condition of the consent order of October 28, 2019, BD provided estimates of fugitive EtO emissions occurring at offsite warehouses in Newton County, showing that the GDC alone emitted 5,600 lbs of EtO per year. A Notice of Violation was issued.[29]

128. EPD's notice stated that EtO emissions from the GDC were so high that BD should have obtained a permit for its GDC operations.

129. EPD suspended operations at the GDC warehouse for new products from December 23, 2019 to January 6, 2020.

[29] EPD issues Notice of Violation to BD in Covington, in The Covington News, https://www.covnews.com/news/epd-issues-notice-violation-bd-covington/

130. On December 18, 2019, EPD cited BD for operating its GDC facility without an air quality permit.[30] (December 18, 2019 EPD Notice of Violation to BD attached as Exhibit "F").

131. EPD estimated the emissions from BD's GDC exceeded those of its sterilization facility, which had also exceeded its permit.

132. In a December 18, 2019 tweet, Governor Brian Kemp stated "These results are highly concerning, and we are demanding answers from @BDandCo to remedy this unlawful activity. I have directed state officials to act swiftly as possible to secure compliance. We are exploring every legal remedy available to us to ensure the health and safety of the surrounding community."[31]

133. EPD also ordered BD to conduct air monitoring at the nearest residential area and nearest school, as well as weekly indoor air monitoring and outdoor fence line monitoring at the GDC, in addition to EPD's continued monitoring of the Covington area.

134. On December 20, 2019, BD disclosed a third facility to EPD where EtO sterilized medical products were being stored, located at 9120 Wheat Street. NE, Covington, Georgia 30014 (the "Wheat Street facility"), which was operating without a permit.

135. EPD determined that BD violated the October 28, 2019 consent order by failing to notify EPD of the Wheat Street facility which was being used to store medical products sterilized using EtO.

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[30] December 18, 2019 Georgia EPD Notice of Violation to Becton, Dickinson and Company; December 23, 2019 BD Letter to Georgia EPD, found at https://epd.georgia.gov/bd-becton-dickinson-and-company-madison

[31] https://twitter.com/GovKemp/status/1207430729862459393?s=20

136. In response, EPD shutdown the Wheat Street facility and ordered BD to remove all of its inventory from the premises. In a December 23, 2019 letter, BD represented that the facility was closed as of the date of the letter.

137. In the December 23, 2019 letter, BD noted that internal preliminary studies revealed that the wood pallets being used in its facilities were a potentially significant source of residual EtO emissions.

138. EPD ordered BD to obtain a permit for the GDC and Wheat Street facility.

139. To date, BD has not obtained permits for the GDC or Wheat Street Facility.

140. BD was ordered to disclose to EPD why the amount of fugitive EtO emissions from sterilized devices was higher than BD estimated in its air-quality permits for its Covington and Madison sterilization plants.

141. Subsequently, EPD and BD entered into two amendments to the Consent Order on January 15, 2020 and March 25, 2020 for further monitoring and compliance of BD's Covington facility.

142. On August 5, 2020, Senate Bill 426 was signed into law to amend O.C.G.A. § 12-9-7, which requires certain actions to be taken by facilities who emit EtO.

143. The new law amending O.C.G.A. § 12-9-7 requires that "[a]s a condition of a permit for operations that include the emission of ethylene oxide, any spill or release of ethylene oxide, regardless of the amount, shall be reported to the division in writing within 24 hours of discovering such spill or release."

144. On August 6, 2020, EPD sent a letter to BD (attached as Exhibit "G"), addressed to Defendant Brothers, informing them that EPD would be amending the Covington Facility's

permit to incorporate these new requirements and that EPD expected BD to begin submitting the required reports effective immediately.

CAUSES OF ACTION[32]

COUNT I: NEGLIGENCE (STATE STATUTORY AND COMMON LAW)
(*BD Defendants and John Doe No. 1-10*)

145. Principles of negligence, including the applicable duties, breach, causation and damages for harm done are set forth under Georgia law in Title 51, Chapters 1, 2, and 12, as well as Georgia common law.

146. Decedent was exposed to harmful levels of EtO as a proximate result of the acts and omissions of each BD Defendant and John Doe No. 1-10, individually and collectively (collectively referred to in Count I as "Defendant" or "Defendants").

147. As a proximate result of each Defendants' negligent acts and omissions, individually and collectively, Decedent developed and ultimately died from cancer.

148. At all times relevant to this Complaint, each Defendant owed a duty to exercise reasonable care in the operation of the Covington Facility, GDC, and/or Wheat Street facility, including regulating the emission of EtO and truthfully disclosing to the public the accurate levels of EtO being released into the air.

149. At all times relevant hereto, each Defendant knew, or should have known, of the carcinogenic properties of EtO generally and also of that being omitted due to the work being conducted at the Covington Facility, GDC, and/or Wheat Street facility.

[32] None of these claims involve the construction or application of federal law.

150. At all times relevant hereto, each Defendant knew or should have known the foreseeability of harm to others, like Decedent if they emitted dangerous amounts of EtO into the air via direct emissions and fugitive emissions.

151. Defendants breached their duty in one or more of the following ways:

a. Emitting excessive, unnecessary, and/or dangerous volumes of EtO into the air from the Covington Facility, GDC, and/or Wheat Street facility;

b. Using EtO as part of its sterilization process when safer alternatives could accomplish the same or similar business purposes without presenting the same level of risk to human health and well-being;

c. Disregarding safe methods to adequately control EtO emissions from the Covington Facility, GDC, and/or Wheat Street facility;

d. Failing to provide necessary equipment or facilities and/or take necessary precautions to prevent the improper disposal and/or release of fugitive emissions of EtO from the Covington Facility, GDC, and/or Wheat Street facility;

e. Witnessing, directing, cooperating, controlling, causing, allowing, contributing to, and/or participating in the improper disposal and/or release of fugitive emissions of EtO from the Covington Facility, GDC, and/or Wheat Street facility;

f. Failing to report fugitive emissions of EtO;

g. Allowing 85 lbs of EtO to be released into the surrounding community from the Covington Facility on January 20, 2016 due to a lack of diligence and prolonged operator error;

h. Allowing 54.5 lbs of EtO to be released into the surrounding community from the Covington Facility in September of 2019 due to a lack of diligence and prolonged operator error;

i. Placing their own economic interest above the health and well-being of those who live or work in the community near the Covington Facility, GDC, and/or Wheat Street facility;

j. Failing to warn or advise Decedent, as well as those who live or work in the community near the Covington Facility, GDC, and/or Wheat Street facility, that they were and are being exposed to EtO;

k. Failing to warn or advise Decedent, as well as those who live or work in the community near the Covington Facility, GDC, and/or Wheat Street facility, that they were and are breathing in EtO;

l. Failing to warn and/or advise Decedent, as well as those who live or work in the community near the Covington Facility, that it was emitting, and continues to emit, a known carcinogen into the air from its Covington Facility;

m. Failing to employ safe policies, procedures, or methods to adequately control, reduce, minimize, and/or mitigate EtO emissions from the Covington Facility, GDC, and/or Wheat Street facility;

n. Failing to adequately study and test the effect of its EtO emission from the Covington Facility, GDC, and/or Wheat Street facility on the quality of air;

o. Misleading state and local government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility, GDC, and/or Wheat Street facility;

p. Concealing the nature and extent of EtO emissions from the Covington Facility, GDC, and/or Wheat Street facility from government entities and the public;

q. Failing to adequately study and test the effect of its EtO emissions from the Covington Facility, GDC, and/or Wheat Street facility on the health and well-being of those who live and work in the nearby community; and

r. Subjecting Decedent and those who live and work near the Covington Facility, GDC, and/or Wheat Street facility to an elevated cancer risk.

152. The Defendants were additionally negligent in the hiring, training, supervision, and retention of their employees and agents, and other employees and agents who participated in the activities of the Covington Facility, GDC, and/or Wheat Street facility.

153. Defendants' negligent, grossly negligent, willful, wanton and reckless conduct, as described herein, was a proximate cause of Decedent's illness and death.

COUNT II: PUBLIC NUISANCE (GEORGIA COMMON LAW)
(BD Defendants)

154. At all relevant times, the BD Defendants (collectively referred to in Count II as "Defendant" or "Defendants") knew or should have known EtO to be hazardous and harmful to humans.

155. At all relevant times, Defendants knew or should have known that the levels of EtO gas emitted from the Covington Facility, GDC, and/or Wheat Street facility would have a toxic,

poisonous, and deleterious effect upon the health, safety, and wellbeing of people living and working in the community.

156. Defendants knew or should have known that the levels of EtO gas emitting from the Covington Facility, GDC, and/or Wheat Street facility have a toxic, poisonous, and deleterious effect upon the health, safety, and wellbeing of persons breathing it on a regular basis.

157. Despite having knowledge that the levels of EtO gas emitting from the Covington Facility, GDC, and/or Wheat Street facility would have a toxic, poisonous, and deleterious effect upon those in the surrounding community, Defendants continued their operation, maintenance, and use of the, GDC, and/or Wheat Street facility until the EPD intervened, and Defendants still continue their operation, maintenance, and use of the Covington Facility and continue to endanger the general public who live and work in the area surrounding the Covington Facility by causing the those in the community to breathe air containing high levels of EtO on a routine and constant basis, causing a substantially elevated risk of cancer.

158. Defendants misled state and local government leaders and regulators regarding Defendants' emissions and leaks of EtO into the surrounding community.

159. Defendants' emissions of carcinogenic EtO caused direct harm to everyone in the community who came into contact with its hazardous emissions.

160. Defendants had a duty to warn, identify, and disclose the presence of the toxic levels of EtO gas emitting from the Covington Facility, GDC, and/or Wheat Street facility and have failed to warn the public of the toxic, poisonous, and deleterious effect upon the health, safety, and wellbeing of those in the community where Defendants conducts their business.

161. The tortious actions and omissions of Defendants constitute a public nuisance, causing dangers to all members of the public who come into contact with it, and caused special damage to Decedent. Because of the tortious actions of Defendants in emitting EtO, Decedent developed cancer and ultimately died.

162. Defendants thereby knowingly and/or recklessly subjected a considerable and increasing number of individuals from the public at large to the harm inherent in exposure to the levels of its emissions of carcinogenic EtO.

163. The tortious actions of Defendants constitute a public nuisance and caused special damage to Decedent.

164. Defendants failed to act on their knowledge of the toxic levels of EtO gas emitting from the Covington Facility, GDC, and/or Wheat Street facility, and failed to act to correct, prevent, or warn of the general public of the dangerous environment created through Defendants' emissions of EtO, which continuously invaded and contaminated the areas surrounding the Covington Facility, GDC, and/or Wheat Street facility, including Decedent's home and/or places of work. Defendants' failure to take appropriate action to remedy or reduce the danger to the public, including Decedent, allowed the toxic emissions from the Covington Facility, GDC, and/or Wheat Street facility to continue unabated, thereby creating a nuisance that continues to this day.

165. As a proximate result of the Defendants' operation, maintenance, and use of the Covington Facility, GDC, and/or Wheat Street facility, and the public nuisance created thereby, Decedent, and the general public's, right to breathe clean air without dangerous levels of carcinogens such as EtO was eliminated and/or severely diminished.

166. As a proximate result of Defendants' operation, maintenance, and use of the Covington Facility, GDC, and/or Wheat Street facility, and the public nuisance created thereby, EtO continuously invaded and contaminated the community surrounding the Covington Facility, GDC, and/or Wheat Street facility, including Decedent's home and/or places of work.

167. As a proximate result of Defendants' use and emission of EtO, and the public nuisance created thereby, Decedent and the general public were exposed to and inhaled a significant, meaningful, and more than *de minimis* amount of EtO.

168. As a proximate result of Defendants' use and emission of EtO, and the public nuisance created thereby, all members of the general public who came into contact with it suffered damages, and specifically, Decedent suffered special harm and sustained special damages.

169. As a proximate result of Decedent's inhalation of EtO from the Covington Facility, GDC, and/or Wheat Street facility, Decedent developed cancer and ultimately died.

COUNT III: PUBLIC NUISANCE (O.C.G.A. § 41-1-3, *et. seq.*)
(BD Defendants)

170. A public nuisance is one that "tends to the immediate annoyance of the public in general, is manifestly injurious to the public health or safety, or tends greatly to corrupt the manners and morals of the public." The negligence by the BD Defendants and Wheat Street Defendants (collectively referred to in Count III as "Defendant" or "Defendants") in failing to act to correct, prevent, or warn the general public of the dangerous environment created through Defendants' emissions of EtO, which continuously invaded and contaminated the areas surrounding the Covington Facility, GDC, and/or Wheat Street facility, including Plaintiff's places of work, was and is injurious to public health and safety and contributes to the corruption of the manners and morals of the public, including, but not limited to, the residents in the areas

surrounding the Covington Facility, GDC, and/or Wheat Street facility and all other members of the general public who came near the facility. The Covington Facility, GDC, and Wheat Street facility are directly adjacent to numerous residences in the community.

171. Defendants knew or should have known that the levels of EtO gas emitting from the Covington Facility, GDC, and/or Wheat Street facility would have a toxic, poisonous, and deleterious effect upon the health, safety, and wellbeing of persons breathing the gas on a regular basis.

172. Despite having knowledge that the levels of EtO gas emitting from the Covington Facility, GDC, and/or Wheat Street facility would have a toxic, poisonous, and deleterious effect upon those in the surrounding community, Defendants continued their operation, maintenance, and use of the GDC and Wheat Street facility until the EPD intervened, and Defendants continue its operation, maintenance, and use of the Covington Facility and continue to endanger the general public who live and work in the area surrounding the Covington Facility by causing the those in the community to breathe air containing high levels of EtO on a routine and constant basis, causing a substantially elevated risk of cancer.

173. Defendants misled state and local government leaders and regulators regarding Defendants' emissions and leaks of EtO into the surrounding community.

174. Defendants' emissions of carcinogenic EtO caused direct harm to everyone in the community who came into contact with its hazardous emissions.

175. Defendants had a duty to warn, identify, and disclose the presence of the toxic levels of EtO gas emitting from its Covington Facility, GDC, and/or Wheat Street facility and

have failed to warn the public of the toxic, poisonous, and deleterious effect upon the health, safety, and wellbeing of those in the community where Defendants conduct their business.

176. The tortious actions and omissions of Defendants constitute a public nuisance, causing dangers to all members of the public who come into contact with it, and causing special damage to Decedent. Because of the tortious actions of Defendants and emissions of EtO, Decedent developed cancer and ultimately died.

177. Defendants thereby knowingly and/or recklessly subjected a considerable and increasing number of individuals from the public at large to the harm inherent in the levels of its emissions of carcinogenic EtO.

178. The tortious actions of Defendants constitute a public nuisance and caused special damage to Decedent.

179. Defendants failed to act on their knowledge of the toxic levels of EtO gas emitting from its Covington Facility, GDC, and/or Wheat Street facility, and failed to act to correct, prevent, or warn the general public of the dangerous environment created through Defendants' emissions of EtO, which continuously invaded and contaminated the areas surrounding the Covington Facility, GDC, and/or Wheat Street facility, including Decedent's home and/or places of work. Defendants' failure to take appropriate action to remedy or reduce the danger to the public, including Decedent, allowed the toxic emissions from the Covington Facility, GDC, and/or Wheat Street facility to continue unabated, thereby creating a nuisance that continues to this day.

180. As a proximate result of the Defendants' operation, maintenance, and use of the Covington Facility, GDC, and/or Wheat Street facility, and the public nuisance created thereby,

Decedent, and the general public's, right to breathe clean air without dangerous levels of carcinogens such as EtO was eliminated and/or severely diminished.

181. As a proximate result of Defendants' operation, maintenance, and use of the Covington Facility, GDC, and/or Wheat Street facility, and the public nuisance created thereby, EtO continuously invaded and contaminated the community surrounding the Covington Facility, GDC, and/or Wheat Street facility, including Decedent's home and/or places of work.

182. As a proximate result of Defendants' use and emission of EtO, and the public nuisance created thereby, Decedent and the general public were exposed to and inhaled a significant, meaningful, and more than *de minimis* amount of EtO.

183. As a proximate result of Defendants' use and emission of EtO, and the public nuisance created thereby, all members of the general public who came into contact with it suffered damages, and specifically Decedent suffered special harm and sustained special damages.

184. As a proximate result of Decedent's inhalation of EtO from the Covington Facility, GDC, and/or Wheat Street facility, Decedent developed cancer and ultimately died.

COUNT IV: PRIVATE NUISANCE
(GEORGIA COMMON LAW AND O.C.G.A. § 41-1-4, *et seq*)
(All Defendants)

185. The right of enjoyment of person and private property is an absolute right of every citizen.

186. At all relevant times, Defendants knew or should have known that EtO is hazardous and harmful to humans.

187. At all relevant times, Defendants knew or should have known that the levels of EtO gas emitted from the Covington Facility, GDC, and/or Wheat Street facility would have a

toxic, poisonous, and deleterious effect upon the health, safety, and wellbeing of people living and working in the community.

188. Defendants knew or should have known that the levels of EtO gas emitting from the Covington Facility, GDC, and/or Wheat Street facility would have a toxic, poisonous, and deleterious effect upon the health, safety, and wellbeing of persons breathing it on a regular basis.

189. Defendants' operation, maintenance, and use of the Covington Facility, GDC, and/or Wheat Street facility caused those who live and work in the area surrounding the Covington Facility, GDC, and/or Wheat Street facility to breath air contaminated with high levels of EtO on a routine and constant basis, causing a substantially elevated risk of cancer.

190. Defendant' emissions of carcinogenic EtO interfere with Decedent's enjoyment of property and cause hurt, inconvenience, or damage to Decedent.

191. As a proximate result of the Defendants' operation, maintenance, and use of the Covington Facility, GDC, and/or Wheat Street facility, Decedent's right to breathe clean air without dangerous levels of carcinogens such as EtO was eliminated and/or severely diminished.

192. As a proximate result of Defendants' operation, maintenance, and use of the Covington Facility, GDC, and/or Wheat Street facility, EtO continuously invaded and contaminated the areas surrounding the Covington Facility, GDC, and/or Wheat Street facility, including Decedent's home and/or places of work.

193. As a proximate result of Defendants' use and emission of EtO, Decedent was exposed to and inhaled a significant, meaningful, and more than *de minimis* amount of EtO.

194. As a proximate result of Defendants' use and emission of EtO and Decedent's inhalation of EtO from the Covington Facility, GDC, and/or Wheat Street facility, Decedent developed cancer and ultimately died.

COUNT V: ULTRAHAZARDOUS ACTIVITY/STRICT LIABILITY (GEORGIA COMMON LAW)
(BD and Covington Managers)

195. Defendants BD and the Covington Managers (collectively referred to in Count V as "Defendant" or "Defendants") use and emission of EtO from the Covington Facility, GDC, and/or Wheat Street Facility constitutes an ultrahazardous activity.

196. Defendants operate a warehouse in which they knowingly allowed, and assisted in, the unregulated storage and emission of dangerous levels EtO which constitutes an ultrahazardous activity.

197. BD owns and operates the GDC in which it knowingly allowed the unregulated storage, use, and emission of dangerous levels EtO which constitutes an ultrahazardous activity.

198. BD owns and operates the Covington Facility in which it knowingly allowed the storage, use, and emission of dangerous levels of EtO which constitutes an ultrahazardous activity.

199. BD carried out its ultrahazardous activities by and through the Covington Managers.

200. Defendants' use and emission of EtO created a high degree of risk to those who live and work in the surrounding area. Further, the likelihood of cancer caused by Defendants' use and emission of EtO is significantly higher than the level of acceptable risk.

201. Defendants' use and emission of EtO is especially inappropriate given the densely populated residential and commercial areas in which the Covington Facility, GDC, and/or Wheat Street facility are located.

202. The activities, as conducted by each and every Defendant, are exceedingly dangerous and offer little to no value to the surrounding community.

203. Because Defendants' activities are ultrahazardous, they are strictly liable for any injuries proximately resulting therefrom.

204. As a proximate result of Defendants' ultrahazardous activities, Decedent was exposed to and inhaled carcinogenic amounts of EtO.

205. As a proximate result of Decedent's inhalation of EtO from the Covington Facility, GDC, and/or Wheat Street facility, Decedent developed cancer and ultimately died.

COUNT VI: AIDING AND ABETTING TORTIOUS CONDUCT
(GEORGIA COMMON LAW)
(*Covington Managers*)

206. At all times during which the Covington Managers assisted BD in using and storing EtO, each knew that BD's operations would emit EtO into the atmosphere.

207. At all times during which the Covington Managers assisted BD in using and storing EtO, each knew or should have known that EtO is carcinogenic to humans.

208. Without assistance from the Covington Managers, BD would not have been able to emit additional harmful levels of EtO into the area surrounding the property.

209. As a proximate result of the Covington Managers' assisting BD in storing products emitting EtO, the Covington Managers negligently breached their duty and failed to exercise

ordinary care for the health and well-being of Decedent, as well as those in the surrounding community

210. The Covington Managers knowingly assisted, aided, and abetted BD in their negligence against Decedent, and are liable to Decedent, along with the other Defendants, for causing and/or contributing to Decedent's illness and resulting death.

211. As a proximate result of the Covington Managers' actions and omissions, Decedent developed cancer and ultimately died.

COUNT VII: *RESPONDEAT SUPERIOR* AND/OR VICARIOUS LIABILITY (GEORGIA COMMON LAW AND O.C.G.A. §§ 10-6-51, 10-6-60, 51-2-1, 51-2-2, 51-2-5) (*BD Defendants*)

212. Upon information and belief, at all times pertinent to this Complaint, the Covington Managers were employees and/or agents of BD.

213. Upon information and belief, at all times pertinent to this Complaint, the Covington Managers were acting within the course and scope of their employment and/or agency with BD.

214. Upon information and belief, at all times pertinent to this Complaint, the Covington Managers were acting in furtherance of the interests of BD.

215. BD is therefore liable under the doctrines of *respondeat superior*, vicarious liability and/or statutory employer liability for the tortious acts and/or omissions of their employees and/or agents.

216. As a proximate cause of the acts and omissions of BD, by and through the Covington Managers, Decedent developed cancer and ultimately died.

COUNT VIII: GEORGIA RICO (RACKETEER INFLUENCE AND CORRUPT ORGANIZATIONS) (O.C.G.A. § 16-14-3, *et seq*)
(*BD Defendants*)

217. The Georgia RICO Act prohibits any person from engaging in certain enumerated activities through a pattern of racketeering or conspiracy.

218. The BD Defendants constitute an "enterprise" under O.C.G.A. § 16-14-3(3). Defendants' enterprise has, and has had, for all times relevant to this Complaint, a continuity of structure and a shared common purpose and scheme or pattern of hiding the dangerous environment created through emissions of EtO, which continuously invaded and contaminated the areas surrounding the Covington Facility and GDC.

219. The Covington Managers, including Defendants Lamontagne, Brothers, Pasdon, McKinnon, Sandbo, Bruette, Darnell, McFalls, Taylor, and Williams, were employed by or were associated with BD as defined by O.C.G.A. § 16-14-4(b). For purposes of Count XIII, the Covington Managers and BD are collectively referred to as Defendant and/or Defendants.

220. Defendants are jointly and severally liable to Plaintiff for this Racketeer Influenced and Corrupt Organization ("RICO") cause of action, and Defendants are each an agent of one another and a co-conspirator with the other relating to the acts alleged herein.

221. Defendants agreed to enter into a conspiracy to violate Georgia law, including but not limited to O.G.C.A. § 16-14-3(5)(A) and 5(B).

222. These offenses were part of a systematic and ongoing pattern of racketeering activity, which Defendants participated in directly through a pattern of racketeering activities.

223. Through this behavior, Defendants engaged in racketeering activities as defined in O.C.G.A. § 16-14-3(5)(B) and (5)(A) including, but not limited to, (xxii) false statements and concealment of facts, mail fraud, and wire fraud.

224. Defendants' use and emission of EtO created a high degree of risk to those who live and work in the surrounding area. Further, the likelihood of cancer caused by Defendants' use and emission of EtO is significantly higher than the level of acceptable risk.

225. Defendants knew, or should have known, that the levels of EtO gas emitting from the Covington Facility and GDC would have a toxic, poisonous, and deleterious effect upon the health, safety, and wellbeing of persons breathing it on a regular basis.

226. Since at least 1996, Defendant Lamontagne has misled government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs to EPD.

227. Since at least 1996, Defendant Lamontagne has concealed from the public the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted, and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs to EPD.

228. Since at least 2018, Defendant Brothers has misled government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than

actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs to EPD.

229. Since at least 2018, Defendant Brothers has concealed from the public the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs to EPD.

230. Since at least 2011, Defendant Pasdon has misled government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted, retroactively reducing the Covington Facility's 2014-2017 EtO emissions data reported to the EPA, and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

231. Since at least 2011, Defendant Pasdon has concealed from the public the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted, retroactively reducing the Covington Facility's 2014-2017 EtO emissions data reported to the EPA, and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

232. Since at least 2011, Defendant McKinnon has misled state government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

233. Since at least 2011, Defendant McKinnon has concealed from the public the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

234. Since at least 2005, Defendant Sandbo has misled state government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

235. Since at least 2005, Defendant Sandbo has concealed from the public the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

236. Since at least the late 1990's, Defendant Bruette has misled state government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

237. Since at least the late 1990's, Defendant Bruette has concealed from the public the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

238. Since at least 1997, Defendant Darnell has misled state government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

239. Since at least 1997, Defendant Darnell has concealed from the public the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

240. Since at least 2013, Defendant McFalls has misled state government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

241. Since at least 2013, Defendant McFalls has concealed from the public the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

242. Since at least 2015, Defendant Taylor has misled state government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than

actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

243. Since at least 2015, Defendant Taylor has concealed from the public the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

244. Since at least 2014, Defendant Williams has misled state government entities and the public in general about the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

245. Since at least 2014, Defendant Williams has concealed from the public the nature and extent of EtO emissions from the Covington Facility by regularly reporting that the Covington Facility emits significantly less amounts of EtO than actually emitted and by consistently failing to report EtO leaks from the Covington Facility in excess of 10 lbs. to EPD.

246. As a result of public concern regarding the emissions of EtO at the Covington Facility, the City of Covington (the City) contracted for seven (7) days of ambient air monitoring in the area surrounding the Facility. The City notified Defendants, EPD, and the public of its plan before the air monitoring commenced. The City worked with Defendants and requested that Defendants put forth an official to certify daily that the company was conducting normal operations during the period of air monitoring. Defendants agreed to do so. The City's contractor conducted the air monitoring from September 17, 2019 through September 23, 2019.

247. From September 17, 2019 through September 23, 2019, Defendants provided the City of Covington with the requested Affidavits certifying that the Facility was operating normally during the seven-day test period. Specifically, Defendant Ron Pasdon certified that BD was conducting its usual operations in accordance with its 2019 Standard Operating Procedures.

248. The Affidavits were provided to the City by Defendants even though Defendants were intermittently releasing EtO 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 Defendants discovered the release. Defendants acted in bad faith in providing the Affidavits to the City because Defendants knew that it was experiencing an unauthorized release in violation of the Permit.

249. By providing these Affidavits to the City despite having this knowledge, Defendants knowingly made false statements to the City of Covington.

250. Despite Defendants' false statements to the contrary, EPD discovered that Defendants' fugitive emissions of nearly 55 lbs of EtO from the Covington Facility, in less than one week's time, violated the requirement to achieve 99% destruction removal efficiency. EPD also discovered that Defendants made false statements regarding Defendants' alleged compliance with release reporting requirements for EtO, which mandate the reporting of EtO releases in excess of 10 lbs in a 24-hour period.

251. On January 2, 2019 and May 3, 2019, Defendant LaMontagne sent letters to Georgia EPD through the U.S. Postal Service, which provided data regarding Defendants' compliance with the 99% EtO destruction efficiency required by their permit.

252. The emissions data reported by Defendant LaMontagne intentionally failed to factor in fugitive emissions, which occur when EtO escapes from anywhere other than the facility's stack (which is the only area actually measured) and is not captured by pollution controls. In doing so, Defendant's letter made false and/or misleading representations regarding Defendants' EtO emissions and normal operating procedures. In so doing, Defendants utilized the United States mail to cover up the true extent of the Covington Facility's fugitive EtO emissions and EtO destruction efficiency.

253. Defendants were aware that these statements and representations were not true and/or misleading at the time they were made. This constitutes racketeering activity by the Defendants which was part of a common and continuous pattern of fraudulent schemes, perpetrated for the same or similar purposes and constituting a "pattern of racketeering activity."

254. Through these racketeering activities, the Defendants deceived state and regulatory officials as well as the general public, including Decedent. As a direct result of these racketeering activities directed toward government officials and the general public, Decedent was exposed to and inhaled carcinogenic amounts of EtO.

255. As a proximate result of Decedent's inhalation of EtO from the Covington Facility and GDC, Decedent developed cancer and ultimately died.

COUNT IX: WRONGFUL DEATH – FULL VALUE OF LIFE
(All Defendants)

256. Plaintiff, as the surviving Next of Kin of Decedent, is the proper party to bring a claim for the wrongful death of Decedent.

257. Defendants, and each of them, are liable to Plaintiff, as the surviving Next of Kin of Decedent, for Decedent's wrongful death and for damages representing the full of value of Decedent's life.

COUNT X: WRONGFUL DEATH – ESTATE DAMAGES
(*All Defendants*)

258. Plaintiff is the court appointed Representative of the Estate of Decedent, and is the proper party to bring a claim for wrongful death on behalf of the Estate for Decedent's pre-death pain and suffering, medical, and funeral expenses.

259. Defendants, and each of them, are liable to Plaintiff, as the court appointed Representative of the Estate of Decedent, for Decedent's medical and funeral expenses, as well as Decedent's pre-death pain and suffering.

COUNT XI: PUNITIVE DAMAGES (O.C.G.A. § 51-12-5.1)
(All Defendants)

260. At all times relevant, Defendants owed a duty to refrain from willful and wanton misconduct and/or conduct which exhibited an indifference and/or conscious disregard to the health, safety, and well-being of Decedent and those living and working in the area surrounding the Covington Facility, GDC, and/or Wheat Street facility.

261. The conduct of each Defendant as set forth hereinabove showed willful misconduct, malice, fraud, wantonness, oppression or that entire want of care which would raise the presumption of a conscious indifference to consequences.

262. Accordingly, punitive damages should be imposed against each defendant pursuant O.C.G.A. § 51-12-5.1 and other applicable laws, to punish and deter each Defendant from repeating or continuing such unlawful conduct, in an amount to be proven at trial.

COUNT XII: ATTORNEY'S FEES AND EXPENSES OF LITIGATION
(O.C.G.A. § 13-6-11)
(All Defendants)

263. Defendants' actions constitute willful, intentional, and tortious conduct. Every intentional tort involves an element of bad faith that entitles a person to recover the expenses of litigation, including attorney's fees.

264. The actions of Defendants and their agents and representatives have caused Plaintiff unnecessary trouble and expense.

265. Plaintiff is entitled to recover attorney's fees and the expense of litigation from the Defendants pursuant to O.C.G.A. § 13-6-11.

WHEREFORE, Plaintiff prays:

a. That process issue according to law;

b. That each Defendant be served with a copy of Plaintiff's Complaint and show cause why the prayers for relief requested by Plaintiff herein should not be granted;

c. That Plaintiff be granted a trial by jury in this matter;

d. That the Court enter a judgment against each Defendant for all general and compensatory damages allowable to Plaintiff;

e. That the Court enter a judgment against each Defendant for all special damages allowable to Plaintiff;

f. That the Court enter a judgment against each Defendant for treble damages allowable to Plaintiff under Georgia RICO law;

g. That the Court enter a judgment against each Defendant serving to award Plaintiff punitive damages under the provisions of O.C.G.A. § 51-12-5.1 and as otherwise provided by law;

h. That the Court enter a judgment against each Defendant for all other relief sought by Plaintiff under this Complaint;

i. That the costs of this action be cast upon Defendants; and

j. That the Court grant Plaintiff such further relief which the Court deems just and appropriate.

Respectfully submitted this 20th day of July, 2021.

PENN LAW LLC

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

GEORGIA
DEPARTMENT OF NATURAL RESOURCES

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.

STATE OF GEORGIA CONSTITUTION WISDOM JUSTICE MODERATION 1776

[Signed]

Richard E. Dunn, Director
Environmental Protection Division

Blumberg No. 5119 EXHIBIT A

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]

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]

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.

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.

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.

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).

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 30th and December 31st of each year. All reports shall be postmarked by the 30th day following the end of each reporting period, July 30th and January 30th. 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.

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.

GEORGIA
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

Richard E. Dunn, Director

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

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*[1].

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 (http://epd.georgia.gov/air/georgia-aermet-meteorological-data). 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

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

* 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.

Residential Areas	Receptor UTM Zone:17		MGLC (μg/m³)*	Averaging Period	AAC (μg/m³)	Ratio of MGLC (μg/m³) to AAC (μg/m³)
	Easting (meter)	Northing (meter)				
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

* 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

* 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.

Residential Areas	Receptor UTM Zone:17		MGLC ($\mu g/m^3$)*	Averaging Period	AAC ($\mu g/m^3$)	Ratio of Ground-level Concentration ($\mu g/m^3$) to AAC ($\mu g/m^3$)
	Easting (meter)	Northing (meter)				
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

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

Model Input Parameters for EtO Emissions Sources

Model ID	Stack Description	Source Type	UTM E[1] (m)	UTM N[1] (m)	Emis %	Modeled EtO Emissions[3] (g/s)	Stack Height		Stack Temperature		Exhaust Gas Flow Rate (cfm)	Exit Velocity		Stack Diameter	
							(ft)	(m)	(°F)	(K)		(ft/s)	(m/s)	(inch)	(m)
EF17	Exhaust Fan	POINT	236,448.9	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
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	10.363	30.0	0.762
EF20	Exhaust Fan	POINT	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
EF21	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	10.363	30.0	0.762
EF22	Exhaust Fan	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	44.0	1.118
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
EF24	Exhaust Fan	POINT	236,487.8	3,722,345.4	10%	7.993E-04	25.0	7.620	70	294.26	24,000	36.2	11.034	45.0	1.143
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
EF26	Exhaust Fan	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	45.0	1.143
EF44*	Exhaust Fan	POINT	236,432.1	3,722,277.0	5%	3.996E-04	28.0	8.534	70	294.26	13,200	40.0	12.192	31.8	0.808
EF45*	Exhaust Fan	POINT	236,433.7	3,722,301.4	5%	3.996E-04	28.0	8.534	70	294.26	13,200	40.0	12.192	31.8	0.808
EF47	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	44.0	1.118
EF48	Exhaust Fan	POINT	236,431.1	3,722,342.5	8%	6.394E-04	25.0	7.620	70	294.26	21,200	33.5	10.211	44.0	1.118
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
RTO	regenerative thermal oxidizer	POINT	236,424.2	3,722,295.0	N/A	1.463E-03	50.0	15.240	250	394.26	29,000	30.5	9.296	48.0	1.219

Notes:

1. Coordinates reflect UTM NAD83, Zone 17. EF20 coordinates were revised based on site plan
2. EF44 and EF45 - Roof mounted upblast type fan, modeled diameters were derived from flow rate and exit velocity
3. EF23~26 - Rectangular Duct shows as the round 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 3×10^{-3} $\mu g/m^3$. Since ethylene oxide is carcinogenic to humans, it belongs to Group A[2] with a cancer risk of 1/1,000,000. Therefore, the annual AAC is calculated as:

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

15-min AAC

The OSHA permissible exposure limit (PEL) for ethylene oxide is 5 ppm. To convert the PEL from ppm to mg/m^3, use the following conversion formula from the guidance:

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

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:

$$\text{15-min AAC} = 9\ mg/m^3 \times 1000\ (\text{convert mg to } \mu g) / 10\ (\text{safety factor}) = \mathbf{900\ \mu g/m^3}$$

[2] 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 µg/m³**

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

AMS Exposure Concentration = Cancer Risk / IUR = $(1/1,000,000)/(0.005/\mu g/m^3)$ = **0.0002 µg/m³**

[3] 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	3.0	9/15/19 2:37 PM	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	CV	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	CV	5	122	121.5	3.2	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	CV	5	113	112.5	3.0	9/21/19 10:12 AM	9/21/19 2:40 PM
194909	CV	5	122	121.5	3.2	9/21/19 8:03 PM	9/22/19 12:32 AM
194890	CV	5	121	120.5	3.2	9/22/19 5:58 AM	9/22/19 10:26 AM
194814	CV	5	115	114.5	3.1	9/22/19 4:06 PM	9/22/19 8:34 PM
		Total	2050		54.5		

AFFIDAVIT

STATE OF GEORGIA

COUNTY OF NEWTON

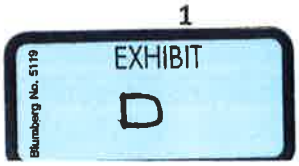
1. My name is Ron Pasdon and I am a resident of Walton County, Georgia. I am over 19 years of age, have personal knowledge of the facts set forth below and am competent and authorized to make this Affidavit.

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.

18 Sept 2019

Ron Pasdon
Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this 18 day of September 2019.

Signature of Notary Public – State of Georgia

CINDY H WILDER
NOTARY PUBLIC
HENRY COUNTY, GEORGIA
MY COMMISSION EXPIRES

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

Attachment A

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

AFFIDAVIT

STATE OF GEORGIA

COUNTY OF NEWTON

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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 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.

R Pasdon 19 Sept. 2019

Ron Pasdon
Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this 19 day of September 2019.

VICTORIA N PLUNKETT NOTARY PUBLIC NEWTON COUNTY, GEORGIA

Victoria N Plunkett

Signature of Notary Public – State of Georgia

VICTORIA N. PLUNKETT

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

Attachment A

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

AFFIDAVIT

STATE OF GEORGIA

COUNTY OF NEWTON

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 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.

6. The number of sterilization load cycles processed on September 19, 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.

R Pasdon 20sept. 2019

Ron Pasdon
Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this 20 day of September 2019.

VICTORIA N PLUNKETT
NOTARY PUBLIC
NEWTON COUNTY, GEORGIA

Victoria N. Plunkett

Signature of Notary Public – State of Georgia

VICTORIA N. PLUNKETT

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

Attachment A

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
194874	9/19/2019	121
194887	9/19/2019	121
194893	9/19/2019	36
11	Daily Total	1160

AFFIDAVIT

STATE OF GEORGIA

COUNTY OF NEWTON

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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.

R Pasdon 23 Sept. 2019

Ron Pasdon
Sr. Operations Manager, BD Covington Facility

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

Victoria N. Plunkett

Signature of Notary Public – State of Georgia

VICTORIA N PLUNKETT NOTARY PUBLIC NEWTON COUNTY, GEORGIA

VICTORIA N. PLUNKETT

Print, type, or stamp commissioned name of Notary
Personally Known ✓ OR Produced Identification ____
Type of Identification Produced _____

Attachment A

Tracking Load Number	Date	EO Used LB
194735	9/20/2019	36
194851	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

AFFIDAVIT

STATE OF GEORGIA

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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.

R Pasdon 23 Sept. 2019

Ron Pasdon
Sr. Operations Manager, BD Covington Facility

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

Victoria N. Plunkett

Signature of Notary Public – State of Georgia

VICTORIA N PLUNKETT NOTARY PUBLIC NEWTON COUNTY, GEORGIA

Victoria N. Plunkett

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

Attachment A

Tracking Load Number	Date	EO Used LB
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
194910	9/21/2019	128
194877	9/21/2019	109
194895	9/21/2019	34
11	Daily Total	1052

AFFIDAVIT

STATE OF GEORGIA

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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.

23Sept. 2019

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

VICTORIA N PLUNKETT NOTARY PUBLIC NEWTON COUNTY, GEORGIA

Victoria N. Plunkett

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

Attachment A

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
194925	9/22/2019	123
194814	9/22/2019	115
194915	9/22/2019	151
12	Daily Total	1327

AFFIDAVIT

STATE OF GEORGIA

COUNTY OF NEWTON

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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.

R. Pasdon 24 Sept. 2019

Ron Pasdon
Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this 24 day of September 2019.

Cindy H Wilder

Signature of Notary Public – State of Georgia

Cindy

Print, type, or stamp Commissioned name of Notary
Personally Known ___ OR Produced Identification ____
Type of Identification Produced _____

CINDY H WILDER NOTARY PUBLIC HENRY COUNTY, GEORGIA MARCH 17, 2021

Attachment A

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

AFFIDAVIT

STATE OF GEORGIA

COUNTY OF NEWTON

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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.

6. The number of sterilization load cycles processed on September 24, 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.

R Pasdon 25 Sept 2019

Ron Pasdon
Sr. Operations Manager, BD Covington Facility

Sworn to and subscribed before me this 25 day of September 2019.

Cindy H Wilder

Signature of Notary Public – State of Georgia

CINDY H WILDER
NOTARY PUBLIC
HENRY COUNTY, GEORGIA
MY COMMISSION EXPIRES

Cindy H Wilder

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

Attachment A

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

City of Covington Ethylene Oxide Ambient Monitoring Sampling Locations

MONTROSE
AIR QUALITY SERVICES

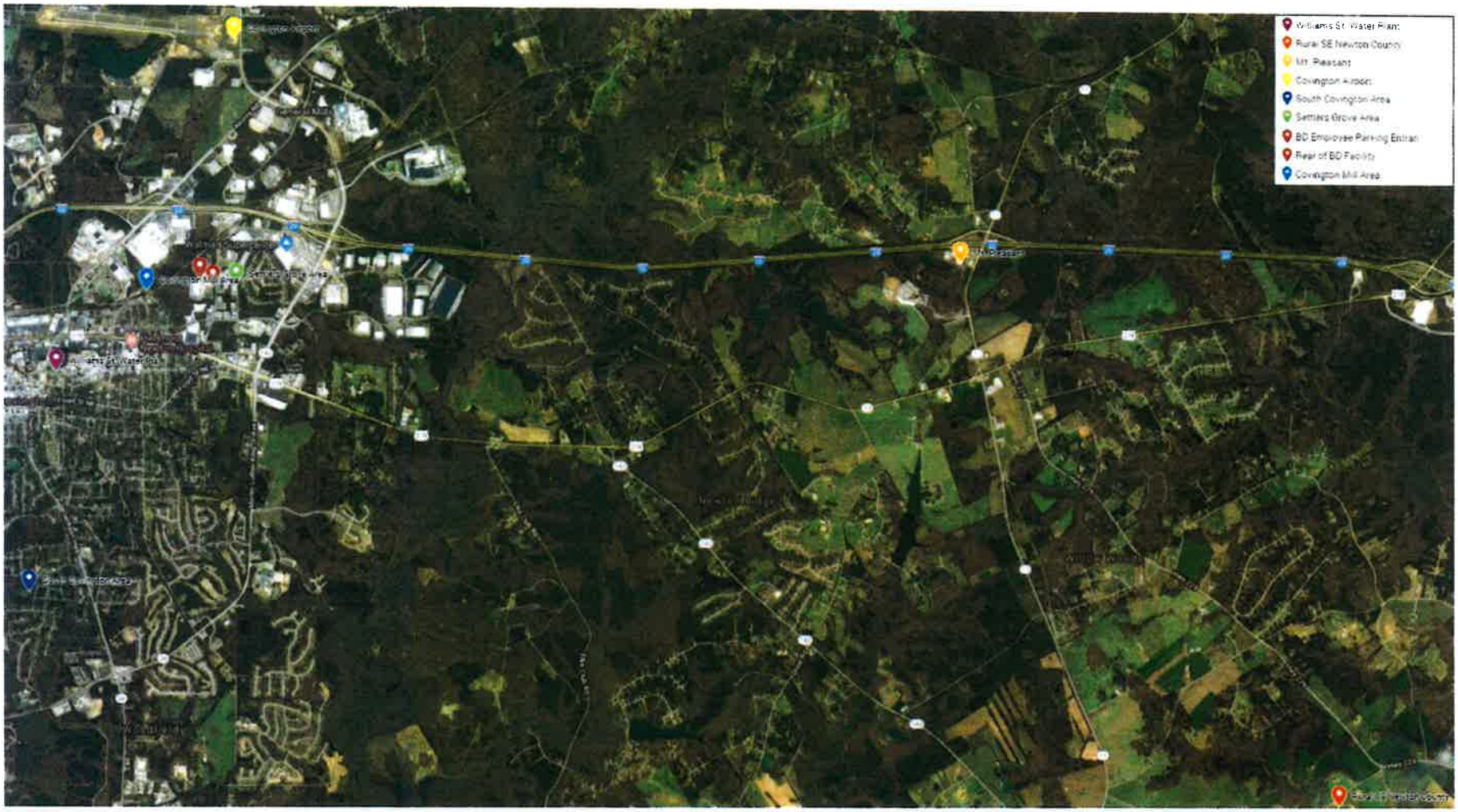


EXHIBIT
E
Blumberg No. 6110

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

Location ID	Sample Location	Montrose Sample ID	Sample Start	Sample End	Result	
					ppbv	ug/m3
1	Rear of BD Facility	641120-1-P-20190917	9/17/2019	9/18/2019	0.715	1.29
1	Rear of BD Facility	641120-1-P-20190918	9/18/2019	9/19/2019	0.220	0.396
1	Rear of BD Facility	641120-1-P-20190919	9/19/2019	9/20/2019	0.168	0.302
1	Rear of BD Facility	641120-1-P-20190920	9/20/2019	9/21/2019	0.604	1.09
1	Rear of BD Facility	641120-1-P-20190921	9/21/2019	9/22/2019	1.87	3.37
1	Rear of BD Facility	641120-1-P-20190922	9/22/2019	9/23/2019	6.85	12.3
1	Rear of BD Facility	641120-1-P-20190923	9/23/2019	9/24/2019	1.61	2.90
1	Rear of BD Facility (ERG)	641120-1-P-20190923	9/23/2019	9/24/2019	0.851	1.54
2	BD 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	BD Employee Parking Entrance	641120-2-P-20190918	9/18/2019	9/19/2019	0.122	0.220
2	BD Employee Parking Entrance	641120-2-P-20190919	9/19/2019	9/20/2019	0.0885	0.160
2	BD Employee Parking Entrance	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
3	Settlers Grove Area	641120-3-P-20190917	9/17/2019	9/18/2019	7.65	13.8
3	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
3	Settlers Grove Area (ERG)	641120-3-P-20190918	9/18/2019	9/19/2019	0.194	0.351
3	Settlers Grove Area	641120-3-P-20190919	9/19/2019	9/20/2019	0.105	0.189
3	Settlers Grove Area	641120-3-P-20190920	9/20/2019	9/21/2019	0.103	0.186
3	Settlers Grove Area	641120-3-P-20190921	9/21/2019	9/22/2019	0.321	0.578
3	Settlers Grove Area	641120-3-P-20190922	9/22/2019	9/23/2019	4.69	8.45
3	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

(Duplicate) = Duplicate Sample Analyzed by Enthalpy
(ERG) = Duplicate Sample Analyzed by Eastern Research Group Laboratory

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

Location ID	Sample Location	Montrose Sample ID	Sample Start	Sample End	Result	
					ppbv	ug/m3
4	Covington Mill Area	641120-4-P-20190923	9/23/2019	9/24/2019	0.142	0.255
5	Williams Street Water Plant	641120-5-P-20190917	9/17/2019	9/18/2019	0.240	0.432
5	Williams Street Water Plant	641120-5-P-20190918	9/18/2019	9/19/2019	0.620	1.12
5	Williams Street Water Plant	641120-5-P-20190919	9/19/2019	9/20/2019	1.01	1.83
5	Williams Street Water Plant	641120-5-P-20190920	9/20/2019	9/21/2019	0.623	1.12
5	Williams Street Water Plant	641120-5-P-20190921	9/21/2019	9/22/2019	1.23	2.21
5	Williams Street Water Plant	641120-5-P-20190922	9/22/2019	9/23/2019	0.825	1.49
5	Williams Street Water Plant	641120-5-P-20190923	9/23/2019	9/24/2019	0.162	0.291
6	Mount Pleasant	641120-6-P-20190917	9/17/2019	9/18/2019	0.108	0.195
6	Mount Pleasant (ERG)	641120-6-P-20190917	9/17/2019	9/18/2019	0.254	0.460
6	Mount Pleasant	641120-6-P-20190918	9/18/2019	9/19/2019	0.785	1.41
6	Mount Pleasant	641120-6-P-20190919	9/19/2019	9/20/2019	0.0829	0.149
6	Mount Pleasant	641120-6-P-20190920	9/20/2019	9/21/2019	0.0654	0.118
6	Mount Pleasant	641120-6-P-20190921	9/21/2019	9/22/2019	0.0831	0.150
6	Mount Pleasant	641120-6-P-20190922	9/22/2019	9/23/2019	0.113	0.203
6	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
8	Rural SE Newton County	641120-8-P-20190917	9/17/2019	9/18/2019	0.120	0.216
8	Rural SE Newton County	641120-8-P-20190918	9/18/2019	9/19/2019	0.0734	0.132
8	Rural SE Newton County	641120-38-P-20190919	9/19/2019	9/20/2019	0.0917	0.165
8	Rural SE Newton County	641120-8-P-20190920	9/20/2019	9/21/2019	0.0906	0.163
8	Rural SE Newton County	641120-8-P-20190921	9/21/2019	9/22/2019	0.0781	0.141
8	Rural SE Newton County	641120-8-P-20190922	9/22/2019	9/23/2019	0.0653	0.118
8	Rural SE Newton County	641120-8-P-20190923	9/23/2019	9/24/2019	0.346	0.624
9	South Covington Area	641120-9-P-20190917	9/17/2019	9/18/2019	0.122	0.219
9	South Covington Area	641120-9-P-20190918	9/18/2019	9/19/2019	0.118	0.212
9	South Covington Area	641120-9-P-20190919	9/19/2019	9/20/2019	0.106	0.192

(Duplicate) = Duplicate Sample Analyzed by Enthalpy
(ERG) = Duplicate Sample Analyzed by Eastern Research Group Laboratory

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

Location ID	Sample Location	Montrose Sample ID	Sample Start	Sample End	Result	
					ppbv	ug/m3
9	South Covington Area	641120-9-P-20190920	9/20/2019	9/21/2019	0.197	0.356
9	South Covington Area (ERG)	641120-9-P-20190920	9/20/2019	9/21/2019	<0.0614	<0.111
9	South Covington Area	641120-9-P-20190921	9/21/2019	9/22/2019	0.259	0.466
9	South Covington Area	641120-9-P-20190922	9/22/2019	9/23/2019	0.199	0.359
9	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

(Duplicate) = Duplicate Sample Analyzed by Enthalpy
(ERG) = Duplicate Sample Analyzed by Eastern Research Group Laboratory

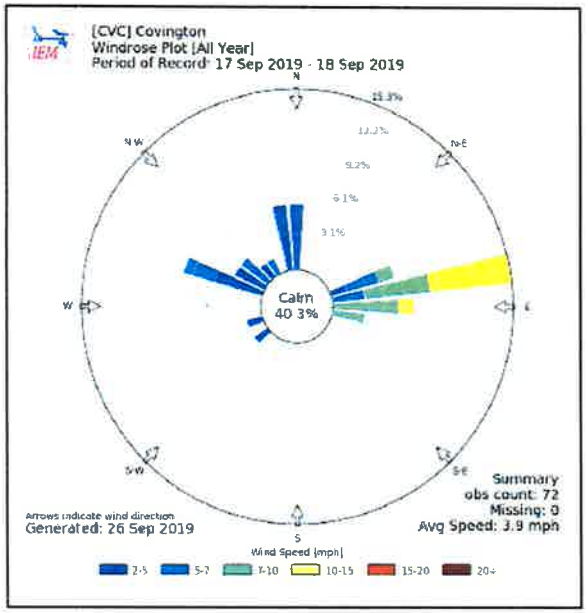
MONTROSE
AIR QUALITY SERVICES

1 Mile

Conyers

Conyers, GA Location		
P	0.154 (ppbv)	0.278 (µg/m³)

Covington Airport		
P	0.0890 (ppbv)	0.160 (µg/m³)



Sampling Period

Tuesday, September 17, 2019 11:13 AM
THROUGH
Wednesday, September 18, 2019 2:45 PM

General Mills

Rear of BD Facility		
P	0.715 (ppbv)	1.29 (µg/m³)

Settlers Grove Area		
P	7.65 (ppbv)	13.8 (µg/m³)
D	6.94 (ppbv)	12.5 (µg/m³)

Walmart Supercenter

1 Mile

Mount Pleasant		
P	0.108 (ppbv)	0.195 (µg/m³)
E	0.254 (ppbv)	0.460 (µg/m³)

Covington Mills Area		
P	3.05 (ppbv)	5.50 (µg/m³)

BD Employee Parking Entrance		
P	5.51 (ppbv)	9.92 (µg/m³)
E	3.53 (ppbv)	6.39 (µg/m³)

Piedmont Newton Hospital

Williams Street Water Plant		
P	0.240 (ppbv)	0.432 (µg/m³)

Willow Woods

Sampling Location	
Sample Type	Concentration ppbv | µg/m³

Legend

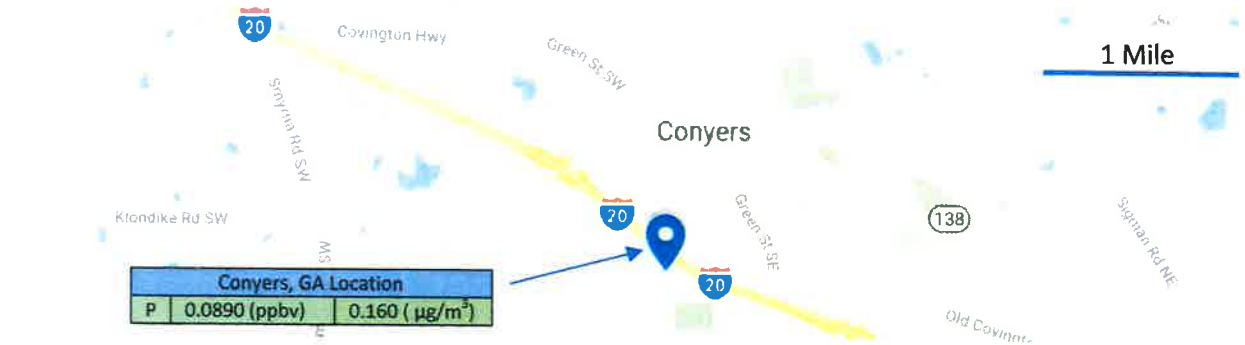
- Air Sample Location
- Weather Station
- Facility
- P Primary Sample
- D Duplicate Sample
- E ERG Analyzed Duplicate

N

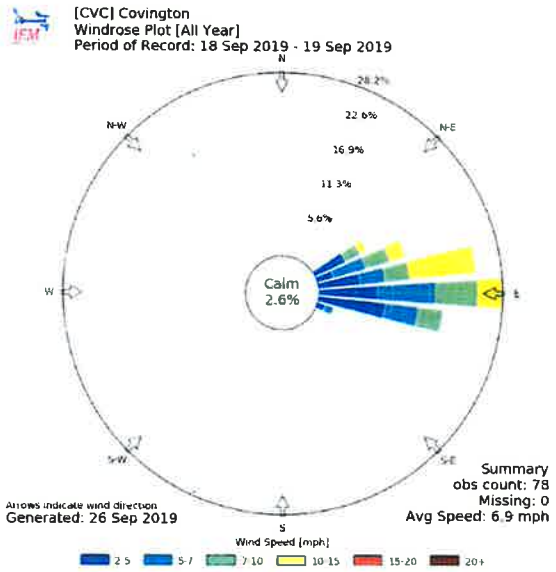
1 Mile

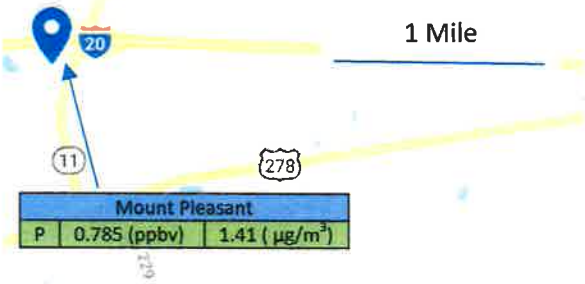
Rural SE Newton County		
P	0.120 (ppbv)	0.216 (µg/m³)

South Covington Area		
P	0.122 (ppbv)	0.219 (µg/m³)



MONTROSE
AIR QUALITY SERVICES





Sampling Period

Wednesday, September 18, 2019 11:06 AM

THROUGH

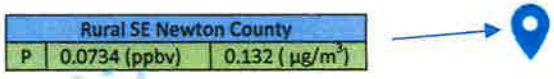
Thursday, September 19, 2019 1:45 PM

Sampling Location	
Sample Type	Concentration ppbv | µg/m³

Legend

- Air Sample Location
- Weather Station
- Facility
- P Primary Sample
- D Duplicate Sample
- E ERG Analyzed Duplicate

N



MONTROSE
AIR QUALITY SERVICES

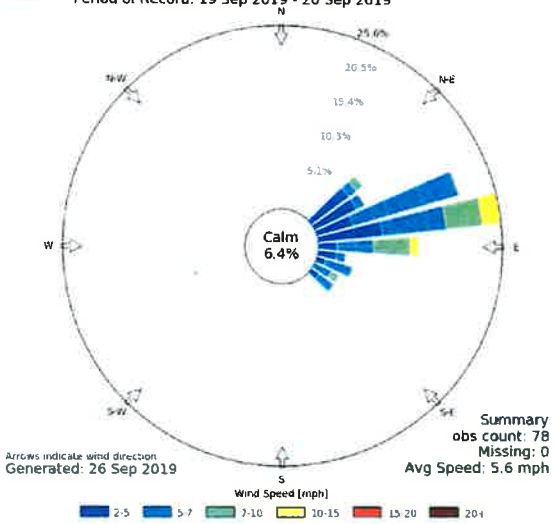
2 Miles

EPD South DeKalb Monitoring Site		
P	0.080 (ppbv)	0.144 (µg/m³)

Conyers, GA Location		
P	0.165 (ppbv)	0.297 (µg/m³)

Covington Airport		
P	0.0865 (ppbv)	0.156 (µg/m³)

[CVC] Covington
Windrose Plot [All Year]
Period of Record: 19 Sep 2019 - 20 Sep 2019



Arrows indicate wind direction
Generated: 26 Sep 2019

Summary
obs count: 78
Missing: 0
Avg Speed: 5.6 mph

Sampling Period
Thursday, September 19, 2019 10:54 AM
THROUGH
Friday, September 20, 2019 3:00 PM

Settlers Grove Area		
P	0.105 (ppbv)	0.189 (µg/m³)

Rear of BD Facility		
P	0.168 (ppbv)	0.302 (µg/m³)

1 Mile

Mount Pleasant		
P	0.0829 (ppbv)	0.149 (µg/m³)

Covington Mills Area		
P	0.328 (ppbv)	0.592 (µg/m³)
E	0.567 (ppbv)	1.03 (µg/m³)

BD Employee Parking Entrance		
P	0.0885 (ppbv)	0.160 (µg/m³)

Williams Street Water Plant		
P	1.01 (ppbv)	1.83 (µg/m³)

Sampling Location	
Sample Type	Concentration ppbv | µg/m³

Legend
- Air Sample Location
- Weather Station
- Facility
- P Primary Sample
- D Duplicate Sample
- E ERG Analyzed Duplicate

N

1 Mile

Rural SE Newton County		
P	0.0917 (ppbv)	0.165 (µg/m³)

South Covington Area		
P	0.106 (ppbv)	0.192 (µg/m³)

MONTROSE AIR QUALITY SERVICES

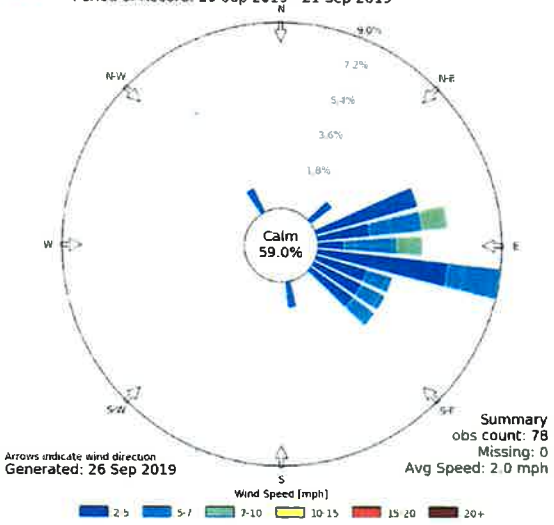
1 Mile

Conyers

Conyers, GA Location		
P	0.107 (ppbv)	0.192 (µg/m³)

Covington Airport		
P	0.0680 (ppbv)	0.123 (µg/m³)

[CVC] Covington
Windrose Plot [All Year]
Period of Record: 20 Sep 2019 - 21 Sep 2019



Arrows indicate wind direction
Generated: 26 Sep 2019

Summary
obs count: 78
Missing: 0
Avg Speed: 2.0 mph

Sampling Period
Friday, September 20, 2019 10:55 AM
THROUGH
Saturday, September 21, 2019 1:41 PM

General Mills

Rear of BD Facility		
P	0.604 (ppbv)	1.09 (µg/m³)

Settlers Grove Area		
P	0.103 (ppbv)	0.186 (µg/m³)

Walmart Supercenter

Covington Mills Area		
P	5.35 (ppbv)	9.64 (µg/m³)
D	5.30 (ppbv)	9.54 (µg/m³)

BD Employee Parking Entrance		
P	0.109 (ppbv)	0.197 (µg/m³)

1 Mile

Mount Pleasant		
P	0.0654 (ppbv)	0.118 (µg/m³)

Sampling Location	
Sample Type	Concentration ppbv | µg/m³

Williams Street Water Plant		
P	0.623 (ppbv)	1.12 (µg/m³)

Willow Woods

Legend
- Air Sample Location
- Weather Station
- Facility
- P Primary Sample
- D Duplicate Sample
- E ERG Analyzed Duplicate

N

1 Mile

South Covington Area		
P	0.197 (ppbv)	0.356 (µg/m³)
E	<0.0614 (ppbv)	<0.111 (µg/m³)

Rural SE Newton County		
P	0.0906 (ppbv)	0.163 (µg/m³)

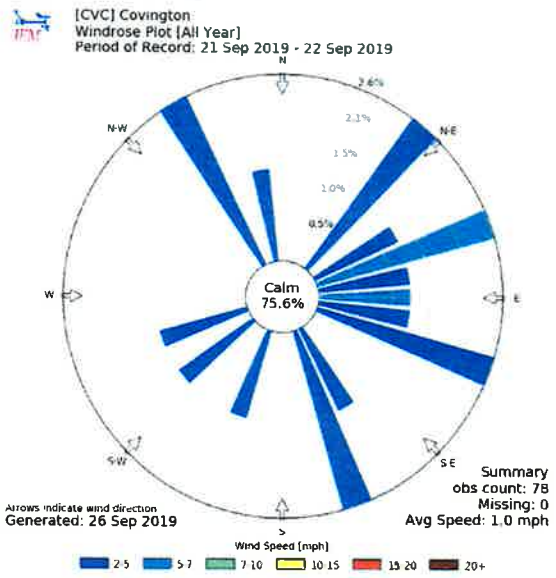
MONTROSE
AIR QUALITY SERVICES

1 Mile

Conyers

Conyers, GA Location		
P	0.0878 (ppbv)	0.158 (µg/m³)

Covington Airport		
P	0.151 (ppbv)	0.273 (µg/m³)



Sampling Period
Saturday, September 21, 2019 10:20 AM
THROUGH
Sunday, September 22, 2019 1:50 PM

General Mills

Rear of BD Facility		
P	1.87 (ppbv)	3.37 (µg/m³)

Settlers Grove Area		
P	0.321 (ppbv)	0.578 (µg/m³)

Walmart Supercenter

Covington Mills Area		
P	7.06 (ppbv)	12.7 (µg/m³)

BD Employee Parking Entrance		
P	0.305 (ppbv)	0.549 (µg/m³)

1 Mile

Mount Pleasant		
P	0.0831 (ppbv)	0.150 (µg/m³)

Sampling Location	
Sample Type	Concentration ppbv | µg/m³

Williams Street Water Plant		
P	1.23 (ppbv)	2.21 (µg/m³)

Willow Woods

Legend
- Air Sample Location
- Weather Station
- Facility
- P Primary Sample
- D Duplicate Sample
- E ERG Analyzed Duplicate

N

1 Mile

Rural SE Newton County		
P	0.0781 (ppbv)	0.141 (µg/m³)

South Covington Area		
P	0.259 (ppbv)	0.466 (µg/m³)

MONTROSE AIR QUALITY SERVICES

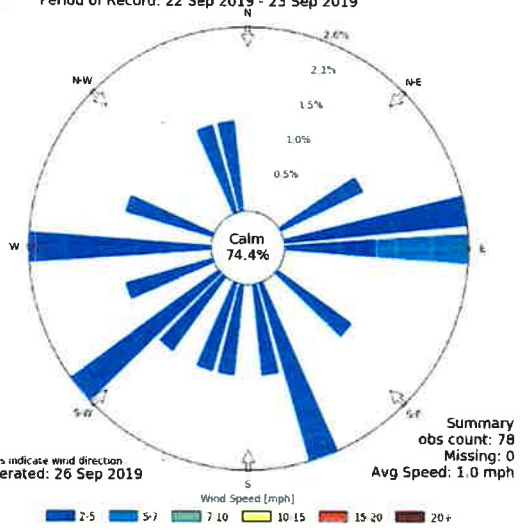
1 Mile

Conyers

Conyers, GA Location		
P	0.119 (ppbv)	0.214 (µg/m³)
E	0.117 (ppbv)	0.212 (µg/m³)

Covington Airport		
P	0.138 (ppbv)	0.248 (µg/m³)

[CVC] Covington
Windrose Plot (All Year)
Period of Record: 22 Sep 2019 - 23 Sep 2019



Arrows indicate wind direction
Generated: 26 Sep 2019

Summary
obs count: 78
Missing: 0
Avg Speed: 1.0 mph

Sampling Period
Sunday, September 22, 2019 10:17 AM
THROUGH
Monday, September 23, 2019 3:27 PM

General Mills

Rear of BD Facility		
P	6.85 (ppbv)	12.3 (µg/m³)

Settlers Grove Area		
P	4.69 (ppbv)	8.45 (µg/m³)

Walmart Supercenter

Covington Mills Area		
P	8.51 (ppbv)	15.3 (µg/m³)
E	5.66 (ppbv)	10.2 (µg/m³)

BD Employee Parking Entrance		
P	6.68 (ppbv)	12.0 (µg/m³)

Piedmont Newton Hospital

Williams Street Water Plant		
P	0.825 (ppbv)	1.49 (µg/m³)

1 Mile

Mount Pleasant		
P	0.113 (ppbv)	0.203 (µg/m³)

Willow Woods

Rural SE Newton County		
P	0.0653 (ppbv)	0.118 (µg/m³)

1 Mile

South Covington Area		
P	0.199 (ppbv)	0.359 (µg/m³)

Sampling Location	
Sample Type	Concentration ppbv | µg/m³

Legend

- Air Sample Location
- Weather Station
- Facility
- P Primary Sample
- D Duplicate Sample
- E ERG Analyzed Duplicate

N

MONTROSE
AIR QUALITY SERVICES

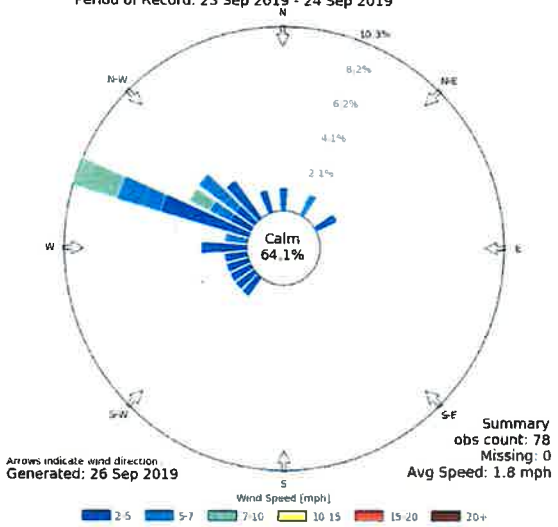
1 Mile

Conyers

Conyers, GA Location		
P	0.0908 (ppbv)	0.164 (µg/m³)

Covington Airport		
P	0.0790 (ppbv)	0.142 (µg/m³)

[CVC] Covington
Windrose Plot [All Year]
Period of Record: 23 Sep 2019 - 24 Sep 2019



Arrows indicate wind direction
Generated: 26 Sep 2019

Summary
obs count: 78
Missing: 0
Avg Speed: 1.8 mph

Sampling Period
Monday, September 23, 2019 11:07 AM
THROUGH
Tuesday, September 24, 2019 12:58 PM

General Mills

Rear of BD Facility		
P	1.61 (ppbv)	2.90 (µg/m³)
E	0.851 (ppbv)	1.54 (µg/m³)

Settlers Grove Area		
P	2.95 (ppbv)	5.31 (µg/m³)

Walmart Supercenter

Covington Mills Area		
P	0.142 (ppbv)	0.255 (µg/m³)

BD Employee Parking Entrance		
P	3.06 (ppbv)	5.51 (µg/m³)

Piedmont Newton Hospital

Williams Street Water Plant		
P	0.162 (ppbv)	0.291 (µg/m³)

1 Mile

Mount Pleasant		
P	0.206 (ppbv)	0.371 (µg/m³)

Willow Woods

Rural SE Newton County		
P	0.346 (ppbv)	0.624 (µg/m³)

1 Mile

South Covington Area		
P	0.0724 (ppbv)	0.130 (µg/m³)

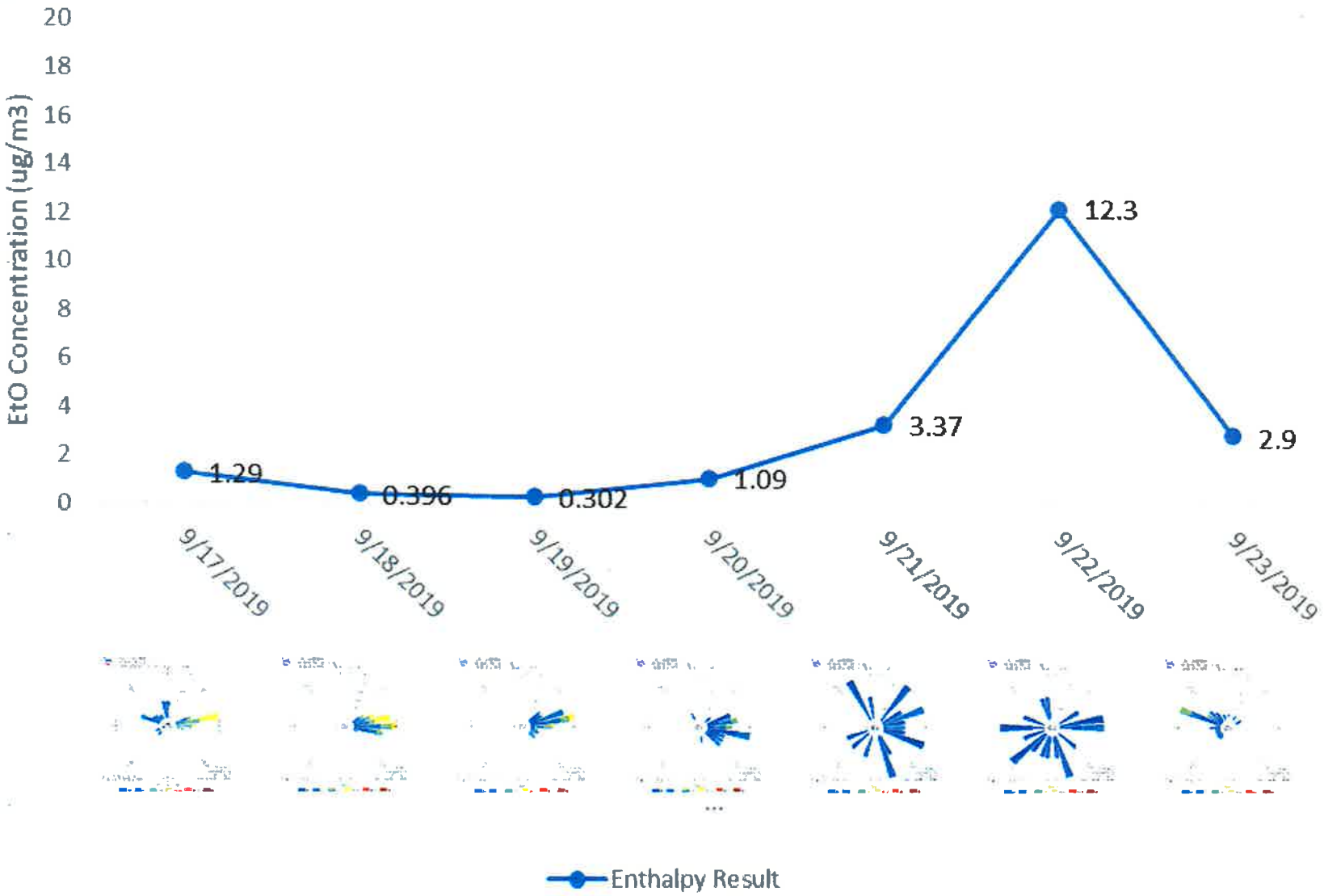
Sampling Location	
Sample Type	Concentration ppbv | µg/m³

Legend
- Air Sample Location
- Weather Station
- Facility
- P Primary Sample
- D Duplicate Sample
- E ERG Analyzed Duplicate

N

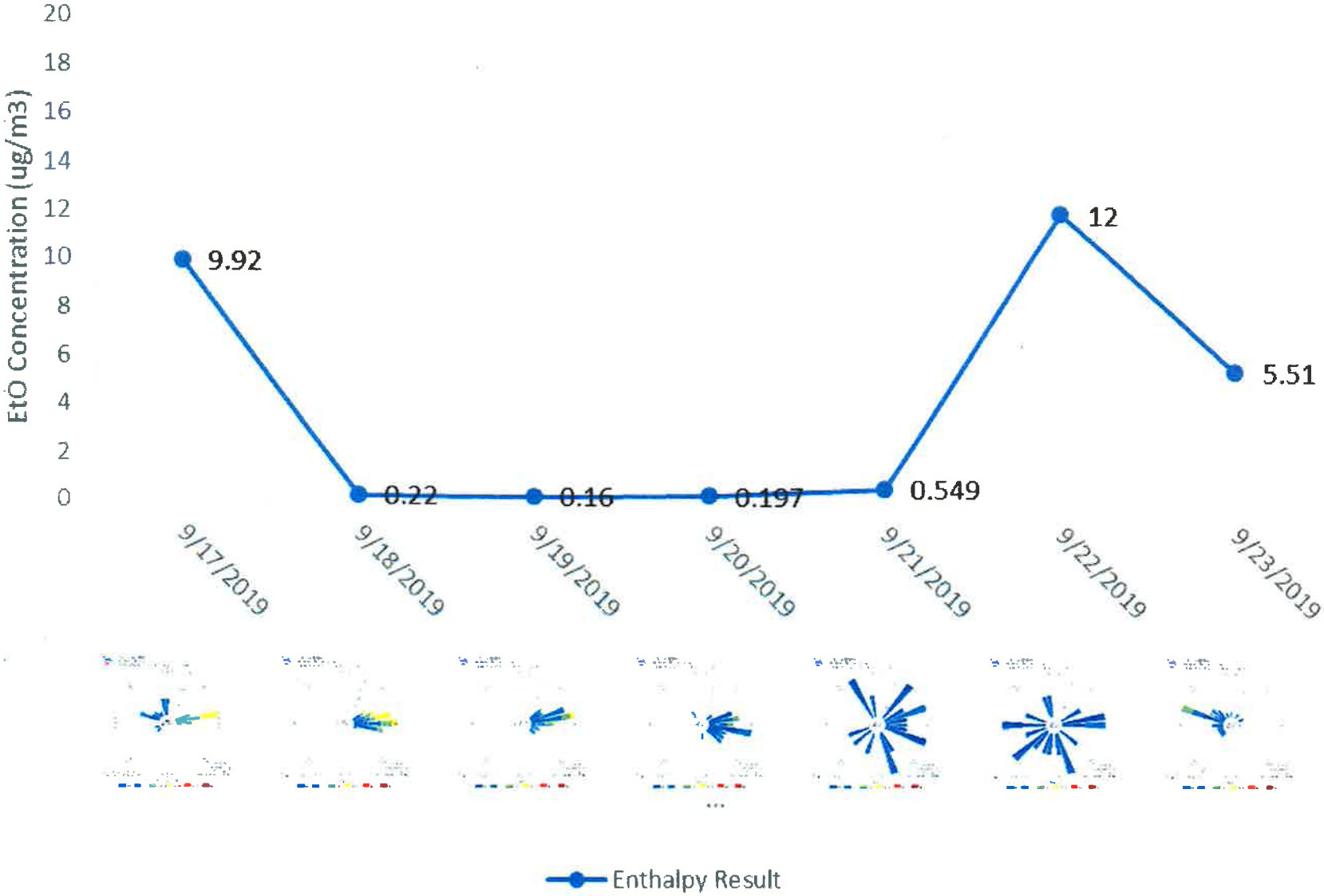
MONTROSE
AIR QUALITY SERVICES

Site 1-Rear of BD Facility



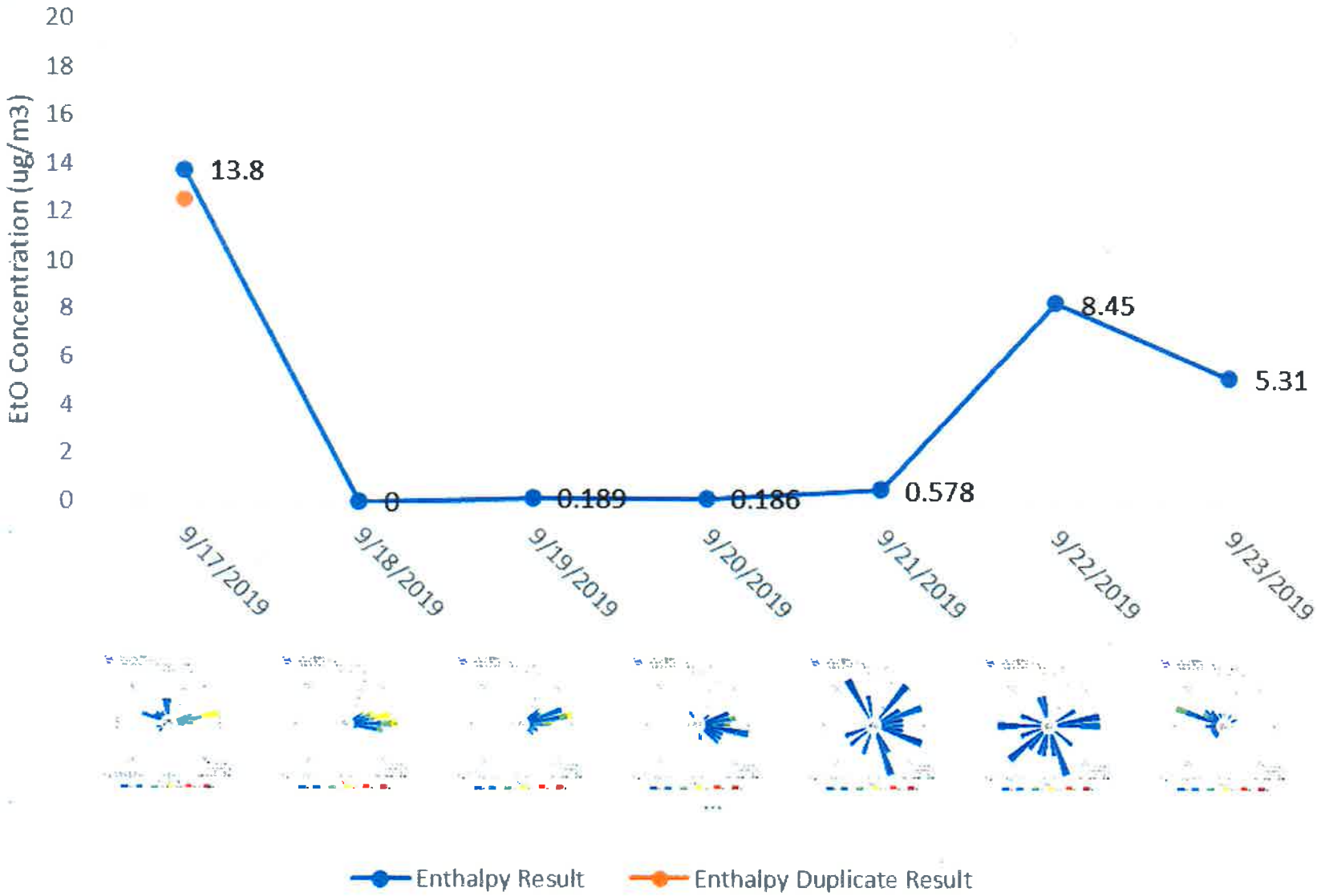
MONTROSE
AIR QUALITY SERVICES

Site 2-BD Employee Parking Entrance



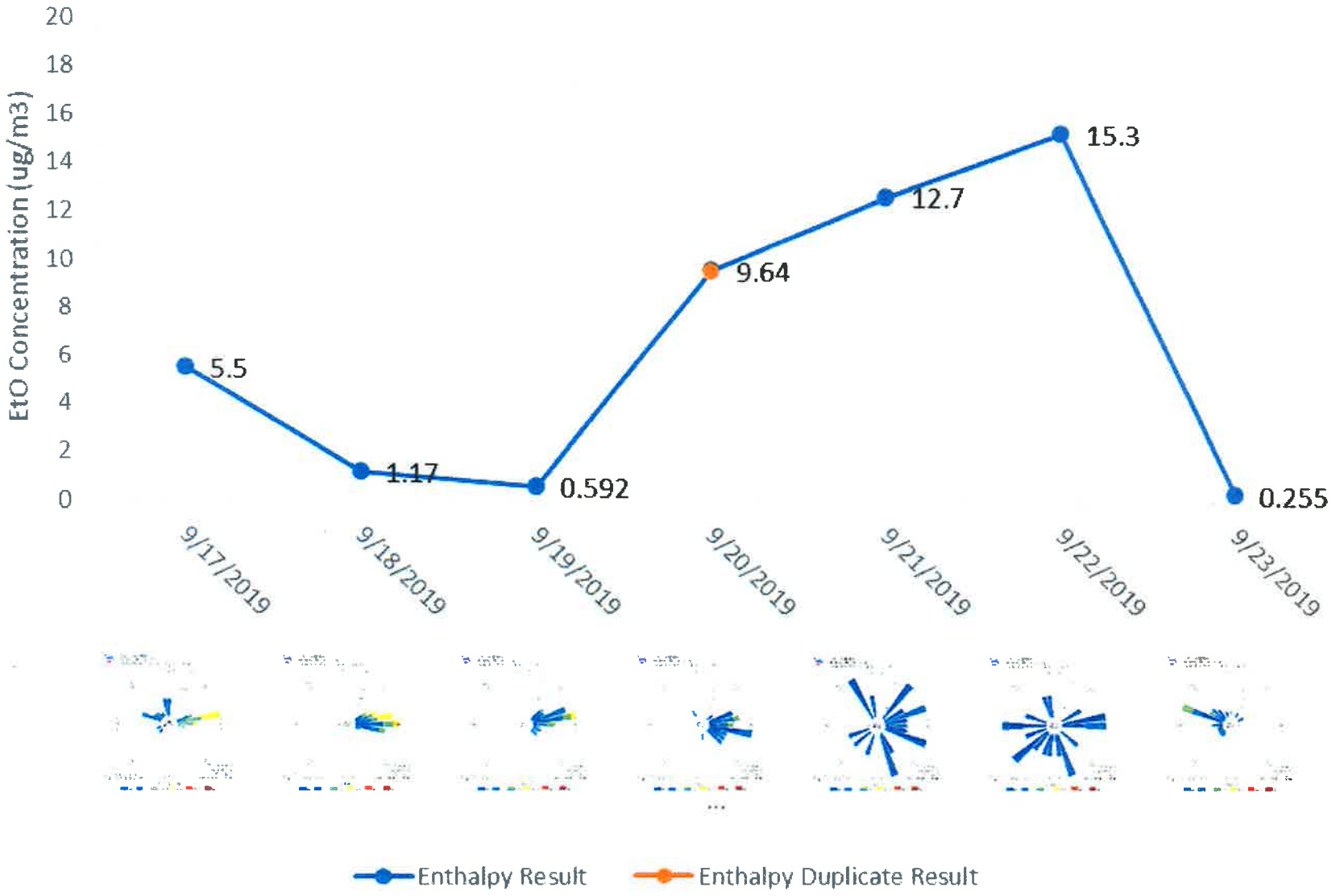
MONTROSE
AIR QUALITY SERVICES

Site 3-Settlers Grove Area



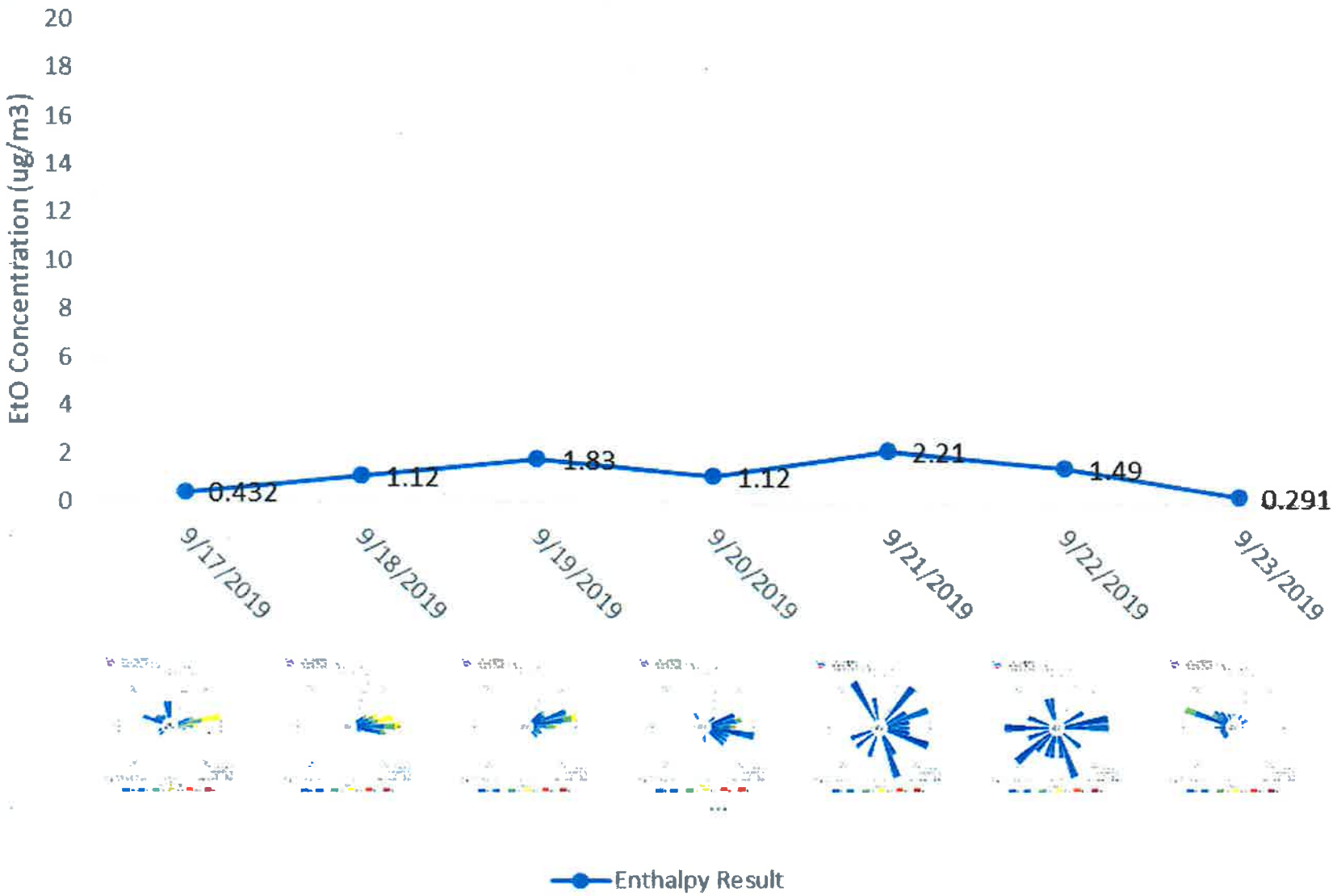
MONTROSE
AIR QUALITY SERVICES

Site 4-Covington Mill Area



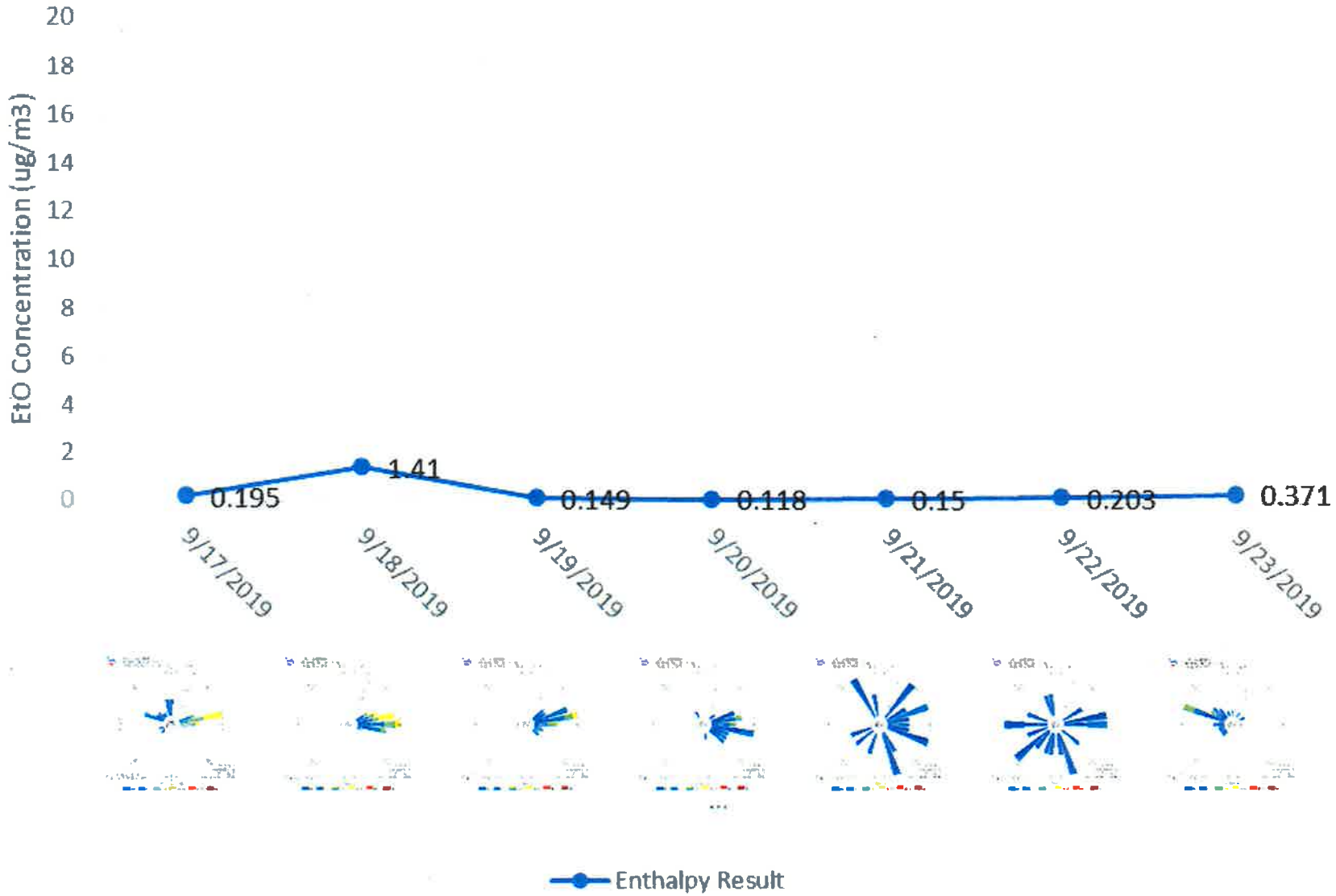
MONTROSE
AIR QUALITY SERVICES

Site 5-Williams Street Water Plant



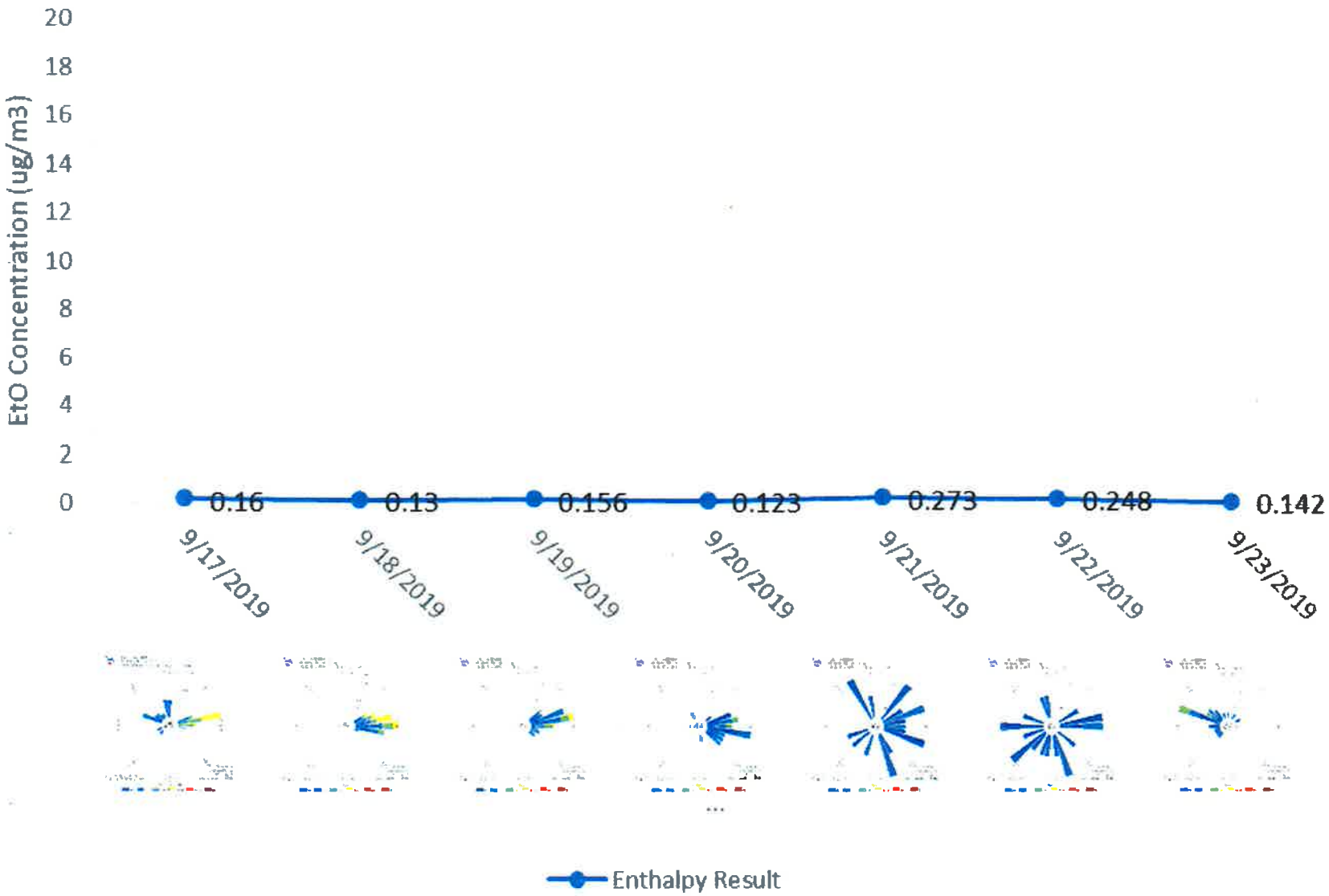
MONTROSE
AIR QUALITY SERVICES

Site 6-Mount Pleasant



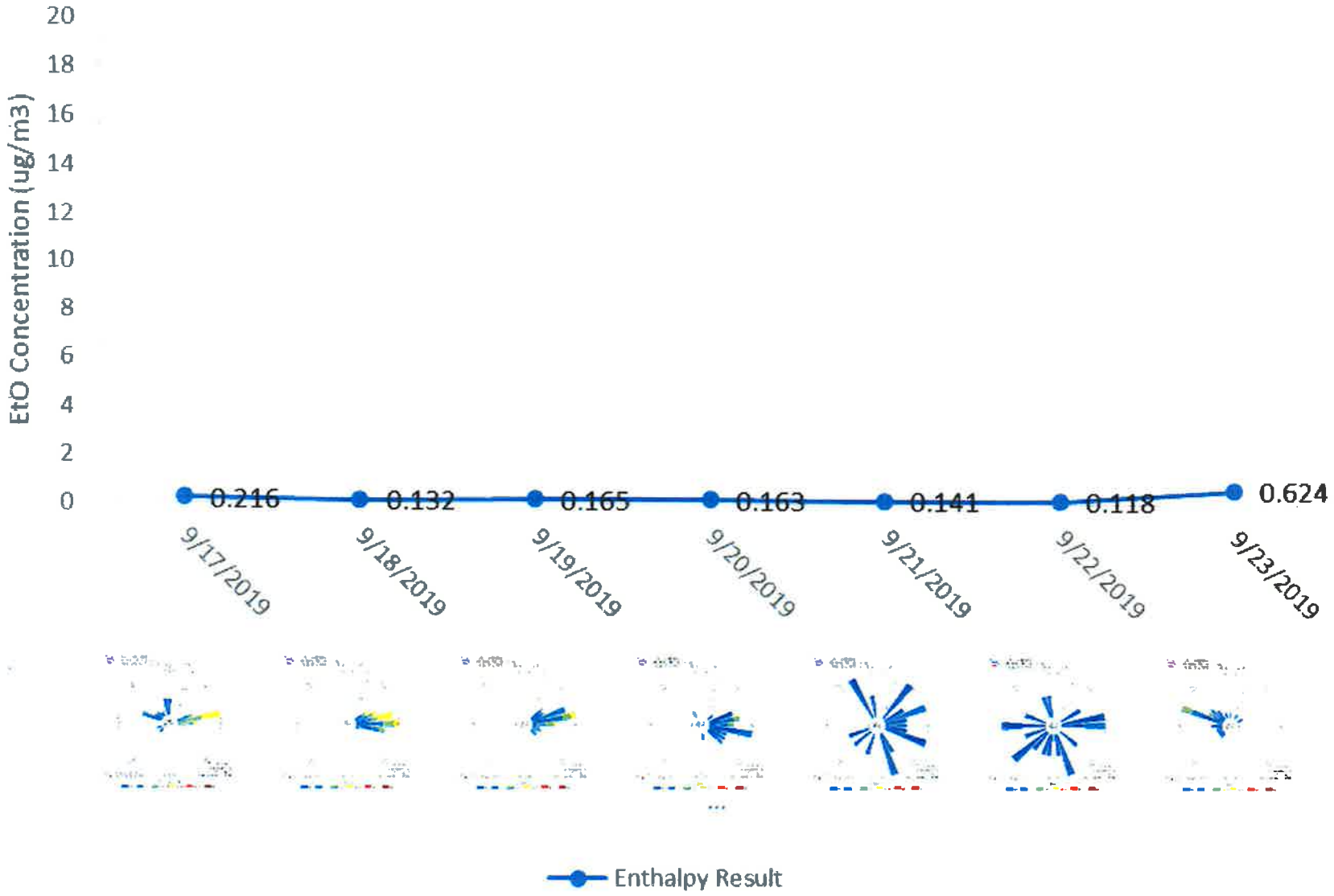
MONTROSE
AIR QUALITY SERVICES

Site 7-Covington Airport



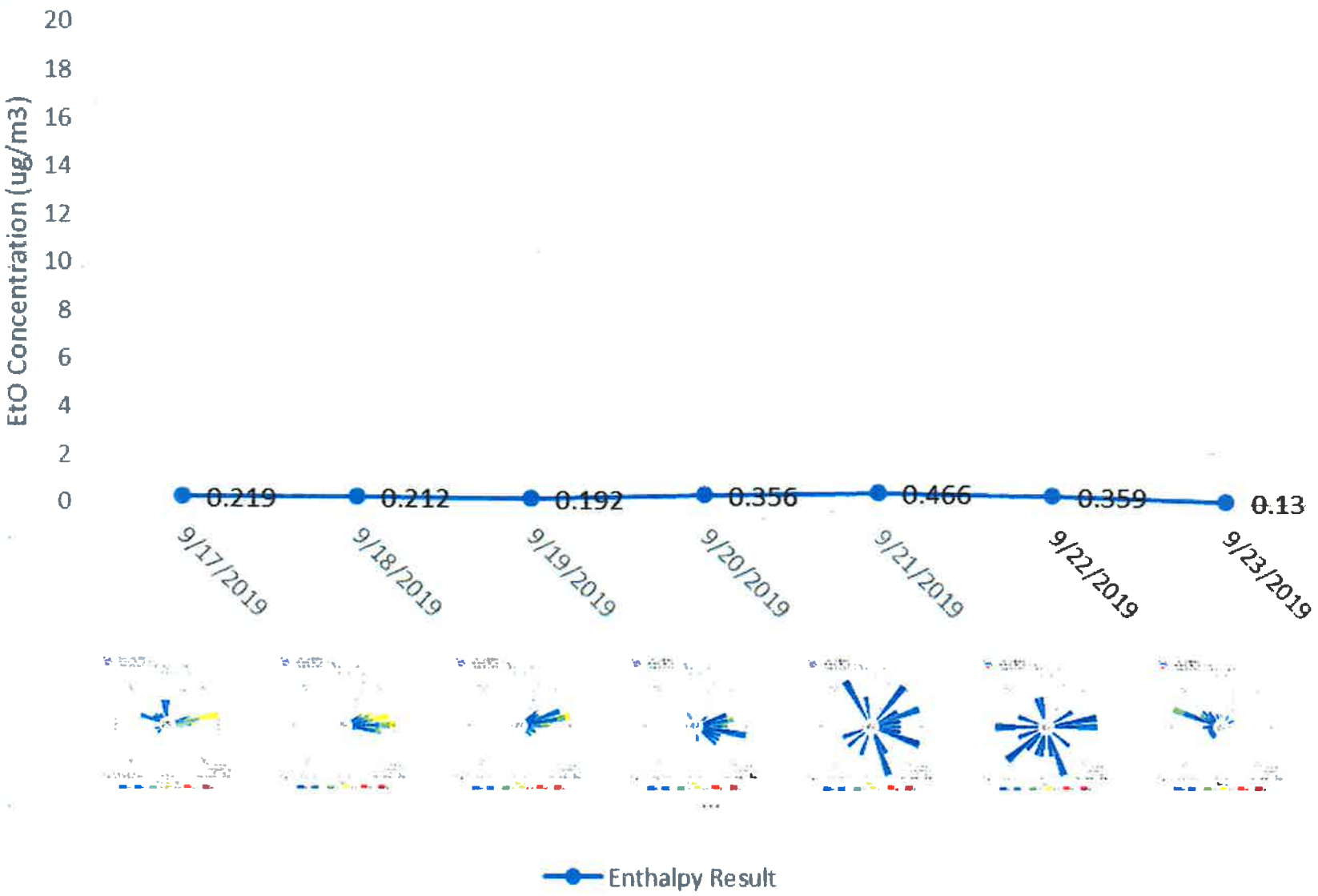
MONTROSE
AIR QUALITY SERVICES

Site 8-Rural SE Newton County



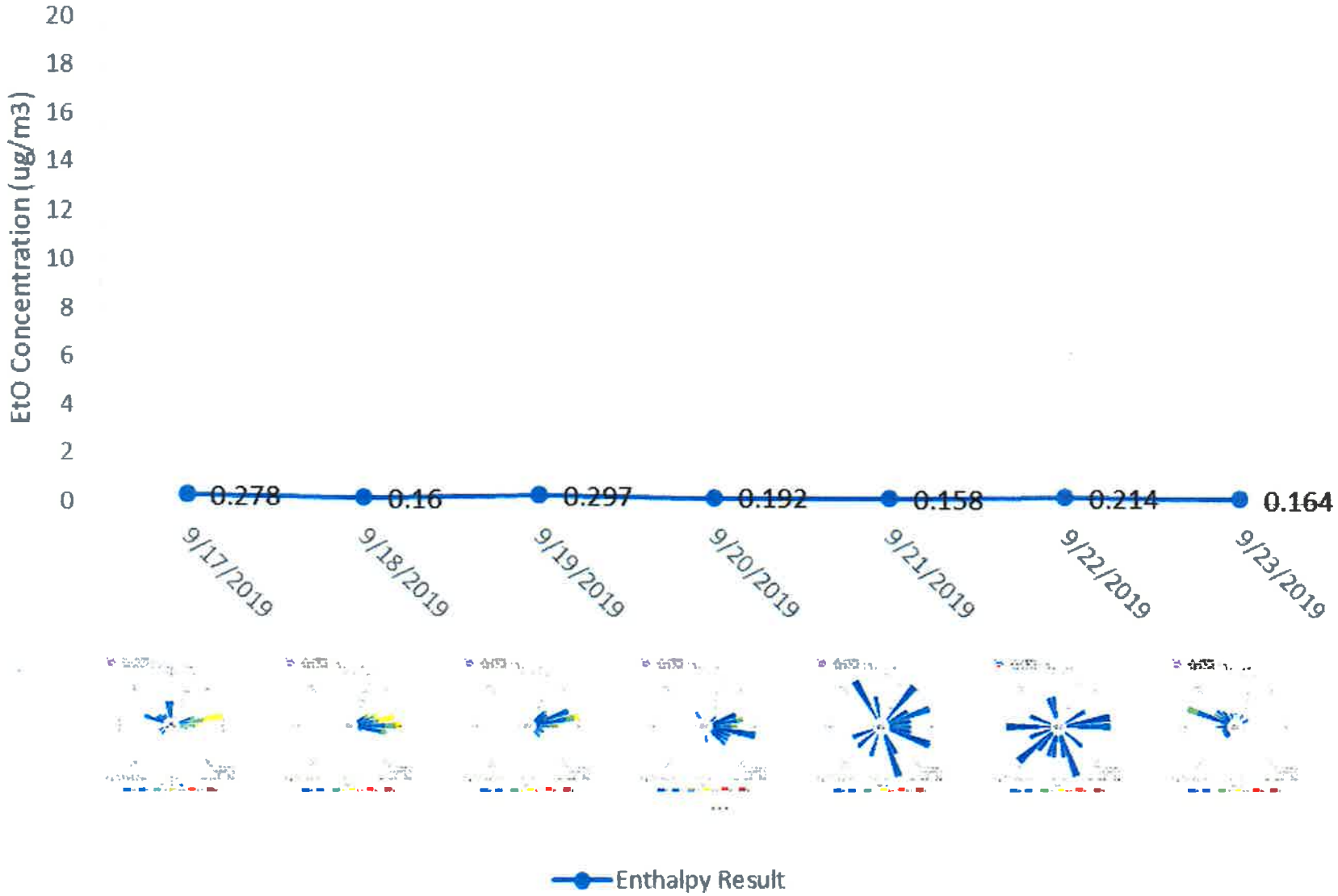
MONTROSE
AIR QUALITY SERVICES

Site 9-South Covington Area



MONTROSE
AIR QUALITY SERVICES

Site 10-Conyers, GA Location



GEORGIA
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

Richard E. Dunn, Director

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

December 18, 2019

Via Electronic Transmission

Ms. Ellen Kondracki
Becton, Dickinson and Company
Vice President, Sustainability and
Environment, Health and Safety

RE: **Notice of Violation**
Operating without an Air Quality Permit
BD Global Distribution Center, Covington, Georgia

Dear Ms. Kondracki:

This letter serves as a Notice of Violation of the Georgia Rules for Air Quality Control (Georgia Rules) to Becton, Dickinson and Company (BD) for operating the Global Distribution Center (GDC), located at 14201 Lochridge Boulevard, Covington, Georgia, without an air quality permit.

Subparagraph 391-3-1-.03(2)(a) of the Georgia Rules requires any person operating a facility or performing an activity which is not exempt under Paragraph 391-3-1-.03(6) from which air contaminants are or may be emitted to obtain an Operating (SIP) Permit from the EPD Director.

The GDC stores product sterilized using ethylene oxide at the BD Covington and BD Madison facilities, as well as product sterilized at other facilities. On December 15, 2019, BD submitted a fugitive emission estimate report for the GDC as required by Paragraph 10 of Attachment A of the October 28, 2019, Consent Order. The report estimated GDC's ethylene oxide emissions at 0.65 pounds per hour. Ethylene oxide is a listed hazardous air pollutant. Any facility that emits or has the potential to emit more than 2 tons per year (or 4,000 pounds per year) of any single hazardous air pollutant is not exempt from the requirement to obtain an air quality permit[1].
The Division calculates the potential ethylene oxide emissions from the GDC at approximately 5,600 pounds per year.

The Division alleges that BD has violated Subparagraph 391-3-1-.03(2)(a) of the Georgia Rules by operating the GDC without a SIP Operating Permit. In order to address the violations, the Division requests the following actions and/or responses.

[1] See Subparagraph 391-3-1-.03(6)(i) of the Georgia Rules for Air Quality Control

No later than 5 PM on December 23, 2019, the Company shall stop placing product that has been sterilized using ethylene oxide into the GDC. This temporary stop shall continue until midnight on January 6, 2020. The Company shall notify the Division at least 24 hours prior to placing any product sterilized using ethylene oxide in another warehouse in Georgia.

No later than 5 PM on December 23, 2019, the Company shall submit to the Division the following information:

1. The outdoor monitoring data mentioned on page 2 of the cover letter to the "Estimation of Fugitive Ethylene Oxide Emissions Report."

2. Updated information on the actions taken or to be taken to address the ethylene oxide emissions at GDC as described in the cover letter to the "Estimation of Fugitive Ethylene Oxide Emissions Report."

3. The amount of product sterilized using ethylene oxide in the GDC as of the date of this letter, broken down as follows: sterilized at BD Covington; sterilized at BD Madison; sterilized at BD facilities located outside of Georgia; sterilized at non-BD facilities located in Georgia; and sterilized at non-BD facilities located outside of Georgia. If the unit of measure is not pounds, include an explanation of the unit of measure.

4. A schedule for establishing air monitoring within 30 days at or adjacent to the nearest residential areas and the nearest school to the GDC. Monitoring frequency shall be no less than 24-hour samples to be collected every three days. The schedule shall also provide that the results of monitoring shall be transmitted to EPD within one business day of receipt.

5. The locations of any other warehouses in Georgia in which BD places product sterilized using ethylene oxide. Include in your response the amount of product sterilized and where that product was sterilized using ethylene oxide.

6. An explanation of why the post-aeration ethylene oxide emissions at the GDC are not consistent with the information contained in the permit applications for BD Madison and BD Covington. Specifically, the December 15, 2019, report appears to suggest that the amount of ethylene oxide that remains in the product after it leaves the aeration chamber is higher than estimated in the permit applications. Include any past evaluations or monitoring of ethylene oxide emissions that are relevant to your explanation.

7. A plan to stop bringing Foley catheter procedural trays into the GDC until such time as an air quality permit is issued to the facility.

8. A plan to remove existing inventory of Foley catheter procedural trays out of the GDC.

9. The amount of product sterilized using ethylene oxide in the GDC, as of the date of this letter, that that was not subject to the 24-hour aeration time and a plan to transfer that product out of the GDC.

10. Any other information the Company considers relevant to the alleged violation.

No later than December 23, 2019, the Company shall initiate weekly indoor air monitoring and outdoor fence line monitoring at GDC, using the procedures described in the "Estimation of Fugitive Ethylene Oxide Emissions Report," to evaluate the impact of the increased aeration times and other interim steps taken by BD to reduce ethylene oxide emissions. The results of monitoring shall be transmitted to EPD within one business day or receipt. The weekly indoor air monitoring and outdoor fence line monitoring shall continue until the air quality permit is issued.

No product coming into the warehouse after January 6, 2020, shall have been aerated for less than 24 hours.

Within 45 days of receipt of this letter, the Company shall submit the following items to the Division:

1. A permit application for the GDC, including air toxics modeling using the procedures described in EPD's Toxic Impact Assessment Guideline.

2. A schedule for designing and installing air pollution control equipment to capture 100% of the ethylene oxide emissions from the GDC with a destruction efficiency of 99% or more. The schedule shall not exceed nine months.

The information provided by the Company will be reviewed by the Division and will be used to determine if further enforcement action is warranted. Further enforcement action may include a Petition for Civil Penalties of up to $25,000 per day and/or other legal remedies authorized under Georgia law. The Division has requested assistance from the U.S. Environmental Protection Agency (EPA) in evaluating the "Estimation of Fugitive Ethylene Oxide Emissions Report" due to recent changes in how EPA characterizes ethylene oxide and their recent Advance Notice of Proposed Rulemaking for the National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilizers and Fumigation Operations. Additional information requests may be forthcoming after the Division evaluates the Company's initial responses.

Please respond to this Notice of Violation in writing via electronic transmission as soon as practicable, but no later than 1 PM on December 20, 2019.

If you have any questions concerning this letter, please contact me at 404-363-7016 or karen.hays@dnr.ga.gov.

Sincerely,

Karen Hays

Karen Hays, P. E.
Chief
Air Protection Branch

GEORGIA
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

Richard E. Dunn, Director

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

August 6, 2020

Submitted electronically to boone.brothers@bd.com

Mr. Boone Brothers, CSP, CHMM
Sr. EHS Manager, UCC Business Unit
Becton, Dickinson and Company
8195 Industrial Blvd
Covington, Georgia 30014

Re: Senate Bill 426 to Address Ethylene Oxide Releases

Dear Mr. Brothers:

On August 5, 2020, Senate Bill 426 was signed into law to amend Section 12-9-7 of the Official Code of Georgia Annotated (Code), which requires certain actions to be taken by facilities who emit ethylene oxide. Specifically, the law requires that "[a]s a condition of a permit for operations that include the emission of ethylene oxide, any spill or release of ethylene oxide, regardless of the amount, shall be reported to the division in writing within 24 hours of discovering such spill or release." For the purposes of this law, a spill or release means the discharge, deposit, injection, dumping, spilling, emitting, releasing, leaking, or placing of ethylene oxide into the air or into or on any land or water of the state, except as authorized by state or federal law or a permit from the division.

Furthermore, the law requires that "[t]he director shall make publicly available on the division's website information regarding any spill or release of ethylene oxide reported to the division pursuant to paragraph (3) of subsection (a) of Code Section 12-9-7."

The Division will be amending your facility's permit to incorporate the requirements of this law. Until such time, it is the Division's expectation that your facility shall begin submitting the required reports effective immediately. Reports shall be submitted via e-mail to Air.Releases@dnr.ga.gov. If the release is equal to or exceeds the reportable quantity as specified in 40 CFR Part 302, or is of an unknown quantity, the release must also be reported to the State's 24-hour Emergency Response line at (800) 241-4113. If you have any questions, please contact me at 404-363-7047 or Sean.Taylor@dnr.ga.gov.

Sincerely,

Sean Taylor
Program Manager
Stationary Source Compliance Program

AIRS No. 213-00021
AIRS No. 217-00021