GEORGIA
DEPARTMENT OF NATURAL RESOURCES

ENVIRONMENTAL PROTECTION DIVISION

Quality Assurance Project Plan
for the Georgia Ambient Air Monitoring Program
to Evaluate New and Emerging Technologies for Ethylene Oxide

Category II

October 2021
Revision 2

Air Protection Branch
Ambient Air Monitoring Program
4244 International Parkway, Suite 120
Atlanta, GA 30354

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Acronyms and Abbreviations

AAMP	Ambient Air Monitoring Program
APB	Air Protection Branch
ASTM	American Society for Testing and Materials
ATMP	Air Toxics Monitoring Program
°C	Degrees Celsius
CAA	Clean Air Act
CFR	Code of Federal Regulations
COC	Chain of Custody
DQA	Data Quality Assessment
DQI	Data Quality Indicator
DQO	Data Quality Objectives
EPA	Environmental Protection Agency
EPD	Environmental Protection Division
ESMB	Extraction Solvent Method Blank
GA EPD	Georgia Environmental Protection Division
GC	Gas Chromatography
GC/MS	Gas Chromatography/Mass Spectrometry
HAPs	Hazardous Air Pollutants
IB	Instrument Blank
ICAL	Initial Calibration
ICB	Initial Calibration Blank
IO	Inorganic
IS	Internal Standards
ISO	International Organization for Standardization
K	Kelvin
kPa	Kilopascal
LCS	Laboratory Control Sample
LCSD	Laboratory Control Sample Duplicate
LIMS	Laboratory Information Management System
MB	Method Blank
MDL	Method Detection Limit
µg	Micrograms
$\mu g/m^3$	Micrograms per Cubic Meter
µg/mL	Micrograms per Milliliter
MS	Matrix Spike
MSD	Matrix Spike Duplicate
MQO	Measurement Quality Objectives
MSA	Metropolitan Statistical Area
NATA	National Air Toxics Assessment
NATTS	National Air Toxics Trends Stations
NIST	National Institute of Standards and Technology
OAQPS	Office of Air Quality Planning and Standards
PAMS	Photochemical Assessment Monitoring Station

PPB	Parts per Billion
PPBV	Parts per Billion Volume
PQAO	Primary Quality Assurance Organization
QC	Quality Control
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
r	Correlation Coefficient
RPD	Relative Percent Difference
RSD	Relative Standard Deviation
RRF	Relative Response Factor
RRT	Relative Retention Time
RT	Retention Time
SB	Solvent Blank
SLAMS	State and Local Monitoring Stations
SOP	Standard Operating Procedure
TAD	Technical Assistance Document
TM	Trademark
TO	Toxic Organic
UATS	Urban Air Toxics Strategy
US EPA	United States Environmental Protection Agency
VOC	Volatile Organic Compound

1.0 Quality Assurance Project Plan Identification Approval

The attached Category II *Quality Assurance Project Plan for the Georgia Ambient Air Monitoring Program to Evaluate New and Emerging Technologies for Ethylene Oxide, Revision 2* is hereby recommended for approval and commits the Georgia Environmental Protection Division (GA EPD) to follow the elements described within.

Georgia Environmental Protection Division

1) Signature: DeAnna J. Oser Date: 11/3/2021
DeAnna Oser – Program Manager/Project Administrator

2) Signature: Mark Tolbert Date: 11/02/2021
Mark Tolbert – Laboratory Program Director

3) Signature: Jaime Gore Date: 11/02/2021
Jaime Gore – Operations 1 Unit Manager

4) Signature: R Ken Buckley Date: 11/03/2021
Ken Buckley – Operations 2 Unit Manager

5) Signature: Farhana Yasmin Date: 11/3/2021
Farhana Yasmin – Quality Assurance Unit Manager

6) Signature: Lynsey Scarbrough Date: 11/03/2021
Lynsey Scarbrough – Operations Support Unit Manager

7) Signature: Janet Aldredge-Byars Date: 11/2/21
Janet Aldredge – Data Analysis Unit Manager

8) Signature: Billy B Murphey, Jr Date: 11/2/21
Bill Murphey – Chief Meteorologist and Meteorological Unit Manager

EPA Region 4

1) Signature: FLOYD WELLBORN Digitally signed by FLOYD WELLBORN Date: 2021.11.08 08:19:30 -05'00' Date: _____
Designated Approving Official, US EPA Region 4 – Laboratory Services and Applied Science Division (LSASD)

2.0 Table of Contents

List of Tables and Figures

3.0 Distribution List

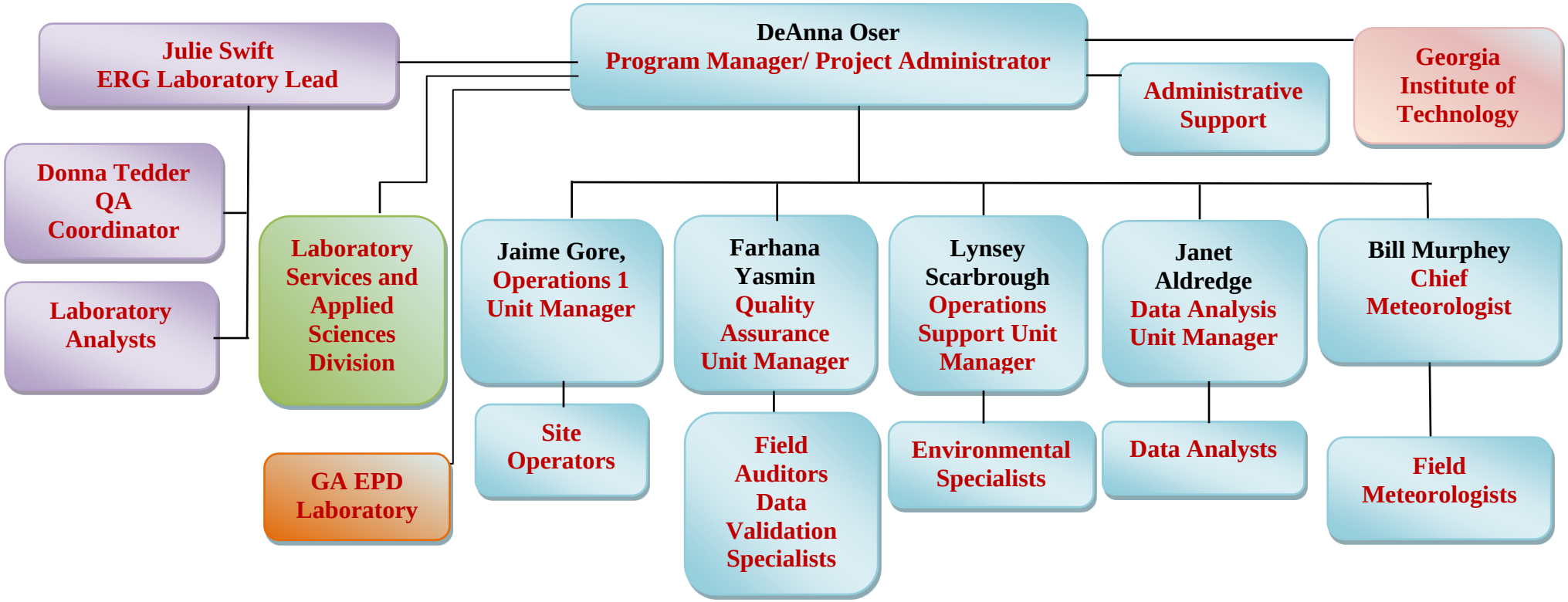
This section is not required for a Category II Quality Assurance Project Plan (QAPP).

4.0 Project/Task Organization

The Georgia Ambient Air Monitoring Program (GA AAMP) and the Eastern Research Group Laboratory (ERG) have important roles in developing and implementing this ethylene oxide study. GA AAMP is responsible for taking this information and developing a study to meet the data quality requirements. ERG is the contract laboratory for the U.S. Environmental Protection Agency (EPA) for air toxics programs such as the National Air Toxics Trends (NATTS) sites. They are the laboratory utilized by EPA for previous ethylene oxide studies. Therefore, the laboratory quality assurance requirements are sufficient for the purposes of this study. For detailed information on the ERG Lab, see the ERG's *Support for the EPA National Monitoring Programs (UATMP, NATTS, CSATAM, PAMS, and NMOC Support) QAPP*, dated February 2020 (Laboratory Attachment of this document). In addition, the Georgia Institute of Technology (GA Tech) will be responsible for performing analysis of the data collected by the continuous ethylene oxide sampler at the GA AAMP's South DeKalb site. Finally, EPA Region 4's Laboratory Services and Applied Sciences Division (LSASD) and the GA Environmental Protection Division Laboratory (GA EPD Lab) will be utilized for comparability of laboratory results.

To make the best use of available resources and to meet timelines for collection and analysis of this study, the flow of information and samples must be optimally organized. The deployment and operation of the project is a shared responsibility among all the involved parties. This section describes the roles of all parties and establishes the lines of authority, communication and reporting, with the goal of facilitating a smoothly operated project. Figure 1 represents the division of function in the organization of the GA AAMP (blue blocks), ERG Lab (purple blocks), LSASD (green block), GA EPD Lab (orange block), and GA Tech (pink block). The following information lists the specific responsibilities of each position.

Figure 1. GA AAMP Project Organizational Chart



4.1 Program Manager/Project Administrator

Under supervision of the GA Air Protection Branch (APB) Chief, the Program Manager of GA AAMP is the Project Administrator for all the ambient air monitoring projects. He/she has the overall responsibilities for managing all aspects of the GA AAMP according to policy. Ultimately, the Program Manager/Project Administrator is responsible for establishing QA policy and for resolving QA issues identified through the QA program. The major responsibilities of the Program Manager/Project Administrator include, but are not limited to:

- Serving as a public relations contact for monitoring activities with this project
  Reviewing and maintaining budgets and milestones for GA AAMP
- Ensuring this study meets EPA quality assurance requirements
- Communicating with the ERG Laboratory Lead on issues related to routine sample analysis and related QA activities
- Reviewing and approving QAPPs and Standard Operating Procedures (SOPs) for the GA AAMP
- Managing GA AAMP's documents and records
- Serving as liaison for GA Tech personnel that conduct analysis of the continuous ethylene oxide data

4.2 Quality Assurance (QA) Unit

4.2.1 Quality Assurance Unit Manager

The QA Unit Manager is the delegated supervisor of the GA AAMP's QA Program for field and data handling activities. He/she has direct access to the Project Administrator (GA AAMP Manager) on all matters pertaining to quality assurance activities regarding field monitoring, sampling, measuring operations, and data handling procedures. His/her responsibilities are detailed below:

- Implementing GA AAMP's quality system in accordance with EPA's and GA EPD's QA policies within the project
- Reviewing and approving GA AAMP SOPs
- Managing data validation of air quality monitoring data
- Reviewing field audit reports
- Ensuring that reviews and audits are scheduled and completed
- Performing data verification of the data for this study

The QA Unit Manager has the authority to carry out these responsibilities and to bring to the attention of the Program Manager/Project Administrator any issues associated with these responsibilities.

4.2.2 Field Auditor

The Field Auditor is responsible for:

- Scheduling and conducting field audits
- Assisting QA Unit Manager in developing and updating QAPPs

- Preparing and finalizing field audit reports

The Field Auditor has the authority to carry out these responsibilities and to bring to the attention of the QA Unit Manager any issues related to these responsibilities.

4.2.3 Data Validation Specialist

The Data Validation Specialist is responsible for:
- Preparing and updating SOPs for data review and validation activities
- Performing review to ensure that the ambient air monitoring data are validated in accordance with GA AAMP's data validation SOPs

4.3 Operations Units

4.3.1 Operations Unit Manager

GA AAMP has two different Operations Units due to the heavy workload on field activities. The Operations Unit Managers are the delegated supervisors of the GA AAMP for the field monitoring and sampling operations, which include the QC activities that are implemented as part of routine data collection activities. The two Operations Units do similar activities, but only one of the Operations Units is involved in EtO operations. Responsibilities of the Operations Unit Managers include:
- Supervising personnel in Operations Unit
- Establishing, operating, and maintaining all ambient air monitoring locations
- Coordinating with ERG Lab for sample delivery
- Coordinating with Georgia EPD Lab for sample media pickup and delivery
- Coordinating with EPA LSASD for sample analysis
- Developing the monitoring plan for this study
- Understanding GA AAMP QA policy and ensuring the Site Operators understand and follow the policy
- Assisting in resolution of technical problems

4.3.2 Site Operators

Under the supervision of the Operations Unit Managers, the Site Operators' responsibilities include:
- Operating the air monitoring samplers following all the manufacturers' specifications, GA AAMP's SOPs, and this QAPP
- Maintaining a schedule of sample collection and shipments
- Verifying that all required QC activities are performed and that measurement quality standards are met as required in this QAPP
- Documenting and reporting all problems and corrective actions to the Operations Unit Managers

4.4 Operations Support Unit

4.4.1 Operations Support Unit Manager

Under supervision of the GA AAMP Manager, the Operations Support Unit Manager is responsible for:

- Directing the activities of staff members responsible for overseeing the functions of GA AAMP Workshop (including inventory, testing of new equipment, maintenance and repair)
- Coordinating with ERG Lab for sample media pickup and sample delivery
- Updating and writing SOPs for new equipment added to the GA AAMP
- Budgeting for the Operations Units in managing purchasing and equipment procurement related to the field monitoring and sampling activities

4.4.2 Environmental Specialist

The Environmental Specialist in the Operations Support Unit assists Operations Support Unit Manager in his/her activities including:

- GA AAMP Workshop activities including testing of new equipment, maintenance and repair, and preventative maintenance activities
- Updating and writing SOPs for new equipment added to the GA AAMP

4.5 Data Analysis Unit

4.5.1 Data Analysis Unit Manager

Under supervision of the GA AAMP Manager, the Data Analysis Unit Manager is responsible for:

- Supervising personnel in Data Analysis Unit
- Managing data analysis of this study
- Composing and updating GA AAMP's QAPPs
- Managing, reviewing and editing SOPs for the GA AAMP

4.5.2 Data Analyst

Under the supervision of the Data Analysis Manager, the Data Analyst's responsibilities include:

- Assisting in data analysis of this study
- Assisting in preparation of QAPPs for the GA AAMP
- Assisting in preparation of SOPs for the GA AAMP

4.6 Meteorological Unit

4.6.1 Chief Meteorologist

The Chief Meteorologist supervises the Meteorological Unit by:

- Supervising, training, and evaluating personnel in the Meteorological Unit

- Evaluating wind rose data in relation to monitoring locations

4.6.2 Field Meteorologist

The Field Meteorologist is responsible for:
- Evaluating wind rose data in relation to monitoring locations

4.7 Eastern Research Group Laboratory

While GA AAMP handles all ambient air monitoring field activities, the ERG Lab handles the laboratory supplies, sample analysis, and laboratory QA/QC. The ERG Lab forwards the analytical data to GA AAMP for further data processing, review, and data validation. The ERG Lab is a contract laboratory and is utilized by US EPA for National Air Toxic Trends Site (NATTS) analysis, which includes the TO-15 analysis, operating under a QAPP approved by EPA Office of Air Quality Planning and Support (OAQPS). Therefore, the quality assurance activities of the ERG Lab are presumed sufficient. For more description of the ERG Lab, see *Support for the EPA National Monitoring Programs (UATMP, NATTS, CSATAM, PAMS, and NMOC Support) QAPP* (Laboratory Attachment of this document).

4.7.1 Laboratory Lead

The Laboratory Lead has overall responsibility for managing all aspects of the ethylene oxide analyses for the ERG Lab. Ultimately, the Laboratory Lead is responsible for establishing the QA policy and for resolving QA issues identified through the Laboratory QA program. The laboratory operates under an EPA approved QAPP for TO-15 analysis for volatile organic compounds.

4.7.2 QA Coordinator

The ERG Lab QA Coordinator has responsibility for ensuring that the ERG Lab follows the ERG Lab's QAPP, as approved by EPA.

4.8 Georgia Institute of Technology

Personnel from the Georgia Institute of Technology (GA Tech) will be analyzing the continuous (hourly) samples of ethylene oxide at the GA AAMP's South DeKalb site. The analysis will consist of a more detailed characterization of the ethylene oxide data, allowing analysis of hourly trends throughout the 24-hour period, analysis of the hourly data along with the wind data[1] collected at the South DeKalb site, and sample analysis comparing the 24-hour averages of the continuous sampler to both canister sampling methods. The GA AAMP Program Manager/Project Administrator will oversee the data analysis of the continuous sampler. GA Tech will submit quarterly reports to GA AAMP to be included with quarterly reports to EPA, per the schedule. GA

[1] Refer to the GA AAMP *Quality Assurance Project Plan of the Ambient Air Monitoring Program for the Criteria Air Pollutants Network and National Core Multi-Pollutant Station* for more details on the GA AAMP meteorological data.

Tech will have oversight of the personnel from their facility. The initial contract for this analysis was effective April 7, 2021 and will be extended as noted in Section 6.5 below.

4.9 Laboratory Services and Applied Sciences Division (LSASD)

A number of samples throughout this project will be sent to EPA Region 4's LSASD for a replicate analysis on a previously analyzed canister to compare the laboratory results. EPA Region 4 LSASD is using method TO-15 to analyze EtO data to compare laboratory analyses on the same canisters from both the ERG Lab and the GA EPD Lab.

4.10 GA EPD Laboratory

The GA EPD Lab will be performing analysis on a number of EtO samples throughout this project using method TO-15. Comparisons will be made to the laboratory analyses performed at the ERG Lab. The GA EPD Lab will follow an EPA approved *Quality Assurance Plan* and is incorporated in GA AAMP's *Quality Assurance Project Plan for Georgia Ambient Air Monitoring Program National Air Toxics Trends Station (NATTS).* The GA EPD Lab will follow the same procedures as are followed when analyzing other NATTS parameters. The Georgia EPD Lab is independent from GA AAMP and reports to the Georgia EPD Director's office.

5.0 Problem Definition/Background

Approximately every three years, the EPA issues a National Air Toxics Assessment (NATA) to identify air toxics, emission sources, and areas of the U.S. that require further study due to possible health risks from air toxics. The NATA relies on air quality modeling perfrormed by EPA that takes into account many sources of air toxics emissions including: large and small industrial sources, on-road and off-road mobile sources (e.g. cars trucks, construction equipment and trains), fires, and natural sources (e.g. naturally occurring emissions from trees). The latest NATA published in August 2018 relied on 2014 information taken from the National Emission Inventory (NEI), and identified 18 areas of the U.S. that required further study, including three census tracks in Georgia. The higher modeled risk was associated with ethylene oxide, a gas used to manufacture ethylene glycol (antifreeze), solvents, detergents, adhesives and to sterilize medical equipment. In this latest version of the NATA, many areas throughout the United States, including in Georgia, were flagged for the first time largely due to changes in the way EPA calculated the risk posed by ethylene oxide, now a confirmed carcinogen. The two known sources of ethylene oxide contributing to the NATA results in Georgia, were facilities that sterilize medical devices using ethylene oxide. Although the NATA was released in 2018, its findings were based on information collected in 2014 that did not account for new air pollution controls installed after 2014.

Using more up-to-date information about the two sterilization facilities identified in the NATA, the Georgia Environmental Protection Division (GA EPD) modeled the impact of their ethylene oxide emissions on neighboring communities. The results of GA EPD's modeling efforts showed that the impacts, although not as high as those modeled in the NATA, required further action including additional air pollution controls. When knowledge of GA EPD's modeling results and

EPA's NATA findings were revealed to the public, there was great concern in the communities surrounding the two facilities identified in the NATA (Covington, Georgia and Cobb County Georgia).

In August 2019, GA EPD and EPA held joint open house and community meetings in Cobb County[2] and in Covington, Georgia[3] to answer questions from a very concerned public. That same month GA EPD committed to monitoring air quality in Covington, Georgia and Cobb County, Georgia[4] for ethylene oxide. GA EPD also committed to monitoring background levels of ethylene oxide at two locations where there were no known sources of ethylene oxide for comparison. In September 2019, EPA approved GA EPD's monitoring plan[5] and GA EPD began collecting air quality samples as part of an air quality study.

Refer to GA EPD's website https://epd.georgia.gov/ethylene-oxide-information for the GA AAMP's original QAPP (*Quality Assurance Project Plan for the Georgia Ambient Air Monitoring Program Ethylene Oxide*) for this project.

GA EPD sought to identify all stationary sources of ethylene oxide emissions in Georgia to further assess their potential public health risk. GA EPD's modeling revealed that another sterilization facility not identified in the NATA and located in Fulton County, Georgia required further action including additional air pollution controls. In January 2020, GA EPD expanded monitoring for ethylene oxide to include a new location in Fulton County. Please see the GA AAMP Additional Sampling Sites Attachment to this document.

GA EPD is now engaged in a long-term study collecting samples of ethylene oxide at five distinct areas of Georgia, three communities near sterilization facilities, one rural area where there are no known sources of ethylene oxide, and one urban background area where there are no known sources of ethylene oxide that is also considered a National Air Toxics Trends Station (NATTS) site.

Because the risks presented in the NATA models are based on long term chronic exposure to ethylene oxide, providing long-term air quality monitoring data to public health agencies and professionals is critically important for concerned communities in Georgia and nationwide. GA EPD has already collected over 12 months of community level ethylene oxide data thus far, which is very rare nationwide. As the levels of ethylene oxide being measured are very close to the detection limits of current instrumentation, the study is helping us understand biases in sample collection that will have nationwide benefits. The two urban and rural background sites are providing information about background levels of ethylene oxide.

EPA has granted GA EPD a Community Scale Air Toxics Monitoring Grant to evaluate new and

[2] https://www.epa.gov/smyrna-eto/agenda-community-meeting-ethylene-oxide-smyrna-ga-sterigenicsfacility
[3] https://www.epa.gov/covington-eto/agenda-community-meeting-ethylene-oxide-covington-ga-bectondickinson
[4] Press release announcing monitoring: https://epd.georgia.gov/press-releases/2019-08-16/georgia-epd-monitorair-quality-covington-and-smyrna-ethylene-oxide-0
[5] https://epd.georgia.gov/document/document/gaaampqappethyleneoxideepasignaturepdf/download

emerging technologies for ethylene oxide. This grant will continue the work conducted on this project, following the procedures outlined in this QAPP. The study that GA EPD has conducted from September 2019 through August 2020 is considered Phase 1 of this study. With the approval of the Community Scale Toxics Air Monitoring grant, GA AAMP will conduct Phase 2 of this study to collect additional data for approximately six months of sampling at these sites to provide a greater dataset to encompass process changes at the identified sterilization facilities and the impact to the associated communities. This monitoring supports EPA's Draft 2018-2022 Strategic Plan, Goal 1, "A Cleaner, Healthier Environment," Objective 1.1 "Improve Air Quality".

The second phase of the study will provide insight and understanding of the impact of the measurement technologies on the quality of the data we collect. The second phase of this study will provide a greater number of samples in the three affected communities, as well as a continuous sampler at the South DeKalb site, thus improving the quality of the data set that will be shared with other agencies such as EPA, the Center for Disease Control's Agency for Toxic Substances and Disease Registry (ATSDR) and the Georgia Department of Public Health.

The proposal requests funds to carry out Phase 2 activities of sampling and associated analyses to characterize the air in the communities identified by the NATA as well as in Fulton County, Georgia. The data collected under both phases of this project will be published as a final report and made available on the GA EPD website https://epd.georgia.gov/ethylene-oxide-information.

This QAPP describes the quality system developed, implemented and maintained by GA AAMP for the collection of air samples; the data quality assessment; the data validation; and the reporting of results to GA EPD's website (https://epd.georgia.gov/ethylene-oxide-information), as applicable. The GA AAMP of the GA EPD acts as primary quality assurance organization (PQAO) in charge of monitoring ethylene oxide data.

6.0 Project/Task Description

This QAPP was developed to ensure that GA AAMP has a quality program to characterize ethylene oxide concentrations in the ambient air. The ethylene oxide monitoring study was developed to ensure consistent data quality is sufficient to characterize the ethylene oxide concentrations in the areas monitored. This study data will be posted to the GA EPD's website (https://epd.georgia.gov/ethylene-oxide-information), as applicable.

The monitoring objectives for this study include the following specific aims:

- Characterizing ethylene oxide concentrations in the ambient air within approximately ¼ mile of two facilities (Sterigenics, Cobb County, Georgia and Becton Dickinson-Covington, Newton County, Georgia)
- Providing background concentrations for comparison at two previously established GA AAMP network sites, South DeKalb (13-089-0002) and the General Coffee monitoring station (13-069-0002)
- Providing quality data for risk characterization by other agencies

- Additional sample locations may be added as resources allow, following the methodologies outlined in this document, as applicable

Before the study began in September 2019, the GA AAMP began preliminary sampling for ethylene oxide at the South DeKalb (13-089-0002) National Air Toxics Trends Site (NATTS) in June of 2019 to gain an understanding of collection and analytical methods of the samples.

This study will utilize passive samplers for the measurement of ethylene oxide in the Atlanta area. For each day that samples are collected in the Covington and Cobb County areas, a sample will also be collected at the South DeKalb site utilizing the same passive sampling equipment. This comparison will provide information on the variability in the ethylene oxide concentrations in an urban area which is not influenced by the two facilities discussed above.

During the study, approximately 16 qualitative samples will be taken at the South DeKalb site utilizing the passive sampling system as well as the ATEC system that was used for the initial measurements prior to the commencement of this study. In addition, due to its proximity to the South DeKalb site and Interstate 285, the GA AAMP will also collect approximately eight ethylene oxide samples with the VOCs canister collection at the Near Road-285 (NR-285) site (13-089-0003) for qualitative comparison to the data collected at the South DeKalb site. The following figure shows the proximity of the two sites. This comparison may provide insight on the contribution of mobile sources to the ethylene oxide concentration measured at the South DeKalb site.

Figure 2. Location of South DeKalb and NR-285 Sites

To determine the ambient monitoring sites near Becton-Dickinson in Covington, GA (Figure 3 and Figure 4) and Sterigenics in Cobb County, GA (Figure 6 and Figure 7), the GA AAMP considered the modeled emission data which was generated by the Planning and Support Program of GA EPD. Dispersion models of the ethylene oxide emissions data from these two facilities had

been conducted to determine concentrations of ethylene oxide around each facility. These models are shown in the following figures. The modeled values are shown in micrograms per cubic meter (µg/m^3). Based on previous ethylene oxide monitoring conducted by EPA, the determination was made to characterize the ethylene oxide concentrations within approximately ¼ mile of the facilities and to qualitatively determine the gradient (change in concentration) within approximately 1 mile of each facility. Therefore, each model was overlaid with ¼ mile, ½ mile and 1 mile radius measurements around each facility (Figure 5 and Figure 8). Note that Figures 3 through 8 illustrate the modeled impact of emissions from Becton-Dickinson and Sterigenics prior to the additional emission controls installed in 2020.

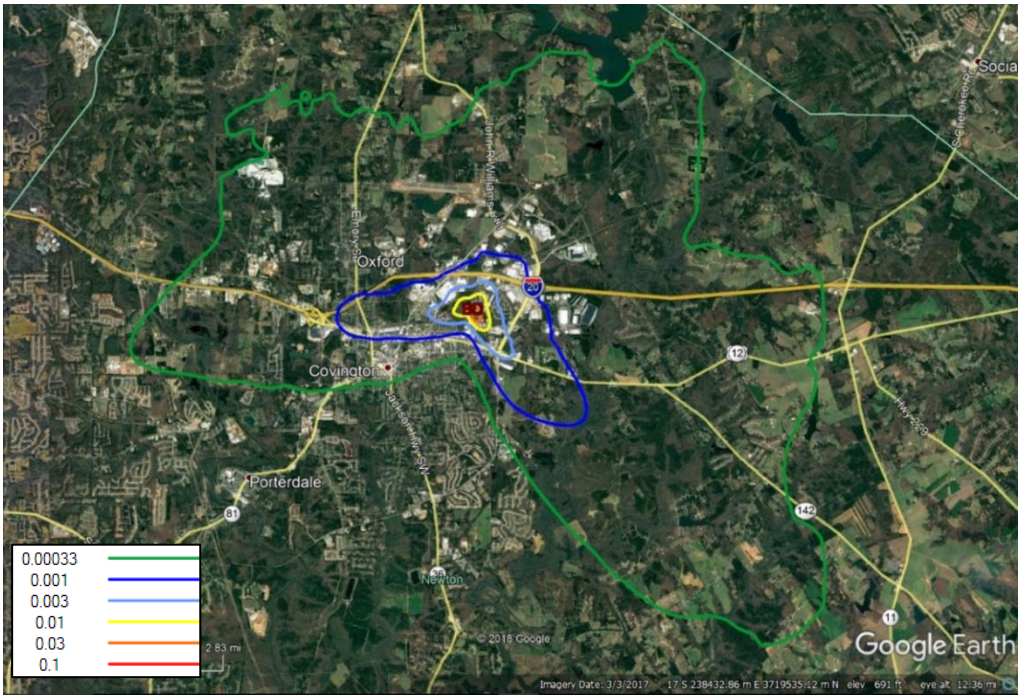


Figure 3. Contours of 5-year Annual Average Ground-level Concentrations (in µg/m^3) of Becton Dickinson (Covington) Modeled Overlaid on a Google Earth Map

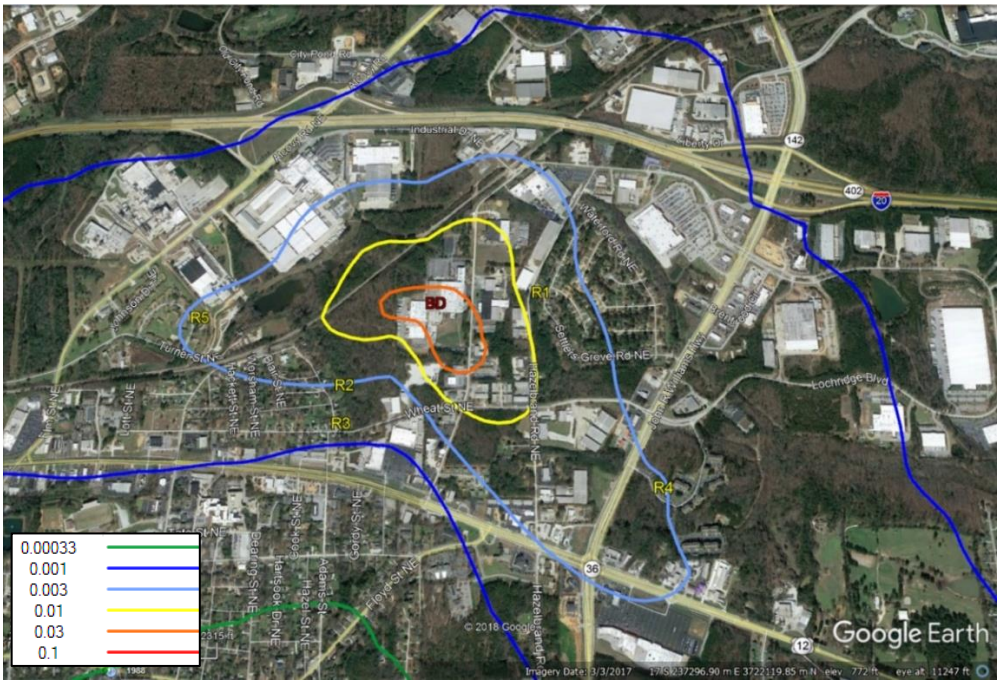


Figure 4. A Close-up of Figure 3 (Becton Dickinson)

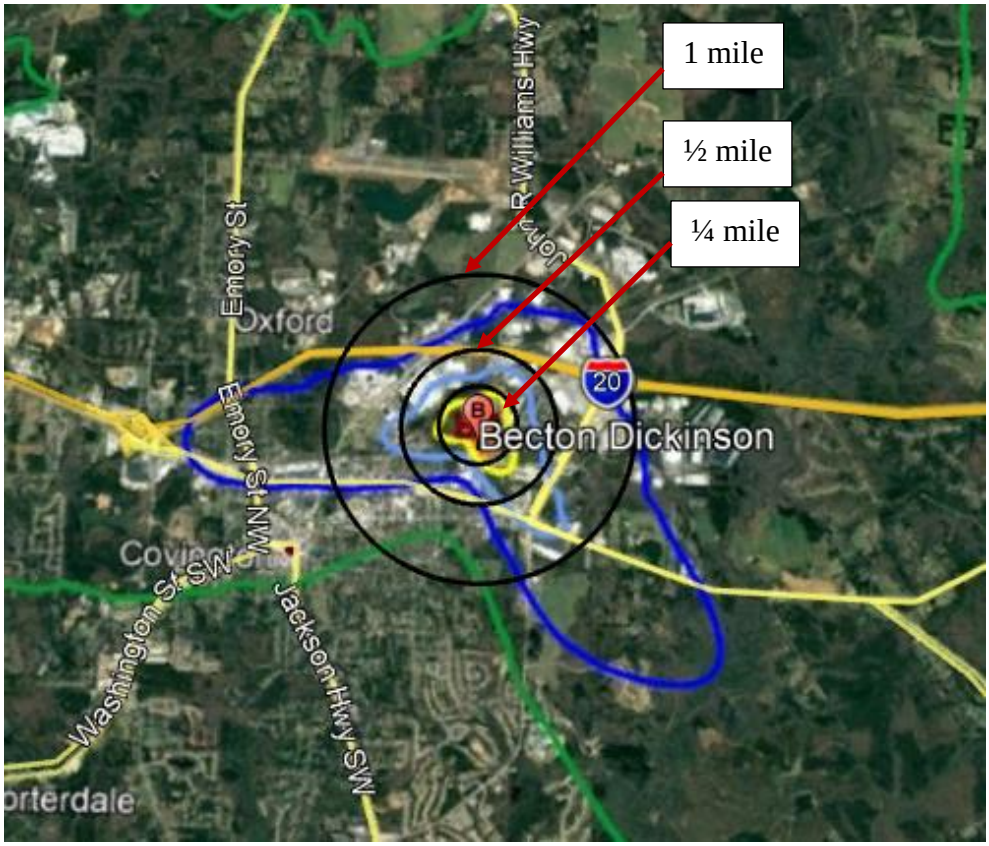


Figure 5. Model Overlaid with Distances from Becton Dickinson

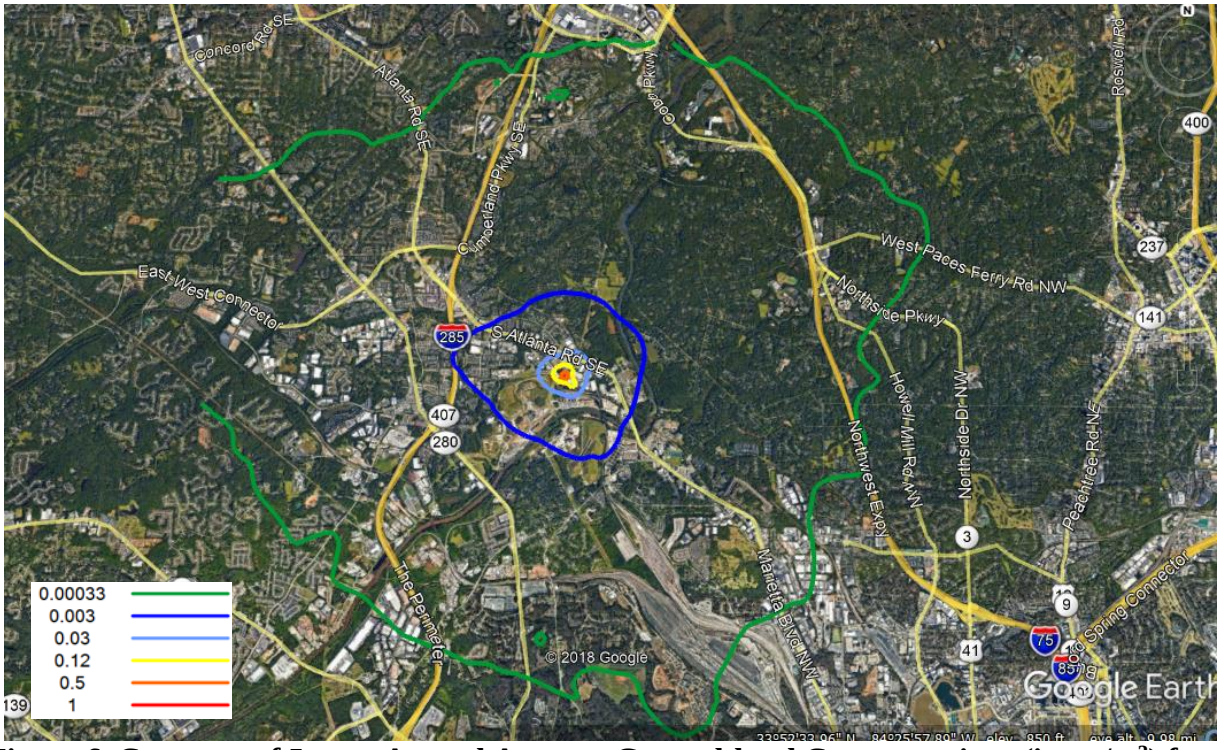


Figure 6. Contours of 5-year Annual Average Ground-level Concentrations (in µg/m^3) from Sterigenics (Cobb County) Modeled with the Current Emission Scenario Overlaid on a Google Earth Map

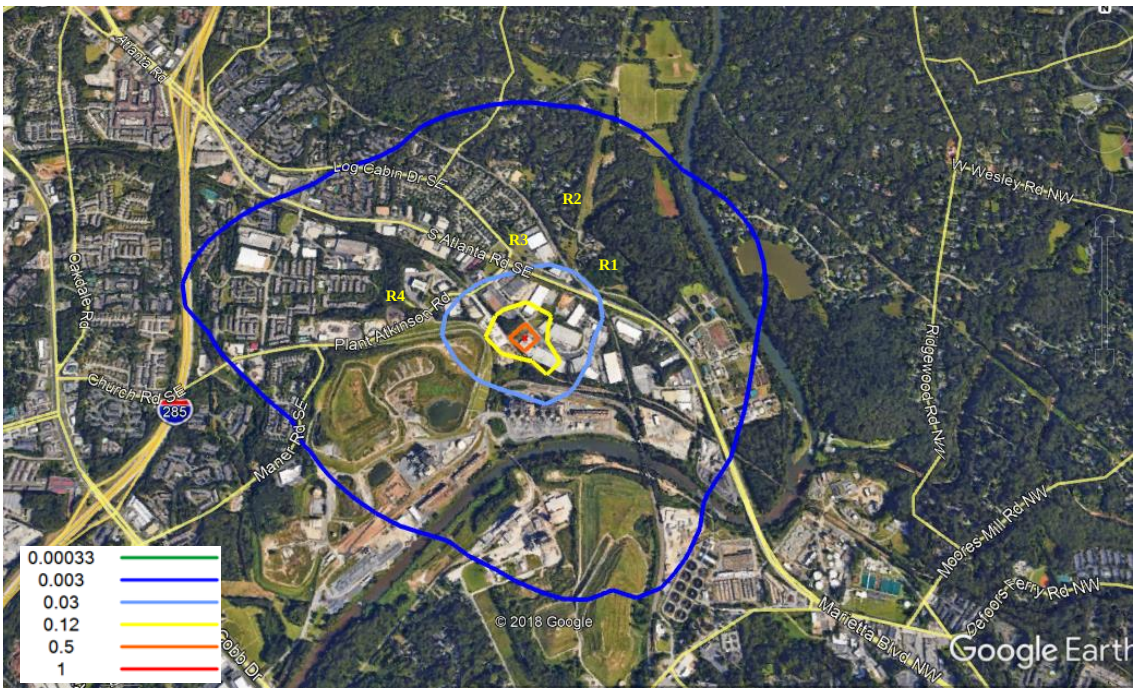


Figure 7. A Close-up Look of Figure 6 (Sterigenics)

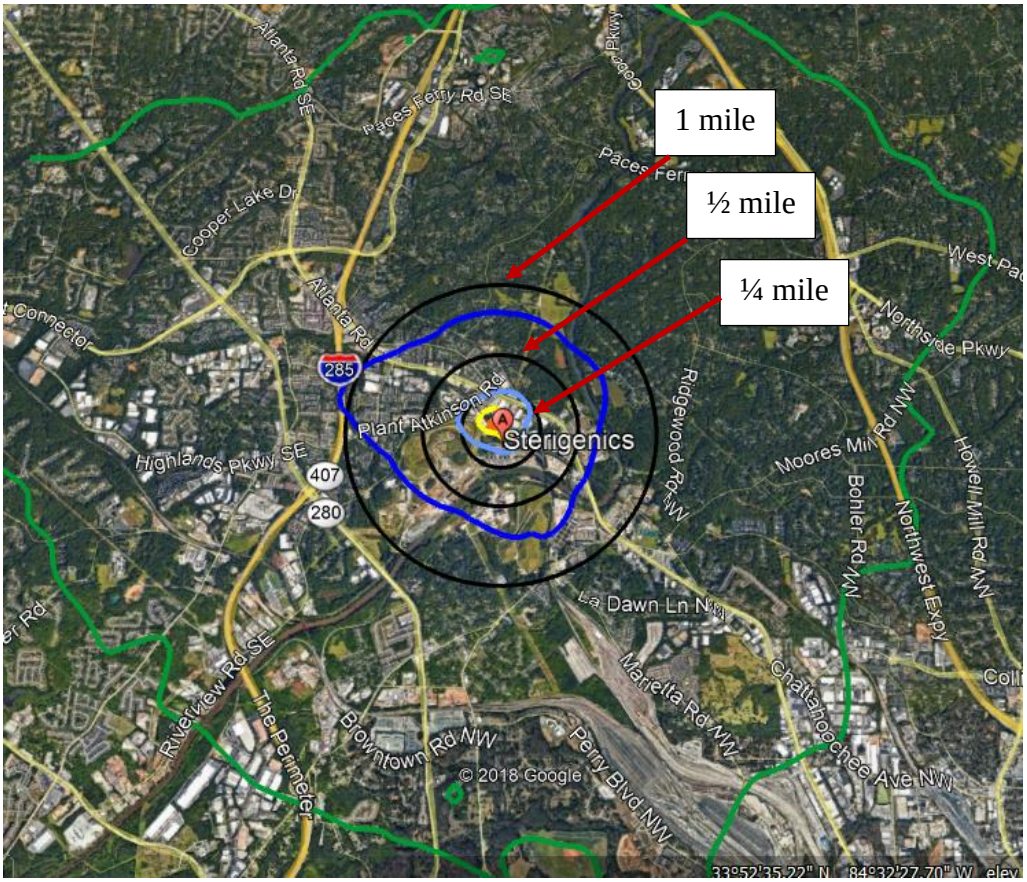


Figure 8. Model Overlaid with Distances from Sterigenics

Wind rose data from airports near each facility was assessed by the GA AAMP, and primary and secondary wind patterns were determined. The available wind data from the Covington Municipal Airport was used for the Becton Dickinson facility, and the available wind data from the Dobbins Air Reserve Base was used for the Sterigenics facility. Distances from the nearby airports to the facility are shown in Figure 9 and Figure 11 below. Wind rose data from each airport is shown in Figure 10 and Figure 12.

Figure 9. Location of Covington Muncipal Airport (Wind Rose Data) in Relation to Becton Dickinson

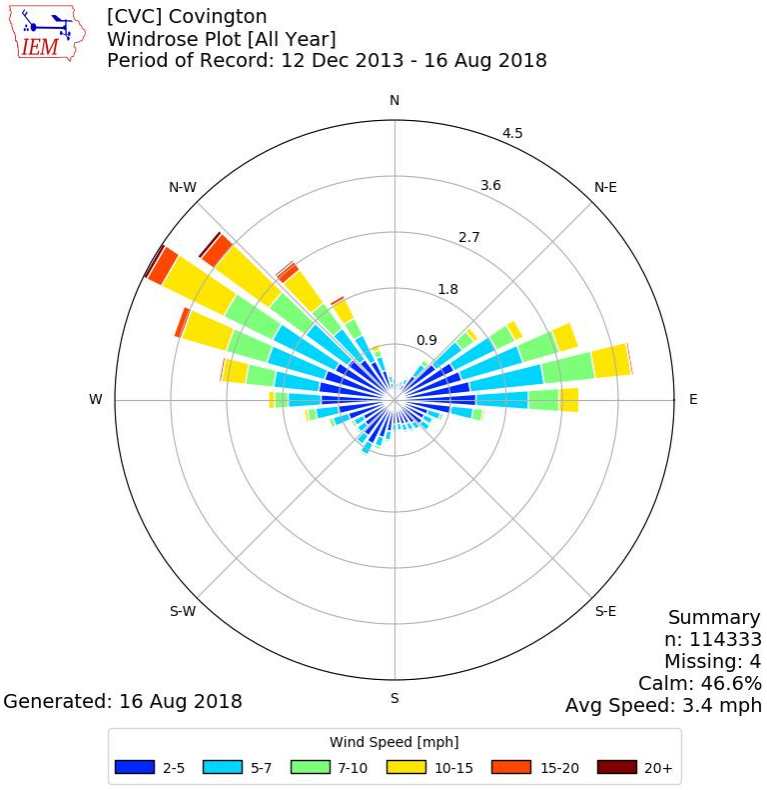


Figure 10. Annual Wind Rose Data from Covington Municipal Airport, 2013-2018

Figure 11. Location of Dobbins Air Reserve Base (Wind Rose Data) in Relation to Sterigenics

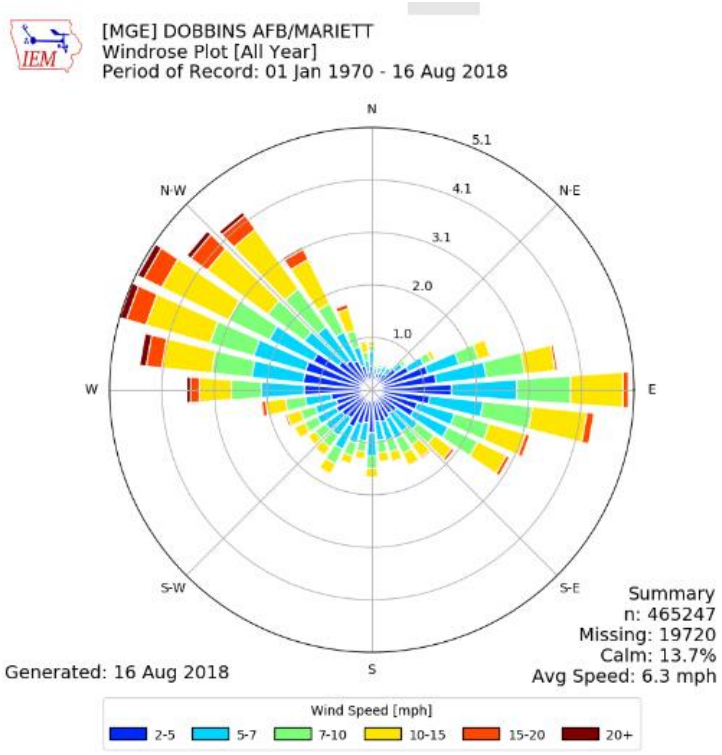


Figure 12. Annual Wind Rose Data at Dobbins Air Reserve Base, January 1970-August 2018

The wind roses were overlaid on Google Earth maps to help pinpoint the appropriate locations to place monitors around each facility. The GA AAMP plans to collect samples within four locations around each facility for each sampling event: primary upwind direction, primary downwind direction, secondary upwind direction and secondary downwind direction (indicated with red polygons for upwind and blue polygons for downwind in Figure 13 and Figure 14). Samples will be taken within approximately ¼ mile of each facility in the four quadrants every six days. Samples will also be taken using the same passive sampling equipment at South DeKalb site for each sampling event. The measurements at the South DeKalb site will provide information for the relative comparison of the three locations (near Becton Dickinson, near Sterigenics, and South DeKalb). To help determine concentrations of spatial relativity to increased distance from the site of emissions, qualitative comparisons will also be made at distances of approximately ¼ mile, ½ mile, and 1 mile radius of each facility. This will be accomplished by comparing a sample taken at approximately ¼ mile to a sample taken at either approximately ½ mile or 1 mile. Refer to Table 1 for more information.

The GA AAMP will take reasonable precautions in placement of the passive samplers to ensure Site Operator safety. The samplers will be placed in the best places to characterize emissions in the air surrounding each facility, at heights up to 10 meters, within the breathing zone, and with an open fetch for unobstructed air flow across the samplers.

In addition, at the South DeKalb site, personnel from GA Tech will analyze the continuous (hourly) samples with the GA AAMP Program Manager's oversight. This will help show a more detailed characterization of the ethylene oxide data, allowing analysis of hourly trends throughout the 24-hour period. Also, the hourly wind data collected at the South DeKalb site will be tracked along with the hourly ethylene oxide measurements to help decipher trends in the data. In addition, GA Tech personnel will be able to do a sample analysis comparing the 24-hour averages of the continuous sampler to both canister sampling methods.

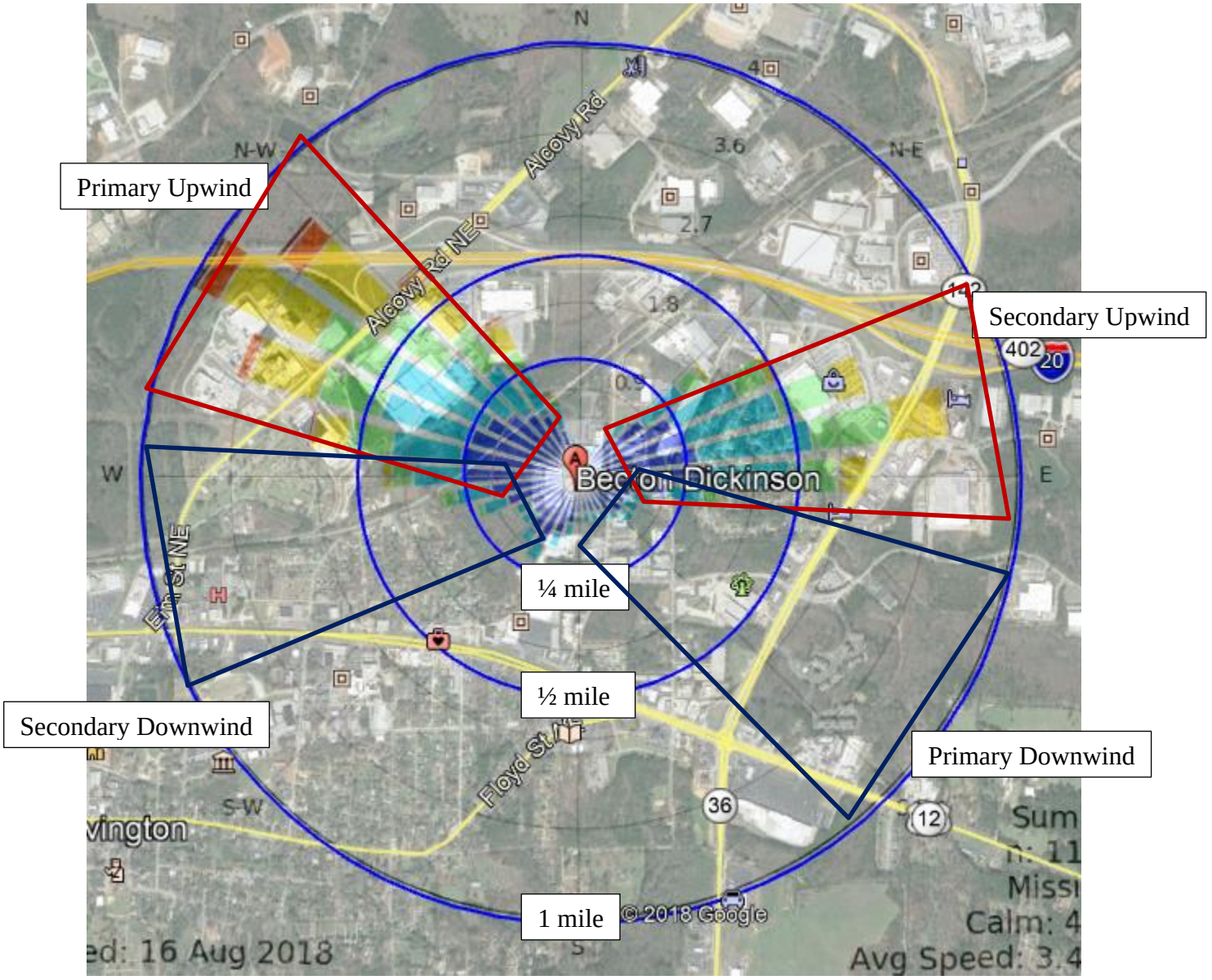


Figure 13. Primary and Secondary Wind Directions and Distances from Becton Dickinson

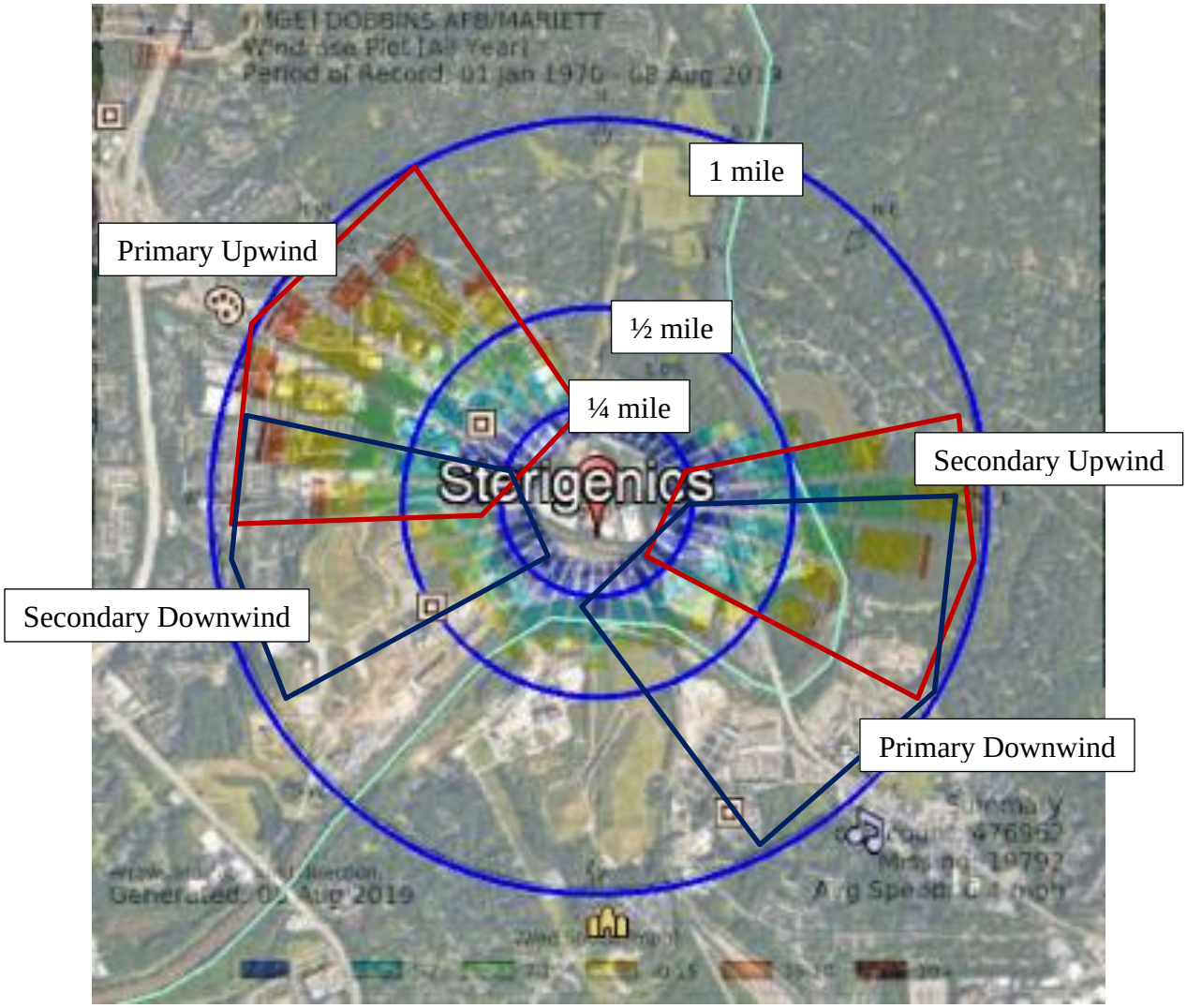


Figure 14. Primary and Secondary Wind Directions and Distances from Sterigenics

The GA AAMP also plans to collect samples at a rural, "background" site to compare to the samples collected near the facilities. This will help determine how much ethylene oxide is in the ambient air, with no influence from urban area activities. This background site is located at the General Coffee site (13-069-0002) (Figure 15) in Coffee County. Samples will be collected on a one in 12- day schedule at the General Coffee site.

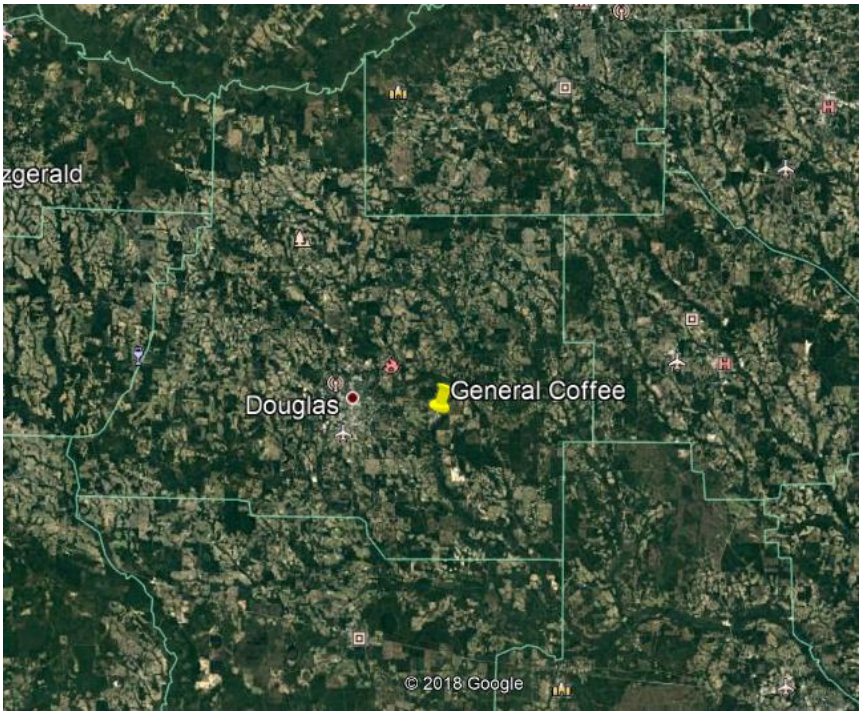


Figure 15. General Coffee Site

Due to the difficulty in laboratory analysis, the ethylene oxide samples will be analyzed by the EPA contract laboratory, ERG Lab, for consistency in measurements as compared to previous EPA studies. In October of 2021, the transition of the analytical laboratory to GA EPD Lab will begin. Please see the GA AAMP Changes in Laboratory Analysis attachment of this document.

The GA AAMP is collecting ethylene oxide data at the South DeKalb, NR-285, and General Coffee sites to make comparisons to the data collected near each facility. In addition, comparison analyses are planned between EPA Region 4 Laboratory at Laboratory Services and Applied Science Division in Athens, GA and the EPA contract laboratory, ERG Lab, for a laboratory comparison as available.

To summarize, the GA AAMP is sampling ethylene oxide as follows (also see Table 1 below):

- Every 6 days, samples will be collected at each of four sites around each identified facility (Becton Dickinson and Sterigenics) at approximately the ¼ mile radius mark to capture primary and secondary upwind and downwind concentrations (see above figures for primary and secondary upwind and downwind quadrants). Please see the GA AAMP Additional Sampling Sites Attachment and the GA AAMP Changes to Monitoring Schedule Attachment of this document.
- Once a month, a collocated sample should be collected at one of four sites around each identified facility (Becton Dickinson and Sterigenics) at approximately the ¼ mile radius mark to capture primary and secondary upwind and downwind concentrations (see above figures for primary and secondary upwind and downwind quadrants). The same site(s) should be used for collocation throughout the study for consistency.

- Once a month, samples should be also collected at approximately ½ mile or 1 mile radius from each facility, in one of the four quadrants, to assess spatial variation. Comparisons will be made between the samples collected within approximately ¼ mile mark and the ½ mile mark or between the samples collected within approximately ¼ mile mark and the 1 mile mark to determine gradient of ethylene oxide concentration at the specified distance from each facility.
- Every 6 days, samples will be collected at the South DeKalb site for comparison.
- Every 12 days, samples will be collected at the background General Coffee site for comparison.
- Approximately 8 samples per study will be collected at the NR-285 site for a qualitative comparison.
- Approximately 16 samples per study will be collected concurrently using the passive canister sampler and the ATEC canister sampler at the South DeKalb site for a qualitative comparison.
- Approximately 620 samples will be collected as part of this ethylene oxide study.
- Additional sample locations may be added as resources allow, following the methodologies outlined in this document, as applicable.
- GA Tech personnel will analyze continuous (hourly) samples at the South DeKalb site for six months for a detailed characterization of 24-hour trends, comparison of hourly data along with hourly wind data collected at the South DeKalb site, and comparison of 24-hour averages to both canister sampling methods (approximately 45 samples will be correlated).

A unique code will be assigned to identify and differentiate each of the monitoring sites during this study.

The GA AAMP will place the collocated samplers at the site with the expected highest concentration within reason and considering the safety of the Site Operators.

The measurement goal of the ethylene oxide study is to estimate the 24-hour average passive canister sampling concentrations in units of micrograms per cubic meter ($\mu g/m^3$). The GA AAMP ethylene oxide monitoring project will follow EPA Compendium Method TO-15, as applicable, for collecting volatile organic compounds. The sampling instruments, sampling media, sampling schedules and monitoring purposes used by GA AAMP to collect air samples for the analyses of ethylene oxide are shown in the following table. Ethylene oxide will be collected at the locations around Becton Dickinson and Sterigenics, the South DeKalb site (13-089-0002), the NR-285 site (13-089-0003), and the General Coffee site (13-069-0002). Refer to the GA AAMP Additional Sampling Sites Attachment for more information regarding additional sites.

Site Location	Sampling Instruments	Sampling Media	Monitor Type	Sampling Schedule	Monitor Purpose
Within approximately ¼ -mile radius of Becton-Dickinson	Entech CS1200E Passive Canister Samplers	6-Liter stainless steel canister	Primary and collocated	Primary-Every 6 days; Collocated-Once a month	Characterization of air surrounding facilities
Within approximately ½ and 1-mile radius of Becton-Dickinson	Entech CS1200E Passive Canister Samplers	6-Liter stainless steel canister	Primary	Approximately one spatial sample per month	Qualitative spatial comparison
Within approximately ¼ mile radius of Sterigenics	Entech CS1200E Passive Canister Samplers	6-Liter stainless steel canister	Primary and collocated	Primary-Every 6 days; Collocated-Once a month	Characterization of air surrounding facilities
Within approximately ½ and 1-mile radius of Sterigenics	Entech CS1200E Passive Canister Samplers	6-Liter stainless steel canister	Primary	Approximately one spatial sample per month	Qualitative spatial comparison
South DeKalb	Entech CS1200E Passive Canister Sampler	6-Liter stainless steel canister	Primary and Collocated	Every 6 days; Collocated - once per month	Comparison/ background
South DeKalb	ATEC 2200 Sampler	6-Liter stainless steel canister	Primary	Approximately 3 per study	Qualitative comparison
South DeKalb	Picarro G2920	N/A	Primary	Continuous, hourly	Detailed characterization
NR-285	Xonteck Model 910 Air Sampler	6-Liter stainless steel canister	Primary	Approximately 3 per study	Qualitative comparison
General Coffee	Xonteck Model 911 Air Sampler	6-Liter stainless steel canister	Primary	Every 12 days	Rural background

Table 1. Sampling Details for Collecting Ethylene Oxide Data

The GA AAMP may place samplers in other locations around additional facilities deemed necessary for the collection of ethylene oxide data. Those samplers will follow this QAPP, and samplers around any additional facilities will follow the monitoring objectives and procedures

defined in this QAPP. For all sites used for this data study that are not established GA AAMP network sites, placement of samplers in relation to any affected source is contingent on the availability of ambient monitoring locations. All other aspects of the sample (from collection to verification) will follow the procedures outlined in this QAPP.

The work required to collect, document and report the ethylene oxide data includes:

- Appropriate placement of the sampler
- Ensuring accurate and reliable monitors records of data collected
- Developing SOPs for equipment checks, operation, and maintenance
- Establishing assessment criteria
- Validating the data produced in accordance with criteria herein

6.1 Field Activities

The Site Operators will perform field activities to include:

- Performing routine site operations and maintenance activities that include verifying sampler status, and recording pertinent field data and measurements
- Performing leak checks
- Collecting ethylene oxide samples and sending to the laboratory for analysis

GA Tech personnel will analyze the continuous ethylene oxide data collected with the continuous sampler at the South DeKalb site, with oversight from the GA AAMP Program Manager/Project Administrator.

The Field Auditor will perform on-site assessments of the ethylene oxide collection, at least once during the study at each of the five target locations (Cobb County, Covington, South DeKalb, NR-285, General Coffee) and any additional sites added (i.e. Fulton County).

6.2 Laboratory Activities

The GA AAMP sends the ethylene oxide samples to the ERG Lab for analysis. The ERG Lab delivers an electronic data package to GA AAMP for validation and upload to the GA AAMP website (https://epd.georgia.gov/ethylene-oxide-information), as applicable. Any issues observed with the laboratory data are discussed with the ERG Lab. The ERG Lab maintains copies of their SOPs and are available to the GA AAMP staff as needed. Copies of the ERG Lab SOPs are available upon request and the ERG Lab's *Support for the EPA National Monitoring Programs (UATMP, NATTS, CSATAM, PAMS, and NMOC Support) QAPP*, dated February 2020 is Laboratory Attachment of this document. In addition, the EPA Region 4's LSASD Lab will do a comparison of the samples collected with both canister sampling methods.

Beginning in October 2021, the GA AAMP will the ethylene oxide samples to the GA EPD Lab for analysis. The GA EPD Lab delivers an electronic data package to GA AAMP for validation and upload to the GA AAMP website (https://epd.georgia.gov/ethylene-oxide-information), as applicable. Any issues observed with the laboratory data are discussed with the GA EPD Lab. The GA EPD Lab maintains copies of their SOPs and are available to the GA AAMP staff as needed.

Copies of the GA EPD Lab SOPs are available upon request. The GA EPD Lab will follow an EPA approved *Quality Assurance Plan* and is incorporated in GA AAMP's *Quality Assurance Project Plan for Georgia Ambient Air Monitoring Program National Air Toxics Trends Station (NATTS).*

6.3 Project Assessment Techniques

The evaluation process used to measure the performance or effectiveness of the system is called an assessment. This includes the audit, performance evaluation, inspection, peer review, or surveillance.

An audit of the Site Operator's sample collection will be conducted at each of the five locations (Cobb County, Covington, South DeKalb, NR-285, and General Coffee) during the study and any additional sites, such as Fulton County. This audit will review equipment, adherence to the SOP, field documentation, and chain of custody records to ensure compliance with the QAPP. The results of the audits (and any identified corrective actions) are summarized in a report to the QA Unit Manager.

6.4 Ethylene Oxide Project Records

The GA AAMP will maintain procedures for preparation, review, approval, use, revision and maintenance of documents and records. The categories and types of records and documents that are applicable to GA AAMP are shown in Table 2. More detail is shown in Section 9.0.

Table 2. Critical Documents and Records

Categories	Record/Document Types
Management and Organization	Organizational Chart of GA AAMP Personnel qualifications
Network & Site Information	Network description Site characterization file Site maps/pictures
Environmental Data Operations	Quality Assurance Project Plans (QAPPs) Standard operating procedures (SOPs) Field and laboratory logbooks Sample handling/custody records Inspection/maintenance records
Raw Data	Any original data
Data Reporting	Data/summary reports Quarterly reports from GA Tech
Data Management	Data Validation Folders
Quality Assurance	Field audits of site operations

6.5 Project Schedule

The schedule for field and laboratory analysis activities are summarized in Table 3. As the project progresses, feedback from local stakeholders may initiate changes to the project. The dates of these activities may change due to unforeseen circumstances. However, this is the general timeline that the GA AAMP will follow for this project.

Table 3. Schedule of Monitoring Activities

Phase 1 (August 2019 – March 2021)

Activity	Date	Comments
Monitoring plan development and sampling device procured	August 2019	
QAPP approval	September 2019	Revised April 2020
Sampling	September 2019 – August 2020	Projected end date of Phase 1
Laboratory analysis begins	September 2019	
Field audit assessment	1 audit per study	Once per location per study

For more details regarding the timeline for ethylene oxide study, refer to the *Quality Assurance Project Plan for the Georgia Ambient Air Monitoring Program Ethylene Oxide, Revision 0*.

Project Phase 2 (April 2021 – October 2022)

Activity	Date	Comments
Sample collection	April 2021 – October 2021	Ongoing data evaluation
Laboratory analysis contract	October 2020	ERG procured as contract laboratory
Laboratory analysis	April 2021- February 2022	
Field audit assessment	1 audit per site	Once per location per study during Project Phase 2
Procurement of Picarro continuous ethylene oxide analyzer	October 2020 – January 2021	
Update QAPP	April 2021	QAPP approved 4/29/2021 Amendment approved 6/30/2021
Verification of Picarro instrument with ethylene oxide standard at GA EPD Laboratory	February 2021	
Sampling data laboratory comparison	October 2020 – October 2021	Ongoing comparison of laboratory analytical comparisons

Comparison of sampling methodologies	April 2021 – October 2021	Ongoing comparison of continuous (Picarro), passive, ATEC, and Xonteck methodologies
Installation of Picarro instrument at South DeKalb monitoring site	March 2021 – October 2021	
Finalize Picarro SOP	August 2021	
Final verification of Picarro instrument with ethylene oxide standard at GA EPD Laboratory	November 2021	
GA EPD submits quarterly grant progress reports to EPA	April 30, 2021 July 31, 2021 October 31, 2021 January 31, 2022 April 30, 2022 July 31, 2022	
Comparison of ethylene oxide concentrations between TO-15 and Picarro results	April 2021- October 2021	Quarterly reports will be submitted by Georgia Tech to GA EPD
Data Analysis of GA EPD measurements	Through July 2022	Georgia Tech's final report is due August 2022
Final Report submitted to EPA and posted on GA EPD website	October 31, 2022	Incorporating all measurements made as part of this grant

7.0 Quality Objectives and Criteria for Measurement Data

The ethylene oxide monitoring study will be conducted under the quality program of the GA AAMP EPA-approved *Environmental Protection Division Air Protection Branch Quality Management Plan,* dated September 2020 where applicable.

7.1 Data Quality Objective (DQO)

The GA AAMP did not go through a formal data quality objective (DQO) process for the ethylene oxide monitoring project; however, the GA AAMP agreed upon measurement quality objectives for this project with the stakeholders. Measurement quality objectives for the various data quality indicators were developed based on the requirements of EPA Compendium Method TO-15.

7.2 Measurement Quality Objectives (MQOs) for Ethylene Oxide

Measurement quality objectives (MQOs), or acceptance criteria, are designed to evaluate and control various phases (sampling, preparation, analysis) of the measurement process. These MQOs are defined in terms of the following data quality indicators (DQIs):

- Precision - "Precision is a measure of agreement between two replicate measurements of the same property, under prescribed similar conditions. This agreement is calculated as either the range or as the standard deviation," (US EPA QA/G-5, Appendix B). This is the random component of error.
- Bias - "Bias is the systematic or persistent distortion of a measurement process that causes errors in one direction," (US EPA QA/G-5, Appendix B). Bias is determined by estimating the positive and negative deviation from the true value as a percentage of the true value.
- Comparability - "Comparability is the qualitative term that expresses the confidence that two data sets can contribute to a common analysis and interpolation. Comparability must be carefully evaluated to establish whether two data sets can be considered equivalent in regard to the measurement of a specific variable or groups of variables," (US EPA QA/G-5, Appendix B).
- Representativeness - "Representativeness is a measure of the degree to which data accurately and precisely represent a characteristic of a population parameter at a sampling point or for a process condition or environmental condition. Representativeness is a qualitative term that should be evaluated to determine whether in situ or other measurements are made and physical samples collected in such a manner that the resulting data appropriately reflect the media and phenomenon measured or studied," (US EPA QA/G-5, Appendix B).
- Completeness - Completeness is a metric quantifying the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions. Completeness can be expressed as a ratio or a percentage. Data completeness requirements are included in the reference methods (40 CFR Part 50).
- Sensitivity – Sensitivity is determined by method detection limits (MDLs) for each measurement method for each pollutant (40 CFR 53.20, Table B-1 and manufacturer's guidance).

The DQIs of representativeness, completeness, precision, bias, and sensitivity must meet specific MQOs, or acceptance criteria. The MQOs for each of the DQIs are as follows:

- Representativeness: For integrated samplers, sampling must occur at one in 6-day frequency, from midnight to midnight local standard time, over 24 ± 1 hours. For continuous sampler, 50% of each hour should be collected.
- Completeness: At least 75% of all 24-hour integrated data available over the course of the study must be reported. For continuous sampler, 50% of each hour should be collected.
- Precision: The percent difference between two field replicate measurements of the same property (under prescribed similar conditions must be no more than 25% for results ≥ 5xMDL
- Bias: Measurement error must be <3X MDL

- Sensitivity: MDL as required by EPA as part of national contract (see ERG Laboratory's QAPP attached)

For the GA AAMP ethylene oxide monitoring project to follow these MQOs, the data produced will be considered of sufficient quantity and quality for the decision making to commence. The MQOs are used by GA AAMP to control and assess measurement uncertainties. The following data validation table outlines the acceptance criteria to meet these MQOs. GA AAMP uses the acceptance criteria provided in EPA supplied guidance *Technical Assistance Document for the National Air Toxics Trends Stations Program, Revision 3*, (TAD) dated October 2016 as a guide, and unless otherwise noted, the references shown in the table refer to this document. The data is collected based on this TAD except for sampling end pressure as noted below. The target range of 2 to 4 inHg for sample recovery is taken from EPA guidance which is considered best practice of TO-15 and NATTS sampling. The project covered under this QAPP does not have to adhere to the NATTS TAD requirements. This study will use weight of evidence approach using all the information received to determine the validity of the samples. Samples that are at ambient pressure upon recovery may be qualified; however, per EPA's memo dated February 23, 2021, samples at ambient pressure upon recovery will be voided. If the receiving laboratory determines that the canister has a vacuum using the laboratory's more precise, certified gauge, the sample will be analyzed for the ethylene oxide concentration in the canister. If the canister is at ambient pressure as measured by the laboratory instruments, the canister will be voided and not analyzed for ethylene oxide concentration.

Table 4. Data Validation Table

VOCs via EPA Compendium Method TO-15

Parameter	Description and Required Frequency	Acceptance Criteria	Reference	Category
Field Readiness Checks and Collection Activities				
Canister Viability	All canisters	Canister must be used within 30 days from final evacuation	Section 4.2.6.2 TO-15 Section 1.3	Operational
Canister Starting Pressure Determination	Each canister prior to collection of a field sample or preparation of a calibration standard or laboratory QC sample	Vacuum ≤ 28 inHg	Section 4.2.5.2.1	Operational
Sample Setup Leak Check	Each canister prior to collection - draw vacuum on canister connection	Leak rate must be ≤ 1 inHg over 5 minutes	Section 4.2.5.2.1	Critical
Sampling Frequency	One sample every six days according to the EPA National Monitoring Schedule	Sample must be valid to be included in ≥75%	Section 4.2.5.3	Critical and MQO
Sampling Period	All field-collected samples	1380-1500 minutes (24 ± 1 hr) starting and ending at midnight	Section 4.2.5.3	Critical and MQO
Field-collected Sample Final Pressure	All field-collected samples	All post sampling Entech passive canisters that enter the ERG Lab should have subambient pressure of 2 to 4 inHg (all other samplers i.e. the ATEC and Xonteck samplers should have an ending pressure of ≥+5 psig).*Must be determined with a pressure gauge	Section 4.2.5.2.4	Operational
Trip Blanks	Once a month on primary field-collected samples	Measurement <3 x MDL	Section 4.3.8.2.2	Operational
Sample Receipt				
Chain-of-custody	All field-collected samples including field QC samples	Each canister must be uniquely identified and accompanied by a valid	Sections 3.3.1.3.7 and 4.2.5.2.4	Critical

		and legible COC with complete sample documentation		
Sample Holding Time	All field-collected samples, laboratory QC samples, and standards	Analysis within 30 days of end of collection (field-collected samples) or preparation (QC samples or standards)	Section 4.2.1 TO-15 Sections 1.3, 2.3, and 9.2.8.1	Operational
Canister Receipt Pressure Check	All field-collected samples upon receipt at the laboratory – measured with calibrated pressure gauge or transducer	Pressure change of ≤3 inHg from the final pressure at retrieval for Entech passive samplers; ≤0.5 psi for ATEC and Xontek	Section 4.2.8	Critical for subambient sample collection, operational for pressurized sample collection
GC/MS Analysis				
Refer to ERG Lab's attached QAPP				
Laboratory Readiness and Proficiency				
Refer to ERG Lab's attached QAPP				
Canister and Sampling Unit Testing and Maintenance				
Refer to ERG Lab's attached QAPP				
Site Specifications and Maintenance				
Sample Inlet Filter	Particulate filter maintenance Beginning of study	Change filter when canister pressure shows necessary Clean or replace the 2-µm sintered stainless steel filter	Section 4.2.3.3 TO-15 Section 7.1.1.5	Operational
Data Reporting				
Data Completeness	Valid samples compared to scheduled samples For duration of study	≥ 75% of scheduled samples	Section 3.2	MQO

* If the receiving laboratory determines that the canister has a vacuum using the laboratory's more precise, certified gauge, the sample will be analyzed for the ethylene oxide concentration in the canister. If the canister is at ambient pressure as measured by the laboratory instruments, the canister will be voided and not analyzed for ethylene oxide concentration.

Table 5. MQOs for Picarro Continuous Ethylene Oxide Sampler

Parameter	Description and Required Frequency	Acceptance Criteria
Data Completeness	Valid samples compared to scheduled samples; hourly; daily	≥ 50% of every hour for a valid hour ≥ 75% of hours for a valid day
Zero Check	Weekly	<10% drift
Comparability	For each 24-hour canister collected	≥5 X MDL of the analytical method for both the 24-hr average and integrated average
Verification	At beginning and end of study	Demonstrate linearity

7.3 Intended Use of Data

This data will be used to:

- Characterize ambient levels of ethylene oxide
- Establish background concentration of ethylene oxide
- Provide ethylene oxide data for risk characterization by other agencies
- Provide an evaluation of new technologies for analyzing ambient air concentrations.

As applicable, the data will be submitted to the EPA Air Quality System (AQS) in concurrence with the EPA OAQPS. The data collected using the ATEC pressurized sampler will also be submitted to AQS as part of the NATTS reporting. The other data collected as part of this study will be posted in a format for the user to import into an applicable database. For the purposes of this study, the canister data collected with the passive samplers and the continuous data collected by the Picarro will be evaluated to see if the results are comparable to the traditional pressurized sampling methodology using the ATEC sampler. The laboratory analyses will also be evaluated by comparing two different laboratories (EPA LSASD and GA EPD) analytical techniques to the analyses performed by EPA's NATTS Contract laboratory, ERG. The quality of the data must be evaluated and controlled to ensure that it is maintained within the established acceptance criteria. Measurement quality objectives (MQOs) are designed to evaluate and control various phases (sampling, preparation, analysis) of the measurement process.

7.4 Measurement Scale

Each sampler operated by GA AAMP is assigned a scale of representativeness based on 40CFR58, Appendix D. The ethylene oxide monitors represent a middle scale to neighborhood scale. These representativeness definitions are found in GA AAMP's *Annual Ambient Air Monitoring Plan* at https://airgeorgia.org/.

8.0 Personnel Training and Development Program

This section is not required for a Category II QAPP.

9.0 Documentation and Records

GA AAMP, as a PQAO performing environmental data operations and management activities, has established and maintained procedures for the timely preparation, review, approval, issuance, use, control, revision and maintenance of documents and records. These procedures are elaborated in this section as a documentation and records management policy to address at least the following elements:

- A list of files considered the official records and their media type (e.g., paper, electronic)
- Schedule for retention and disposition of records
- Storage and retrieval system of records
- Person(s) responsible at each level of storage and retrieval for records
- Assignment of appropriate levels of security

A document, from a records management perspective, is a volume that contains information that describes, defines, specifies, reports, certifies, or provides data or results pertaining to environmental programs. Table 6 lists the categories and types of records and documents that are applicable for document control in the GA AAMP. Information on key documents in each category is included in this section. With the exception of Field Logbooks which are kept with the Site Operator, all paper records are stored in the GA AAMP central office. In addition to paper records, all the applicable documentation referred to in this section is saved as an electronic record with a format of MS Word, MS Excel, or PDF on the local network on the GA AAMP server. Retention of both paper and electronic records is explained in Section 9.3 below. The paper and electronic records are stored in a logical order for ease of access. For details of the ERG Lab's record management process, refer to the ERG Lab's QAPP. For details of the GA EPD Lab's record management process, refer to the GA EPD Lab's QAPP attached.

Table 6. Types of Information Retained Through Document Control

Categories	Record/Document Types	Electronic Copy	Paper Copy
Management and Organization	Organizational Chart of GA AAMP	X	X
	Personnel qualifications	X	X
	Support contracts	X	X
Network & Site Information	Network description	X	X
	Site description for study	X	X
	Site characterization file	X	X
	Site maps/pictures	X	X
Environmental Data Operations	Quality Assurance Project Plans (QAPPs)	X	X
	Standard operating procedures (SOPs)	X	X
	Field logbooks		X
	Sample handling/custody records	X	X
	Inspection/maintenance records	X	X
	NIST traceable records	X	X
Raw Data	Any original data	X	X
Data Reporting	Data/summary reports	X	X
Data Management	Data Validation Folders	X	X
Quality Assurance	Field Audits of Site Operations	X	X
	NIST traceable records	X	X

For the GA AAMP SOPs/QAPPs/QC/QA forms, the original copies are considered controlled copies and are maintained by the Program Manager or designee. GA AAMP SOPs/QAPPs/QC/QA forms are available in 'read only' format on local network drive and through online database records for operations. Current GA AAMP SOPs are retained in a folder for GA AAMP's S:\Ambient\SOPs for Operations Unit, S:\Ambient\SOPs for Quality Assurance Unit, and S:\Ambient\SOPs for Meteorology Unit. Current GA AAMP QAPPs are retained at

S:\Ambient\QAPPs. GA AAMP's historical SOPs/QAPPs are removed as they are updated and/or replaced. Paper copies of historical SOPs are kept in the site files in the central office, and electronic copies of the historical SOPs are kept in 'read only' format in the Program Manager's or designee's files on the local network. Working versions are kept in password protected files on the local network in the Data Analysis Unit's files and made available only for annual review and update. The Program Manager or designee notifies GA AAMP staff by email when a new version of a QAPP/SOP or QC/QA data form is available on the local network drive.

The GA AAMP maintains a master list of current, controlled SOPs on the local network at S:\Ambient\SOPs and QAPPs Master List. A color-coded Excel sheet maintained by the Data Analysis Unit is available to indicate when an SOP needs to be reviewed. The GA AAMP staff notifies the Data Analysis Unit Manager when a working version is needed for annual review, and the Data Analysis Unit Manager or designee makes the working version available on the local network at S:\Ambient\SOPs in Progress for review and edit by GA AAMP staff. Once the GA AAMP staff has completed their review and updates, the Data Analysis Unit and Manager review and edit as needed, make available for the QA Unit Manager to review, then the Program Manager reviews, and finally it is sent to EPA. The different stages of this process are documented in the S:\Ambient\SOPs and QAPPs Master List files, which are maintained by the Data Analysis Unit. As new versions replace old versions, the old versions are stored in 'read only' format in the Program Manager's or designee's folders on the local shared drive.

A master list of the GA AAMP QAPPs are also available on the local network at S:\Ambient\SOPs and QAPPs Master List. The GA AAMP QAPPs are reviewed annually updated by the Data Analysis Unit. The Data Analysis Unit Manager works with the other Unit Managers and Program Manager to review and edit the QAPP, and then it is sent to EPA for approval. As new versions replace old versions, the old versions are stored in 'read only' format in the Data Analysis Unit folders on the local shared drive.

The GA AAMP's raw data records on the AirVision database are backed up every 24 hours. The GA AAMP's records on the local shard network are backed up every 24 hours. Laboratory files are stored by month on network drive and backed up every 24 hours. In addition, the AirVision database files are kept as a redundant system to ensure proper storage of GA AAMP raw data records.

The GA AAMP's raw data records that are housed on the AirVision database are only available to the GA AAMP staff, through a limited access password-protected website. Historical QA documents are retained in hardcopy in GA AAMP files and/or electronic 'read only' access.

The GA AAMP's raw data records that are housed on the local network are only available to the GA AAMP staff. The raw data is validated as discussed in Section 20.0 and posted to the GA EPD's website (https://epd.georgia.gov/ethylene-oxide-information), as applicable. Historical QA documents are retained in hardcopy in GA AAMP files and/or electronic 'read only' access. Any of GA AAMP's hard copy site information (maps, photos, etc.) is housed in the central files.

9.1 Routine Data Activities

GA AAMP maintains records in appropriate files that allow for the efficient archival and retrieval of records. Ambient air quality information is included in this system. Table 6 includes the documents and records that are filed according to the statute of limitations discussed in Section 9.3.

9.2 Documentation Control

The details of the documents and records listed in Table 6 will be discussed in the appropriate sections of this document. All raw data required for calculations is collected electronically or on data forms that are included in the field and analytical methods. All hardcopy information shall be filled out in indelible ink. Corrections shall be made by inserting one line through the incorrect entry, initialing and dating this correction, and placing the correct entry alongside the incorrect entry, if this can be accomplished legibly, or by providing the information on a new line if the above is not possible.

9.2.1 Logbooks

Each Site Operator is responsible for obtaining appropriate field logbooks uniquely numbered and associated with the individual and/or a specific program. These logbooks will be used to record information about the site and laboratory operations, as well as document routine operations.

Completion of data entry forms, associated with all routine environmental data operations, are required even when the field logbooks contain all appropriate and associated information required for the routine operation being performed.

- Field Logbooks - Logbooks are used for each monitoring site, specific program, audit, or individual. Each notebook should be hardbound and paginated. After use in the field, field logbooks are retained in Site Operator's office.
- Laboratory Logbooks – Logbooks are used for sample custody, sample preparation and instrumental analysis. Each notebook should be paginated. An electronic database (Laboratory Information Management System or LIMS) exists in which the analytical laboratory retains all data records pertaining to sample tracking, preparation, and analysis, as well as general comments and notations and other pertinent information required for support of the GA AAMP's data integrity activities. Refer to each of the Laboratory Attachments for more details.

9.2.2 Chain-of-Custody Forms

For any samples that are taken to the analytical laboratory for analysis or sent to R4 LSASD for secondary anlaysis, a Chain-of Custody (COC) form is created. Custody records document the "chain of custody": the date and person responsible for the various sample handling steps associated with each sample and the information that acknowledges that sample integrity remained intact. Custody records also provide a reviewable trail for quality assurance purposes and can be used as evidence in legal proceedings. The GA AAMP and the analytical laboratory track and

document the whereabouts of each sample at each stage throughout the data collection operation using the Field Data Sheet and the COC form as shown in the applicable SOPs listed in Table 8. Entries on the COC form are made by hand. The information is then entered into the sample tracking system, where an electronic record is kept. More information about COC forms is detailed in Section 12.0.

9.3 Data Archiving and Retrieval

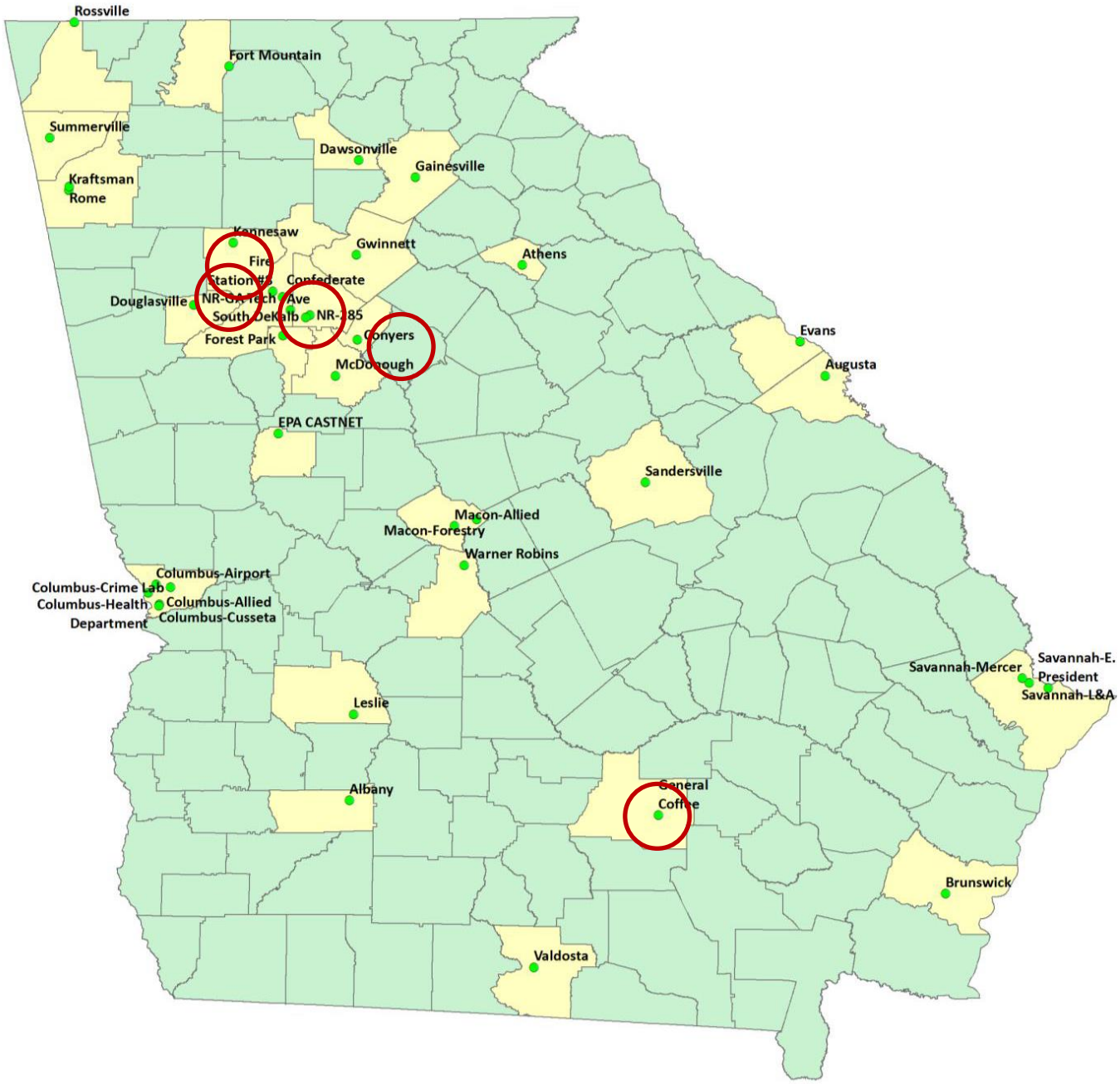
The storage and retrieval of the air quality monitoring data are conducted through the archiving system of GA EPD. All the information listed in Table 6 will be retained in house for at least five years from the date of collection. However, if any litigation, claim, negotiation, audit, or other action involving the records has been started before the expiration of the five-year period, the records will be retained until completion of the action and resolution of all issues which arise from it, or until the end of the five year-period, whichever is later.

10.0 Network Description

For a detailed description of the GA AAMP's ethylene oxide study sampling design, refer to Section 6.0. Figure 16 shows the areas that the GA AAMP will monitor for ethylene oxide (indicated by red circles). Refer to GA AAMP Additional Sampling Sites Attachment for a description of Fulton County sites.

Details regarding the South DeKalb, NR-285, and General Coffee sites can be found in GA AAMP's *Annual Ambient Air Monitoring Plan* at https://airgeorgia.org/.

The GA AAMP may place samplers in other locations around additional facilities deemed necessary for the collection of ethylene oxide data. Those samplers will follow this QAPP, and samplers around any additional facilities will follow the monitoring objectives and procedures defined in this QAPP. For all sites used for this data study that are not established GA AAMP network sites, placement of samplers in relation to any affected source is contingent on the availability of ambient monitoring locations. All other aspects of the sample (from collection to verification) will follow the procedures outlined in this QAPP.



Note: Refer to the GA AAMP Additional Sampling Sites Attachment for information regarding the Fulton County area sites.

Figure 16. Location of Ethylene Oxide Monitoring Sites

10.1 Monitoring Objective

The GA AAMP's ethylene oxide sites are representative of a middle to neighborhood scale and collect data with a source-oriented monitoring objective.

10.2 Sampling Frequency

For a detailed description of the GA AAMP's ethylene oxide study sampling frequency, refer to Section 6.0. Latitude and longitude coordinates will be disclosed after the study is complete. Samples will be collected from midnight to midnight. Sampling frequencies are shown in Table 7. After discussions with EPA, the frequency of the ATEC 2200 samplers was increased to once every 6 days; the passive samplers are now used for qualitative comparisons at the South DeKalb site.

Table 7. Sampling Frequency of Ethylene Oxide Monitors

Site Location	Sampling Instruments	Sampling Media	Monitor Type	Sampling Schedule	Monitor Purpose
Within approximately ¼ -mile radius of Becton-Dickinson	Entech CS1200E Passive Canister Samplers	6-Liter stainless steel canister	Primary and collocated	Primary-Every 6 days; Collocated-Once a month	Characterization of air surrounding facilities
Within approximately ½ and 1-mile radius of Becton-Dickinson	Entech CS1200E Passive Canister Samplers	6-Liter stainless steel canister	Primary	Approximately one spatial sample per month	Qualitative spatial comparison
Within approximately ¼ mile radius of Sterigenics	Entech CS1200E Passive Canister Samplers	6-Liter stainless steel canister	Primary and collocated	Primary-Every 6 days; Collocated-Once a month	Characterization of air surrounding facilities
Within approximately ½ and 1-mile radius of Sterigenics	Entech CS1200E Passive Canister Samplers	6-Liter stainless steel canister	Primary	Approximately one spatial sample per month	Qualitative spatial comparison
South DeKalb	Entech CS1200E Passive Canister Sampler	6-Liter stainless steel canister	Primary and collocated	Every 6 days; Collocated – once a month	Qualitative comparison

South DeKalb	ATEC 2200 Sampler	6-Liter stainless steel canister	Primary and collocated	Every 6 days; Collocated once a month	Comparison/Background
South DeKalb	Picarro G2920	N/A	Primary	Continuous, hourly	Detailed characterization
NR-285	Xonteck Model 910 Air Sampler	6-Liter stainless steel canister	Primary	Approximately 3 per study	Qualitative comparison
General Coffee	Xonteck Model 911 Air Sampler	6-Liter stainless steel canister	Primary	Every 12 days	Rural background

10.3 Site Selection

GA AAMP considered the following aspects when establishing the ethylene oxide air monitoring sites:

- Understanding the monitoring objective(s)
- Identifying the spatial scale most appropriate for the monitoring objective(s)
- Identifying the general locations where the monitoring site(s) should be placed according to wind direction
- Identifying specific monitoring sites

The sites will be chosen as GA AAMP's ethylene oxide sites due to the following factors:

- Modeled ethylene oxide emissions data showing highest concentrations
- Transport of pollutants downwind of facilities
- Characterize air upwind of facilities

11.0 Sampling Method Requirements

11.1 Field Collection Description

Ethylene oxide samples are collected in 6 Liter stainless steel canisters. The Site Operators receive certified "clean" canisters from the analytical laboratory. These canisters are evacuated to at least 28 inches of mercury gauge pressure when connected to the samplers. When not attached to the sampler, the canister is capped using a brass or stainless steel cap. Unique sample identification (ID) numbers are printed on tags attached to the canister (Figure 23, in next Section). Each canister also has a unique ID permanently written on the canister. For this study, the passive ethylene oxide monitor kits were sent to ERG Lab for a zero leak check at the beginning of the study. These results were evaluated and no contamination was found. The ERG Lab data is available upon request.

Prior to sampling, each canister must pass the leak check procedure. Primary samples will be collected on a one in 6-day schedule. Collocated samples should be collected once a month. Refer to Section 6.0 for more details regarding sampling schedules. The sample will run for 24 hours ± 1 hour. The Entech passive sampler is complete when it reaches subambient pressure, typically 2 to 4 inches mercury (inHg) (all other samplers i.e., the ATEC and Xonteck samplers should have an ending pressure of ≥+5 psig). The filled canister is then removed from the VOC sampler and subsequently delivered to the laboratory for analysis. All field-collected samples upon receipt at the laboratory are measured with calibrated pressure gauge or transducer. For the Entech passive sampler, the pressure change should be ≤3 inHg from the final pressure at retrieval. For the ATEC and Xonteck samplers, the pressure change should be ≤ 0.5 psi from the final pressure at retrieval. For more information regarding the analytical laboratories, see the respective Laboratory Attachments of this document.

All samples collected as part of this study as of samples recovered after February 23, 2021 will be remeasured upon receipt at the laboratory with a more precise, certified pressure gauge or transducer. For any canister collected by the Entech passive sampler with a final pressure of less than 1 inHg at recovery, the analytical laboratory will determine the canister vacuum using the laboratory's gauge. If the analytical laboratory canister pressure measurement results in a vacuum of no more than 3 inHg, the sample will be analyzed for the ethylene oxide concentration in the canister if less than or equal to 3 inHg are measured. If the canister is at ambient pressure as measured by the laboratory gauge, the canister will be voided and not analyzed for ethylene oxide concentration.

For the Picarro ethylene oxide sampler at South DeKalb, data is collected on a continuous basis and sent to AirVision. The sampler should perform a zero check hourly. The GA AAMP will be responsible for operation and validation of the data from the continuous ethylene oxide sampler in AirVision, and personnel from GA Tech will analyze the data. Refer to the GA AAMP's *Standard Operating Procedure for Operation of Picarro G2920 Continuous Ethylene Oxide Sampler.*

11.2 Sampling Methodology

The methods described herein provide for measurement of the relative concentration of ethylene oxide in ambient air for a 24-hour sampling period. The method described in this section is based on *Compendium Method for the Determination of Toxic Organic Compounds in Air, United States Environmental Protection Agency, Section TO-15*, January 1999. The samplers located near the facilities and at the South DeKalb site will be a CS1200E Passive Sampler from Entech Instruments, which will connect directly to a 6-liter stainless steel canister (Figure 17). A TM1200 Canister Sampling Timer treated with silica for non-reactivity will be used to automatically start and stop the sampling at a 24-hour period. See GA AAMP's *Standard Operating Procedure Entech CS1200E Passive Sampler Kit* for more details.

Figure 17. Entech CS1200E Passive VOCs Sampler Set-Up

In addition, at the South DeKalb site, the ethylene oxide sampler will be the ATEC 2200 with a 6-liter stainless steel canister (Figure 18). See GA AAMP's *Standard Operating Procedure for Operation of a Volatile Organic Compound (VOC) Canister Sampler for a National Air Toxics Trends Station (NATTS)* for more details.

Figure 18. ATEC 2200 VOCs Sampler

Also at the South DeKalb site, personnel from GA AAMP will operate a Picarro G2920 continuous ethylene oxide sampler (Figure 19. Picarro G2920 Sampler). The Picarro G2920 uses cavity ring-down spectroscopy (CRDS) which is capable of measuring at levels less than 100 parts per trillion

(ppt). For more details regarding this technology, refer to https://www.picarro.com/company/technology/crds and https://mktg.picarro.com/acton/fs/blocks/showLandingPage/a/39674/p/p-0024/t/page/fm/8. See GA AAMP's *Standard Operating Procedure for Operation of Picarro G2920 Continuous Ethylene Oxide Sampler* for more details.

Figure 19. Picarro G2920 Sampler

The ethylene oxide sampler at the NR-285 site will be the Xonteck Model 910 Sampler with a 6-liter stainless steel canister (Figure 20). See GA AAMP's *Standard Operating Procedure for the Xonteck Model 910 VOCs Canister Sampler* for more details.

Figure 20. Xonteck Model 910 VOCs Sampler

At the General Coffee site, the ethylene oxide sampler will be the Xonteck Model 911 Sampler with a 6-liter stainless steel canister (Figure 21). See GA AAMP's *Standard Operating Procedure for Xonteck Model 911 VOCs Canister Sampler* for more details.

Figure 21. Xonteck Model 911 VOCs Sampler

11.3 Standard Operating Procedures

In order to perform the sampling, analysis, and QC activities consistently, GA AAMP has prepared and updated standard operating procedures (SOPs) for each routine or repetitive task as a part of the QAPP. The SOPs prepared and updated by GA AAMP for the ethylene oxide monitoring study are summarized in Table 8. At the time of writing this QAPP, some SOPs were still being updated.

The GA AAMP and ERG Lab's SOPs detail the instrument operation requirements. Table 8 shows a current list of GA AAMP's SOPs that apply to the VOCs samplers. For ERG Lab's SOPs, see Section 8.0 and Appendix D of the ERG Laboratory Attachment of this document.

Table 8. GA AAMP's SOPs for Ethylene Oxide Collection

SOP	Revision	Date
Standard Operating Procedure for Operation of a Volatile Organic Compound (VOC) Canister Sampler for a National Air Toxics Trends Station (NATTS)	2	July 2019
Standard Operating Procedure to Audit the ATEC Model 2200 VOCs Sampler	2	July 2019
Standard Operating Procedure for the Xonteck Model 910 VOCs Canister Sampler	0	September 2019
Standard Operating Procedure to Audit the Xonteck Model 910 VOCs Sampler	0	August 2019
Standard Operating Procedure for Xonteck Model 911 VOCs Canister Sampler	0	September 2019

Standard Operating Procedure to Audit the Xonteck Model 911 VOCs Sampler	0	December 2019
Standard Operating Procedure Entech CS1200E Passive Sampler Kit	0	September 2019
Standard Operating Procedure for Data Validation and Verification of Integrated Data	4	January 2021
Standard Operating Procedure for Operation of Picarro G2920 Continuous Ethylene Oxide Sampler	0	June 2021
Standard Operating Procedure for Data Validation of Picarro G2920 Continuous Ethylene Oxide Analyzer	0	July 2021

11.4 Sample Probe/Sample Train

For the VOCs samplers at the ethylene oxide monitoring sites, the GA AAMP uses the Entech Passive VOCs samplers, ATEC samplers, and the Xonteck 910/911 VOCs samplers, which are free standing samplers and do not have a sampler probe/train that requires maintenance. In addition to the leak checks described in these documents and in Section 14.0 of this QAPP, GA AAMP will clean the exterior of the VOCs sampler at least once per year, or as needed. Details are shown in the applicable Operations' SOPs listed in Table 8.

11.5 Sampler Leak Check

The GA AAMP performs a leak check before each sample is collected. Details are explained in the applicable Operations' SOPs listed in Table 8. Per the SOPs noted above and Table 4 contained in this QAPP, the passive ethylene oxide samplers underwent a leak check performed by the ERG Laboratory prior to beginning this study.

11.6 Maintenance of Sampler Probe/Sampler Train

Preventative maintenance is performed on the ethylene oxide samplers by GA AAMP as described in the applicable SOPs listed in Table 8. Per the SOPs noted above and Table 4 contained herein this QAPP, the following maintenance is performed as stipulated. The GA AAMP replaces the sample inlet filter as indicated by pressure issues. The sample probes and inlets will be cleaned as needed, in addition to the sample line replacement.

11.7 Modifications to Samplers

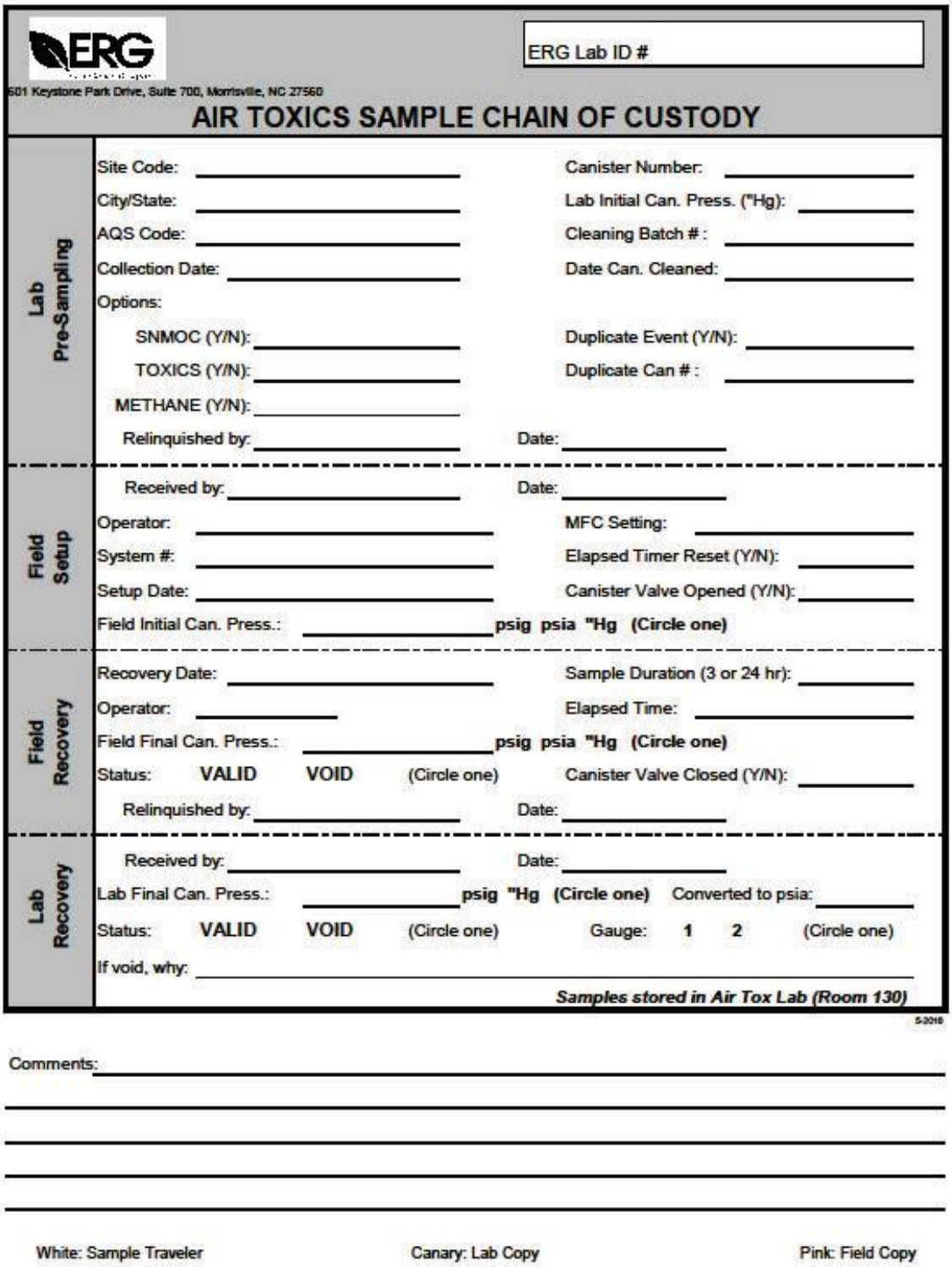
In the event of needed corrective action, the Site Operator notifies the Operations Unit Manager. The QA Unit Manager and Program Manager should also be notified. Details are described in the applicable SOP listed in Table 8.

12.0 Sample Numbering and Custody

Unique sample IDs are generated by the ERG Lab and labeled appropriately on the sampling media (see Section 11.0 for details of how sample IDs are addressed). The GA AAMP utilizes these sample IDs to match the laboratory data to the field data, as applicable. GA AAMP may employ custody seals on the samples, and except during shipment, the samples are either in secured GA EPD buildings, analytical laboratory buildings, secured at the sampling location, or in the possession of GA AAMP or laboratory personnel.

A critical activity within any data collection phase involving physical samples is the handling of sample media prior to sampling; transporting sample media to the field, handling samples in the field at the time of collection; storage of samples (in the field or other locations); transport of samples from the field site; and the analysis of the samples. Custody records document the "chain of custody": the date and person responsible for the various sample handling steps associated with each sample and the information that acknowledges that sample integrity remained intact. Custody records also provide a reviewable trail for quality assurance purposes and can be used as evidence in legal proceedings. The GA AAMP and analytical laboratory track and document the whereabouts of each sample at each stage throughout the data collection operation using the Field Data Sheet, Chain-of-Custody (COC) Form, and, if applicable, analytical laboratory Tracking Tag as shown in the applicable SOPs listed in Table 8. Entries on the COC form are made by hand. The information is then entered into the analytical laboratory sampling tracking system (LIMS), where an electronic record is kept. More details are shown in the SOPs in Table 8 and the respective analytical Laboratory Attachment of this document. Examples of the COC Form, Sample Tracking Tag, and Logbook are shown below.

Figure 22. Example of Chain-of-Custody Form



ERG

601 Keystone Park Drive, Suite 700, Morrisville, NC 27560

ERG Lab ID #

AIR TOXICS SAMPLE CHAIN OF CUSTODY

Lab Pre-Sampling

Site Code: _____ Canister Number: _____

City/State: _____ Lab Initial Can. Press. ("Hg): _____

AQS Code: _____ Cleaning Batch # : _____

Collection Date: _____ Date Can. Cleaned: _____

Options:

SNMOC (Y/N): _____ Duplicate Event (Y/N): _____

TOXICS (Y/N): _____ Duplicate Can # : _____

METHANE (Y/N): _____

Relinquished by: _____ Date: _____

Field Setup

Received by: _____ Date: _____

Operator: _____ MFC Setting: _____

System #: _____ Elapsed Timer Reset (Y/N): _____

Setup Date: _____ Canister Valve Opened (Y/N): _____

Field Initial Can. Press.: _____ **psig psia "Hg (Circle one)**

Field Recovery

Recovery Date: _____ Sample Duration (3 or 24 hr): _____

Operator: _____ Elapsed Time: _____

Field Final Can. Press.: _____ **psig psia "Hg (Circle one)**

Status: **VALID** **VOID** (Circle one) Canister Valve Closed (Y/N): _____

Relinquished by: _____ Date: _____

Lab Recovery

Received by: _____ Date: _____

Lab Final Can. Press.: _____ **psig "Hg (Circle one)** Converted to psia: _____

Status: **VALID** **VOID** (Circle one) Gauge: **1** **2** (Circle one)

If void, why: _____

Samples stored in Air Tox Lab (Room 130)

5-2016

Comments: _____

White: Sample Traveler Canary: Lab Copy Pink: Field Copy

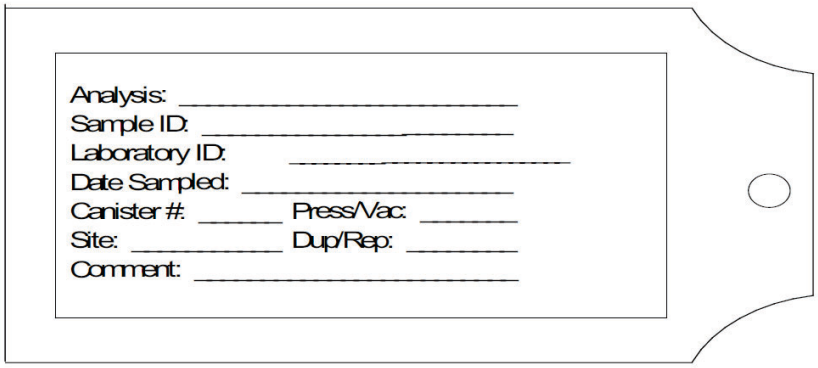
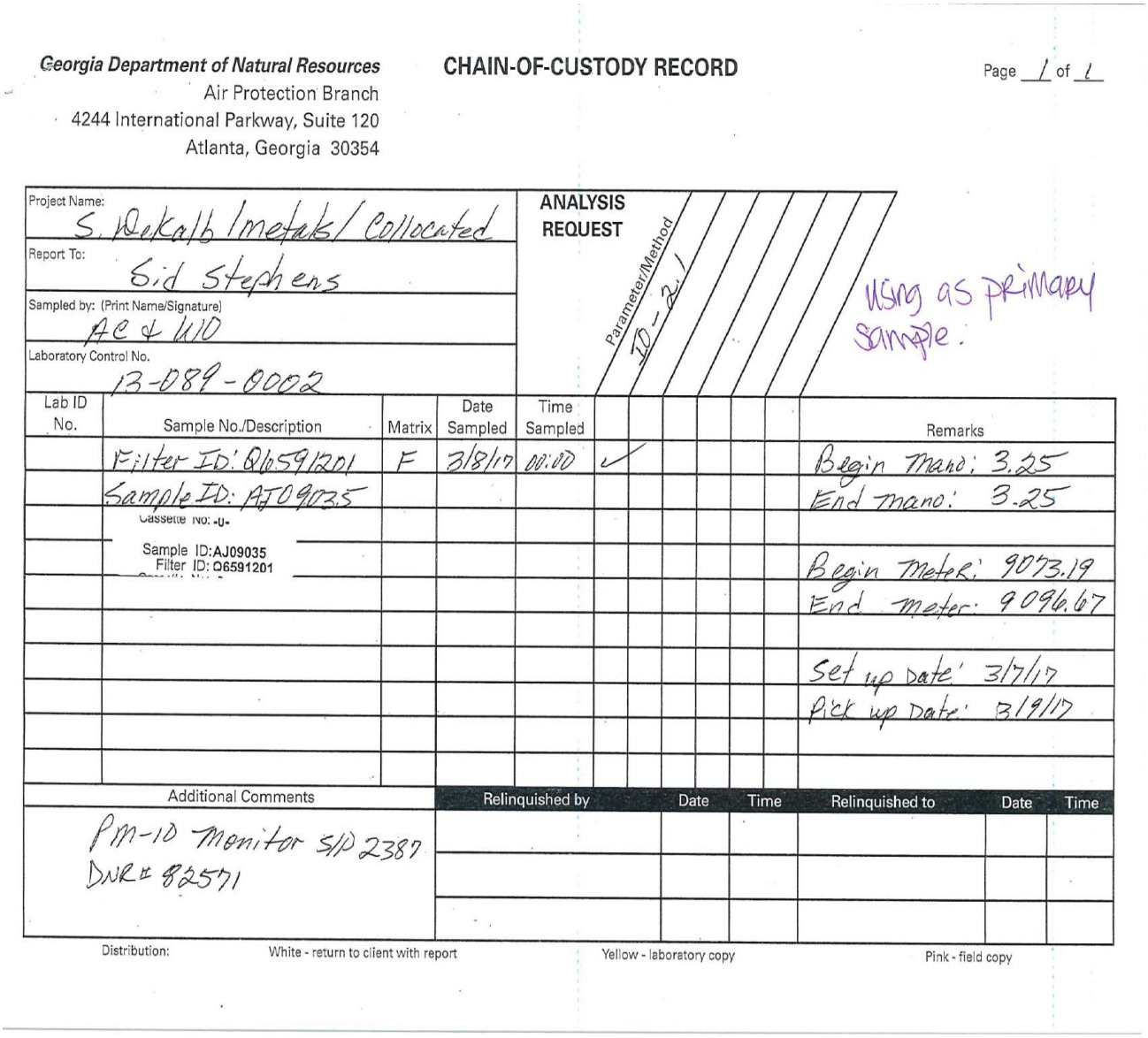


Figure 23. ERG's Sample Tracking Tag



Georgia Department of Natural Resources
Air Protection Branch
4244 International Parkway, Suite 120
Atlanta, Georgia 30354

CHAIN-OF-CUSTODY RECORD

Page 1 of 1

Project Name: S. DeKalb Imetals/ Collocated
Report To: Sid Stephens
Sampled by: (Print Name/Signature) AC & WO
Laboratory Control No. 13-089-0002

ANALYSIS REQUEST

Parameter/Method: ID-2.1

Using as primary sample.

Lab ID No.	Sample No./Description	Matrix	Date Sampled	Time Sampled							Remarks
	Filter ID: Q6591201	F	3/8/17	00:00	✓						Begin mano: 3.25
	Sample ID: AJ09035										End mano: 3.25
	Cassette No: -U-										
	Sample ID: AJ09035 Filter ID: Q6591201										Begin Meter: 9073.19
											End meter: 9096.67
											Set up Date: 3/7/17
											Pick up Date: 3/9/17

Additional Comments	Relinquished by	Date	Time	Relinquished to	Date	Time
PM-10 Monitor S/P 2389 DNR# 82571						

Distribution: White - return to client with report Yellow - laboratory copy Pink - field copy

Figure 24. Example of Chain-of-Custody Form from GA EPD Lab

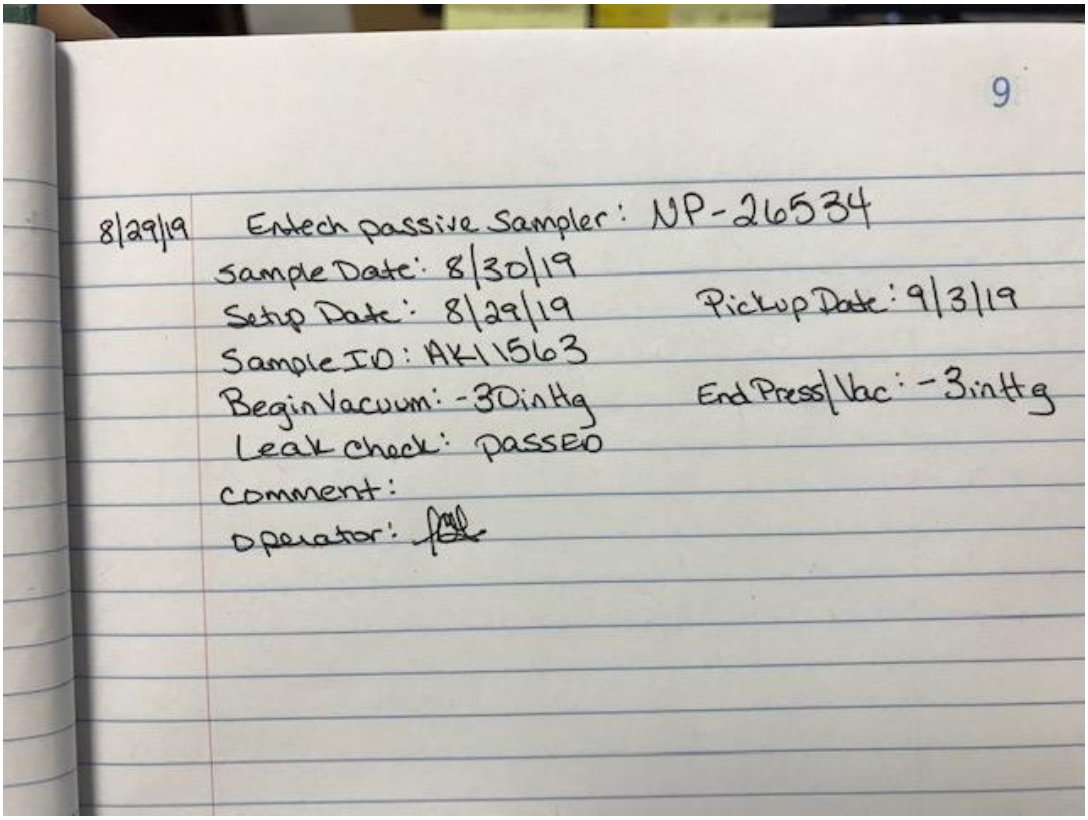


Figure 25. Example of the GA AAMP Logbook Entry

12.1 Pre-Sampling Custody

The pre-sampling custody is the sample handling stage that includes sample media purchasing, logging in, labeling, identification, pre-sampling weighing, transportation, and installation on sampler. For GA AAMP's SOPs, see the applicable SOPs listed in Table 8 for more details. For each of the analytical laboratories, see the respective Laboratory Attachment for more details.

12.1.2 Sample Preparation

Sample preparation is an essential portion of the ethylene oxide project. Cleaning, evacuation, testing, verification and storage of canisters are functions that are required for sample preparation.

Sample set-up of the ethylene oxide samplers take place any day after the previous sample has been recovered. Canisters for air collection for VOCs analyses must be used within 30 days after certified clean. Detailed sample set-up procedures are available from the corresponding GA AAMP's SOPs. For a description each of the analytical laboratories sample preparation, see the respective Laboratory Attachment of this document.

12.1.3 Sample Volume

The volume of air to be sampled is specified by the manufacturer and is in the method specifications. Samples are expected to be 24 hours; therefore, the Site Operators must set the flow rates to collect a sufficient sample to obtain the minimum sample volume. In some cases, a shorter sample period may occur due to power outages. A valid sample run should not be less than 23 hours or greater than 25 hours. If the sample period is less than 23 hours or greater than 25 hours, the sample will be nulled and the Operations Unit Manager notified. The Entech passive sampler is complete when it reaches subambient pressure, typically 2 to 4 inHg (all other samplers i.e. the ATEC and Xonteck samplers should have an ending pressure of ≥+5 psig). All samples collected as part of this study as of samples recovered after February 23, 2021 will be remeasured upon receipt at the laboratory with a more precise, certified pressure gauge or transducer. For any canister collected by the Entech passive sampler with a final pressure of less than 1 inHg at recovery, the analytical laboratory will determine the canister vacuum using the laboratory's gauge. If the analytical laboratory canister pressure measurement results in a vacuum of no more than 3 inHg, the sample will be analyzed for the ethylene oxide concentration in the canister if less than or equal to 3 inHg are measured. If the canister is at ambient pressure as measured by the laboratory gauge, the canister will be voided and not analyzed for ethylene oxide concentration. If the analytical laboratory analyzes the sample and the canister has a pressure reading, GA AAMP will use a qualifier code of '2'. If the analytical laboratory does not analyze the sample, then GA AAMP will use a null code of 'AA'.

12.2 Post Sampling Custody

Post sampling procedures include: sample removal, field record keeping and transportation of samples, how to protect the sample from contamination, temperature preservation requirements, and the permissible holding times to ensure against degradation of sample integrity. See the applicable GA AAMP's SOP in Table 8, and for the analytical laboratory, see the respective Laboratory Attachment, for more details.

12.2.1 Sample Contamination Prevention

To prevent contamination during transport to the laboratory, the VOCs stainless steel canisters should be capped and handled to ensure that the valve to canister connection remains intact and the interior surface is not compromised.

12.2.2 Temperature Preservation Requirements

During transport from the analytical laboratory to the sample location, VOCs canisters have no specific requirements for temperature control per TO-15 Compendium Sections 1.3, 2.3, and 9.2.8.1.

12.2.3 Permissible Holding Times

The *Technical Assistance Document for the National Air Toxics Trends Station Program, Revision 3,* dated October 2016 states the permissible holding times for the VOCs samples. The VOC Canister analysis should be within 30 days of end of collection or preparation according to TO-15 Compendium Sections 1.3, 2.3, and 9.2.8.1.

12.3 Delivery to Analytical Laboratory

Once the ethylene oxide samples are collected and prepared for delivery, the Site Operators send the samples to the ERG Lab via UPS, following protocol in applicable SOPs. For the GA EPD Lab, the Site Operators either deliver the samples or send the samples via UPS. When the samples are received at the analytical laboratory, the chain-of custody form is filled in to record the sample receipt by Laboratory personnel. The laboratory analyst maintains records of sample preparation, analysis, and data input and management. See the applicable laboratory SOPs and respective analytical Laboratory Attachment for details.

12.4 Make-up Samples

Due to the number of sites involved in this study, there will not be make-up ethylene oxide samples taken. The frequency and duration of the sampling should ensure sufficient ethylene oxide data is available.

13.0 Analytical Methods

The method stated here provides for chromatographic analyses at the analytical laboratory for samples collected at the GA AAMP ethylene oxide sites. The basic method used by ERG Lab is based on the Toxic Organic Compendia (TO-15) listed in Section 11.0. The sample media used to collect samples at ethylene oxide sites is a canister as shown in Table 1. In addition, the trip blank and laboratory blank must also be prepared. See Section 12.1.2 and the applicable laboratory SOPs for more detail. The instruments used for laboratory analysis of the samples collected at the GA AAMP's ethylene oxide sites are listed in Table 9.

Table 9. Instruments Used in the ERG Lab

Parameter	Instrument	Method
VOCs at ERG Lab	Agilent HP 8890/5977B with Entech 7200A interface Agilent HP 6890/5973 with Entech 7200A interface	GC/MS, TO-15
VOCs at GA EPD Lab	6890N/5973 with 7100A Entech Preconcentrator 6890N/5975 with 7200 Entech Preconcentrator 6890N/5977 with 7200 Entech Preconcentrator	GC/MS, TO-15

13.1 Sample Contamination Prevention

The analytical support component of the ethylene oxide sites has rigid requirements for preventing sample contamination. To minimize contamination, the sample media clean-up and sample preparation rooms are separate from the instrumentation rooms. In addition, heating and ventilation systems are checked by certified technicians. Hoods are also checked quarterly.

For the VOCs analytical method, the best prevention of contamination is not opening the canister in the laboratory. All post sampling Entech passive canisters that enter the analytical laboratory should have subambient pressure of 2 to 4 inHg (all other samplers i.e. the ATEC and Xonteck samplers should have an ending pressure of ≥+5 psig). Care must be taken when the canisters are under vacuum and stored in the laboratory. If there is a slight leak in the canister cap or valve, then laboratory air can enter into the canister and contaminate the run.

For any sample that was recovered at less than 1 inHg, the analytical laboratory will remeasure the vacuum with their more precise instrumentation. If the analytical laboratory determines that the canister has a vacuum using the laboratory's more precise, certified gauge, the sample will be analyzed for the ethylene oxide concentration in the canister. If the canister is at ambient pressure as measured by the laboratory instruments, the canister will be voided and not analyzed for ethylene oxide concentration.

The Picarro G2920 system will be operated by personnel from GA AAMP. GA AAMP is developing best practices for acceptance criteria for the continuous sampler. The contamination will be checked by verifying the linearity of the ethylene oxide response in the sampler. For more details on this procedure and acceptance criteria refer to the GA AAMP *Standard Operating Procedure for Operation of Picarro G2920 Continuous Ethylene Oxide Sampler.*

13.2 Temperature Preservation Requirements

There are no temperature requirements.

13.3 Permissible Holding Times

The permissible holding times for the ethylene oxide samples are detailed in the TO Compendia and the SOPs shown in Table 8.

14.0 Quality Control Requirements

Quality Control (QC) is a means of periodic evaluation of the acceptability of the data. That is, does the data meet certain criterion. This section contains descriptions of the various QC checks which GA AAMP performs in conjunction with collecting ethylene oxide data. For a description of the analytical laboratory's quality control requirements, see the respective Laboratory Attachments.

14.1 Instrument Checks

For this study, the passive ethylene oxide monitor kits were sent to ERG Lab for collection and analysis of a zero sample, as well as a leak check, at the beginning of the study. The certification data is stored on the GA AAMP's local network for reference by anyone in the GA AAMP. The samplers should be rechecked annually by GA AAMP personnel. The flow rate of the sampler should be calibrated annually and verified quarterly. The ATEC sampler was zero checked prior to this study as part of the NATTS Network requirements and is checked annually by the manufacturer. For any samplers that were not zero checked, if high values are suspected due to a bias in the data, a comparison between that sampler and the passive sampler may be done for qualitative purposes. Each sampler will be uniquely identified. For a description of ERG Lab's calibration requirements, see ERG's Laboratory Attachment, Section 13.0.

The initial canister pressure must be checked prior to sample collection by measurement of the canister vacuum with a pressure gauge or pressure transducer. If a built-in gauge on the sampling unit cannot be calibrated, a standalone gauge will be employed for this measurement. This initial pressure will be documented on the sample collection form. Canisters should show at least 28 inHg.

Once vacuum is verified, the canister is connected to the sampling unit and a leak check is performed. A leak check may be performed by quickly opening and closing the valve of the canister to generate a vacuum in the sampling unit. The vacuum/pressure gauge in the sampling unit will be observed for a minimum of 5 minutes to ensure that the vacuum does not change by more 1 inHg.

For the Picarro G2920 continuous ethylene oxide sampler at the South DeKalb site, GA AAMP is developing proper procedures for instrument checks. For more details on this procedure and acceptance criteria refer to the GA AAMP *Standard Operating Procedure for Operation of Picarro G2920 Continuous Ethylene Oxide Sampler*.

14.2 Precision Checks

One of GA AAMP's ethylene oxide samplers at each facility will be collocated with an additional sampler that will allow GA AAMP to make precision determinations. Collocated samplers operate monthly. There are two types of precision that will be determined for ethylene oxide data: collocated precision and replicate precision.

14.2.1 Precision Determination

Collocated precision evaluates the results of two monitors sampling side by side. The monitors separately operate at the same time and undergo the same sample collection, handling, and analysis procedures. In order to determine the precision, one compares results from the primary sampler concentration to the collocated sampler concentration by using the Relative Percent Difference noted below:

Equation 14.2.1: Relative Percent Difference (RPD) = $\left[\frac{ABS(Value_1 - Value_2)}{\frac{(Value_1 + Value_2)}{2}}\right] X\ 100\%$

The replicate precision is a measure of the reproducibility of the laboratory analyses. A replicate evaluation is performed on each batch by the analytical laboratory with results sent to GA AAMP. A replicate is simply a re-analysis of the same canister of sample and then comparing the results of the replicate analysis to the first analysis. The analytical laboratory will perform replicate analysis on 10% of samples. The percent RPD calculation for determining replicate precision is the same as the collocated calculation. Refer to the Laboratory Attachment for the applicable analytical laboratory for more details.

14.2.2 Precision Acceptance Criteria

Precision acceptance criteria are found in Section 7.2 of this QAPP.

14.2.3 Corrective Actions

Any non-conformances from the criteria specified in Section 14.2 above would be determined on a case-specific basis. In general, data validity for posting results on the GA EPD website purposes is a collective team effort and appropriate actions will be considered based on the circumstances. See the GA AAMP's *Standard Operating Procedure for Data Validation of Integrated Data* for further details. For a description of the analytical laboratory's corrective actions, see the applicable Laboratory Attachment of this document, Section 16.3 for ERG Lab, and Section 5 for GA EPD Lab.

14.3 Quality Assurance Audits

An in-house technical systems audit (TSA) will be performed on the GA AAMP's ethylene oxide sampling equipment once per location per study. This will include a review of the Site Operators' implementing SOPs, sampler maintenance, QC checks, and use of field logbooks and chain of custody forms. Audits are performed by the independent QA Unit in the GA AAMP. A summary report will be prepared by the Field Auditor. Please see the appropriate SOP shown in Table 8 for further details.

14.4 Trip Blanks

Trip blanks are collected for primary ethylene oxide samples once per month at the Sterigenics, (Cobb County) and Becton Dickinson (Covington) monitoring locations as well as any other community sampling locations added as part of this QAPP. Please see the GA AAMP's VOCs SOPs for details of the trip blanks. Trip blank acceptance criteria are found in Section 7.0 of this QAPP. Any non-conformances from the criteria specified in Section 7.0 would be determined on a case-specific basis. In general, data validity is a collective team effort and appropriate actions will be considered based on the circumstances. See the GA AAMP's *Standard Operating Procedure for Data Validation of Integrated Data* for further details.

15.0 Instrument/Equipment Testing, Inspection, and Maintenance Requirements

15.1 Maintenance

The GA AAMP sent each passive ethylene oxide sampler to the ERG Lab for an initial maintenance and leak check. This was conducted prior to beginning this study and should be conducted by GA AAMP annually, or as needed. For details of ERG's maintenance and leak check procedures, see ERG's Laboratory Attachment, Section 12.0. See the applicable Operations SOPs for maintenance of other ethylene oxide samplers.

15.2 Instrument Check-In

15.2.1 Receipt from Maintenance

When GA AAMP receives a VOCs monitor after it has undergone its maintenance, GA AAMP inspects the monitor for any damage during shipment. GA AAMP also turns on the unit and evaluates for proper operation.

15.2.2 Zero Bias Check

Please see the *Standard Operation Procedure for Operation of a Volatile Organic Compound (VOC) Canister Sampler for a National Air Toxics Trends Station* for further details of how to determine bias using ultra pure zero air or nitrogen.

15.3 New Equipment

When GA AAMP receives a new VOCs sampler, the same procedures will be used for instrument check-in as outlined in Section 15.2.

15.4 Spare Parts Inventory

The GA AAMP maintains appropriate spare parts for the VOCs samplers. Primarily, GA AAMP has at least two backup monitors which are rotated through the maintenance program so that the GA AAMP has ample supply in case of failure of a critical part in a sampler. In addition, spare stainless steel valves and sample lines are available as needed.

15.5 Site Maintenance

15.5.1 Cleaning of the Sample Inlets

For the ethylene oxide samplers, leak checks will be performed before sampling. The particulate filter should be replaced as indicated by the final pressure on the canister. Pressure/vacuum indicates a blockage. Vacuum pressure gauges are calibrated initially before use. Documentation of these checks is stored on the GA AAMP local network drive.

15.5.2 Quality Assurance Audits

An audit of the Site Operator's sample collection will be conducted at each of the five locations (Cobb County, Covington, South DeKalb, NR-285, General Coffee, and any locations added as part of this QAPP) during the study. This audit will review equipment, adherence to the SOP, field documentation, and chain of custody records to ensure compliance with the GA AAMP's QAPP. The results of the audits (and any identified corrective actions) are summarized in a report to the QA Unit Manager.

16.0 Instrument Checks Frequency

For the Entech CS 1200E Passive VOCs Canister Samplers at the sites near each facility and at the South DeKalb site, the ERG Lab performed a canister leak check and blank check on each canister prior to beginning this study. The initial canister pressure/vacuum is checked prior to each sampling. The initial pressure will be documented on the sample collection COC form. Canisters should show at least 28 inches Hg vacuum to conduct sampling. Once vacuum is verified, the canister is connected to the sampling unit and a leak check is performed. A leak check is performed in the field by quickly opening and closing the valve of the canister to generate a vacuum in the sampling unit. The vacuum/pressure gauge in the sampling unit will be observed for a minimum of 5 minutes to ensure that the vacuum does not change by more than 1 inHg. The vacuum/pressure gauges are calibrated initially before use, and on an as needed basis. Particulate filters are disposable and replaced if the sampling flow rate or final canister pressure/vacuum indicates a blockage or buildup of particulates.

For the Xonteck Model 910 (NR-285), Xonteck Model 911 (General Coffee) and ATEC 2200 (South DeKalb) VOCs Samplers, the GA AAMP uses a NIST traceable flow measurement device, a thermometer (if separate from flow meter), and barometer (if separate from flow meter). The calibration standards were sent to the supplier for NIST traceable certification prior to the study. An Excel spreadsheet is maintained by the GA AAMP to ensure that these standards are re-certified in a timely manner.

For the Picarro G2920 continuous sampler at the South DeKalb site, refer to the GA AAMP's *Standard Operating Procedure for Operation of Picarro G2920 Continuous Ethylene Oxide Sampler*.

For a description of ERG Lab's calibration requirements, see Laboratory Attachment, Section 13.0 of this document.

17.0 Inspection, Acceptance, Requirements for Supplies and Consumables

This section is not required for a Category II QAPP.

18.0 Non-Direct Measurements

GA AAMP relies on the data that is generated through field and laboratory operations. However, other significant data is obtained from sources outside the GA AAMP or from historical records. This section addresses data not obtained by direct measurement from the GA AAMP. Possible databases and types of data and information that might be used include:

- Chemical and Physical Properties Data
- Sampler Manufacturers' Operational Literature
- Geographic Location Data
- External Monitoring Databases
- Population Data from the US Census Bureau
- Traffic Data from Georgia Department of Transportation
- Wind Roses and other atmospheric data from other meteorological stations
- Emission Inventory from EPA

Any use of outside data will be quality controlled to the extent possible following the QA procedure outlined in this document and in applicable EPA guidance documents.

18.1 Chemical and Physical Properties Data

Physical and chemical properties data and conversion constants are often required in the processing of raw data into reporting units. This type of information that has not already been specified in the monitoring regulations will be obtained from the following nationally and internationally recognized sources. Other data sources may be used with approval of the Program Manager.

- National Institute of Standards and Technology (NIST)
- ISO, IUPAC, ANSI, and other widely-recognized national and international standards organizations
- EPA
- The current edition of certain standard handbooks may be used without prior approval of the QA Unit Manager

18.2 Sampler Operation and Manufacturers' Literature

Another important source of information needed for sampler operation is manufacturers' literature. Operations manuals and users' manuals frequently provide numerical information and equations pertaining to specific equipment. The GA AAMP’s personnel are cautioned that such information is sometimes in error, and appropriate cross-checks will be made to verify the reasonableness of information contained in manuals. Whenever possible, the Site Operators will compare physical and chemical constants in the operations’ manuals to those given in the sources listed above. If discrepancies are found, the applicable Operations Manager should be the one to determine the correct value by contacting the manufacturer. The following types of errors are commonly found in such manuals:

- Insufficient precision
- Outdated values for physical constants
- Typographical errors

- Incorrectly specified units
- Inconsistent values within a manual
- Use of different reference conditions than those called for in EPA guidance

18.3 Geographic Location

Another type of data that will commonly be used in conjunction with the GA AAMP ethylene oxide project is geographic information. The GA AAMP locates the site using global positioning system (GPS) that meets the requirements in Appendix A of EPA's National Geospatial Data Policy (August 2005). Google Earth is used as the primary means for locating and siting sampling locations.

18.4 External Monitoring Databases

Data from the GA AAMP/GA EPD website may be used in published reports with appropriate caution. Care must be taken in reviewing and using any data that contain flags or data qualifiers. If data is flagged, such data shall not be utilized unless it is clear that the data still meets critical QA/QC requirements. It is impossible to assure that a database such as the GA AAMP/GA EPD website is completely free from errors including outliers and biases, so caution and skepticism is called for in comparing GA AAMP data from other reporting agencies. Users should review available QA/QC information to assure that the external data are comparable with GA AAMP measurements and that the original data generator had an acceptable QA program in place.

19.0 Data Management

This section identifies the procedures that are followed to acquire, transmit, transform, reduce, analyze, store, and retrieve ambient air monitoring data by the field and office personnel of GA AAMP. The details of the processes and procedures in the ERG Lab are described in the ERG Lab's *Support for the EPA National Monitoring Programs (UATMP, NATTS, CSATAM, PAMS, and NMOC Support) QAPP,* and the ERG Laboratory Attachment of this document. The details of the processes and procedures in the GA EPD Lab are described in the GA EPD Lab *Quality Assurance Plan,* and the GA EPD Lab Attachment of this document.

GA Tech will perform data analysis on the continuous ethylene oxide data as measured by the Picarro and the results of the canister sampling (both passive and pressurized). This comparison will allow GA AAMP to evaluate the comparability of the various sampling methods. GA Tech will also look at the continuous ethylene oxide data and the wind data[6] to better understand the behavior of ethylene oxide concentration as the wind changes.

The following charts show the flow of ambient air data collection process for the data. Figure 26 shows the flow of the integrated data, and Figure 28 shows the flow of continuous data. The

[6] Refer to the GA AAMP *Quality Assurance Project Plan of the Ambient Air Monitoring Program for the Criteria Air Pollutants Network and National Core Multi-Pollutant Station* for more details on the GA AAMP meteorological data.

collection and management of the data involves four operational entities: GA AAMP (blue blocks), initial analytical lab (purple blocks), GA Tech (pink blocks), second analytical lab, if applicable, (orange blocks), and LSASD Lab, if applicable, (green blocks). The GA AAMP performs the field activities, and the analytical laboratory conducts the analytical operations. Figure 27 shows the timeline for the applicable analytical laboratory. For more description of each analytical laboratory's sample and data flow, see the respective Laboratory Attachment. In addition, please refer the applicable GA AAMP SOPs listed in Table 8 for more detail.

Figure 26. Flow Path of Integrated Ethylene Oxide Data

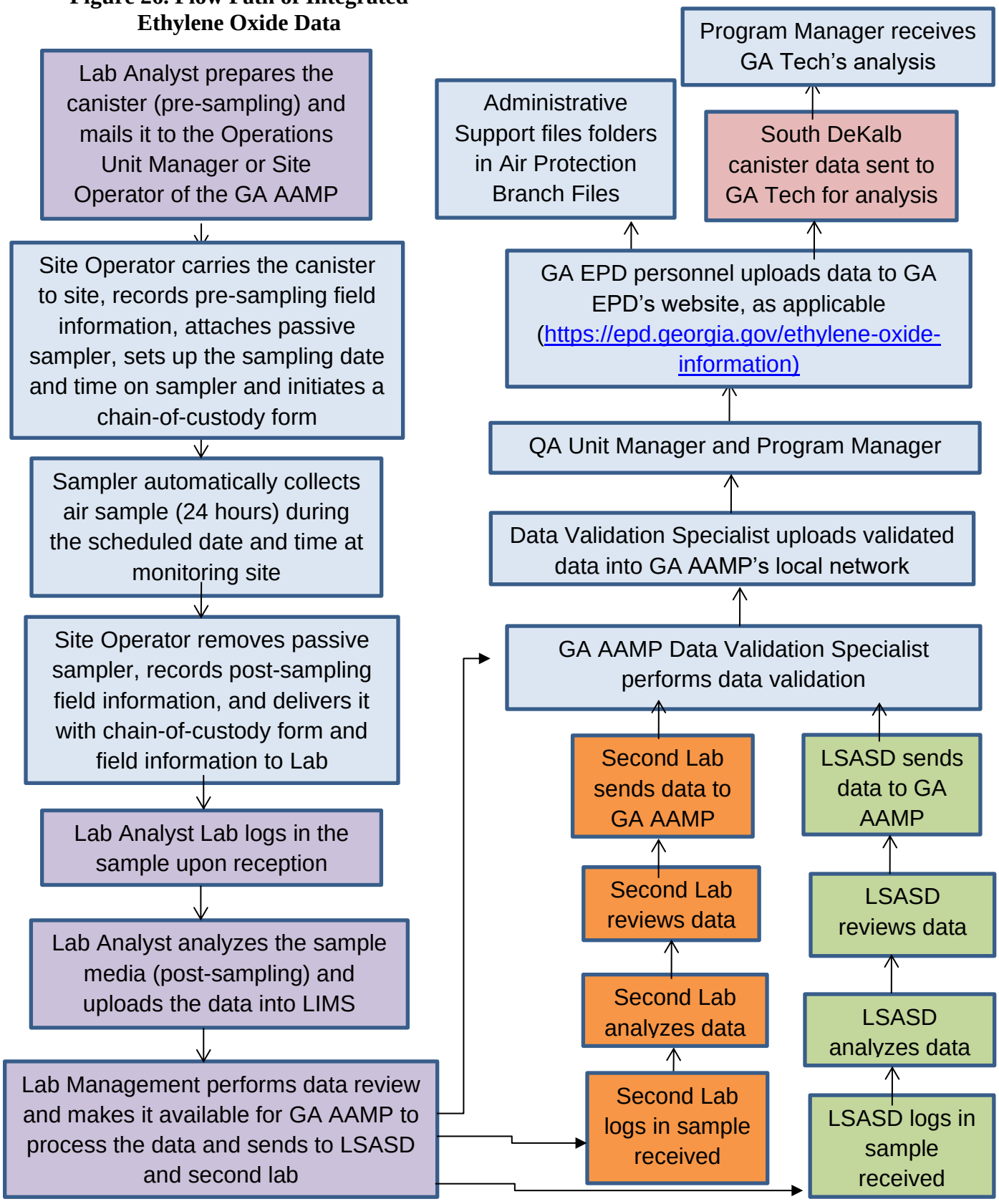


Figure 27. Applicable Analytical Laboratory Timeline for this QAPP

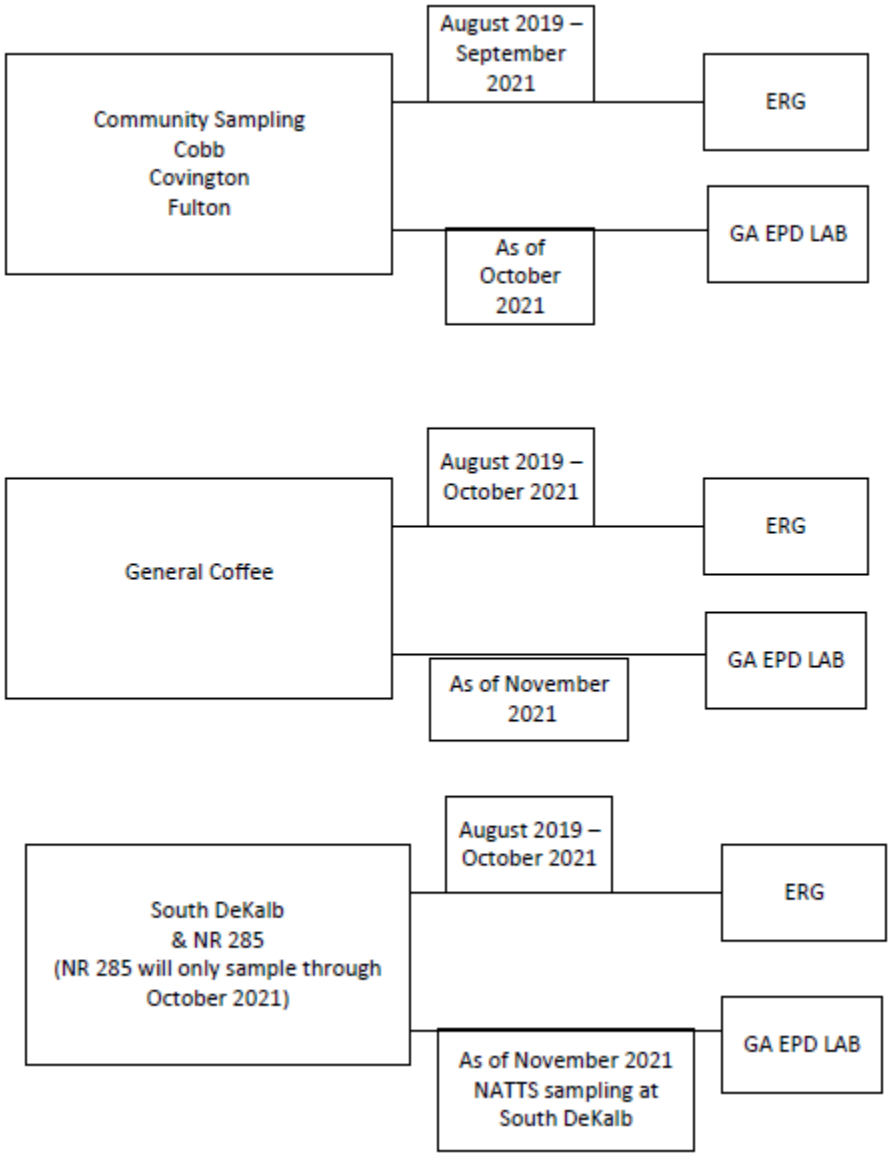
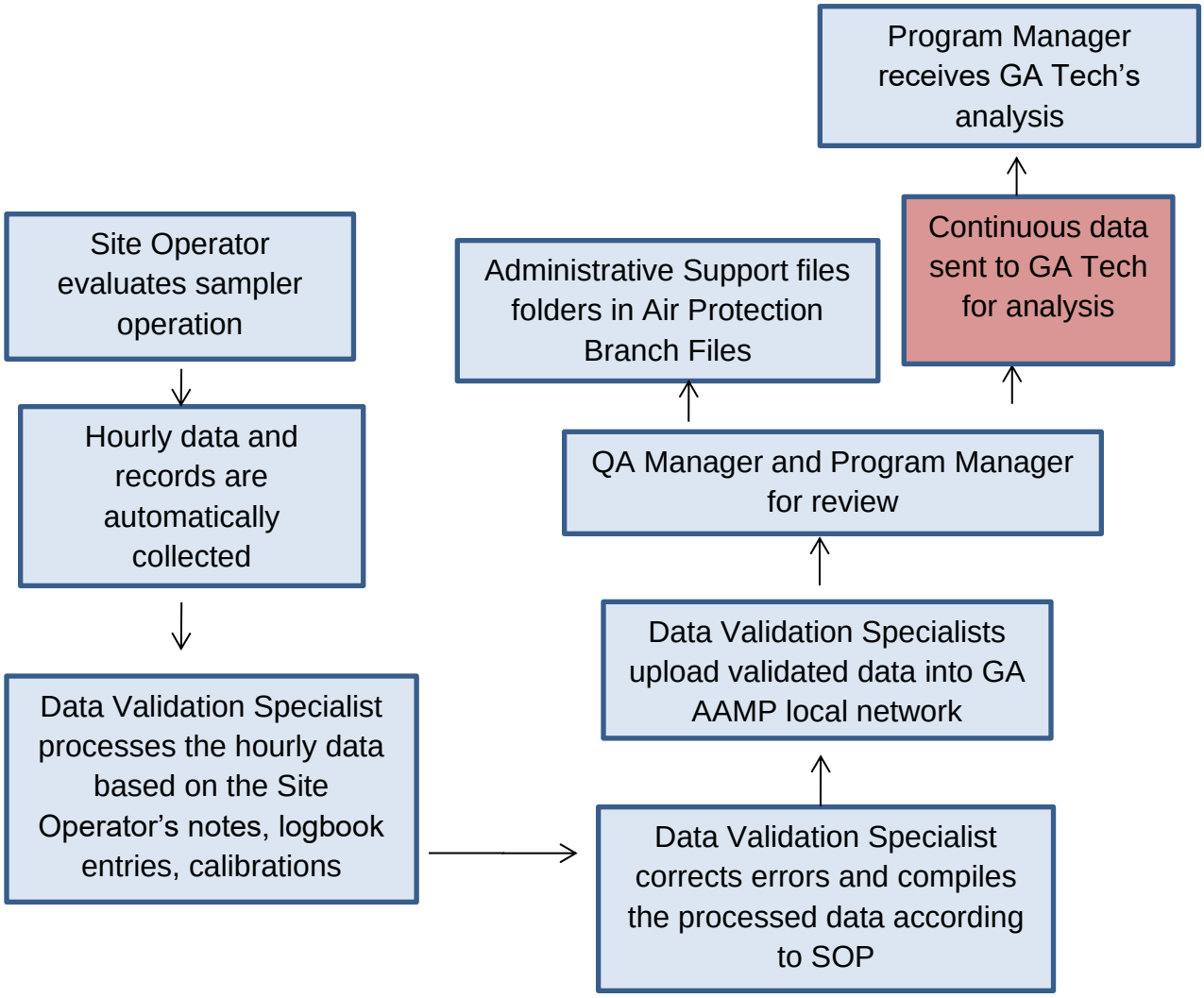


Figure 28. Flow Path of Continuous Ethylene Oxide Data



19.1 Data Collection and Recording

The GA AAMP uses EPA-approved ambient air samplers for collection of ethylene oxide data. The canisters are collected manually and sent to the analytical laboratory for analysis. The analysis results are saved in the lab's Laboratory Information Management System (LIMS) and sent to the GA AAMP where the data is shared on the GA AAMP's local network. The leak check data is collected by the Site Operator and recorded on the local shared network for the Data Validation Specialist to review the data. The audit information is collected by the Field Auditor and recorded on the local shared network for the Site Operator and Data Validation Specialist to review.

19.2 Data Transmittal

For the GA AAMP ethylene oxide data, all sampling media is sent back to the analytical laboratory for analysis. Once the laboratory analysis is complete, the data is sent to GA AAMP office via email in a 'read only' portable document format (pdf) and an Excel file.

19.3 Data Review and Reduction (Validation)

For ethylene oxide data, the analytical laboratory analyzes the samples and summarizes the data as well as the corresponding QA/QC information in the lab's LIMS system and sends a copy to the GA AAMP. These files are 'read only' to ensure the data are not modified or deleted. The Data Validation Specialist reviews the laboratory data from the analytical laboratory and the corresponding information on the chain-of-custody form and field data sheet. The holding time and delivery storage requirements for samples as listed in the SOPs shown in Table 8 must be followed; otherwise, the data will be invalidated. After completion of data review, the Data Validation Specialist prepares the final data associated with any applicable flags or null data codes into reportable data format and prepares a hard copy folder of the relevant information. For more detail, refer to the GA AAMP *Standard Operating Procedure for Data Validation and Verification of Integrated Data*.

19.4 Data Storage and Retrieval

The storage and retrieval of the air quality monitoring data are conducted through the archiving system of GA EPD. The raw data is stored in the GA AAMP's local network (electronic data), and central file room (paper copy) for a period of at least five years, unless any litigation, claim, negotiation, audit, or other action involving the records has been started before the expiration of the five-year period. If this happens, the records will be retained until completion of the action and resolution of all issues that arise from it, or until the end of the regular five-year period, whichever is later.

The GA AAMP's raw data records that are housed on local network are only available to the GA AAMP staff. The raw data is then validated as discussed in the next Sections and posted to the GA EPD's website (https://epd.georgia.gov/ethylene-oxide-information), as applicable.

20.0 Assessment and Response Actions

Assessments are used to measure the performance and effectiveness of the quality system. These assessments and evaluations ensure the implementation of this QAPP, and that the ethylene oxide data is being collected for its intended use.

An in-house technical systems audit (TSA) will be performed on the GA AAMP's ethylene oxide sampling equipment. This will include a review of the Site Operators' implementing SOPs, sampler maintenance, QC checks, and use of field logbooks and chain of custody forms. These audits are performed by Field Auditor of the independent QA Unit in the GA AAMP. A summary report will be prepared by the Field Auditor.

The field assessments are performed as described in Section 14.0. The data validation will be performed as described in Sections 22.0 and 23.0. Detailed procedures of the quality assessment items can be found in the corresponding GA AAMP's SOPs (Table 8).

The laboratory assessments are performed as described in the ERG Lab's QAPP and GA EPD Lab's *Quality Assurance Plan*. As EPA contract laboratory, the ERG Lab is subject to oversight by the EPA contract auditing group.

Although the GA AAMP produces quality data, the ethylene oxide data does not have to be certified by the GA AAMP Program Manager/Project Administrator, as the samplers are not SLAMS samplers.

21.0 Reports to Management

With each set of ethylene oxide samples, a report summarizing the information will be sent to the GA AAMP and GA EPD management. The report will include a summary of sampling and analysis. Communication is an integral part of operating the GA AAMP ethylene oxide sites, and the status of the sites is directly communicated with the Site Operators, Operations Unit Manager, QA Unit Manager, and Program Manager as necessary. In addition, each of the Unit Managers meets with the Program Manager at least on a monthly basis to discuss pertinent issues.

22.0 Data Validation and Usability

In order for the ethylene oxide data to be usable, the data undergoes validation procedures to determine that the data has met quality specifications. Validation, performed by Site Operators and Data Validation Specialists, can be defined as confirmation, through provision of objective evidence, that the particular requirements for a specific intended use are fulfilled. Site Operators and Data Validation Specialists evaluate the data to establish and confirm that the data was collected according to this QAPP and the SOP requirements. The Data Validation Specialist estimates the potential effect that any deviation from the QAPP and SOP may have on the usability of the associated data item, its contribution to the quality of the reduced and analyzed data, and its effect on decisions.

For GA AAMP, data validation is a process of reviewing and reducing raw data, with the use of objective evidence, to confirm requirements have been fulfilled and the intended use of the processed data for posting on the GA EPD's website (https://epd.georgia.gov/ethylene-oxide-information), as applicable. The data validation process is based on sound documentation and checks. It will use the weight of evidence approach using all the information received to determine the validity of the samples. It is a systematic approach to produce reportable data that is accurate and complete. The GA AAMP performs data validation as data is received from the ERG Lab. Following validation of the continuous and integrated data at South DeKalb, GA Tech will perform further data analysis. It involves the data handling personnel of all units in GA AAMP as shown in the organization chart (Figure 1 in Section 4). Refer to the GA AAMP's *Standard Operating Procedure for Data Validation of Integrated Data* for more information.

22.1 Sampling Design

The GA AAMP chose the ethylene oxide monitoring sites according to emission models, wind rose data, proximity to the facilities, and proximity to the interstate or rural area as described in Section 6.0 and Section 10.0.

22.2 Sample Collection Procedures

The ethylene oxide sample collection procedures for the GA AAMP are outlined in Section 12.0 of this QAPP. The field audits discussed in Section 14.0 verify that the applicable SOPs listed in Table 8 are being followed when collecting samples. Potentially unacceptable data points are routinely identified through the application of error flags/codes. Each flag/code is associated with a unique error shown in Table 10. These error flags/codes are routinely reviewed as part of the data validation process. This activity assists in identifying suspect data points that could invalidate the resulting averaging periods. Any deviation from the established sampling criteria must be documented in the appropriate logbook and on the field data sheet. Accurate and complete documentation of any sample collection deviations will assist in any subsequent investigations or evaluations. Investigations and evaluations may be necessary to determine whether the data obtained from a particular site may qualify as a baseline or indicator for other sites.

Table 10. Data Codes

Null Codes	Description
AA	Sample Pressure out of Limits
AB	Technician Unavailable
AC	Construction/Repairs in Area
AD	Shelter Storm Damage
AE	Shelter Temperature Outside Limits
AF	Scheduled but not Collected
AG	Sample Time out of Limits
AH	Sample Flow Rate out of Limits
AI	Insufficient Data (cannot calculate)
AJ	Filter Damage

AK	Filter Leak
AL	Voided by Operator
AM	Miscellaneous Void
AN	Machine Malfunction
AO	Bad Weather
AP	Vandalism
AQ	Collection Error
AR	Laboratory Error
AS	Poor Quality Assurance Results
AT	Calibration
AU	Monitoring Waived
AV	Power Failure
AW	Wildlife Damage
AX	Precision Check
AY	Q C Control Points (zero/span)
AZ	Q C Audit
BA	Maintenance/Routine Repairs
BB	Unable to Reach Site
BC	Multi-point Calibration
BD	Auto Calibration
BE	Building/Site Repair
BG	Missing ozone data not likely to exceed level of standard
BH	Interference/co-elution/misidentification
BI	Lost or damaged in transit
BJ	Operator Error
BK	Site computer/data logger down
BM	Accuracy check
BN	Sample Value Exceeds Media Limit
BR	Sample Value Below Acceptable Range
CS	Laboratory Calibration Standard
DA	Aberrant Data (Corrupt Files, Aberrant Chromatography, Spikes, Shifts)
DL	Detection Limit Analyses
FI	Filter Inspection Flag
MB	Method Blank (Analytical)
MC	Module End Cap Missing
SA	Storm Approaching
SC	Sampler Contamination
ST	Calibration Verification Standard
TC	Component Check & Retention Time Standard
TS	Holding Time Or Transport Temperature Is Out Of Specs.
XX	Experimental Data

Qualifier Codes	Description
1	Deviation from a CFR/Critical Criteria Requirement
2	Operational Deviation
3	Field Issue
4	Laboratory Issue
5	Outlier
6	QAPP Issue
7	Below Lowest Calibration Level
9	Negative value detected - zero reported
1V	Data reviewed and validated
CB	Values have been Blank Corrected
CC	Clean Canister Residue
CL	Surrogate Recoveries Outside Control Limits
DI	Sample was diluted for analysis
EH	Estimated; Exceeds Upper Range
FB	Field Blank Value Above Acceptable Limit
FX	Filter Integrity Issue
HT	Sample pick-up hold time exceeded
LB	Laboratory blank value above acceptable limit
LJ	Identification Of Analyte Is Acceptable; Reported Value Is An Estimate
LK	Analyte Identified; Reported Value May Be Biased High
LL	Analyte Identified; Reported Value May Be Biased Low
MD	Value less than MDL
MS	Value reported is 1/2 MDL substituted.
MX	Matrix Effect
ND	No Value Detected
NS	Influenced by nearby source
QX	Does not meet QC criteria
SQ	Values Between SQL and MDL
SS	Value substituted from secondary monitor
SX	Does Not Meet Siting Criteria
TB	Trip Blank Value Above Acceptable Limit
TT	Transport Temperature is Out of Specs.
V	Validated Value
VB	Value below normal; no reason to invalidate
W	Flow Rate Average out of Spec.
X	Filter Temperature Difference out of Spec.
Y	Elapsed Sample Time out of Spec.
Inform Code	Description
IA	African Dust
IB	Asian Dust
IC	Chem. Spills & Industrial Accidents

ID	Cleanup After a Major Disaster
IE	Demolition
IF	Fire – Canadian
IG	Fire - Mexico/Central America
IH	Fireworks
II	High Pollen Count
IJ	High Winds
IK	Infrequent Large Gatherings
IL	Other
IM	Prescribed Fire
IN	Seismic Activity
IO	Stratospheric Ozone Intrusion
IP	Structural Fire
IQ	Terrorist Act
IR	Unique Traffic Disruption
IS	Volcanic Eruptions
IT	Wildfire-U. S.
J	Construction

Null codes are used when the data is not usable and needs to be invalidated.

Quality Assurance ("QA") qualifier codes are input when there is an issue that may affect the data due to a procedural malfunction, or general quality assurance.

Informational qualifiers ("INFORM") are only for informational purposes.

22.3 Sample Handling

Pertinent deviations from established sample-handling protocols for each sample physically retrieved for monitoring sites and equipment must be recorded on the sample custody sheet assigned to each filter for collection and recorded in the applicable electronic database for all pollutants.

22.4 Analytical Procedures

The ethylene oxide data is validated and verified utilizing both manual and electronic methods. Specific criteria are utilized at the analytical laboratory with blanks, duplicates, replicates, and collocated samples to determine acceptable data, the minimum acceptable values, and other criteria that are indicative of valid qualifying data. The analytical laboratory can flag suspect data utilizing the list provided in Table 10.

22.5 Instrument Check Procedures

Refer to Section 16.0 for details regarding checking the sampling instruments. More information can be found in applicable Operations' and Data Validation SOPs found in Table 8.

22.6 Quality Control Procedures

Section 14.0 specifies the QC checks that are to be performed during sample collection, handling, and analysis. These include analyses of standards, blanks, spikes, and replicates, which provide indications of the quality of data being produced by specified components of the measurement process. For each specified QC procedure, the acceptance criteria and corrective action (and changes) should be specified. Data Validation Specialists should document the corrective actions that were taken, which samples were affected, and the potential effect of the actions on the validity of the data. More information regarding QC checks and corrective actions can be found in Section 14.0, as well as the applicable Operations' and Data Validation SOPs found in Table 8.

22.7 Data Reduction and Processing Procedures

As mentioned in the above sections, internal technical systems audits will be performed to ensure the data reduction and processing activities mentioned in the QAPP are being followed. Data will be reviewed and final concentrations will be validated by the Data Validation Specialist. The data will also be reviewed to ensure that associated flags or any other data qualifiers have been appropriately associated with the data and that appropriate corrective actions were taken. Upon completion of adjustments and/or corrective actions, the Data Validation Specialist uploads the final monitoring data, along with any applicable null codes, to the GA AAMP's local shared drive. Also, he/she notifies the Data Analysis Unit Manager, Operations Unit Manager, Site Operator, and Quality Assurance Unit Manager with the results of validation. The final values uploaded to the local shared drive should match the independent spreadsheet. Then the final ethylene oxide data will be uploaded to GA EPD's website (https://epd.georgia.gov/ethylene-oxide-information) by GA EPD personnel, as applicable.

23.0 Validation and Verification Methods

For GA AAMP, data validation is a process of reviewing and reducing raw data, with the use of objective evidence to confirm requirements have been fulfilled. Data verification is the process of independently (QA) checking the processed data, and verifying, with objective evidence, the validity and intended use of the processed data for upload to GA EPD's website (https://epd.georgia.gov/ethylene-oxide-information), as applicable. The data validation and verification process is based on sound documentation and valid Quality Control (QC) and Quality Assurance (QA) checks. It is a systematic approach to produce reportable data that is accurate and complete. GA AAMP performs data validation as the data is received from the ERG Lab. It involves the data handling personnel of all units in GA AAMP as shown in the organization chart (Figure 1 in Section 4). Refer to GA AAMP's *Standard Operating Procedure for Data Validation and Verification of Integrated Data* for more information.

The following outline shows steps involved in the data review. Data validation and verification are discussed in more detail below the outline.
Level 0 (Raw data review):

- Site Operator evaluates samples as they are collected and notes any anomalies observed with sample collection.

Level 1 (Data analyzed):

- Laboratory Analyst processes samples and notes any anomalies as samples are processed.

Level 2 (Data Validation):

- Data Validation Specialist reviews data from ERG Lab, field data sheets, COCs, etc., ensuring MQOs are met. Applies null data codes or qualifier codes, and prepares file for upload.

Level 3 (Data Verification):

- Data Verification Specialist ensures proper null data codes are applied, and ensures MQOs are met. Returns to Data Validation Specialist for upload to AQS for applicable sites. Data verified to ensure uploaded to AQS correctly.

23.1 Data Validation

The analytical laboratory analyzes the ethylene oxide samples and posts the data in a spreadsheet in their LIMS system. Once the laboratory analysis is complete, the data is sent to GA AAMP office via email in a 'read only' portable document format (pdf) and an Excel file. The continuous ethylene oxide data is polled directly from the analyzer and imported into AirVision for review. The Data Validation Specialist reviews the data, as well as the corresponding QA/QC information and the corresponding information on the chain-of-custody form and field data sheet. The MQOs for the ethylene oxide samples as listed in Table 4 must be followed, otherwise the data will be flagged or invalidated appropriately, according to Table 10. After completion of data review, a data folder is then generated by the Data Validation Specialist as data is received from the analytical laboratory for the next steps of data validation. Data will be reviewed to ensure that associated flags or any other data qualifiers have been appropriately associated with the data and that appropriate corrective actions were taken. Upon completion of adjustments and/or corrective actions, the Data Validation Specialist uploads the final monitoring data, along with any applicable null codes, to the GA AAMP's local shared drive and notifies the QA Unit Manager that the data is ready for his/her review. The final values uploaded to the local shared drive should match the independent spreadsheet. Also, the Data Validation Specialist notifies the Operations Unit Manager and Site Operator with the results of validation.

23.2 Data Verification and Upload

The QA Unit Manager receives the folder prepared by the Data Validation Specialist and verifies the information therein. He/she ensures proper qualifying data codes or null data codes have been applied, and ensures data is acceptable and complete. The QA Unit Manager makes appropriate notation of review, and comments if any corrections need to be made by the Data Validation Specialist. The QA Unit Manager submits the data to the Program Manager for final approval, and the data is then forwarded through GA EPD management for posting on the GA EPD website (https://epd.georgia.gov/ethylene-oxide-information), as applicable.

24.0 Reconciliation with User Requirements

A preliminary data review will be performed to uncover potential limitations to using the data, to reveal outliers, and generally to explore the basic structure of the data. The next step is to calculate basic summary statistics, generate graphical presentations of the data, and review these summary statistics and graphs to determine if representativeness, comparability, completeness, precision, bias, and sensitivity, were met. Representativeness can be assessed with site location information and is based on potential sources and select weather station information. Comparability is based on method measure of the level of confidence with which one data set can be compared to another. Completeness is measured by the amount of valid sample data obtained compared to what was expected. Precision is determined from replicate collocated analyses. Sensitivity is demonstrated through MDLs.

If the sampling design and statistical tests conducted during the final reporting process show results that meet acceptance criteria, it can be assumed that the network design and the uncertainty of the data are acceptable. Further use of the data will include characterizing concentrations in potentially affected nearby neighborhoods based on method sensitivity.

To determine if the GA AAMP will continue sampling ethylene oxide data, a qualitative analysis of the data will be assessed. In addition, the GA AAMP will ensure that the MQOs for data completeness and percent difference are met.

A summary of collected and analyzed data as part of this QAPP should be included in the final report to EPA.

Revision History

Versions of *Quality Assurance Project Plan for the Georgia Ambient Air Monitoring Program Ethylene Oxide*		
Revision 0	April 2021	Original version
Revision 1	June 2021	Added GA AAMP Changes to Monitoring Schedule Attachment
Revision 2	October 2021	Updated SOPs list; added additional analysis laboratory of GA EPD Lab; updated data quality objectives for continuous analyzer

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https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1025
https://www.epa.gov/national-air-toxics-assessment/2014-national-air-toxics-assessment
https://www.epa.gov/air-emissions-inventories/2014-national-emissions-inventory-nei-data

GA AAMP Additional Sampling Sites Attachment

Sterilization Services of Georgia (SSG) in Fulton County is not a source of ethylene oxide that was identified by the 2018 NATA; however, the Planning and Support Program of GA EPD conducted modeling and SSG was modeled to have emissions above Georgia's Acceptable Ambient Concentrations (AACs). Computer models were used to predict the concentrations of toxic air pollutants (TAPs) being analyzed using facility information provided by the source and other information developed by GA EPD staff. The modeling results were compared to the 15-min, 24-hour, and annual AACs. GA EPD's 15-min and 24-hour AACs are derived from Occupational Safety and Health Administration (OSHA) permissible exposure limits (PEL), OSHA Total Weight Average (TWA) PEL. GA EPD's annual AACs are derived from U.S. EPA's risk values which are found in EPA's Integrated Risk Information System (IRIS) Risk Based Air Concentration (RBAC) database. The impacts of facility-wide ethylene oxide emissions were evaluated according to the Georgia Air Toxics Guideline.

To determine the ambient monitoring sites near SSG in Fulton County, GA, the GA AAMP considered the modeled emission data which was generated by the Planning and Support Program of GA EPD. Dispersion models of the ethylene oxide emissions data from the facility were conducted to determine concentrations of ethylene oxide around the facility prior to the installation of additional emissions controls in January 2020. This model is shown in the following figures. The modeled values are shown in micrograms per cubic meter ($\mu g/m^3$) and identified nearby residential areas with ethylene oxide concentrations above the annual AAC. Due to the limited availability of acceptable locations which can be considered ambient air in the industrialized area surrounding SSG, the GA AAMP identified two acceptable sampling locations within approximately ¼ mile and ½ mile of the facility for the purposes of the ethylene oxide study. The sampling sites are both located in the primary downwind direction from SSG, and can also be used for spatial comparisons. These locations were selected due to areas of highest modeled concentrations and the identification of vulnerable populations in the vicinity of the facility. Both sampling locations are within or adjacent to a residential community. A third site has been identified for portions of this study.

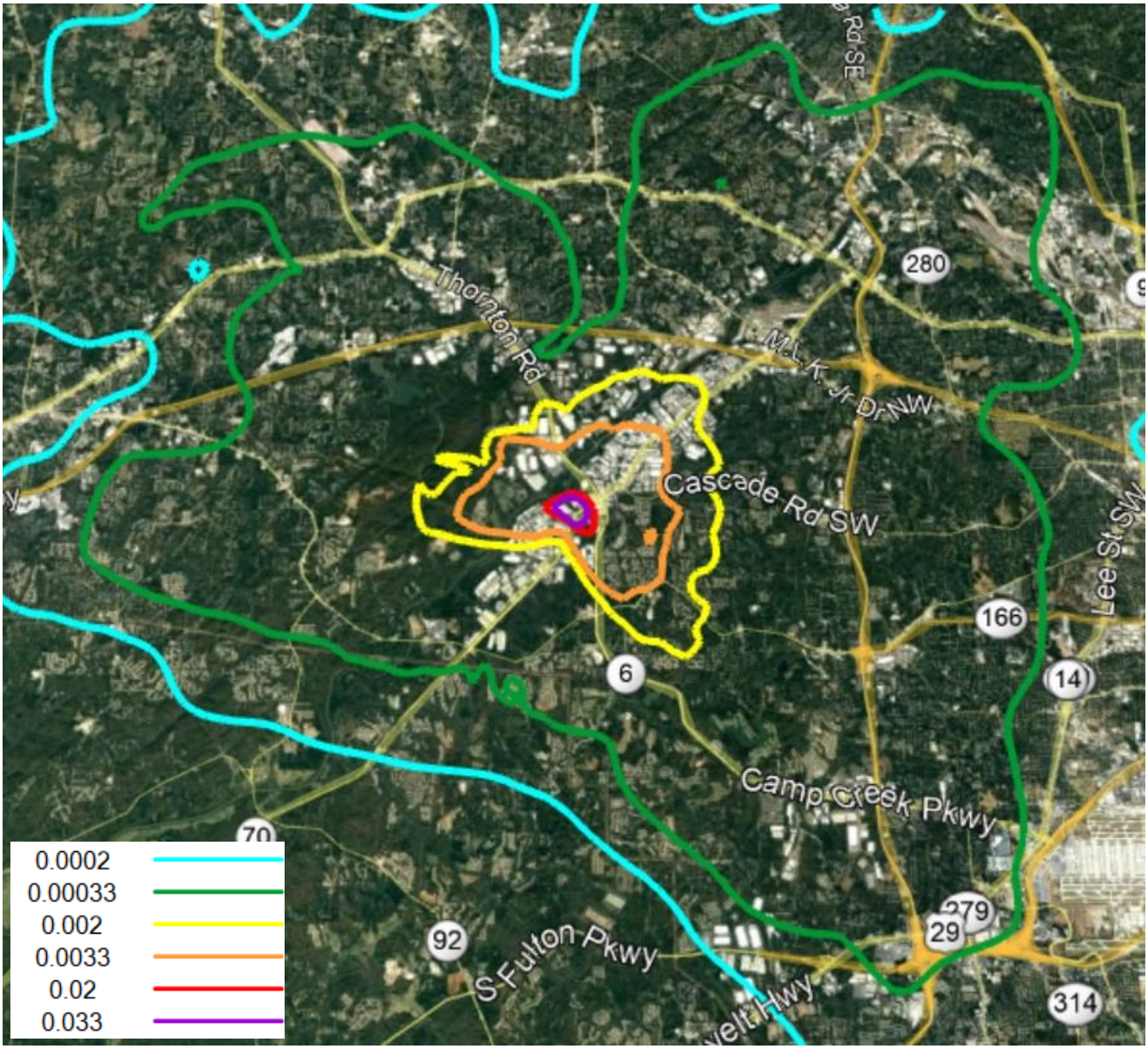

Figure 29. Contours of Modeled Annual Averaged Ground-level Concentrations Across the 5-Year Period (in μg/m³) for the Current Scenario Overlaid on a Google Earth Map

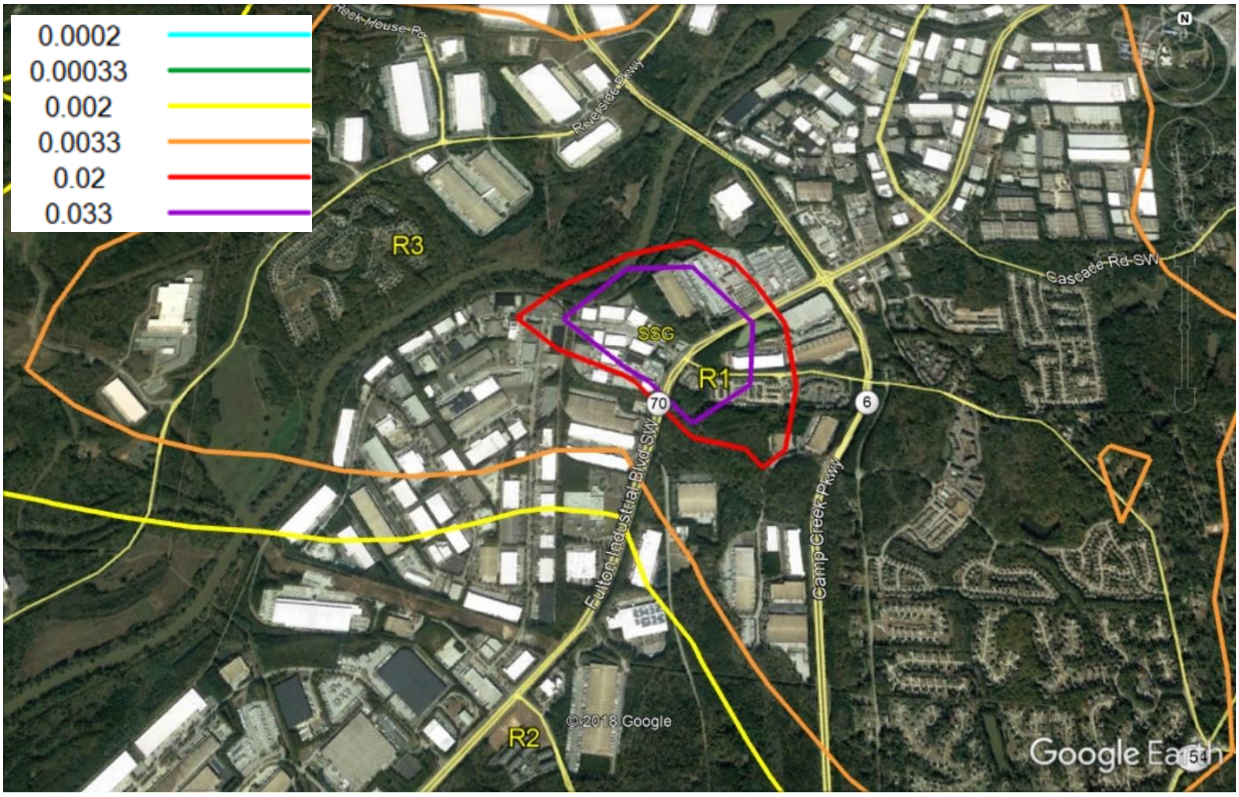

Figure 30. A Close-up of Figure 25

Wind rose data from the Atlanta Fulton County Airport near SSG was assessed by the GA AAMP, and primary and secondary wind patterns were determined. Distance from the Atlanta Fulton County Airport to SSG is shown in Figure 31 below. Wind rose data from the Atlanta Fulton County Airport is shown in Figure 32.

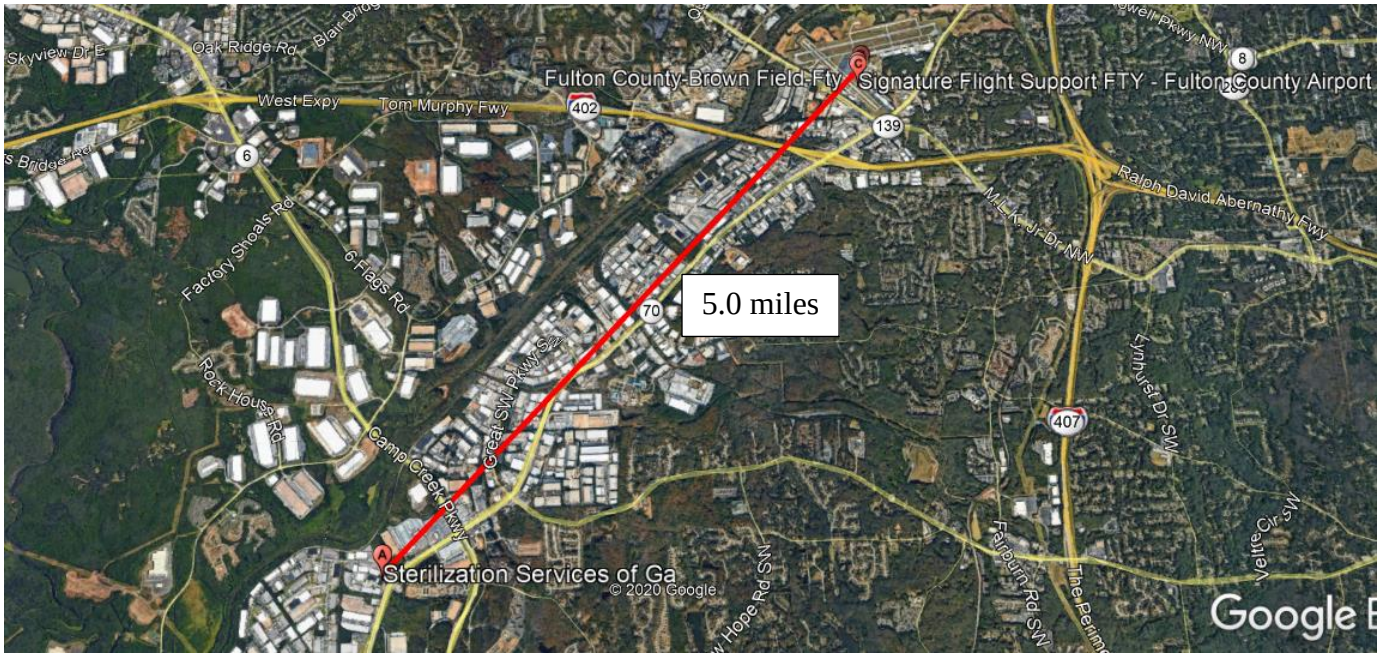

Figure 31. Distance from SSG to Atlanta Fulton County Airport

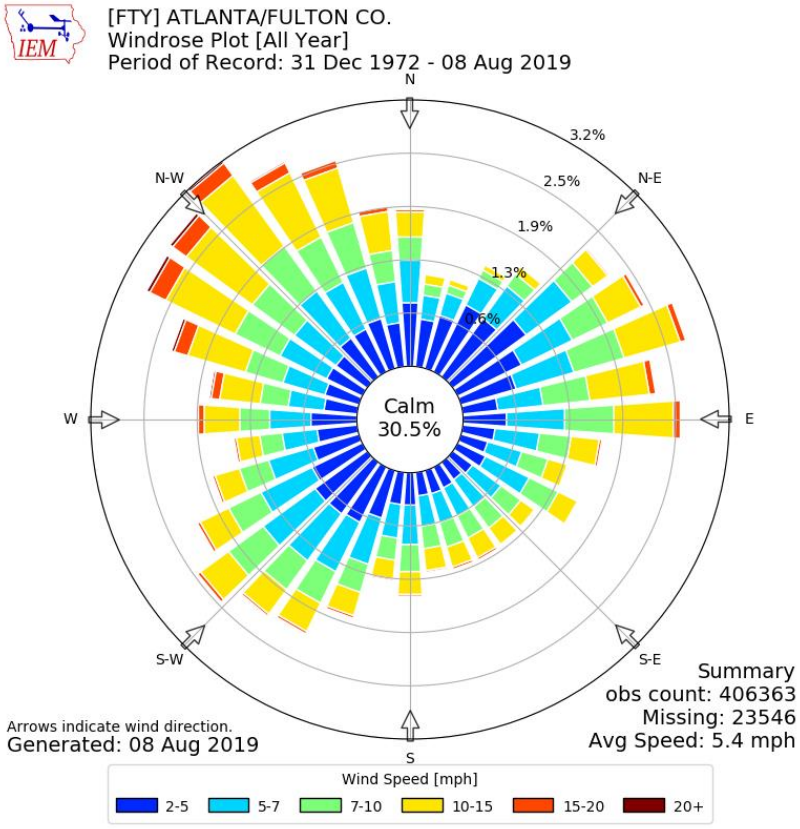

Figure 32. Annual Wind Rose Data at Atlanta Fulton County Airport, December 31, 1970-August 8, 2019

The GA AAMP began sampling near SSG on January 16, 2020. The sampling will follow the sampling schedule of once every six days as discussed for the other monitoring sites in Section 6.0 of this document. A collocated sample should be collected each month from the site nearest the residential community. Other than the number of sites used to characterize the ethylene oxide concentration around the facility, the quality assurance procedures described in this QAPP will be followed for the sampling in Fulton County. For the duration of the project, the sampling timeframe in Fulton County will be concurrent with the sampling timeframe for the Cobb County and Covington sites described in Section 6.0.

GA AAMP Changes to Monitoring Schedule Attachment

Beginning in June 2021, GA AAMP will reduce the sampling frequency to 1 in 12 days schedule for all of the ethylene oxide samplers except the NATTS South DeKalb site. The South DeKalb site will retain the 1 in 6 sampling schedule for the integrated sampling, and will continue the continuous hourly sampler. The comparisons for the sample collection methodology and laboratory analysis discussed in this QAPP will continue.

In addition, GA AAMP will begin reducing the number of sampling sites in each of the three areas (Cobb, Covington, and Fulton). Sampling at the site with the lowest average concentration from the course of this study will be discontinued in the summer of 2021. Thereafter, approximately one site each month will be discontinued from each area. The site to be discontinued each time will have the lowest average concentration of the remaining sites. In June 2021, the collocated sampling will be relocated to the site with highest average concentration measured during the course of this study to ensure that the collocated samples are continued through the last sampling site. In addition, the GA AAMP intends to continue collecting spatial samples each month for the remaining duration of the study to allow further understanding of the spatial variation of ethylene oxide.

ERG Laboratory Attachment

ERG Laboratory QAPP available upon request.

GA EPD Laboratory Attachment

In October 2021, the Georgia EPD Lab began analysis of the canisters collected in the communities of Cobb, Covington, and Fulton. The GA EPD Lab analyzes for ethylene oxide analysis under the *Quality Assurance Project Plan for Georgia Ambient Air Monitoring Program National Air Toxics Trends Station (NATTS), Revision 3, September 2021.*

Prior to this, the Eastern Research Group (ERG) Laboratory had been conducting the ethylene oxide analysis for all sites. ERG will perform the analysis of the ethylene oxide samples collected in October 2021 from GA AAMP's South DeKalb, Near Road 285, and General Coffee monitoring sites, as applicable for the sampling comparisons to evaluate emerging technologies for ethylene oxide.

In November 2021, all ethylene oxide analyses will be performed by the GA EPD Lab. The following information pertaining to the laboratory analysis of ethylene oxide is provided by the GA EPD Lab. As ethylene oxide is analyzed as part of the suite of compounds under the National Air Toxics Trends Site (NATTS), the laboratory attachment from the NATTS QAPP has been included in this document. The portions of the document relevant to ethylene oxide analysis have been included. The [Reserved] portions reflect information relevant to other compounds analyzed under this document in the NATTS QAPP.

Signature Page

Approvals and Concurrences for the GA AAMP NATTS QAPP Laboratory Attachment

This is to certify that we have reviewed the GA AAMP NATTS QAPP Laboratory Attachment and approve of its content.

Signature: Mark Tolbert _____ **Date:** 11/02/2021

Mark Tolbert, Laboratory Program Director

Signature: Jeffrey Moore _____ **Date:** 11/02/2021

Jeffrey Moore, Laboratory Program Director

Georgia Environmental Protection Laboratory (GAEPDLab)

NATTS Analysis Data Quality Objectives (DQOs)

Scope and Summary of NATTS Technical Assistance Document (TAD) Recommendations

This attachment to the Quality Assurance Project Plan for the Georgia Ambient Air Monitoring Program

National Air Toxics Trends Station (NATTS) further details the procedures, DQOs, and data flow for the GAEPDLab. A general sample receiving and logging in summary will be given, followed by several tables and explanations to clarify the GAEPDLab's role in analyzing and reporting data to GAAMP. Standard Operating Procedures (SOPs) have not been included due to the prohibitive size of the final document but are referenced and can be provided upon request.

1.0 Sample Receiving – SOP # 3-001 r4

All samples are submitted to our Sample Receiving Section. Samples for Air Toxics are received, unpacked, checked for temperature if appropriate (< 4℃ for several types of Air Toxics samples), compared to the Chain of Custody (COC), verified that all information on the COC is correct (and contact the collector if there is an issue), log the samples into our LIMS and distribute to the appropriate Laboratory for storage and prep/analysis. Examples of Chain of Custody forms are provided by the GAAMP. Sample receipt/log-in is detailed below:

NATTS SAMPLES LABORATORY LOGIN AND DISTRIBUTION

I. Samples Received at Laboratory

- ***a. Check for damage***
- ***b. Check preservation, if required***
- ***c. Verify CoC and enter physical information***
  - ***i. Temperature (if appropriate)***
  - ***ii. Date/Time Received***
  - ***iii. Name/initials of Receiving Lab Personnel***
- ***d. Enter into LIMS (LabWorks)***
- ***e. Label each sample with Laboratory ID***
- ***f. Adhere sample ID label on CoC***
- ***g. Distribute Sample to appropriate Laboratory***
  - ***i. [Reserved]***
  - ***ii. [Reserved]***
  - ***iii. [Reserved]***
  - ***iv. VOC canisters go to GC/MS Lab***

Each Laboratory will store, prepare and analyze samples according to the requirements in the appropriate method and/or current revision of the TAD.

2.0 Standard Operating Procedures (SOPs)

*All methods, tasks, data collection and report generation are detailed at the GAEPDLab with SOPs. The following Table (**Table 1**) lists the applicable SOPs for EPA NATTS Sample Analyses:*

Table 1

SOP ID	***Title***	***Revision***	***Date***
3-001	*Receiving Lab Log-in Procedures*	*4*	*12/4/2017*
TO15-7	*VOCs in Ambient Air by GC/MS TO-15*	*24*	*2/02/2018*
MDL-6	*Determination of MDLs*	*3*	*7/26/2017*
PAMS-7	*VOCs in Ambient Air by GC/FID PAMS*	*14*	*4/17/2017*
[Reserved]			
[Reserved]			
[Reserved]			

3.0 EPA Methods used for Sample Analyses

Table 2

Analyte Group	***Method***	***Date***	***Laboratory SOP ID***
[Reserved]			
[Reserved]			
Toxic (Volatile) Organic Compounds	*EPA Method TO-15*	*January 1999*	*TO15-7*
[Reserved]			
[Reserved]			

4.0 Summary of Quality Control Requirements

All Laboratory Analytical SOPs have a Summary of Calibration and QC Requirements for the analysis they represent. The following table (13.3 in the SOP) is an example from SOP TO15-7 for sample analysis by EPA Method TO-15:

Table 13.3 Summary of Calibration and QC Procedures for Method EPA TO-15

Method	***Applicable Parameter***	***QC Check***	***Minimum Frequency***	***Acceptance Criteria***	***Corrective Action***	***Flagging Criteria***
TO-15	*Volatile Organics*	*Six-point initial calibration for all analytes*	*Initial calibration prior to sample analysis*	*%RSD for all calibration analytes $\leq$ 30% with at most two exceptions up to a limit of 40%. If more than two compounds are above the 30% RSD limit in initial calibration curve then a linear fit is still allowed if the Coef of Det (R^2) $\geq$ 0.990.* *Note: Benzyl chloride may be calibrated by quadratic fit.*	*Correct problem then repeat initial calibration*	
		Calibration verification	*Daily, before sample analysis, every 24 hours of analysis time*	*%D for each target compound must be within ± 30%, if use linear fit curve concentration-ion should be in ±30% of true value. OK if fail high and not detected in batch. If necessary, Calibration Verification may be reanalyzed once to meet criteria.*	*Correct problem then repeat initial calibration*	

Table 13.3 Summary of Calibration and QC Procedures for Method EPA TO-15

Method	***Applicable Parameter***	***QC Check***	***Minimum Frequency***	***Acceptance Criteria***	***Corrective Action***	***Flagging Criteria***
		Initial Demonstration: *Demonstrate ability to generate acceptable accuracy and precision using four replicate analyzes of a QC check sample*	*Twice/year per analyst*	*QC acceptance criteria, Table 2*	*Recalculate results; locate and fix problem with system and then rerun demonstration for those analytes that did not meet criteria*	
		Check of mass spectral ion intensities using BFB	*Prior to initial calibration and calibration verification*	*Refer to criteria listed in the method description*	*Retune instrument and verify*	
TO-15	*Volatile Organics*	*Int Std QC for Blanks and Daily QC and Samples*	*Immediately after or during data acquisition of calibration check standard*	*Retention time ±0.33 minutes. Internal std area within ± 40% of initial calibration curve average area*	*Inspect mass spectrometry or GC for malfunctions; mandatory reanalysis of samples analyzed while system was malfunctioning*	
		Int Std QC for Initial Calibration Curve	*After curve is built*	*Retention time for each level <20 sec. of the curve average.* *Int. Std. area ±40 % curve average area.* *RRT ±0.06.*	*Recalculate, if still fails inspect instrument, rerun calibration curve.*	

Table 13.3 Summary of Calibration and QC Procedures for Method EPA TO-15

Method	***Applicable Parameter***	***QC Check***	***Minimum Frequency***	***Acceptance Criteria***	***Corrective Action***	***Flagging Criteria***
		Method Blank	*One per analytical batch*	*No analytes detected >0.2ppbv*	*Ensure no contamination then reanalyze method blank and all samples processed with the contaminated blank*	*Any detects are flagged per NATTS guidelines.* *Any target compound in the blank will also be flagged with LB in any sample in the batch.*
		LCS/LCSD for all analytes	*One LCS/LCSD per analytical batch*	*QC acceptance criteria* *Table 2*	*List batch QC sample in exceptions log with precision over 25 but %R passing for LCS if target compound is not detected in any samples of batch.*	
		Surrogate spike	*Every sample, spiked sample, standard, and method blank*	*Recovery must be from 80%-120%*	*Correct problem then reanalyze sample.*	
		MDL study *7 separate canisters are used or MDL spike results acquired thru the year.*	*Once per year*	*The calculated MDL must be within 10 times the MDL spike level.*	*Check calculation , redo MDL analysis and redo results, prepare higher or lower conc, as needed.*	

Table 13.3 Summary of Calibration and QC Procedures for Method EPA TO-15

Method	***Applicable Parameter***	***QC Check***	***Minimum Frequency***	***Acceptance Criteria***	***Corrective Action***	***Flagging Criteria***
		Estimated amount for analytes above the 6- pt calibration curve	*None*	*All analytes < 10ppbv.*	*Sample must be diluted and reanalyzed.*	*Apply "EH" to all analytes out of range that cannot be diluted.*
		Precision between sample and sample duplicate or replicate	*One per analytical batch*	*25RPD if amount detected over 0.25ppbv.*	*Noted in comment field and correction action logbook which analyte failed precision QC*	
		QC can for certifying cleaning batch	*One per cleaning batch*	*No analytes >0.2ppbv*	*Re-clean the entire canister cleaning batch or flag sampled canisters on final report if re-cleaning was not possible.*	*Flag final report for any detect >0.20 PPBV found in all canisters in cleaning batch with "CC" for clean canister residue*

All analytical SOPs have this summary table which provides a quick reference for the QC required by the referenced analytical method.

5.0 Laboratory Corrective Actions

The following is Section 9 from our Laboratory QA Manual which describes corrective actions laboratory wide and gives an example of a corrective action form:

9.0 CORRECTIVE ACTION

9.1 Introduction

Corrective Actions may be initiated by any member of the Laboratory Staff for any non-conformance situation concerning facilities or analytical systems. Corrective action will be initiated when any measurement system is determined to be out of control or for any other situation that may affect data quality. Routine analytical problems and corrections are identified by the analyst on the bench sheet or run log and do not require the initiation of formal corrective action. Additionally, if it is determined that analytical results are to be reported, even though quality control criteria has not been met, corrective action will be initiated to determine appropriate data comments for the final report.

9.2 Procedure

9.2.1 Initiation and Documentation

Corrective action is initiated according to the guidelines in section 9.3 and on form 9.1. Each event is assigned a log number according to the following format. The laboratory unit identification number followed by the date of initiation and sequential numbered event (laboratory number-mm/dd/yy-event number). The corrective action form (Form 9.1) is filled out and presented to the Laboratory Manager or Supervisor who approves or makes an appropriate recommendation for resolution. The QA Manager reviews a percentage of corrective actions for all Laboratories on an ongoing basis. When the QA Manager's approval will result in delays and possibly jeopardize sample holding times, the Laboratory Manager may proceed with analysis prior receiving approval.

9.2.2 Record Keeping

Corrective action forms are maintained in the correction action log in each laboratory. A copy of the corrective action for each specific event is attached to the raw data package by the analyst and remains a permanent part of the data package. The Laboratory Manager and Supervisors ensure any data comments recommended by the corrective action are entered into LIMS and reported with the final sample data. The final report contains the method specific comment followed by the corrective action log number. The log is divided in to two sections, current and active and completed and closed. As a corrective action is completed and closed, Manager moves the divider as appropriate to indicate the position of the oldest

open corrective action in a particular log. All forms are filed according to the event log number regardless of the completed and closed date.

9.2.3 Corrective Action Monitoring

Each Laboratory Manager and Supervisor monitors corrective action status on a weekly basis. The Laboratory QA Manager and Program Director monitor corrective actions involving the entire Laboratory.

9.3 Corrective Action Events

9.3.1 Corrective Action Criteria

Measurement system corrective actions are required any time method calibration or quality control criteria cannot be met. The criteria includes, but is not limited to, LCS recovery, LCSD precision, MS recovery, MSD precision, initial calibration verification, and surrogate recovery. Resolution may require red tagging of the instrument system and completion of instrument maintenance forms. Other issues, such as problems with analytical reagents and analyte standards for calibration and quality control applications are covered under this type of corrective action. The corrective action involves the identification of samples affected by the out of control situation and the appropriate data qualifier comments for the final report. The final report contains the method specific comment followed by the corrective action log number.

9.3.2 Documentation Revisions

Method documentation revisions or improvements of the QA Manual, SOP's, bench sheets, or run logs can be initiated with corrective action. This type of corrective action begins with the analyst after consultation with the Laboratory Manager. Resolution must be approved by the QA Manager.

9.3.3 Laboratory Facility

Laboratory facility corrective actions are initiated when a specific problem with the laboratory facility such as air conditioning, plumbing, or fume hood operation prevents normal operation of the Laboratory. These corrective actions are presented by a Laboratory Manager directly to the Program Director or QA Manager who will place a maintenance call to the property manager if unable to resolve the problem.

9.3.4 Proficiency Testing

Proficiency testing corrective action is initiated when the results of proficiency samples demonstrates a systematic problem with a measurement system. If sample results have been affected by the problem, project managers within EPD are notified of the data and the implications of the problem on reported sample data. This type of corrective action originates with the Laboratory QA Manager.

9.3.5 Internal Audits

Internal audit corrective action is initiated when an internal system or method audit identifies a data quality or procedural deficiency. Laboratory Supervisors, Managers or the QA Manager may conduct audits. Audits of analytical methods are conducted on an annual basis or more often as required by the QA Manager. When data quality deficiencies are identified, the QA Manager initiates a corrective action to identify the source and resolution of the deficiency. All samples affected by the deficiency are identified and the project manager notified of the samples. Laboratory Management will work with project managers to determine data usability of the affected samples.

9.3.6 Audits of Corrective Action Logs

Corrective action logs are reviewed for compliance with the procedures outlined in this section as part of annual method audits. Deficiencies, if any, are brought to the attention of the Laboratory Manager by technicians, analysts, or supervisors.

Georgia Dept. of Natural Resources **Form 9.1 Rev. 1**
Environmental Protection Division Laboratory

Corrective Action Form (Chemistry)

ID#: ____ - _____ - ____ **Batch:** _____ - _____ **QC Sample:** _____
Lab mmddyy Log# Test Code Batch# Sample ID

Initiated by (Initials - Date): _____ - _____

Check all that apply: ☐ LCS/LCSD Recovery ☐ LCSD Precision ☐ MS/MSD Recovery ☐ MSD Precision
☐ Method/Other Blank(s) ☐ Internal Standard ☐ Surrogate Recovery
☐ Calibration Criteria ☐ Calibration Verification ☐ Other

1a.) Description of Problem(s): ☐Attachments ☐Additional Info (Section 7)	1b.) Criteria: ☐NA
_____	_____
_____	_____
_____	_____

2.) Recommended Resolution(s): Check all that apply: ☐ Labworks Comments Required ☐ Attachments
☐ CCV/ICV Rerun Once ☐ High Bias, No Detects in Samples ☐ Recalibrate ☐ Matrix Interference
☐ Routine Maintenance – Rerun Affected Samples/QC ☐ Major Maintenance – Red Tag

_____
_____

3.) Laboratory Supervisor Approval to Proceed: ☐Additional Info (Section 7)
Comments: _____
_____
_____
Initials - Date: _____ - _____

4.) ☐ **Resolution Completed:** ☐Additional Info (Section 7)
Comments/Resolution Outcome: _____
_____
_____
_____
Analyst's Initials - Date _____ - _____ **Primary Supervisor's Initials – Date** _____ - _____

5.) Laboratory Manager Review:	6.) Quality Assurance Manager Review:
Initials - Date: _____ - _____	**Initials - Date:** _____ - _____
Comments: _____	**Comments:** _____
_____	_____

Georgia Dept. of Natural Resources **Form 9.1 Rev. 1**
Environmental Protection Division Laboratory

Corrective Action Form (Chemistry)

7.) Additional Information:

ID#: __ - _____ - _____

6.0 Laboratory Standards, Measurement and Traceability

All analyses and/or measurements within the Laboratory are detailed in each SOP. As noted above, each SOP has a summary table which provides a reference for the associated QC requirements for that method and procedure.

The following excerpt is Section 6 from the Laboratory QA Manual which describes how standards and other measuring devices are certified per US EPA requirements:

6.0 MEASUREMENT TRACEABILITY

6.1 Introduction

The EPD Laboratory has procedures in place to ensure measurement system accuracy and support equipment calibration. Measurement systems and equipment calibrations are verified accurate to established criteria and are traceable to national standards of measurement or reference materials. All verifications are ensured and documented before a measurement system or support equipment is utilized in the generation of analytical data.

6.2 Sample Preparation and Measurement System Calibration

6.2.1 Calibration Standards

Stock solutions or standard grade chemicals for calibration of a measurement system are obtained from commercial vendors under contract with the Laboratory. The EPD Laboratory requires that all stock solutions are certified traceable to national standards. Copies of certification statements or other documentation signifying traceability of the standard are maintained at the laboratory or on file with the vendor. Complete records of standard preparation are maintained in standard preparation logs in each laboratory. Standard reference numbers are recorded with the instrument generated printout of the calibration information. This procedure requires that all sample analysis is traceable to the calibration standards used to calibrate the measurement system.

6.2.2 Titrimetric Solutions

Titrimetric solutions are obtained from commercial vendors under contract with the Laboratory. The EPD Laboratory requires that titrimetric solutions are traceable to national standards. Copies of certification statements or other documentation signifying traceability of the standard are maintained at the laboratory or on file with the vendor.

6.2.3 Analytical Reagents

All analytical reagents utilized in the analysis of samples meet or exceed the method requirements for quality. Individual method SOPs document the specific requirement for analytical reagents. Certificates of analysis or purity are maintained at the Laboratory or are on file with the vendor. Sample preparation sheets, such as digestion or extraction logs,

record the analytical reagents and the manufacture's lot number of the reagents. Reagents and lot numbers are recorded on automated instrument generated printouts for analyses that do not require a preparation procedure.

6.2.4 Laboratory Deionized Water

The EPD Laboratory utilizes mixed bed ion exchange water system to prepare reagent grade water. The system is monitored for water quality on a daily basis with a resistance in-line meter. A resistance of greater than 10 megohms indicates an acceptable resistivity for Type I reagent water. When the resistance is less than 10 megohms the water continues to meet Type I requirements, but the initial deionizing tank is in need of replacement.

Additional polishing systems are located in individual Laboratories as required by analytical procedures. The purity of reagent water is monitored by the analysis of method blanks with all analyses. The result of method blank analysis is maintained with analytical batch data for each method.

6.3 Support Equipment

6.3.1 Balances

Analytical balances used in the generation of analytical data are certified annually by a vendor under contract with the Laboratory. Copies of certification documentation are maintained at the Laboratory. Several sets of ASTM Class 1 weights are located throughout the Laboratory and are used to monitor the accuracy of analytical balances on a daily basis, as required. Two weights are checked and recorded in the balance log each day the analytical balance is used. A full range of weights is checked quarterly. The individual sets of class "I" weights are routinely recertified every year.

6.3.2 Thermometers

Thermometers are utilized throughout the Laboratory in monitoring temperatures for sample receipt, storage and analytical processes. All liquid bearing thermometers are checked annually for a current certification or certified thermometers are purchased each year as required to maintain certification. The Laboratory has an NIST traceable thermometer for verifying the accuracy of in-house thermometers. The NIST traceable thermometer is returned to the vendor every three years for re-certification. Digital thermometers are verified quarterly by comparison with a NIST traceable thermometer. Infrared thermometers are checked daily against an ice water bath to ensure accuracy at 0˚C and verified every six months by comparison with a NIST traceable thermometer. Certified and traceable digital and infrared thermometers may be per purchased in lieu of in-house verification of existing units.

6.3.3 Laboratory Glassware

The use of appropriate glassware is essential to the production of quality analytical data. A certificate of accuracy is required for all volumetric glassware purchased from commercial suppliers. The EPD Laboratory utilizes Class A volumetric glassware for the preparation of calibration standards, reagents and in sample preparation where required by the method. Laboratory method SOPs specify the class of glassware required by the number of significant figures required for the volumetric measurement. Volumetric pipets or burets are required where the volume is designated to two decimal places as in 1.00 ml. Volumetric flasks are required where methods specify 100 ml or 1000 ml rather than 0.1 L or 1 L. Glassware washing procedures are documented in individual Laboratory SOPs.

7.0 Labeling Procedure for Standards, Reagents, Filters, Etc.

All standards, reagents, filters, etc. are labeled with date received, date opened and if not on the container, expiration date. If there is no expiration date available we will use a reasonable time before discarding the product (usually 1 year for powders and liquids). With the large number of and types of reagents the laboratory utilizes there are specifications set for each standard or reagent, either by consultation with the vendor or by experience. Regardless, all of these "consumables" are given set dates for disposal if appropriate.

8.0 Data Flow in the Laboratory

The following is section 15 of our Laboratory QA Manual. It gives a detailed description of how data is reviewed from analysis until reporting for all data in the Laboratory. Our Laboratory analyzes samples for several major State Programs (Drinking Water, Water Quality, Wastewater, Hazardous Wastes and of course Air). Because of this, we review results of analyses for all data in a similar manner with any differences dictated by methods or other documents (such as the NATTS TAD) noted by the SOP during the reviews. For this reason it is important to include all the facets of review that are involved. The Microbiological Reviews have been removed because they are not pertinent to this document.

Section 15 of the GA EPD QA Manual:

15.0 SAMPLE AND DATA VALIDATION

15.1 Introduction

The EPD Laboratory has individual Laboratory procedures to validate analytical data produced within each Laboratory. The procedures establish specific requirements for the

review and validation of analytical data at the analyst, supervisor, manager and quality assurance staff levels. All data is fully reviewed and validated prior to reporting. The validation of each sample is recorded in the LIMS.

15.2 Staff Responsibility

Laboratory Program Director- *Ensures data validation procedures are performed as required by the Quality System. Reviews internal audit results for compliance with data validation procedures. Initiates administrative corrective action when data reported contains errors from insufficient validation reviews. Conducts data reviews on individual projects when required.*

QA Manager- *Responsible for reviewing and approving individual Laboratory data review, data verification and data validation procedures. Establishes Quality System requirements for data validation of data quality objectives. Reviews corrective action logs in individual Laboratories to ensure data discrepancies are correctly logged and commented on final data reports. Reviews all QC Batch reports submitted to ensure data meets Laboratory data quality objectives and that there is agreement between QC Batch reports and the corrective action logs.*

Laboratory Managers- *Develops individual Laboratory procedures for data validation and assigns data validation responsibilities to staff members. Establishes and requires adherence to method specific data quality objectives as required by each method and the EPD Laboratory Quality System. Sets control limits in LIMS for data quality objectives. Conducts reviews of Laboratory generated data to ensure sufficient data validation steps are in place to monitor measurement system performance. Approves Scientist and Supervisor initiated corrective actions. Conducts sufficient additional reviews of analytical data packages to ensure overall data quality.*

Laboratory Supervisors- *Reviews all analytical data packages completed by staff Scientists in respective Laboratory. Ensures data quality objectives requirements are complete and documented for each analytical data package. Evaluates data package for technical merit, adherence with specific method requirements and compliance with Laboratory data quality objectives. Ensures all calculations required to produce final sample results are correct. Verifies that LIMS entries are accurate and complete. Reviews and approves corrective actions initiated by staff Scientists.*

Laboratory Scientists- *Evaluates each data package for technical merit, adherence with specific method requirements and compliance with Laboratory data quality objectives. Ensures all documentation for the analytical batch is complete and accurate. Initiates corrective action for data discrepancies requiring final report to be commented. Instrumentation or measurement system response is evaluated for the influence of matrix introduced interference that could affect the accuracy of the reported sample result.*

15.3 General Laboratory Procedures

15.3.1 Chemistry/Protozoan Laboratories

Specific and detailed data validation procedures are documented in the individual Laboratory Data Validation SOP. General summaries are presented below.

15.3.1.1 Laboratory Scientist evaluates the following:

- *Data package for technical merit to ensure adherence to specific method requirements and compliance with Laboratory Data Quality Objectives.*
- *Evaluates the instrumentation for the influence of matrix introduced interference that could affect the accuracy and/or precision of the reported sample result.*
- *Ensures documentation for the analytical batch is complete and accurate.*
- *Initiates corrective action for data discrepancies that require the final result to be reported.*
- *Enters data into LIMS after Laboratory Supervisor review.*

15.3.1.2 Laboratory Supervisor evaluates the following:

- *Reviews the data package to ensure adherence to specific method requirements and compliance with Laboratory Data Quality Objectives.*
- *Ensures all calculations required to produce final sample result are correct.*
- *Reviews and approves corrective actions and comments associated with the data package.*

15.3.1.3 Laboratory Manager performs the following:

- *Prints reports and conducts final data review at the project level.*
- *Reviews project data with the Laboratory Director and QA Manager, where required.*

15.3.2 [Reserved]

15.3.2.1 [Reserved]

15.3.2.2 [Reserved]

15.3.2.3 Laboratory Scientist and Supervisor review of sample analysis data.

- *Ensures method performance criteria are met.*
- *Verify method performance criteria are recorded in LIMS accurately.*
- *Initiates Corrective Action where data quality objectives are not met and insure sample comments are entered into LIMS.*

- *Review sample calculations for accuracy.*

15.3.2.4 Laboratory Manager

- *Review final reported data.*
- *Prepare Quality Assurance and Quality Control report for sample batches.*
- *Final validation of reported result*

15.3.4 Quality Assurance

- *The QA Manager reviews all QC Batch reports for each batch of samples analyzed. Corrective actions are reviewed for data quality objectives not meeting established Laboratory control limits.*

15.3.5 Sample Receipt

- *Verifies sample shipment documentation.*
- *Ensures sample shipment packages meet regulatory and method collection and shipment requirements, such as bottle type and preservation.*
- *Ensures that notices of sample receipt discrepancies are recorded and that sample collectors are notified in writing.*
- *Verifies that sample receipt discrepancies are recorded in LIMS, ensuring final report is commented*

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