QUALITY ASSURANCE PROJECT PLAN

Ethylene Oxide Monitoring Study

December 2021
Revision 0

West Virginia Department of Environmental Protection
Division of Air Quality
601 57th Street, SE,
Charleston, WV 25304
304-926-0499

This page intentionally left blank

Acronyms and Abbreviations

AD – Assistant Director
ADQ - Audit of Data Quality
AQS - Air Quality System (EPA's Air database)
COC – Chain of Custody
DAQ – Division of Air Quality
DQA - Data Quality Assessment
DQI - Data Quality Indicators
DQO - Data Quality Objective
EDO - Environmental Data Operation
EPA - Environmental Protection Agency
ERG – Environmental Resource Group
ERS – Environmental Resource Specialist
ERPM – Environmental Resource Program Manager
EtO – Ethylene Oxide
FSP – Field Sampling Plan
MDL – Method Detection Limit
MQAG - Monitoring and Quality Assurance Group
MQO - Measurement Quality Objective
OAQPS - Office of Air Quality Planning and Standards
QAPP - Quality Assurance Project Plan
QA/QC - Quality Assurance/Quality Control
QMP – Quality Management Plan
SOP - Standard Operating Procedure
WVDEP – West Virginia Department of Environmental Protection

This page intentionally left blank

1.0 PROJECT PLAN IDENTIFICATION AND APPROVAL

Quality Assurance Plan for the Ethylene Oxide Monitoring Study, Revision 0

The attached QAPP is hereby recommended for approval and commits the *West Virginia Department of Environmental Protection Division of Air Quality to follow the elements described within.*

West Virginia Department of Environmental Protection – Division of Air Quality

Signature: Renu M. Chakrabarty Digitally signed by: Renu M. Chakrabarty DN: CN = Renu M. Chakrabarty email = renu.m.chakrabarty@wv.gov C = US O = WV Department of Environmental Protection OU = WVDEP Date: 2021.12.14 12:52:20 -05'00' Date: _____
Renu M. Chakrabarty- Assistant Director

Signature: Mark Drake Digitally signed by: Mark Drake DN: CN = Mark Drake email = s.mark.drake@wv.gov C = US O = WV DEP OU = Air Monitoring Date: 2021.12.14 14:01:20 -05'00' Date: _____
S. Mark Drake- Environmental Resources Program Manager

Signature: Jason Thomas Digitally signed by Jason Thomas Date: 2021.12.14 13:04:31 -05'00' Date: _____
Jason Thomas – Chemist 3 – QA Assessor

Signature: Keith M Foreman Digitally signed by: Keith M Foreman DN: CN = Keith M Foreman email = keith.m.foreman@wv.gov C = US OU = DAQ Date: 2021.12.14 12:47:01 -05'00' Date: _____
Keith Foreman – Micro Computer Support Specialist

EPA Region 3 Air and Radiation Division

Signature: ALICE CHOW Digitally signed by ALICE CHOW Date: 2021.12.15 09:57:33 -05'00' Date: _____
Alice H. Chow, Chief – Air Quality Analysis Branch

Signature: VERENA JOERGER Digitally signed by VERENA JOERGER Date: 2021.12.14 14:32:52 -05'00' Date: _____
Verena Joerger - Quality Assurance Officer – Air Quality Analysis Branch

Signature: HOWARD SCHMIDT Digitally signed by HOWARD SCHMIDT Date: 2021.12.15 09:25:00 -05'00' Date: _____
Howard Schmidt - Technical Lead – Air Quality Analysis Branch

Signature: AMANDA MCCULLOUGH Digitally signed by AMANDA MCCULLOUGH Date: 2021.12.15 09:46:51 -05'00' Date: _____
AJ McCullough - Grants Manager

This page intentionally left blank

2.0 TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

This page intentionally left blank

3.0 DISTRIBUTION LIST

An electronic copy of this document shall be distributed to the individuals in Table 3-0. The document is also available on the DAQ secured network drive.

Table 3.0: Distribution List

Charleston Office
Main Phone Number: 304-926-0499

Name	Position	Email	Ext.
Renu M. Chakrabarty	Assistant Director	Renu.M.Chakrabarty@wv.gov	41249
S. Mark Drake	ERPM	S.Mark.Drake@wv.gov	41254
Tyler Fewell	ERS 1	Tyler.Fewell@wv.gov	41259
Michael Egnor	AT Coordinator	Michale.Egnor@WV.gov	41255
Jason Thomas	Chemist 3	Jason.Thomas@wv.gov	4327*
Keith Foreman	MCSSS2	Keith.M.Foreman@wv.gov	41260

* Guthrie Lab Main: 304-558-4323

EPA Region 3
Area Code: 215

Alice H. Chow	Chief, AQ Analysis Branch	Chow.Alice@Epa.gov	814-2144
Verena Joerger	QA Officer	Joerger.Verena@Epa.gov	814-2218
Howard Schmidt	Technical Lead	Schmidt.Howard@Epa.gov	814-2133
AJ McCullough	Grants Manager	McCullough.Amanda@Epa.gov	814-2093

This document may be distributed to other personnel and site operators beyond this list.

4.0 PROJECT/TASK ORGANIZATION

The Ethylene Oxide Monitoring Study (EtO Study) is managed and implemented by the West Virginia Department of Environmental Protection - Division of Air Quality (DAQ). DAQ will conduct the ambient sampling described in this project and the laboratory sample analysis will be conducted by Eastern Research Group Laboratory (ERG). EPA Region 3 will provide funding and guidance for the project.

4.1 Office of Air Quality Planning and Standards (OAQPS)

OAQPS is the organization charged under the authority of the Clean Air Act (CAA) to protect and enhance the quality of the nation's air resources.

Within the OAQPS Emissions Monitoring and Analysis Division, the Monitoring and Quality Assurance Group (MQAG) is responsible for the oversight of the Ambient Air Quality Monitoring Network. MQAG has the following responsibilities:

- Ensuring that air pollution measurements methods and procedures are adequate to meet program objectives and the resulting data are of satisfactory quality;
- Evaluating (technical systems audits and management systems reviews) the performance of organizations making air pollution measurements of importance to the regulatory process;
- Implementing satisfactory quality assurance programs related to EPA's Ambient Air Quality Monitoring Network, including air toxics monitoring;
- Ensuring that guidance pertaining to the quality assurance aspects of the Ambient Air Program, and air toxics monitoring are written and revised as necessary;
- Ensuring that EPA contract laboratories have satisfactory quality assurance programs in place;
- Rendering technical assistance to the EPA Regional Offices and air pollution monitoring community;

4.2 EPA Region III Office

EPA Regional Offices have been developed to address environmental issues related to the states within their jurisdiction and to administer and oversee regulatory and congressionally mandated programs. The major quality assurance (QA) responsibilities of EPA's Region III Office, regarding the Ambient Air Quality Program, are the coordination of QA matters at the Regional levels with the State and local agencies. This is accomplished by the designation of

EPA Regional Project Officers who are responsible for the technical aspects of the program including:

- Reviewing QAPPs by Regional QA Officers who are delegated the authority by the Regional Administrator to review and approve QAPPs for the Agency;
- Evaluating quality system performance, through technical systems audits, performance evaluations and network reviews whose frequency is addressed in the Code of Federal Regulations and Section 20 of this QAPP;
- Acting as a liaison by making available the technical and QA information developed by EPA Headquarters and the Region to the State and local agencies and making EPA Headquarters aware of the unmet QA needs of the State and local agencies.

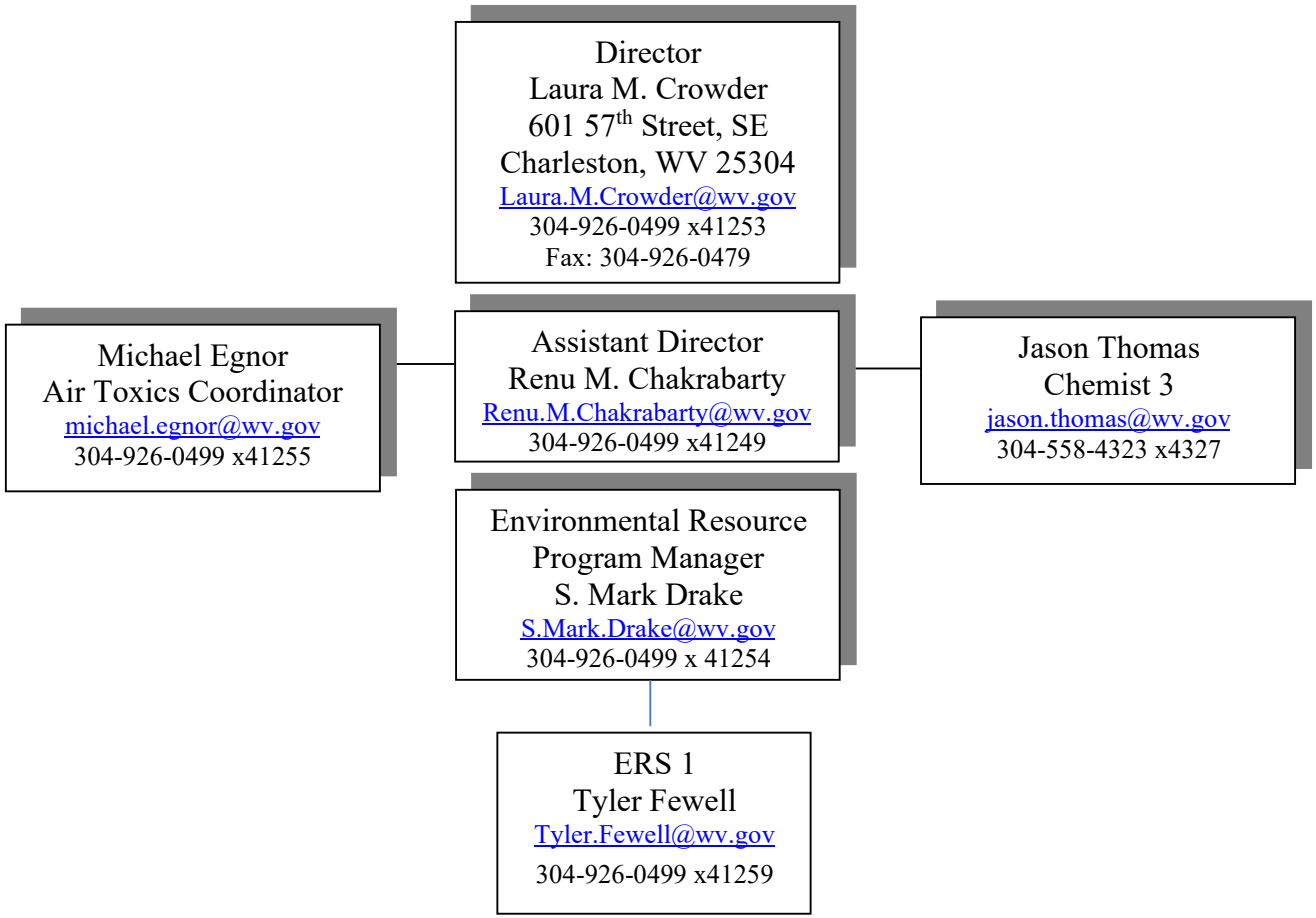
The DAQ will direct all technical and QA questions regarding the EtO Study to Region III.

4.3 West Virginia Department of Environmental Protection, Division of Air Quality

The major responsibility of State agencies is the implementation of a satisfactory monitoring program, which includes the implementation of an appropriate QA program. It is the responsibility of State agencies to implement QA programs in all phases of the environmental data operation (EDO), including field work, internal laboratories and any external consultants and contractor laboratories which they may use to obtain data. An EDO is defined as work performed to obtain, use, or report information pertaining to environmental processes or conditions.

The field operations and data analysis for the EtO Study is performed by the Division of Air Quality (DAQ). Figure 4.0 represents the organizational structure of the DAQ Air Monitoring Section relative to the EtO Study, including specific job titles and contact information.

Figure 4.0: West Virginia Department of Environmental Protection Division of Air Quality – EtO Study Organization Chart



4.3.1 Director of the Division of Air Quality

The Director has overall responsibility for managing the DAQ. The responsibility for assuring data quality rests with management. Major responsibilities of the Director include:

- Approving the budget and planning processes;
- Assuring that the Division develops and maintains monitoring sites;
- Assuring that the Division develops and maintains a current Quality Assurance Project Plan (QAPP);
- Maintaining an active line of communication with the Assistant Directors;
- The Director delegates the responsibility of QA/QC development, implementation and oversight to the Assistant Director, Air Monitoring Section.

4.3.2 Assistant Director

The Assistant Director (AD) is the delegated manager of EtO Study which includes applicable QA/QC activities. Responsibilities include:

- Develop the EtO Study Field Sampling Plan (FSP);
- Communicating with EPA and ERG personnel on issues related to EtO sampling, laboratory analysis and QA activities;
- Understanding applicable EPA monitoring and QA regulations and guidance and ensuring subordinates understand and follow these regulations and guidance;
- Understanding Department QA policy and ensuring subordinates understand and follow the policy;
- Understanding, approving, and ensuring adherence to the EtO Study QAPP and Standard Operating Procedure (SOP);
- Reviewing acquisition packages (contracts, grants, cooperative agreements, and inter-agency agreements) for the EtO Study;
- Assisting in developing EtO Study budgets and providing program costs necessary for EPA allocation activities;
- Ensuring that all personnel involved in the EtO Study have access to any training or QA information needed to be knowledgeable in QA requirements, protocols, and technology;
- Reviewing EtO Study data results;
- Recommending required management-level corrective actions.

The AD has the authority to carry these responsibilities and to bring to the attention to the Director any issues associated with these responsibilities. The AD may retain these

responsibilities or delegate certain responsibilities, or portions thereof, to the Environmental Resource Program Manager (ERPM).

4.3.3 Environmental Resource Program Manager (ERPM)

The Charleston ERPM is the EtO Study main point of contact within the DAQ air monitoring section. The ERPM' responsibilities under the EtO Study include:

- Implementing and overseeing the DAQs QA policy for the EtO Study;
- Acting as a conduit for QA information to monitoring staff;
- Participate in the development, and revision of the EtO Study SOP and FSP;
- Assisting the AD in developing applicable QA policies and procedures;
- Assisting in solving QA-related problems;
- Ensuring the timely implementation of corrective actions;
- Ensuring that site operators follow the EtO Study QAPP and SOP;
- Reviewing EtO Study Chain of Custody (COC) sheets.
- Backup the ERS.

The ERPM has the authority to carry out these responsibilities and to bring to the attention of the AD any issues related to these responsibilities. Certain responsibilities may be delegated to the Environmental Resource Specialists (ERS).

4.3.4 Environmental Resource Specialist (ERS)

The ERS is the person who performs the EtO Study field/site operations. These responsibilities include:

- Remaining current on applicable EtO Study QAPP, SOP and FSP;
- Ensuring timely follow-up and corrective actions resulting from QA and evaluation activities;
- Communicate with the ERPM on issues related to routine sampling and QA activities;
- Comprehension of the EtO Study QAPP, SOP and FSP;
- Recommend corrective actions to the ERPM;
- Providing input to SOP and FSP;
- Verifying that all required EtO Study monitoring program QA activities are performed;
- Performing and documenting applicable preventative maintenance;
- Documenting deviations from established procedures and methods;
- Flagging/notating suspect EtO Study field samples;
- Handling, receiving, transport, setup/retrieval, and shipping of the EtO Study canisters;
- Maintain an EtO Study field logbook;

4.3.5 Laboratory

The DAQ laboratory has no responsibilities under the EtO Study program. ERG performs all laboratory analysis of the EtO Study field samples. The ERG analysis is conducted in accordance with ERG's *Support for the EPA National Monitoring Programs (UATMP, NATTS, CSATAM, PAMS, and NMOC Support) QAPP, 2020*.

5.0 PROBLEM DEFINITION AND BACKGROUND

The DAQ will conduct short-term air sampling in South Charleston and Institute, West Virginia for subsequent laboratory analysis by the United States Environmental Protection Agency (EPA) national contractor, Eastern Research Group, Inc. (ERG), determine any presence of EtO.

Field sampling will begin upon approval of the QAPP and FSP by EPA, and EPA release of funding (anticipated in fourth quarter 2021), and will take place over an approximately three month period. EtO Study background samples will be collected at Guthrie, WV. It is anticipated that the EtO study will produce data to allow for an assessment of EtO at the monitoring location, including short-term air dispersion modeling.

EPA's National Air Toxics Assessment (NATA) review identified 25 communities across the United States as potentially having the highest cancer risk from EtO air emission. Two of these communities - South Charleston and Institute – are in West Virginia. DAQ performed a detailed review of EtO emissions and updated air dispersion modeling inputs and conducted air dispersion modeling.

The DAQ has identified the monitoring sites herein based upon the updated long-term AERMOD modeling results. EPA has also used the DAQ model inputs to update their Human Exposure Model. Additional information may be found at: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/inspector-general-follow-ethylene-oxide-0. Additional details regarding the ambient sampling are found in the EtO Study SOP and FSP and as referenced herein.

The EtO Study will be used to address the following objective:

- Collect ambient EtO samples in South Charleston and Institute, WV to determine its presence.
- Collect ambient background EtO samples at Guthrie, WV (where there are no known sources of EtO air emissions).

U.S. EPA regulations require that all projects involving the generation, acquisition and use of environmental data be planned, documented, and have an approved QAPP. This QAPP, along with the SOP, FSP and ERG QAPP are the planning documents for the EtO Study and applicable Quality Assurance/Quality Control (QA/QC) activities.

6.0 PROJECT/TASK DESCRIPTION

6.1 Description of Work to be Performed

The EtO Study requires the use specialized sampling canisters, supplied by ERG, to collect air samples for subsequent laboratory analysis to characterize the concentration of EtO in ambient air. The goal is to implement the EtO Study using the appropriate samplers, laboratory analysis and applicable QA/QC procedures to produce usable information.

Table 6.0: Expected Project Timeline

Activity	Expected Timeline
DAQ starts sampling	Upon approval of QAPP, SOP and FSP by EPA
DAQ completes sampling	Approximately 3 months from starting sampling
DAQ receive analytical results from lab	4-6 weeks after sampling dates
DAQ requests Modeling Checklist (emissions) & meteorological data from facilities	Concurrent with sampling
DAQ receives Modeling Checklist (emissions) & meteorological data from facilities	2 weeks from sampling date
DAQ performs modeling and shares draft with EPA	4-6 weeks after modeling checklists and met data received from facilities
DAQ QA of monitoring data, including review with EPA	As soon as possible following receipt of monitoring results from the lab
DAQ releases of monitoring data	Following QA of monitoring data
DAQ drafts report	2-3 months after final sampling and modeling are completed
DAQ sends draft report to EPA	3-4 months after sampling data received and modeling is completed
EPA provides advice on analyses and comments on draft report	Throughout, and 2-4 weeks after draft report
DAQ releases final report to the public	6 months after final monitoring data received from lab

6.2 Field Activities

DAQ Charleston personnel will perform activities to support operation of the EtO Study. The performance requirements of the canister samplers have been specified by ERG and can be found in ERG EtO QAPP. Field activities that support network operations include receiving and logging samplers from ERG, deploying samplers, performing leak checks, initiate sampling, recording pertinent field data, retrieving samplers, scanning COCs and shipping samplers to ERG. For additional information, refer to the "Standard Operating Procedure Collection of Ethylene Oxide Samples Using Passive Sampling Technique" Version 0.

6.3 Laboratory Activities

ERG performs all laboratory activities. After sampling, the DAQ sends the EtO Study samples to ERG for analysis. ERG sample analysis is performed in accordance with their QAPP. Upon completion of analysis and review, ERG sends the data to DAQ for review. Laboratory issues, observed by the DAQ, will be discussed with ERG.

6.4 Project Assessments

An assessment is an evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation (PE), peer review, inspection, or surveillance. For the DAQ EtO Study field operations, the assessment will consist of the ERPM or AD visiting the sites to observe field operations, and reviewing the field logbook, COCs and shipping method. Applicable ERG assessments are conducted in accordance with their QAPP.

6.5 Project Records

The DAQ has established procedures for the timely preparation, review, approval, issuance, use, control, revision and maintenance of documents and records. Table 6.0 represents the categories and types of records and documents which are applicable to the EtO Study.

Table 6.1: Critical Documents and Records

Categories	Record/Document Types
Management and Organization	Organizational structure Personnel qualifications and training Quality Management Plan (QMP)
EtO Site Information	Field Sampling Plan (FSP)
Environmental Data Operations	QA Project Plans (DAQ and ERG) Standard Operating Procedures (SOPs) Field logbooks Chain of Custody Records (COC)
Raw Data	COC and ERG analytical results
Data Reporting	Data/summary reports
Data Management	Quality Assurance Project Plan (QAPP) EtO Data Review
Quality Assurance	Logbooks Field Site Assessment by ERPM or AD ERG QAPP procedures

7.0 MEASUREMENT QUALITY OBJECTIVES AND ACCEPTANCE CRITERIA

7.1 Data Quality Objectives

The Data Quality Objective (DQO) for the EtO Study is to conduct EtO air sampling in South Charleston and Institute, West Virginia for to determine its presence. In addition, background EtO Study sampling will be conducted at Guthrie, WV.

The DQO process establishes the link between the specific end use(s) of the data and the data collection process, which is important for identifying the quality and quantity of data needed to meet a program's goal.

The DQOs are assessed using data quality indicators (DQIs) which are the quantitative statistics (e.g., precision, bias, completeness, detectability) and the qualitative descriptors used to interpret the degree of acceptability or utility of data to the user. The DQIs can then be used to establish the measurement quality objectives (MQOs).

7.1.1 Goals and Intended Use of Data

The goal of the DAQ EtO Study is to meet the monitoring objective listed in Section 5.0.

7.2 Measurement Quality Objectives

Once a DQO is established, 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 to ensure that total measurement uncertainty is within the range prescribed by the DQOs. MQO is defined in terms of the following 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." This is the random component of error. Sample precision will be determined by a collocated sample as per the FSP. Laboratory analytical precision is determined by the ERG QAPP.

• ***Bias:*** "Bias is the systematic or persistent distortion of a measurement process that causes errors in one direction." Bias is determined by estimating the positive and negative deviation

from the true value as a percentage of the true value. Analytical bias is determined by the ERG QAPP.

• ***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 data sets can be considered equivalent regarding the measurement of a specific variable or groups of variables." Data from this study that meets the criteria of Table 7.0 and the ERG QAPP will be considered comparable.

• ***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." Sampling frequency and time periods will be conducted per the FSP. A 24 hour ± 2 hour sample will be collected. Samples times between 22-23 hours and 25-26 hours are flagged by ERG.

• ***Completeness:*** Completeness (creditable sample) is a metric quantifying the amount of valid data obtained from a measurement system compared to the amount that were expected to be obtained under correct, normal conditions. Completeness can be expressed as a ratio or a percentage. While all valid data is considered usable, it is desirable to collect 75% of the total number of scheduled field samples over the EtO Study period.

7.2.1 EtO Study General Measurement Quality Objectives

The following data validation template provides MQO acceptance criteria to be used in the EtO Study.

Table 7.0: EtO Study Data Validation Table

Parameter	Description/Frequency	Acceptance Criteria
Canister sample holding time	All canisters	Analyze sample within 30 days of sample collection
Canister starting pressure	Each field sample	Vacuum ≥ -28 inHg or per ERG QAPP/ SOP
Sample frequency	Per FSP	N/A
Sample leak check	Each field sample	≤1 inHg over 5 minutes or per ERG QAPP/DAQ SOP
Sampling duration	Each field sample	24 hours ± 2 hour

Canister final pressure	Each field sample	Ideally between 2 to 8 inHg. Field sample compared to ERG received sample should be < 3 in Hg per ERG QAPP
Trip blank	Once per study period	Per ERG QAPP < 3X MDL or 0.20 ppbv, whichever is lower
Precision (collocated sample)	Once per study period	Per ERG ±25% of primary.
Chain of Custody	Each field sample	Unique sample ID, complete field COC
Final canister pressure check	Determined by pressure gauge for each field sample	Per SOP
ERG analysis	All field sampled EtO Study canisters	Per ERG QAPP/ SOP
Data completeness	Valid samples vs scheduled samples	All valid data may be used for DQO, but DAQ minimum goal is 75% collection

7.3 Network Scale

The EtO Study sampling locations are provided in the FSP and may be considered to represent a middle to neighborhood scale, based on the definitions of 40 CFR Part 58 Appendix D.

8.0 SPECIAL TRAINING REQUIREMENTS

8.1 Training

Personnel assigned to the EtO Study will review the "Standard Operating Procedure: Collection of Ethylene Oxide Samples Using Passive Sampling Technique, Revision 0" and meet the educational, work experience, responsibility, and training requirements for their position. Records on personnel qualifications and training will be maintained in personnel files.

9.0 DOCUMENTS AND RECORDS

9.1 Information Included in Documents/Records

The following sections provide information on project/task document updates and revisions and on archiving procedures for records, reports, and data.

Routine Data Activities

The DAQ has a records system that allows for the retention and retrieval of records. The following list includes the documents and records that will be retained for the EtO Study.

- Training certifications (may also reside in WVDEP and Department of Personnel records);
- QMP for WVDEP, DEP-QMP-2021;
- QAPP - Ethylene Oxide Monitoring Study, Rev 0;
- SOP - Collection of Ethylene Oxide Samples Using Passive Sampling Technique, Rev 0;
- FSP - Ethylene Oxide Monitoring – Characterization of South Charleston and Institute, West Virginia, Rev 0;
- Field logbooks;
- Chain of Custody forms;
- ERG transmitted data, including monitoring results;
- Modeling checklists with emissions data provided by the facilities (FSP, Appendix A)
- Meteorological data provided by the facilities
- Modeling files and final modeling results
- Final report;

Data Reporting Package Format and Documentation Control

EtO Study field data is recorded on COCs, forms and logbooks. All hardcopy information is filled out in indelible ink. Corrections are made by inserting one line through the incorrect entry, initialing this correction, and placing the correct entry alongside the incorrect entry, or by providing the information on a new line.

Logbooks - The EtO Study logbooks will contain all pertinent information relative to the EtO sampling site and samplers. All logbooks will be bound.

All logbooks and COCs are subject to review for completeness and accuracy by the ERPM and AD.

Data Reporting Package Archiving and Retrieval

The DAQ will retain the EtO related electronic records, such as scanned COCs and data spreadsheets, on the secured network drive that is backed up periodically. Hardcopy records, such as logbooks will be stored in the air monitoring section. Records referenced in this section will be retained for three years past the year of collection. The DAQ may, at its discretion, retain those records for a longer period.

10.0 NETWORK DESCRIPTION

The primary objective of the EtO Study is to conduct short-term EtO monitoring in South Charleston and Institute, West Virginia to determine its presence in atmosphere. Background samples will be collected at Guthrie, WV. The FSP provides additional detail regarding sampling locations.

10.1 EtO Study Site Selection and Sampling Frequency

The DAQ considered the following aspects when establishing the EtO Study monitoring sites:

- The monitoring objective(s).
- Identifying the spatial scale most appropriate for the monitoring objective.
- Identifying the general locations where the samplers should be placed referenced to the long-term dispersion model results.
- Identifying sampling frequency.
- Identifying availability, accessibility, and general security of the site location.

Refer to the FSP for additional details regarding site selection and sampling frequency.

11.0 SAMPLING METHODS REQUIREMENTS

11.1 Purpose

The purpose of this section is to identify the sampling methods and the procedures for collecting the EtO Study data. This section also identifies the corrective actions needed, responsible parties to implement the corrective actions and methods required to verify corrective action effectiveness.

The EtO Study FSP and SOP contain more detailed descriptions of the sampling and procedures used in the EtO Study, support activities and materials and processes for data handling.

11.2 EtO Study Samplers, Sample Collection and Support, Analytical Methodologies

The EtO Study samples are collected in passive 6 Liter stainless steel canisters provided by ERG. The DAQ receives certified "clean" canisters from the ERG Lab. The canisters have been evacuated to a sub-ambient pressure of at least -28 in Hg, gauge pressure, prior to shipping by ERG. When not sampling the canister is capped using a brass or stainless-steel cap. Unique sample identification (ID) numbers are printed on tags attached to the canister. Each canister also has a unique ID permanently written on the canister. For sampling, canisters are connected to an air sampling assembly (supplied by ERG) consisting of a filter, sample tube, critical orifice, flow regulator and vacuum gauge. The DAQ refers to the canister and the attached air sampling assembly as a canister assembly. Canister assemblies are leak checked by the site operator before sampling. When the canister valve is opened to initiate sampling, the critical orifice is designed to maintain steady flow over a 24 hour period. After sampling, the canister valve is closed. Final canister pressure is recorded by the site operator. The canister is taken back to DAQ for shipping to ERG.

The EtO Study FSP and SOP contain more detailed descriptions of the sampling and procedures used in the EtO Study, support activities, and materials and processes for data handling.

The EtO Study support facility includes the instrument and laboratory facilities located at the Charleston office and ERG, respectively. Receiving and shipping of canisters occurs at both facilities. The DAQ utilizes a secured building and room to receive samplers, prepare for deployment and ship back the ERG.

Sample analysis will be conducted by ERG in accordance with their QAPP and SOP.

11.3 EtO Study Sampling Corrective Action

Corrective action measures at the EtO Study sites will be taken to ensure the data quality objectives are attained. Any corrective actions will be documented on the COC. The ERPM and AD are to be notified of any corrective actions needed or undertaken.

The ERPM or AD may assess sites, logbooks, or field operations. Any audits of the ERG laboratory are addressed in their QAPP.

ERG corrective action procedures are provided in their QAPP and SOP.

12.0 SAMPLE CUSTODY

ERG is responsible for providing sampler Chain of Custody (COC) sheets with each canister. Unique sample IDs are generated by ERG. The DAQ EtO Study utilizes these COCs and sample IDs. An example of the COC may be found in Figure 6.1 of the SOP. The DAQ secures the canisters at the DEP Headquarters building. Canisters will be shipped using ERG supplied shipping labels, containers, and recommended courier.

Critical activities involving canisters include receiving the canisters from ERG, handling of canisters prior to sampling, transporting canisters to the field, handling canisters in the field at the time of collection, transport, and storage of canisters from the field site, shipping canisters to ERG and the laboratory analysis of the canister samples by ERG. Canisters should be sampled within 30 days after cleaning and analysis performed within 30 days after sample collection. Custody records document the sample COC and include the date and person responsible for the various sample handling steps associated with each sample, and the information that acknowledges the sample integrity remained intact. Custody records also provide a reviewable trail for quality assurance purposes. The DAQ and ERG track and document each canister throughout the data collection operation using the COC form. Entries on the COC form are made by hand. The original COCs stay with the canister.

12.1 Site and Instrument Records

An EtO Study logbook documenting all site activities is maintained by the site operator. The logbook provides a record of field activity and any applicable site observations, QA (e.g., leak checks) and maintenance activities.

12.2 Laboratory Records

ERG is responsible for any laboratory records associated with the EtO Study as documented in their QAPP and SOP.

13.0 ANALYTICAL METHODS REQUIREMENTS

The ERG Laboratory is responsible for the analysis of the EtO Study sample. All applicable requirements regarding the EtO Study laboratory analysis are contained in the ERG Laboratory QAPP and SOP.

14.0 QUALITY CONTROL REQUIREMENTS

The DAQ will collect one collocated sample(s) during the EtO Study period to assess precision. Additionally, a leak check will be performed prior to canister deployment. Table 7 notes the acceptance criteria.

14.1 QC Equipment

QC equipment for precision consists of setting up a second collocated canister sampler next to the primary canister sampler. Collocated precision is determined by the ERG laboratory analytical results of two samplers. The samplers operate at the same time and undergo the same sample collection, handling, and analysis procedures.

14.2 Calibrations

Calibrations are applicable to the critical orifice used in the canister sampling assembly and to the laboratory instruments used by the ERG for the analysis of canisters collected in the EtO Study.

14.3 Precision Checks

Precision is assessed by comparing results from the primary sampler concentration to the collocated sampler using the equation below:

Precision = [(Primary sampler - Collocated sampler)/(Collocated sampler)] X 100

Precision is determined by the ERG Laboratory.

14.4 Completeness

Completeness is defined as the amount of data collected compared to a pre-specified target amount. Ideally, 100% of the target amount of data would always be collected. However, in practice, that value is less for many reasons, including equipment failure. While all valid EtO Study data will be utilized in the assessment, the DAQ EtO Study has a completeness goal of collecting 75% of the scheduled samples.

Table 7.0 lists other applicable quality control checks for the EtO Study.

15.0 INSTRUMENT/EQUIPMENT TESTING, INSPECTION, AND MAINTENANCE REQUIREMENTS

For the EtO Study, the DAQ will utilize canisters and sampling apparatus supplied by ERG. For details regarding ERG's testing, inspection and maintenance of the sampling canisters and apparatus refer to the ERG Laboratory QAPP and SOP.

The DAQ will inspect the sampling canisters upon receipt from ERG. Prior to sampling, the site operator will leak test the canister assembly. If a leak is detected, the canister assembly fittings should be tightened to locate the source of the leak. Canister assemblies that continue to fail a leak test will be replaced, noted on the COC, and the ERPM will be notified. The ERPM may notify ERG so that a replacement canister may be shipped. If the canister passes a leak test, it will be assumed to be operating properly.

The DAQ will keep spare chains, combination locks and secure sampling tripods at the site as needed. The ERPM or AD may periodically inspect the equipment, applicable supplies, and the sites.

16.0 INSTRUMENT CALIBRATION AND FREQUENCY

ERG is responsible for calibrations and standards used in the laboratory analysis of the canisters. ERG utilizes a calibrated vacuum gauge to measure canister pressure prior to shipping/sampling and upon receipt of the sampled canister at the laboratory. Canister starting and final pressure must meet the criteria provided in Table 7.0.

17.0 INSPECTION/ACCEPTANCE FOR SUPPLIES AND CONSUMABLES

17.1 Purpose

The purpose of this element is to establish and document a system for inspecting and accepting canisters for use in the EtO Study. Refer to Section 16.1 of this QAPP.

18.0 DATA ACQUISITION REQUIREMENTS

This section addresses data not obtained by direct measurement from the EtO Study. This includes both outside data and historical EtO monitoring data. Non-monitoring data and historical monitoring data may be used by the DAQ in a variety of ways. The policies and procedures described in this section apply both to data acquired through the DAQ EtO Study sites and to information acquired from outside sources.

18.1 Acquisition of Non-Direct Measurement Data

The DAQ relies on data that are generated through the EtO Study field operations and ERG analysis of the EtO Study samples. However, other related data may be obtained from sources outside the DAQ or from historical records.

18.1.1 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. Other data sources may be used with approval of the AD. The following sources may be used in the EtO Study without prior approval:

- National Institute of Standards and Technology (NIST)
- EPA
- The current edition of certain standard handbooks may be used without prior approval, such as the CRC Press' *Handbook of Chemistry and Physics* and *Lange's Handbook.*

18.1.2 Sampler Operation and Manufacturers' Literature

Another important source of information needed for the EtO Study sampler operation is manufacturers' literature. Operations manuals, users' manuals and product specification sheets frequently provide narrative, graphical, and numerical information and equations pertaining to specific equipment. DAQ staff 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. The following types of errors are commonly found in such manuals:

- Outdated values for physical constants;
- Outdated or incorrect product information;
- Typographical errors;

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

18.1.3 Geographic Location

Another type of data that will commonly be used is geographic information. USGS maps were historically used as the primary means for locating and siting stations in the existing network. Mapping software and handheld GPS devices are also utilized.

18.1.4 Historical Monitoring Information

Historical EtO data and summary information derived from that data may be used in conjunction with current EtO Study. It is important to verify that historical data are comparable to current monitoring data. If different methodologies were used to gather the historical data, the biases and other inaccuracies should be described, if available, in reports based on that data. Specific historical comparisons may be evaluated on an individual basis.

18.1.5 External Monitoring Databases

It is the practice of the DAQ that no data obtained from the internet, computer bulletin boards, or databases from outside organizations shall be used in creating reportable data or published reports for the air monitoring section without approval of the Assistant Director. This is intended to ensure the use of high-quality data in DAQ publications.

EtO data from the EPA AQS database may be used with appropriate caution. Care must be taken in reviewing/using any data that contain flags or data qualifiers. It is impossible to assure that a database such as AQS is completely free from errors including outliers and biases, so caution and skepticism is called for when comparing data from other reporting agencies as reported in AQS. Users should review available QA/QC information to assure that the external data are comparable with DAQ measurements and that the original data generator had an acceptable QA program in place.

19.0 DATA MANAGEMENT

19.1 Purpose/Background

The following section will identify the processes and procedures to acquire, transmit, transform, reduce, analyze, store, and retrieve the EtO Study data. These processes and procedures will maintain the data integrity and validity through application of the identified data custody protocols.

19.2 Data Recording

All pertinent data regarding the EtO Study canisters, except for the ERG analytical results, is recorded on the COC. ERG analytical results are recorded in accordance with their QAPP and SOP. The COC will be scanned to the DAQ secured common drive and a hardcopy retained prior to shipping of the sampled canister to ERG. ERG will complete the COC upon receipt of the canister. The DAQ has requested that ERG transmit an electronic version of the final completed COC to DAQ along with the analytical results.

Procedures regarding the flow of data for the EtO Study is as follows:

- ERG prepares the canister and COC and ships to the DAQ.
- DAQ receives the canister and COC, inspects the canister and records receipt date on COC. The canister and COC is placed in secured, dedicated storage until ready for field deployment.
- The canister and COC are transported to sampling site. Pre-sampling information, including leak check results, is recorded on the COC and sampling is manually initiated. Due to potential outdoor exposure, the COC remains with the site operator.
- After sampling, the site operator retrieves the canister, and records post sampling information, including final canister pressure on the COC. The canister and COC are transported back to DAQ and placed in a secured, dedicated storage until prepared for shipment,
- The site operator prepares the canister and COC for shipping. The ERG shipping label is attached to the shipping container. The shipping information is recorded on the COC. The COC is scanned to the DAQ secured common drive and a hardcopy is retained. If available, shipping currier tracking data is downloaded and retained on the DAQ secured common drive.
- Upon receipt of sample at ERG, ERG will complete the COC and email a copy to DAQ upon request.

- ERG is responsible for data tracking and management in accordance with their QAPP and SOP once the canister is received at their lab.
- ERG will electronically transmit to the AD all analytical and QA results.

19.3 Data Validation

EtO Study data validation is a combination of checking that data processing operations have been carried out correctly and monitoring the quality of the field operations. Data validation can identify problems in either of these areas. Once problems are identified, the data can be flagged or invalidated.

ERG employs data validation methods that are provided in their QAPP and SOP. ERG will notify the DAQ of samples that do not meet their validation criteria. The following validation functions are used by the DAQ to ensure quality of the EtO Study field data entry and data processing operations:

- **Record review** – EtO Study COC's are subject to review by the AD or ERPM. Questionable entries are discussed with the site operator and resolved by the ERPM or AD.

- **Completeness Checks** - While all valid data is considered, it is desirable to collect 75% of the scheduled field samples over the study period.

- **Data Retention** – EtO Study data are retained on file in the DAQ office for a minimum of three years from the year of data capture. After three years, hardcopy records may be discarded upon approval by the AD.

- **Statistical Data Checks** - Errors found during statistical screening will be traced back to original data entry files.

- **Sample Data Validation** - During the data validation process, applicable flags or codes that are generated by ERG, QC values outside of acceptance criteria are associated with the data.

19.4 Data Storage and Retrieval

EtO Study data will be stored on the DAQ secured common drive for at least three years after the year of collection. After three years, hardcopy records may be discarded upon approval by the AD.

20.0 ASSESSMENTS AND RESPONSE ACTIONS

An assessment is defined as an evaluation process used to measure (1) the performance or effectiveness of the quality system, (2) the entire monitoring network or individual site, and (3) various phases of the data operation.

The ERPM or AD may assess, observe, and review the EtO Study field operations, canister handling and shipping activities. ERG performs laboratory assessments in accordance with their QAPP and SOP.

EtO Study site operators may observe operational deficiencies at an EtO Study site. Any observed safety, security structural problems shall be reported to the ERPM and AD.

If a pre-sampling leak is detected, canister assembly fittings should be tightened to locate the source of the leak. Canister assemblies that continue to fail a pre-sampling leak check will be replaced, noted on the COC, and the ERPM will be notified. The ERPM will notify ERG of the failed leak check.

21.0 REPORTING REQUIREMENTS

The AD may require various reports detailing and summarizing the EtO Study sampling and data. Applicable reports for ERG are specified in their QAPP and SOP.

The final report released to the public may include:

- A summary of the analytical lab results of monitored EtO concentrations;
- A characterization of which EtO-emitting processes were operating during the sampling period;
- Site background results which will be subtracted from the source-oriented monitors prior to review along with short-term modeling results;
- Additional review of source-oriented monitors without background correction with short-term modeling results;
- For each sample date, comparison of highest 24-hr monitor value around a site, with the highest modeled 24-hr average over the domain; and
- A discussion of the limitations of the data and analyses

22.0 DATA REVIEW

The purpose of data review is to decide the degree to which each data item has met its quality specification.

22.1 Sampling Design

The FSP provides the EtO Study sampling design.

22.2 Sample Collection Procedures

The EtO Study sample collection procedures are available in the FSP and SOP.

22.3 Data Reduction and Processing

The data will be reviewed to ensure that associated flags or any other data qualifiers have been appropriately associated with the data and that applicable corrective actions were taken. Refer to Section 19 and Section 23 for additional information. ERG reviews and flags the analytical data according to their QAPP.

Data that meets the criteria established in Table 7.0 is considered acceptable for the intended purpose of this study.

23.0 VALIDATION AND VERIFICATION METHODS

Data verification is the process of evaluating the data set against the method, procedural or contractual requirements. Data validation is an analyte and sample-specific process that extends the evaluation of data beyond method, procedural or contractual compliance (i.e., data verification) to determine the analytical quality of a specific data set. Refer to Section 19 for additional information.

The following outline shows steps involved in the data review.

Level 0 (Raw data review): Site Operator evaluates samples as they are collected in the field and notes, on the COC and/or field logbooks, any anomalies observed such as sampler integrity issues or unusual weather conditions. See Section 6.2 of the SOP.

Level 1 (Data analyzed): ERG processes the samples and notes any anomalies in accordance with their QAPP.

Level 2 (Data Validation): ERG reviews COCs, analytical results, and laboratory QA then applies any applicable null data codes or qualifier codes and prepares file for transmittal to DAQ.

Level 3 (Data Verification): DAQ AD review of data received from ERG.

23.1 Data Validation

ERG analyzes and QA's the EtO Study samples in accordance with their QAPP and SOPs. ERG transmits the QA'd data to the DAQ AD via email. The AD reviews the data, as well as applicable QA/QC information and the corresponding information on the COC. Data will be reviewed to ensure that associated flags or data qualifiers have been appropriately applied to the data. The final monitoring data, along with any applicable null codes, is uploaded to the DAQs secured common drive.

Table 23.0: Null Codes and Flags

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
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.

23.2 Data Verification

ERG analytical data results are verified in accordance with their QAPP and SOP prior to transmittal to the DAQ. The DAQ AD reviews and verifies the EtO Study data.

.

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. Basic summary statistics and graphs and review of ERG results can be utilized to assess the EtO Study data representativeness, completeness, precision, and sensitivity. Representativeness can be assessed with site location information compared to EtO-emitting processes that were operating during the monitoring period. Completeness is measured by the amount of valid sample data obtained compared to what was expected. Precision is determined from collocated analyses. Sensitivity is demonstrated through MDLs generated by ERG.

If the sampling design results meet acceptance criteria, it can be assumed that the network design, and the uncertainty of the data are acceptable. The AD is responsible for overseeing the project, including QA and final review of sampling results.

Calculation of Summary Statistics and Generation of Graphical Presentations. Some internal summary statistics can be generated for the EtO Study. The summary statistics can be calculated for the 24 hour sampling period and will include only valid samples. The summary statistics may include:

- Mean concentration
- Maximum concentration
- Minimum concentration
- Minimum Detectable Limit

The final report will include a discussion of the limitations of the data and analyses. Section 21 of the OAPP provides a list of what may be included in the final report. Table 6.0 provides an expected project timeline.