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DAQ-14-001 Standard Operating Procedure (SOP) for Preparing SOPs for the North Carolina Division of Air Quality (NCDAQ)



1.0 Approval Sign-Off Sheet

I certify that I have read and approve of the contents of the Standard Operating Procedure for Preparing SOPs written here with an effective date of May 21, 2021.

Director, Air Quality Division		
Mike Abraczinskas		
Signature: Michael Abraczinskas	_ Date:	5/10/2021
Ambient Monitoring Section Chief		
Patrick Butler		
Signature: Patrick Butler	_ Date:	5/10/2021
Laboratory Analysis Branch Supervisor		
Jim Bowyer, Environmental Program Supervisor		
Signature: Jim Bowyer C068804826C0841D	_ Date:	5/10/2021
Projects and Procedures Branch Supervisor		
Joette Steger, Environmental Program Supervisor		
Signature:	_ Date:	5/10/2021
Primary SOP Author		
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Signature: Eay Roberts	_ Date:	5/10/2021
EPA Region 4		
Designated Approving Official		
Signature:	_ Date:	_

Disclaimer:

This document, and any revision hereto, is intended solely as a reference guide to assist individuals in the preparation of Standard Operating Procedures, related to the North Carolina Division of Air Quality's Ambient Monitoring Program.

SOP Acronym Glossary

ADQ - Audit of data quality

AQS - Air Quality System (EPA's Air database)

CFR – Code of Federal Regulations

Chief – Ambient Monitoring Section chief

DAQ - North Carolina Division of Air Quality

DAS – Data acquisition system

DEQ - North Carolina Department of Environmental Quality

Director – Division of Air Quality Director

ECB - Electronics and Calibration Branch

e-log – electronic logbook

EPA – United States Environmental Protection Agency

FEM - Federal equivalent method

FRM - Federal reference method

MDL - Method detection limit

PM – Particulate matter

PPB – Projects and Procedures Branch

QA – Quality assurance

QA/QC - Quality assurance/quality control

QAPP - Quality assurance project plan

QC – Quality control

RCO - Raleigh central office

SOP - Standard operating procedure

TSA - Technical systems audit

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2.0 SCOPE AND PURPOSE

In order to perform operations consistently, standard operating procedures (SOPs) must be written as part of an organizations' Quality Assurance Project Plan (QAPP). These are defined below:

- QAPP A written document that details the results of a project's technical planning process, providing in one place a clear, concise, and complete plan for the environmental data operations and its quality objectives and identifying key project personnel. The QAPP shows how environmental data operations are planned, implemented, and accessed during the life cycle of a program. Directive CIO 2105.1 and applicable Federal regulations (2 CFR 1500.12) establish a mandatory Quality System. Organizations must ensure that data collected for the characterization of environmental processes and conditions are of the appropriate type and quality for their intended use and that environmental technologies are designed, constructed, and operated according to defined expectations. The QAPP is a key project-level component of the quality assurance program. In addition, 40 CFR Part 58, Appendix A states that each quality assurance program must be described in detail. A QAPP is typically more general in nature as opposed to a SOP.
- SOP A written document that gives detailed instructions on how a monitoring organization will perform daily tasks: field, laboratory and administrative. SOPs should ensure consistent conformance with organizational practices, serve as training tools, provide ready reference and documentation of proper procedures, reduce work effort, reduce error occurrences in data and improve data comparability, credibility and defensibility. They should be sufficiently clear and written in a step-by-step format to be readily understood by a person knowledgeable in the general concept of the procedure. SOPS are a required element of a QAPP.

A QAPP and SOP Tracking Database (DAQ-0014-002.5) was developed to aid the central office. The goals of the QAPP and SOP Tracking Database are to help staff identify documents needing to be reviewed, to generate status reports for PPB management, and to provide an overview of changes that are required as a result of the review. All new or revisions to SOPs should be included in the QAPP and SOP Tracking Database.

3.0 ELEMENTS OF AN SOP

3.1 First Three (3) Pages

1) Title Page -

- Font type and size can be "Times Roman" 16 or "Calibri" 13 and consistent throughout the document.
- Provide the title of the SOP, the unique number (obtained using DAQ Document ID Builder), along with the user type if applicable, whether it is for "ECB" which has been assigned a user type of .1, "Operator" which has been assigned a user type of .2, "Regional Ambient Monitoring Coordinator" which has been assigned a user type of .3, or "Central Office Responsibilities" which

has been assigned a user type of .5. Additional information may be added that will make the document easily identified as to its purpose.

- Add header information, which should contain the following:
 - o Document ID Number
 - o Revision Number
 - o Effective Date
 - Page number (xx of xx)

The document ID numbering follows a specific format: DAQ-XX-XXX.X. All SOPs will begin with DAQ as this is the section set aside in the DAQ QAPP for the location of such documents. "XX" is the unique number assigned for the specific type of document (e.g., QAPP, Network Assessment and Review, General Quality Assurance, Forms, etc.) The "XXX" value is automatically assigned for the type of SOP or document being drafted when using Document Builder (DAQ Document ID Builder)

The final "X" is also automatically assigned by DAQ Document ID Builder once the user type has been chosen. If the document is for multiple users or all users, leave the user type off of the document number.

2) Approval Sign-Off Sheet

The first full page following the Title Page will be the "Approval Sign-Off Sheet". This will provide the names and titles of the individuals responsible for approving the QAPP/SOP and a line for their actual or electronic signature and the date signed. These will include the primary author of the document, the Projects and Procedures Branch supervisor, the Ambient Monitoring Section Chief and the Director, Air Quality Division, or their designee. The signees on the approval page should match the signees on the associated QAPP or QAPPs.

3) Table of Contents

- Major section headings must be numbered sequentially using Arabic numerals, such as 1.0, 2.0, etc.
- Sub-sections must be numbered sequentially using additional places to the right of the major section heading numerals and separated by decimals, for example, 1.1, 1.2, etc.
- Items or list within sub-sections should be bulleted or numbered sequentially.

The elements of the body of the text are shown in the next section individually for ECB, Operator, Database Manager, Regional Offices and Central Office. Font type and size will be "Times Roman" 12 or "Calibri" 11 for the text body and consistent throughout the document. The document should follow the AP Style Guide.

3.2 Elements Specific to the ECB SOP

Following the Table of Contents, the next full page will be the beginning of the main document. Current procedure is to initiate the numbering sequence beginning with 1.0, 2.0, etc. as an example, adding subsections as needed. Examples are listed below:

1.0 Approval Sign-Off Sheet

- 2.0 Scope, Purpose and ECB Responsibilities introduction, purpose, and description of the monitor.
- 3.0 Equipment Selection and Procurement discusses the process and rational for selecting the specific monitor.
- 4.0 Description of the Specific Monitor/Analyzer (from the Manual) discusses the principles of operation of the monitor along with specifications as stated in the manual along with a diagram or picture if available.
- 5.0 Description of Equipment Checks discusses and details the major components of the monitoring system. Subsections may include:
 - 5.1 Calibrator
 - 5.2 Zero Air Generator and Certification
 - 5.3 EPA Protocol Gas Cylinders
 - 5.4 Dedicated PC and Modem along with a Data Acquisition System
- 6.0 Initial Start-up of the Specific Monitor/Analyzer discusses the process ECB uses to conduct and document, initial operational test, exact procedures, and operating criteria before deploying an instrument. Including flow charts of major components, if available, would be beneficial. Subsections may include:
 - 6.1 Receipt and Inspection
 - 6.2 Assembly, Modification, and Initial Verification
 - 6.3 Initial Laboratory Setup
 - 6.4 Standard and Service Modes
 - 6.5 Verification of Lamp Voltage or Photometer
 - 6.6 Selecting the Range setting of the monitor, checks of internal flow measurement devices, concentration units, averaging times.
 - 6.7 Diagnostic Checks and Settings
 - 6.8 Alarm Settings
 - 6.9 Leak Checks and Calibration
- 7.0 On-site Installation detailed discussion on each activity to be performed to prepare the monitor/calibration equipment, data acquisition system and any support equipment for installation at a site. Instructions for where and how to document monitor activities and routine maintenance performed (i.e., site logbook, maintenance logbook and/or 109 forms) should be included here. This should also include actual site installation procedures.
- 8.0 Routine Maintenance by ECB discusses periodic maintenance procedure that should be performed by ECB staff when needed. Maintenance includes preventative, routine and corrective, including where and how to document.
- 9.0 Accuracy Audits details the frequency and equipment requirements for accuracy audits performed by ECB personnel.
- 10.0 Revision History
- 11.0 Appendices (if applicable)

3.3 Elements Specific to the OPERATOR SOP

Following the Table of Contents, the next full page will be the beginning of the main document. Current procedure is to initiate the numbering sequence with 1.0, 2.0, etc. as an example, adding subsections as needed. Examples are listed below:

- 1.0 Approval Sign-Off Sheet
- 2.0 Scope and Purpose introduction, purpose, description of monitor, should include a diagram or picture if available.
- 3.0 Equipment Checks -topics specific to the monitoring system that will be discussed in detail in subsequent sections, providing exact procedures, schedules, pass/fail criteria when applicable. Subsections may include:
 - 3.1 Monitor/Analyzer Operational Checks
 - 3.2 Residence Time Check
 - 3.3 Dilution Gas Calibrator Operational Checks
 - 3.4 Calibration Gas Cylinder Check
 - 3.5 Zero Air Generator Check
- 4.0 Site Checks detailed discussion of each activity to be performed during a site visit. Subsections may include:
 - 4.1 Site Visit
 - 4.2 Shelter Temperature
 - 4.3 Electrical Power and Sample Line Check
 - 4.4 Date and Time Check
- 5.0 Detailed Procedures detailed procedures for activities to be performed to operate the monitor must include the pass/fail criteria for each activity. Subsections should include:
 - 5.1 Calibration
 - 5.2 Multi-Point Verification
 - 5.3 One-Point QC Check
- 6.0 Logbook Submittal and Data Review detailed discussion of where and how to document all monitoring activities (elogs), reviewing and verifying data (daily/monthly), storing data, file management, use of null codes, Level 1 and Level 2 review, etc. Subsections should include:
 - 6.1 Logbook Submittal
 - 6.2 Data Review
- 7.0 File Management
 - 7.1 Opening, Naming and Storing the Site Files
- 8.0 File Quality Assurance and Data Handling
 - 8.1 Monthly Verification
- 9.0 Trouble Shooting and Corrective Actions discusses common problems observed and actions to take to resolve them.
- 10.0 Revision History Should list all significant changes since the previous revision providing the reference section number, the previous procedure or criteria and the current/revised procedure or criteria.
- 11.0 Appendices (if applicable)

3.4 Elements Specific to the DATABASE MANAGER SOP

Following the Table of Contents, the next full page will be the beginning of the main document. Current procedure is to initiate the numbering sequence with 1.0, 2.0, etc. as an example, adding subsections as needed.

- 1.0 Approval Sign-Off Sheet
- 2.0 Scope/Application/Purpose should contain introduction, purpose, description or overview of DAS and General information
- 3.0 Equipment
- 4.0 DAS Set-up should include information for adding/removing users, initial set-up for installation at sites. Subsections may include:
 - 4.1 Users
 - 4.2 Sites
- 5.0 Data & Data Management discusses procedures to complete data sequence from point of acquisition to point of submission of data to EPA. Subsections may include:
 - 5.1 Data Handling
 - 5.2 Software Documentation
 - 5.3 Data Validation and Correction
 - 5.4 Data Processing
 - 5.5 Reports
 - 5.6 Data Submission
 - 5.7 Database back up procedures
- 6.0 Internal Reporting
 - 6.1 Reports
 - 6.2 Responsibilities
- 7.0 DAS Scheduled Events should discuss automated hourly events scheduled. Subsections may include:
 - 7.1 Site polling
 - 7.2 FTP of data from external sources
- 8.0 Routine Maintenance discusses the back-up and archival procedures. Subsections may include:
 - 8.1 Sequel database management
 - 8.2 Archival procedures of data
- 9.0 External Reporting
 - 9.1 DAQ Ambient Monitoring Website
 - 9.2 IBEAM
 - 9.3 AirNow
- 10.0 Revision History
- 11.0 References
- 12.0 Appendices (if applicable)

3.5 Elements Specific to CENTRAL OFFICE RESPONSIBILITIES SOP

Following the Table of Contents, the next full page will be the beginning of the main document. Current procedure is to initiate the numbering sequence with 1.0, 2.0, etc. as an example, adding subsections as needed.

- 1.0 Approval Sign-Off Sheet
- 2.0 Scope/Application/Purpose an introduction and purpose
- 3.0 Data Reporting Conventions subsections may include:
 - 3.1 Reporting Units
 - 3.2 Rounding Conventions
- 4.0 Data Verification and Validation Steps General should discuss procedures for reviewing data for anomalies and applying proper null codes to data in monthly data summary reports. Subsections may include:
 - 4.1 Performance Acceptance Criteria for specific pollutants
 - 4.2 Data Reporting Conventions
- 5.0 Pollutant Specific Data Verification and Validation (Level 3 Review) Steps Subsections may include:
 - 5.1 Ozone
 - 5.2 Sulfur Dioxide
 - 5.3 Nitrogen Dioxide
 - 5.4 Carbon Dioxide
- 6.0 Independent Accuracy Audit Reporting discusses procedure for the review of calibration check results and data entry submitted to AQS. Final review is done by the Level 4 reviewer.
- 7.0 Calibration (Precision) Check Reporting discussed procedures for the review of calibration check results and data entry submitted to AQS. This is done by the Level 4 reviewer.
- 8.0 Data Validation and Certification discusses procedures for the validation and certification of all monitoring data, data entry into AQS. Subsections may include:
 - 8.1 Annual System Audits
 - 8.2 Annual Data Certification
- 9.0 Trouble Shooting and Corrective Actions discusses common problems observed.
- 10.0 Revision History Should list all significant changes since the previous revision providing the reference section number, the previous procedure or criteria and the current/revised procedure or criteria.
- 11.0 Appendices (if applicable)

4.0 SOP REVIEW PROCESS

The SOP development, review and revision process is intended to be a team effort with input from central office, ECB, LAB and regional staff. Typically, a central office chemist will "lead" the effort. However, they may work with a designated regional chemist and an ECB technician. The lead regional chemist should share drafts with other regional chemists.

In making changes to an SOP, it is expected that EPA regulations will be followed unless there is a formal waiver or exception from Region 4. The waiver/exception will be documented in the SOP appendix for

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future reference. Any discussions that result in actions more stringent than the EPA requirements should be based on consensus agreement and the justification should be noted. If consensus cannot be reached, the issue will be bumped up to the PPB supervisor or Ambient Monitoring Section Chief.

The SOP is considered to be "the sole source' for how to operate a monitor – employees are not to be criticized for following the SOP. If central office, ECB, the LAB or a region disagrees with what is in the SOP then they should propose a change through the Ambient Monitoring Workgroup (typically meets monthly). The operator should not have to refer to other documents, policy memos, or miscellaneous emails – everything about operating a specific monitor should be included in the SOP.

It is intended that changes to the SOP will occur no more frequently than once/year. Exceptions can be made based on revised regulations. Other change should be deferred until the next revision unless deemed urgent by central office, ECB and the region.

5.0 REVISION HISTORY

- 1. Update definition of QAPP
- 2. Added Reference Section
- 3. Updated header on cover page

6.0 REFERENCES

- 1. 40 CFR Part 58, <u>Appendix A</u> Quality Assurance Requirements for Monitors used in Evaluations of National Ambient Air Quality Standards.
- 2. Guidance for Quality Assurance Project Plans (EPA QA/G-5) (EP240/R-02/009) December 2002.
- 3. EPA Requirements for Quality Assurance Project Plans (EPA QA/R5) (EPA/240B-01/003) May 2001.
- EPA IT/IM Directive Policy Environmental Information Quality Policy (<u>Directive No: CIO 2105.1</u>) (07/07/2005)
- 5. 2 CFR 1500.12, Quality Assurance. [79 FR 76050, Dec. 19, 2014, as amended at 80 FR 61088, Oct. 9, 2015. Redesignated at 85 FR 61573, Sept. 30, 2020]