

**Standard Operating Procedure (SOP)**  
**for**  
**Preparing Quality Assurance Plans/SOPs**  
**for the**  
**North Carolina Division of Air Quality (NCDAQ)**  
**SECTION 2**

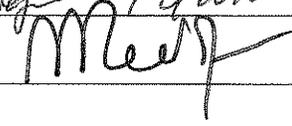
### Approval Sign-Off Sheet

I certify that I have read and approve of the contents of this revision of the "SOP for Preparing a QAP/SOP" with an effective date of 11/1/10.

Joette Steger, PPB Supervisor:

 10/28/2010

Donnie Redmond, Ambient Monitoring Section Chief:

 10/18/10

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## **2.39 Standard Operating Procedure for Preparing Quality Assurance Plans/Standard Operating Procedures for the North Carolina Division of Air Quality (NCDAQ)**

### **2.39.1 Introduction**

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

- **QAPP**-A document that shows how environmental data operations are planned, implemented, and assessed during the life cycle of a program. As provided in 40 CFR Part 31.45 (State and Local Governments) quality assurance programs must be established. 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.

The NCDAQ has chosen to combine elements of both the QAPP and SOP and titled them as QAP/SOP.

### **2.39.2 Elements of a QAP/SOP**

#### **2.39.2.1 First Three (3) Pages**

1) Title Page-

- Font type and size will be "Times Roman" 16;
- Provide the title of the QAP/SOP, identifying it as "Section 2" along with the monitor type, whether it is for "ECB", "Operators", "Regional Office Polling and

Data Review” or “Central Office Responsibilities”. Additional information may be added that will make the document easily identified as to its purpose;

- Add header information to include abbreviated title, section number, revision number (0.0, 1.0, 2.0, etc.), page number (xx of xx) and date. The section numbering follows a specific format: 2.XX.Y. All QAP/SOPs will begin with “2” as this is the section set aside in the DAQ QAPP for the location of such documents. “XX” is a unique number assigned to each monitor type (see Ambient Monitoring Section Chief for the list.) “Y” will be either “1” for ECB, “2” for Operators, “3” for Regional Office Polling and Data Review or “4” for Central Office Responsibilities.

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/titles of the individuals responsible for approving the QAP/SOP and a line for their actual signature and the date signed. These may include the regional chemist assigned as the coordinator for the regions, the document preparer, the appropriate branch supervisor, the PPB supervisor and the Ambient Monitoring Section Chief.

3) Table of Contents-

- Major section headings must be numbered sequentially using Arabic numerals, for example 2.34.2.1. 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, 2.34.2.1.1.

The elements for the **body** of the text are shown in the next sections individually for ECB, Operators, Regional Offices and Central Office. Font type and size will be “Times Roman” 12 for the text body.

### **2.39.2.2 Elements Specific to the ECB QAP/SOP**

**2.39.2.2.1** 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 “2.34.1”, as an example, followed by a preparer’s **NOTE** that will 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.

**2.39.2.2.2 Scope/Application/Purpose;** i.e., introduction, purpose, description of monitor; should include diagram or picture if available. (example numbering would be 2.34.1.1)

**2.39.2.2.3 Installation;** topics that will be discussed include monitor selection and initial laboratory monitor check-out, providing exact procedures, schedule, acceptance criteria, etc. (example numbering would be 2.34.1.2).

**2.39.2.2.4 Operational Set-Up and Start-Up;** detailed discussion on each activity to be performed to prepare the monitor/calibration equipment, data loggers and any support equipment for installation at a site. This would also include actual site installation procedures.

**2.39.2.2.5 Site Documentation and Data Handling;** detailed discussion of where and how to document monitor activities (i.e. maintenance log book).

**2.39.2.2.6 Site Support;** discusses what, when and how routine maintenance is to be performed.

**2.39.2.2.7 Quality Control;** discusses topics such as MDL determinations (where applicable) and performance audits (when, how and pass/ fail criteria).

**2.39.2.2.8 Appendices** (if applicable).

### **2.39.2.3 Elements Specific to the OPERATOR'S QAP/SOP**

**2.39.2.3.1** 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 "2.34.2", as an example, followed by a preparer's "NOTE" that will 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.

**2.39.2.3.2 Scope/Application/Purpose;** i.e., introduction, purpose, description of monitor; should include diagram or picture if available. (example numbering would be 2.34.2.1)

**2.39.2.3.3 Overview of major topics;** topics specific to the monitor that will be discussed in detail in subsequent sections, providing exact procedures, schedule, pass/fail criteria where applicable, etc. (example numbering would be 2.34.2.2).

**2.39.2.3.4 Site Visits;** detailed discussion on each activity to be performed during a site visit.

**2.39.2.3.5 Site Documentation and Data Handling;** detailed discussion of where and how to document all monitoring activities (elogs), reviewing and validating data (daily/monthly), storing data, file management, use of null codes etc.

**2.39.2.3.6 Preventative Maintenance;** discusses what, when and how routine maintenance is to be performed.

**2.39.2.3.7 Quality Control;** discusses topics such as performance audits, when, how and pass/ fail criteria

**2.39.2.3.8 Appendices** (if applicable)

#### **2.39.2.4 Elements Specific to the REGIONAL OFFICE POLLING and DATA REVIEW QAP/SOP**

**2.39.2.4.1** 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 “2.34.3”, as an example, followed by a preparer’s “NOTE” that will 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.

**2.39.2.4.2 Scope/Application/Purpose;** i.e., introduction, purpose, description of monitor; (example numbering would be 2.34.3.1).

**2.39.2.4.3 EDAS Set-Up;** discussion of EDAS set-up in the regional office to allow daily polling and review of data. (example numbering would be 2.34.3.2).

**2.39.2.4.4 Daily Data Review;** discusses procedures for polling monitors, reviewing data for anomalies, and applying proper null codes to data in monthly data summary reports.

**2.39.2.4.5 Reporting and Data Back-Up;** detailed discussion of where and how to document all monitoring activities (elogs), precision (AQ-98) and accuracy (AQ-99) reports, reviewing and validating data (daily/monthly), storing data, file management, use of null codes etc.

**2.39.2.4.6 ELOGS;** discusses what, when and how to review, archive and post on p:drive .

**2.39.2.4.7 QA Procedures;** discusses topics such as performance audits, 14-day calibration checks as to when, how and pass/ fail criteria.

**2.39.2.4.8 Appendices** (if applicable)

### **2.39.2.5 Elements Specific to the CENTRAL OFFICE RESPONSIBILITIES QAP/SOP**

**Note: A great deal of this document will be common to all monitor types.**

**2.39.2.5.1** 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 “2.34.4”, as an example, followed by a preparer’s “NOTE” that will 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.

**2.39.2.5.2 Scope/Application/Purpose;** i.e., introduction, purpose; (example numbering would be 2.34.4.1).

**2.39.2.5.3 Data Processing and Polling;** discussion of Central Office EDAS daily polling of all monitors across the state and how and to whom the data is distributed for review. (example numbering would be 2.34.4.2).

**2.39.2.5.4 Daily Data Review;** discusses procedures for reviewing data for anomalies, and applying proper null codes to data in monthly data summary reports.

**2.39.2.5.5 Start-Ups/Shut-Downs;** detailed discussion of procedures for start-up and shut-down of monitors.

**2.39.2.5.6 Independent Accuracy Audit Reporting;** discusses procedures for the review of audit results and data entry into AQS (AQ-99).

**2.39.2.5.7 Calibration (Precision) Check Reporting;** discusses procedures for the review of calibration check results and data entry into AQS (AQ-98).

**2.39.2.5.8 Data Validation and Certification;** discusses procedures for the validation and certification of all monitoring data, data entry into AQS. (This may also include such topics as annual systems audits, data logger comparisons, and annual network review.)

**2.39.2.5.9 Appendices** (if applicable).

### **2.39.3 QAP/SOP Review Process**

The QAP/SOP development, revision, and review process is intended to be a team effort with input from central office, ECB, and the regions. Typically, a central office chemist will “lead” the effort. However, they will work with a designated regional chemist and

an ECB technician. The lead regional chemist will share drafts with the other regional chemists.

In making changes to the QAP/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 QAP/SOP appendix for future reference. Any decisions 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 Section Chief.

The QAP/SOP is considered to be “the sole source” for how to operate a monitor -- employees are not to be criticized for following the QAP/SOP. If central office, ECB, or a region disagrees with what is in the QAP/SOP then they should propose a change through the Ambient Monitoring Workgroup. The operator should not have to refer to other documents, policy memos, or miscellaneous emails – everything about operating the monitor should be included in the QAP/SOP.

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