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DAQ-15-002 Standard Operating Procedure (SOP)
North Carolina Division of Air Quality Corrective Action Process
OPERATOR RESPONSIBILITIES

Revision 0



North Carolina Department of Environmental Quality | Division of Air Quality
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1.0 Approval Sign Off-Sheet

I certify that I have read and approve of the contents of the North Carolina Division of Air Quality Corrective Action Process Operator Responsibilities Standard Operating Procedure with an effective date of December 1st, 2021.

Director, Air Quality Division

Michael Abraczinskas

Signature:  Date: 11/15/2021

Ambient Monitoring Section Chief

Patrick Butler

Signature:  Date: 11/15/2021

Laboratory Analysis Branch Supervisor

Jim Bowyer, Environmental Program Supervisor II

Signature:  Date: 11/15/2021

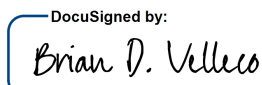
Projects and Procedures Branch Supervisor

Joette Steger, Environmental Program Supervisor II

Signature:  Date: 11/9/2021

Primary SOP Author

Brian D. Velleco, Chemist I

Signature:  Date: 11/9/2021

Disclaimer: This document, and any revision hereto, is intended solely as a reference guide to assist individuals in the operation of the instrument, 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

CAPA – Corrective Action, Preventive Action

COC – Chain of custody

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

LAB – Laboratory Analysis Branch – DAQ Lab located at 4403 Reedy Creek Rd in Raleigh, NC

MDL – Method detection limit

NC – North Carolina

NPEP – National Performance Evaluation Program

PAMS – Photochemical assessment monitoring station

PM – Particulate matter

PPB – Projects and Procedures Branch

PT – proficiency test (audit sample)

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

UAT – Urban Air Toxics

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2.0 SCOPE AND PURPOSE

The scope and purpose of this SOP is to describe the actions to be taken upon the discovery of a nonconformance to the North Carolina Division of Air Quality (DAQ) quality systems across all monitoring programs. Nonconformances are broken down into the following categories and are defined as follows:

- Repeated Calibration Failure
 - Multiple calibration failures that are not corrected by established standard operating procedures. These require further investigation and support if the ECB or LAB cannot resolve the issue with their respective expertise and typical remedial action.
- Incorrect Sample Storage Conditions
 - Samples requiring controlled temperature conditions for storage or shipping that did not meet requirements require a root cause analysis and investigation when a trend of exceedance is observed. For purposes of the corrective action process a trend occurs when the temperature limits are not met 3 times under similar circumstances.
- Persistent Blank Contamination
 - Multiple blank contamination analyses that are not corrected by established standard operating procedures. These require further investigation and support if the ECB or LAB cannot resolve the issue with their respective expertise and typical remedial action.
- Incorrect Standard Operating Procedures Followed
 - Standard operating procedures not followed via direct observation or through verification and validation of collected measurement data. An exception is made for staff under training or where data quality is not impacted.
- Repeated QC Acceptance Criteria Failure
 - Multiple QC check failures that are not corrected by standard operating procedures. These require further investigation and support if the ECB or LAB cannot resolve the issue with their respective expertise and typical remedial action.
- Unacceptable Proficiency Test (PT), National Performance Evaluation Program (NPEP) or Audit Results
 - Failure to meet satisfactory PT/NPEP results for a given monitoring activity requires further investigation and support. Suggest procuring a PT sample or internal audit with a known value to test equipment internally.
 - Regional or ECB audit failures require further investigation and support if ECB or the region cannot resolve the issue.
 - Internal LAB PT failures require further investigation and support if the LAB cannot resolve the issue.
- All Other (as defined by operator/reviewer/validator and detailed appropriately)
 - E.g., repeated site lightning strikes or flooding.

When one of the above events is observed a corrective action report (CAR) will be initiated via **DAQ-16-016** the **Corrective Action Report Form**. This SOP will aid the initiator of the corrective action as well as all other staff involved in the CAR process to document the nonconformance, complete the investigation, employ the corrective action, and audit the affected equipment or process. The goal of this SOP is to inform the parties involved in the corrective action on how to conduct the process in a standardized manner to alleviate the possibility of a future nonconformance. CAR from each calendar year will be summarized to look for trends across the monitoring network to improve resiliency.

3.0 EQUIPMENT CHECKS AND MATERIALS

This section describes the equipment and materials that are required to complete the steps described in this document. Additional subsection(s) or SOPs will also describe the equipment and materials as needed.

3.1 Equipment and Material List

- NC State Computer equipped with:
 - Keyboard and Mouse
 - Adobe Reader DC
 - Printer/Scanner
 - Microsoft Office 365 or equivalent
 - Microsoft Teams
- Corrective Action Report Form – DAQ-16-016 [See Appendix A for a Blank Form]
- SOP(s) involved in the nonconformance methodology
 - Any Chemicals, Materials, or Support equipment required per the written SOP.
- Staff involved in the nonconformance
- Projects and Procedures Branch (PPB) or Laboratory Analysis Branch (LAB) staff to audit the methodology after the corrective action has been employed

3.2 Chemical, Materials and Support Equipment Checks

The chemicals, materials, and support equipment required will be unique to each corrective action process. DAQ does not use any expired chemical reagents, materials or uncertified support equipment when conducting the procedures of any SOP or investigation of a nonconformance. All supporting materials should be verified according to the steps defined in the associated SOP(s) with the nonconformance in question.

4.0 SITE CHECKS

Site checks will be unique to each corrective action process. For field equipment, verify that the monitoring site is in good condition: the site landscaped, utilities secure, intakes for equipment free of obstructions and sited appropriately. Document any irregularities surrounding the corrective action dates in the appropriate site log.

5.0 DETAILED PROCEDURES

The sections below detail how to utilize the CAR Form **DAQ-16-016 (refer to Appendix A)** section by section. Multiple staff members will be involved so fluid communication is required during the CAPA process.

5.1 Section 1: Corrective Action Initiation

- 1 The initiator of a CAPA will obtain a blank CAR Form from IBEAM. The document can be filled out using Adobe Reader or by hand. If handwritten, the form must be filled out in indelible ink and all writing legible. Corrective actions will be initiated by the PPB or LAB staff, depending on the monitoring activity nonconformance.
- 2 Each corrective action must have a unique identifier. DAQ will use the date (**YYYY-MM-DD**) as the CAR number and the branch or regional office where the nonconformance occurred to differentiate each corrective action

report. Where **YYYY** is the 4-digit year, **MM** is the 2-digit month and **DD** is the 2-digit day. Fill out the header on each page of the CAR. E.g., A corrective action initiated on August 20th, 2021, at the LAB would be entered as 2021-08-20 for the CAR number with the office field filled as LAB.

- 3 Fill out the operator/chemist involved in the CAR in the **Operator/Chemist** field.
- 4 Record the date(s) of the nonconformance in the **Date of Nonconformance** field.
- 5 Record the **Corrective Action Initiation Date** in the appropriate field.
- 6 List the SOP(s) involved in the corrective action in the **SOP(s) Affected** field.
- 7 Select a reason for the corrective action and the monitoring program affected by checking the appropriate box. If the other field is used, describe in detail why a CAPA is being initiated and attach additional pages as required.
- 8 Enter the start date of the CAR proceedings in the **Start Date** field. Enter the **End Date** once the CAR is completed.
- 9 List all measurement parameters affected by the nonconformance in the **Parameter(s) affected** field.
E.g., ozone
- 10 Assign an anticipated completion date, work with the staff and supervisors involved to determine this date.
- 11 **Submit** the form to the PPB or LAB supervisor, depending on the monitoring activity affected, for signature and date received. This is their acknowledgement that a corrective action process is underway in relation to DAQ ambient monitoring activities. The supervisor will take control of the CAR and assign it to a chemist for investigation of the nonconformance.

5.2 Section 2: Description and Investigation of Nonconformance

- 1 The supervisor of the PPB or the LAB will assign a chemist to investigate the nonconformance requiring a corrective action in the **Chemist** field. They will then assign the CAR to that individual for completion within a mutually agreed timeline.
- 2 The chemist will detail the instruments involved, including serial numbers, in the **Instruments Involved** field.
- 3 The chemist will describe the reported nonconformance, detailing what happened and how the observations do not conform to DAQ quality systems.
- 4 An investigation into the nonconformance will occur by detailing how it was discovered and what is affected by the nonconforming parameter.
- 5 A root cause analysis will be conducted to determine why this deviation from DAQ quality systems occurred. The industry standard is to exhaust the question; why?
- 6 Investigate similar areas of the nonconformance for issues. See if the issue is prevalent in other measurement systems that employ similar equipment and if the root cause determined applies to this process as well. e.g., ozone generator is determined to be the cause of an ozone measurement nonconformance. Investigate other measurement systems that employ ozone generators to see if there are similar issues that can be prevented.

5.3 Section 3: Remedial Corrective Action Employment

- 1 The chemist involved will complete the **Chemist Assigned** field.
- 2 Denote any data type and periods involved with the nonconformance, e.g., carbon monoxide from 8/1/2021 to 8/15/2021.
- 3 Detail the immediate or long-term remedial corrective action steps required to return the measurement system back to proper operating conditions. These steps can be detailed in a logbook or e-log and referred to by refence. Append the logbook/e-log entries to the end of the CAR for completeness.
- 4 Detail who took the corrective remedial actions in the **Action Taken By** field.

- 5 **Assign an Anticipated Due Date** for long-term issues that cannot be rectified with materials on-hand (e.g., a part is determined to be the corrective action and back ordered with no fulfillment date). **Record the Date Completed** in the corresponding field.
- 6 **Record** the parameter(s) affected in the **Parameter(s) affected** field.
- 7 **Denote** the data impacts by referring to the appropriate QAPP and SOP.
- 8 **Record** the **Data Flag/Invalidation Start** and **Data Flag/Invalidation End** dates in the corresponding sections.
- 9 **Submit** the CAR back to the issuing supervisor to schedule an audit of the monitoring activity.

5.4 Section 4: Corrective Action Effectiveness Assessment

- 1 The LAB or PPB supervisor will assign an auditor to the CAR and relinquish the CAR to the assigned staff member. The staff member who employed the remedial corrective actions cannot audit his or her own work.
- 2 The auditor will fill his or her name in the **Auditor** field of the form.
- 3 The auditor will schedule a follow up audit of the nonconforming parameter with the branch/regional office supervisor at a mutually agreeable time. Record this date and time in the **Follow Up Audit Date and Time** field.
- 4 The auditor will assess the corrective action effectiveness and record any observations. The auditor will observe and interview the operator or chemist involved for adherence to the SOP(s) involved. The auditor should familiarize themselves with the measurement techniques and SOPs involved if not intimately familiar.
- 5 The audit will document a **Demonstration of a Return to Conformance**, e.g., if the AutoGC system was not passing blank criteria and exhibiting persistent blank contamination the auditor would look for conformance to the SOP surrounding blank criteria as well as any other criteria detailed: calibration checks, prescribed frequency for checks, *et. al.*
- 6 Further, the auditor can make any additional comments about the audit and recommendations per his or her experience on any facet of his or her audit.
- 7 The auditor will formally approve or disapprove of the corrective action and recommend the closure of or require further investigation, with details as to why to the supervisor of the monitoring activity.
- 8 The auditor will return the CAR to the supervisor of the monitoring activity for assessment.

5.5 Section 5: Corrective Action Closure

- 1 When a corrective action has been recommended for closure by the auditor, the auditor will sign indicating his or her approval in the **Supervisor Approval** and **Date** section of the CAR.
- 2 The LAB or PPB supervisor will review the proceedings and denote his or her approval in the **LAB or PPB Supervisor Approval** and **Date** section of the CAR.
- 3 The Ambient Monitoring Section Chief will review the proceedings and denote his or her approval in the **Ambient Monitoring Section Chief** and **Date** section of the CAR.
- 4 The **Director**, lastly, will review the CAR and approve of its closure with a final signature and date in the applicable field.
- 5 The **PPB supervisor** or designee will then archive the completed CAR in IBEAM under the CAR number and section, e.g., for a corrective action initiated at the RRO on 2021-08-15 and confirmed closed by all signatories the **CAR number** would be **2021-08-15 RRO**.

6.0 DATA REVIEW

Data review, while of paramount importance, is not defined in this SOP. See the affected SOP(s) section of the CAR to determine the appropriate data review process(es) associated with the affected parameter.

7.0 FILE MANAGEMENT

This section describes how the completed CAR is stored and maintained by DAQ.

7.1 IBEAM Upload

The **PPB supervisor** or designee will archive the completed CAR in IBEAM under the CAR number and section, e.g., for a corrective action initiated at the RRO on 2021-08-15 and confirmed closed by all signatories the **CAR number** would be **2021-08-15 RRO**.

8.0 FILE QUALITY ASSURANCE

The CAR is a fixed, controlled document that cannot be changed by the end user. DocuSign can be utilized for signatures in lieu of wet signing the report.

Annual review of the CAR should be conducted to summarize corrective actions for upper management each January for the preceding year. There will be one summary report for the LAB corrective actions and one summary report for PPB corrective actions. The purpose of these summaries is to look for trends and areas of improvement across monitoring programs division wide.

9.0 TROUBLESHOOTING AND CORRECTIVE ACTIONS

This section is reserved for troubleshooting and corrective actions in instrumental SOPs. Refer to the SOPs listed on the CAR for troubleshooting steps and possible corrective action.

10.0 REVISION HISTORY

1. 12/01/2021 **BDV** – Initial Publication

11.0 REFERENCES

1. North Carolina Department of Environmental Quality, Division of Air Quality (2021). Quality Assurance Project Plan for the North Carolina Division of Air Photochemical Assessment Monitoring Stations (PAMS) Required Site Network for Speciated Volatile Organic Compounds, Carbonyls, and Meteorological Parameters Including Mixing Layer Height. Revision 0. Raleigh, NC. DAQ Document ID: DAQ-01-007. Steger, Joette; Walters, Steven and Velleco, Brian D.

2. State of California, California Environmental Protection Agency, California Air Resources Board, Monitoring and Laboratory Division (2020). Standard Operating Procedures Corrective Action Notification. Revision 5. Sacramento, CA. Gilani, Greg and Singh, Manisha.

12.0 APPENDICES

1. Appendix A – **DAQ-16-016** Corrective Action Form

Appendix A – DAQ-16-016 Corrective Action Report

North Carolina Division of Air Quality Corrective Action Report (CAR)	CAR # _____ Branch/Regional Office: _____
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This form is used to document, investigate, and remediate nonroutine issues that impact data quality, completeness, storage or reporting for the North Carolina Division of Air Quality Ambient Monitoring Section Programs.

SECTION 1: Corrective Action Initiation

Operator/Chemist:	Date(s) of Nonconformance:
Corrective Action Initiation Date:	SOP(s) Affected:
Reason for Corrective Action (select all that apply):	
<input type="checkbox"/> <u>Repeated</u> Calibration Failure <input type="checkbox"/> Incorrect Sample Storage Conditions <input type="checkbox"/> <u>Persistent</u> Blank Contamination <input type="checkbox"/> Incorrect Standard Operating Procedures Followed <input type="checkbox"/> <u>Repeated</u> QC Acceptance Criteria Failure <input type="checkbox"/> Unacceptable Proficiency Test (PT), National Performance Evaluation Program (NPEP), or Regional/ECB Audit Result <input type="checkbox"/> Other (please describe in space below):	Program Affected (select all that apply): <input type="checkbox"/> NCore Multipollutant Monitoring Network <input type="checkbox"/> Photochemical Assessment Monitoring Station (PAMS) <input type="checkbox"/> Urban Air Toxics (UAT) <input type="checkbox"/> Particulate Matter (PM) <input type="checkbox"/> Meteorology (Met) <input type="checkbox"/> Criteria Pollutant Monitors (O ₃ , SO ₂ , CO, NO _x) <input type="checkbox"/> Rainwater Collection Network (RCN) <input type="checkbox"/> Other (please describe in the space below):
<i>(Attach additional pages as required)</i>	
Start Date:	End Date:
Parameter(s) affected:	Anticipated Completion Date:
Supervisor Signature:	Date Received:

North Carolina Division of Air Quality Corrective Action Report (CAR)	CAR # _____ Branch/Regional Office: _____
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SECTION 2: Description and Investigation of Nonconformance

Chemist Assigned:	Instruments Involved:
Description of the Nonconformance (what happened, how does it not conform?): Investigation of the Nonconformance (how was it discovered, what is affected by the nonconforming work?): Root Cause Analysis (what caused the nonconformance – think “ask why” five times): Investigate Similar Areas or Methodologies of Nonconformance: <div style="text-align: right;"><i>(Attach additional pages as required)</i></div>	
Investigation Conducted By (Name and Title):	Date:
Monitoring Site:	Anticipated Completion Date:
Instrument Downtime Start:	Instrument Downtime End:

North Carolina Division of Air Quality Corrective Action Report (CAR)	CAR # _____ Branch/Regional Office: _____
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SECTION 4: Corrective Action Effectiveness Assessment

Auditor:	Follow Up Audit Date and Time:
Assessment of Corrective Action Effectiveness:	
Demonstration of Return to Conformance:	
Auditor Comments/Recommendations:	
(Attach additional pages as required)	

Section 5: Corrective Action Closure

Auditor Approval:	Date:
LAB or PPB Supervisor Approval:	Date:
Ambient Monitoring Section Chief Approval:	Date:
DAQ Director Approval:	Date: