DEP 01-4
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STANDARD OPERATING PROCEDURE FOR PERFORMING CORRECTIVE ACTION

STATE OF FLORIDA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
OFFICE OF AIR MONITORING

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DOCUMENT HISTORY

Revision No.	Date	Responsible Person	Description of Change
0	5-2016	Florida PQAO	Initial Release
1	3-2017	Florida PQAO	Revision of immediate corrective actions for failed low level audits

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1.0 Introduction

The State of Florida's Division of Air Resource Management Office of Ambient Monitoring utilizes a corrective action procedure to enhance the documentation involved in the collection of defensible air quality data. The corrective action process is used to identify and document conditions outside of the control limits, while keeping the appropriate levels of management informed. The procedure is maintained in order to reduce or prevent the collection of poor quality data and/or the loss of data. This standard operating procedure (SOP) is based on the Statewide Quality Assurance Air Program Plan, DEP QAPP-002, Section 11.7.0, and the EPA Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Section 16.1.5. This SOP is also part of the State of Florida's Primary Quality Assurance Organization (PQAO) quality assurance documents.

The corrective action process documents issues that may impact or potentially impact data quality, completeness, storage, or reporting. This process is the overall effort to investigate and correct air monitoring issues and to prevent recurrence. It may also be used to identify recommended practices and procedures to improve the quality of data generated. The objective of the corrective action process is to improve data quality and to ensure compliance with statewide and federal requirements.

2.0 Scope and Applicability

Any person in the air monitoring organization that comprises the Florida PQAO, may initiate the corrective action process when a potential air monitoring issue is identified. Therefore, the process should be performed for any issues that involves loss of data for an extended period of time; or, in some instances, questionable data identified by staff.

Issues prompting the corrective action process may include, but are not limited to, incomplete logbook or record documentation; incorrect frequency or failure of calibrations or routine checks; expired standards; missed or invalid samples; missing or anomalous data. Issues resolved through procedural practices or other documented mechanisms such as the instrument's user manual, technical notes, other SOPs, etc., which do not present a significant impact to data quality, completeness, storage, or reporting, may not prompt the corrective action process. However, all corrective actions require notations in the site and analyzer logbooks, at a minimum. Additional notations and/or the appropriate qualifier or null codes should be applied to the data in data systems (i.e. AirVision, FAMAS, etc.).

The corrective action process must be used whenever a failure or deviation from accepted standards arises and action is taken to rectify the problem. This process is concluded when the issues have been resolved, and in some cases, will not require documentation with an official corrective action report. However, all variations of non-conformance must be documented in logbooks or filed emails to ensure there is a record of the event.

The corrective action report is a summary of specific problem(s) affecting the collection of data at an air monitoring site. Additional documentation such as emails, purchase orders and site documents may be appended to the corrective action report to serve as supplemental documentation.

A corrective action report must be filled out for all nonconformance items that are considered "major items" or results in significant data loss. "Major items" include, but are not limited to, the following:

a. Quarterly data completeness is less than 75%
b. Data loss occurs for a consecutive 72 hours
c. Data loss occurs for a consecutive 24 hours for a continuous monitor malfunction.
d. Major equipment repair
e. Exceedance of critical criteria limits
f. Exceedance of SOP calibration and control limits
g. Failed quality assurance performance audits resulting in data loss
h. Issues impairing an instrument's ability to produce legally defendable data

3.0 Summary of the Method

"Immediate" and "long-term" are the two common forms of corrective action within Florida's air monitoring organization.

3.1 Immediate Corrective Action

Immediate corrective actions are typically performed by the field personnel and only require notations in the site logbooks, forms, and null codes/qualifiers in the database along with comments (i.e. AirVision, FAMAS, etc.). Adaptation and documentation of these corrective actions can reduce or prevent the collection of poor quality data. Immediate corrective actions may include: resetting the GFI circuit breaker, a temporary power outage, time synchronizations, thermostat adjustments, etc.

Furthermore, specific control procedures such as monitor calibrations and pre-sampling operational checks are designed to detect instances where corrective actions are necessary; while troubleshooting guides provided in the manufacturers' instrument manuals and agency SOPs are used for immediate corrective action.

Example (1): A failed leak check on an R&P 2025 may only involve cleaning as a short-term corrective action in addition to documenting the field sheets.

Example (2): An exceedance of the control limit on continuous monitors or particulate monitors may trigger a corrective action. This may lead to an investigation of the control conditions and a recalibration of the instrument.

3.1.1 Corrective Action for Low Level Audits

An audit is considered as failed audit when the audit results for levels 3-10 are outside of the control limits for that specific pollutant (see Florida QAPP Revision No. 2, Section 5, Table 5.1). Audit failures at low levels (levels 1 and 2 only) are not considered failed audits, however, an evaluation of the instrument should be conducted to ensure the data quality and defensibility is maintained. The evaluation process must include but are not limited to the following:

- Evaluate the level of zero drift on the instrument
- Perform a sample line integrity check (SLIC)
- Assess the frequency of zero adjustments on the instrument

Any corrective actions taken based on the evaluation of the instrument must be documented in the site records and clearly state all applicable results.

3.2 Long-Term Corrective Action

The purpose of long-term corrective actions are to identify and eliminate causes for systemic or systematic failures. It consists of a thorough assessment and identification of the cause of the problem as well as objectively developing preventative methods to avoid recurrence. These issues may require extensive follow-up procedures or extended actions to rectify and provide a final resolution. Any issues that involve a significant loss of data (more than 72 consecutive hours) need to be documented with a corrective action report. Additionally, a corrective action involving data capture of less than 75% for a single quarter MUST include a detailed narrative and the Quality Assurance (QA) Coordinators and managers should also be notified.

1. The initiator commences the corrective action process when a nonconformance issue is discovered**.**
2. The initiator will make a decision as to how the issue may be addressed or solved as well as how it impacts or potentially impacts the collection of data. This may be done through the use of troubleshooting techniques, SOPs and/or equipment manuals.
3. If the problem can be resolved immediately, the only documentation required will be a notation in the site logbooks and/or forms as well as null codes/qualifiers and comments, where appropriate, in the database (i.e. AirVision, FAMAS, etc.)
4. If the issue requires a long-term corrective action, the initiator should notify and consult with the QA Coordinator and/or Manager as soon as possible.
5. The initiator will proceed with appropriate corrective action(s) and resolution process. The initiator will also complete the corrective action form explaining the problem ("Reason for Corrective Action" section); identify all persons involved; the actions taken ("Corrective Action Taken" section) and the final resolution summary ("Resolution" section).
6. Additionally, the field technician should also notate the issues and final resolutions in the site logbooks and forms, as needed.
7. A copy of the completed form should be provided to the QA Coordinator and/or Manager for review and an approval signature.
8. The QA Coordinator and/or Manager will ensure that the corrective action forms have been completed properly and the necessary personnel were notified. Additionally, they will ensure that the data has been handled appropriately in the database (i.e. null codes/qualifiers and/or comments have been entered).
9. The QA Coordinator and/or Manger will store an electronic copy of the completed report for recordkeeping.

4.0 Definitions

- QA Coordinator - individual designated by an ambient air monitoring program manager to oversee the quality assurance activities within a reporting organization.
- Initiator - the person originating the corrective action report.
- Manager or Supervisor - Ambient Air Program Manager or Supervisor.
- Corrective action(s) - any actions that may be taken to correct a problem within the air monitoring system.
- Nonconformance - failure to conform/adhere to the accepted standards as determined by the QAPP, SOP, CFR, etc.
- Audit corrective action - A corrective action initiated due to a performance evaluation or systems audit in which data was invalidated.
- Corrective Action Form DEP 01-4 - this form is to be used to document a nonconformance issue and additional pages may be used as needed.
- Corrective Action Form DEP 01-4-A - this form is to be used to notate any additional narrative or documentation to supplement the information on the Corrective Action DEP 01-4 or DEP 01-4-F forms.
- Corrective Action Form DEP 01-4-F - this is a follow-up corrective action form, and it is to be used to document the follow-up corrective action process.
- Narrative – this is a succinct account of the entire corrective action process including the resolution. The purpose of this narrative is to provide clarity and transparency to the finalized corrective action process.

5.0 Follow-Up Corrective Action

A review must be conducted, in sufficient detail, to assess that the corrective action(s) that have been implemented are effective and are truly preventing the reoccurrence of a problem/event. Follow-up corrective action will enhance the data quality and completeness.

Follow-up corrective action will be documented on the Corrective Action Form DEP 01-4-F and should be used in a similar manner as Corrective Action Form DEP 01-4.

Follow-up corrective action permits a slight deviation from the prescribed SOP guidance, as long as the following criteria are met:

a. A brief narrative of purpose and objective of follow-up corrective action is provided.

b. The control limits prescribed in SOP are met.

c. The follow-up process must enhance data quality and apply proven techniques to quantify the practicality of the actions performed.

d. More frequent equipment checks and tests are performed to enhance the acquisition of legally defendable data.

e. The procedures aid to prevent the recurrence of nonconformance issues.

f. All documentation must be clear and transparent.

g. The follow-up corrective action must include an initial start date and completion date.

h. The follow-up corrective action process **cannot** exceed 45 days from the initiation date.

6.0 Forms

The completed and signed copies of the forms must not be editable in PDF format. If subsequent changes need to be made to the form, a new form must be completed or additional documents appended to the original completed form.

Corrective Action Form DEP 01-4

Corrective Action Form DEP 01-4 is to be used to document agency corrective action reports. The two-section form details the reason for the corrective action; any actions taken to remedy problem and the final resolution report.

- Section I – Identifies the site, initiation date, describes reason for corrective action, parameter, QA coordinator/manager involvement and comments.
- Section II – Summarizes the corrective actions taken to resolve the deficiency/problem described, date of completion, final resolution summary, personnel who corrected the problem and management final approval.

Corrective Action Form DEP 01-4-A

Corrective Action Form DEP 01-4-A is to be used for attachments when additional narrative/documentation is needed. The form can be used in support of both Corrective Action Form DEP 01-4 and 01-4-F. The form includes three text fields where specific narratives can be notated.

Corrective Action Form DEP 01-4-F

Corrective Action Form DEP 01-4-F is to be used for follow-up corrective action as a complete summation detailing the entire process. The form consists of four sections:

1. Purpose – Identifies the objective, goal or benefit of performing the follow-up corrective action process. Identifies the site and initial start date.
2. Plan of Action– Shall include specific guidelines, policies, quality assurance measures and technical guidance regarding follow-up corrective action process.
3. Activity Log & Comments– Includes documentation of all activities performed during process. A detailed tracking log of checks performed. It should identify dates, task performed and status of equipment operation.
4. Final Resolution & Assessment– A summary of the results and overall status of follow-up process. This should be completed within 45 days of the initial start date on form. It must be closed loop corrective action meaning that the entire corrective action process has been closed with a meaningful and documented resolution; lessons learned have been documented, conveyed, and implemented appropriately; the data or acknowledgement of data impacts have been handled accordingly, etc.

Corrective Action Forms:
Form DEP 01-4 – Origination Worksheet & Action Resolution Form
Form DEP 01-4-A – Attachment Worksheet
Form DEP 01-4-F – Follow-Up Corrective Action Form

6.1 Form Naming Convention

The form name will be named to start with the parameter followed by the form number, AQS site number, equipment/property ID number and the date (see examples below).

Guidance Table:

Parameter File Name	Parameter
O3	Ozone
O3PS	Ozone Primary Standard
SO2	Sulfur Dioxide
SO2TL	Sulfur Dioxide Trace (N-Core)
CO	Carbon Monoxide
COTL	Carbon Monoxide Trace (N-Core)
NO	Nitrogen Oxides
NOy	Nitrogen Oxides Trace (N-Core)
PM25C	Continuous PM2.5
PM25M	FRM PM2.5 Manual
PM10	Continuous PM10

Date naming format: year (4 digits), month (2 digits), and date (2 digits)

Note: *Equipment/property ID number (please limit to 6 digit maximum length.*

Example: *Corrective Action Form DEP 01-4*
Sanford AQS Site #: 12-117-1002
Ozone Analyzer Property #: 132282
Date: March 29, 2016

In this example, the file name would be O3 DEP 01-4 1171002 132282 20160329
Note: *AQS State of Florida code (12) not to be used in form naming format.*

In the event additional forms are needed; add a capital letter (A) at the end, or (B) and (C) for the third and fourth forms, respectively.

Example: O3 DEP 01-4 1171002 132282 20160329A

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Corrective Action Form

Required Signatures: Adobe Signature

Form DEP 01-4 Corrective Action Form

SECTION I: (to be completed by Initiator)
Site Name: _____ **Site AQS #:** _____
Initiation Date: _____ **Initiator:** _____
Reason For Corrective Action Notification (continue on an attachment if needed):

_____
_____
_____
_____
_____

Estimated? Yes

Start Date & Time: _____ **End Date & Time:** _____
Parameter(s) affected: _____ **Expected Completion Date:** _____
*Up to 45 days from Initiation Date

Manager/QA Approval N/A
Manager/QA Coordinator: _____ **Date:** _____
Comments:

_____
_____

SECTION II: (to be completed by responsible staff or assignee)
Corrective Action Taken (continue on an attachment if needed):

_____
_____
_____
_____
_____

Action Taken By: _____ **Date:** _____

Resolution (continue on an attachment if needed): *Include changes to prevent recurrence, and any effect on data

_____
_____
_____
_____
_____

Final Resolution & Completion Date: _____

Resolved By: _____ *(Responsible staff or Assignee)

Resolution Approved By: _____ *(Program Administrator/Manager/QA Cord)

DARM DEP 01-4 REV. NO. 1: 4/16

To complete Form DEP 01-4, the following information is required:

- Site Name
- Site AQS number
- Initiation date … the origination date problem identified
- Initiator … staff who identifies problem and initiates corrective action form
- Reason for corrective action … A detailed description or brief narrative of original problem identified
- Start date & time … if available, date & hour problem started
- End date & time … if available, date & hour problem ended
- Estimated? … dropdown tab (Yes/No) to be used for long term corrective action or N/A if problem resolved in expected time frame
- Parameter … criteria pollutant data effected
- Expected completion date … as stated
- Manager/QA approval … dropdown tab for manager approval for expected completion date
- Manager/QA Coordinator … signature
- Date … date of signature & approval
- Corrective Action Taken … a detailed narrative of actions taken to correct or fix a problem
- Action taken by … signature of responsible staff or assignee who perform task
- Date
- Resolution … a summary of final resolution results to correct problem
- Final resolution & completion date
- Resolved by … signature of assignee who performed final resolution
- Resolution approved by … final signature Administrator/Manager/appropriate staff validating closed loop corrective action completed

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Corrective Action Form

Required Signatures: Adobe Signature

Form DEP 01-4-A Corrective Action Form (attachment)

Site Name: _____ **Site AQS #:** _____
Initiation Date: _____ **Attachment ID#** _____
Narrative Category: N/A

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Date: _____ **Narrators Name:** _____

Narrative Category: N/A

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Date: _____ **Narrators Name:** _____

Narrative Category: N/A

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Date: _____ **Narrators Name:** _____

Final Signature: _____ **Manager/QA Signature:** _____

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To complete Form DEP 01-4-A, the following information is required:

- Site Name
- Site AQS number
- Initiation Date … must be the same as listed on CAF-1 or CAF-3
- Attachment ID … use form naming guidance prescribed in section 6.1
- Narrative Category … form includes dropdown menu specific to sections on CAF-1 & CAF-3
- Date … narrative entry
- Narrator's Name
- Final Signature … the narrator who add final narrative to form
- Manager/QA Signature … Manager/QA/Program Administrator final signature & lock form

Note: There are three identical narrative category sections on form. In the event section not used, be sure to select N/A from the dropdown tab and apply a redline strike through for blank text areas.

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Follow-Up Corrective Action Form

Required Signatures: Adobe Signature

Form DEP 01-4-F (Follow-Up Corrective Action)

Site Name: _____ **Site AQS#:** _____

Initial Start Date: _____ **Follow-Up Corrective Action**

Purpose: (continue on an attachment if needed)

Plan of Action: (continue on an attachment if needed)

Approved By: **Date:** _____

Assigned To:

Activity Log & Comments: (continue on an attachment if needed)

Final Resolution & Assessment: (continue on an attachment if needed)

Completion Date: _____

Assignee:

Air Program Administrator: **Date:** _____

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To complete Form DEP 01-4-F, the information to the following listed items will be required:

- Site Name
- Site AQS number
- Initial start date
- Purpose … the objective of follow-up corrective action being performed
- Plan of Action … details of guidelines and quality assurance measures to be taken during process
- Approved by … Manager or QA Coordinator. signature
- Date … date manager approves plan of action
- Assigned to … Assignee's signature (signature of the person the task is assigned to)
- Activity log & comments … details & checks performed during process
- Final Resolution & assessment … final results of follow-up corrective action
- Completion date … no more than 45 days after initial start date
- Assignee…person the task is assigned to
- Air Program Administrator … Manager or QA Coordinator signature
- Date … date Air Program Administrator approves the completion of the closed loop corrective action