SCAQMD Quality Assurance (QA)

Corrective Action Process

Definition

- Corrective action - Any measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence (SCAQMD Quality Management Plan, April 2016)

Identifying the need for corrective action

- Nonconformance or deviation from requirements discovered during performance evaluations, technical system audits (TSAs), data review, by staff performing the work, or other evaluations
- Any person, agency or entity that identifies a nonconformance or deviation is encouraged to contact QA about it via an audit report, correspondence, or through a Quality Assurance Alert (internal)

When to use Corrective Action

THE CORRECTIVE ACTION PROCESS IS USED FOR BIGGER ISSUES OR PROBLEMS THAT ARE SYSTEMIC AND/ OR RECURRING AND WHICH IMPACT DATA QUALITY OR SAFETY

OCCASIONAL MALFUNCTIONS, ONE-TIME PROBLEMS REQUIRING REPAIR, RECALIBRATION, MISTAKES AND SIMILAR SINGULAR OCCURRENCES ARE NOT SUBJECT TO CORRECTIVE ACTIONS

Corrective Action Components

- Identify Issue
- Investigate (is it system wide or random/ limited)
- **Document** (audit results, photos, data, etc.)
- Issue a Corrective Action Request (CAR - a formal document requiring a response)
- Resolve
- System review and preventive action
- Follow up
- Close
- Entire process is logged and tracked

Corrective Action Process

- CAR issuer: QA, Auditor
- Recipient(s): Lab, Air Monitoring Group

Issuing Party (QA or Auditor)

- Identify, review and document the Problem (Deviation/ Nonconformance Occurs in a process or instrument).
- Include data impacts
- Determine Root Cause of the problem Process/Instrument if possible.
- Initiate corrective action request (CAR)
- Identify the recipient(s) of the CAR (Supervisor of the group responsible for resolving the issue), CC the manager of the group and the QA manager.
- Document finding, location, date of finding, assessor name, and CAR recipient(s) in the CAR form.

- Recommendation (propose an appropriate solution that will minimize the potential for reoccurrence). This will often mean a change to the process or the instrument).
    - In some cases, QA will recommend data invalidation, or will invalidate data.

- Assign an expected completion date for the CAR normally two weeks. (Receiving party has the opportunity to propose a new completion date if the issue is complicated or more resources need to be allocated before work can begin)

- Use MS Outlook calendar meeting function to inform staff of CAR issuance; attach a copy of the CAR and CAR completion instructions and use the Outlook meeting start time as the expected completion date.
- Follow up when the Outlook reminder appears if a response is not received by the due date.
- Close the CAR once a response stating the resolution and actions taken to prevent recurrence is received.

Recipient (Lab or AM Staff)

- Accept the CAR with the expected completion date, **OR** propose a new date for completion if the issue is complicated and require additional resources (e.g. moving a site because it is no longer meeting 40 CFR part 58 siting criteria).
- Confirm the finding and correct the problem (e.g. how did it happen, why did it happen, could it happen again).
- Preventive action plan which include(s) identifying action(s) needed to correct and prevent recurrence of the problem (e.g. training, instrument preventive maintenance or implementing training programs).
- Record changes to methods and procedures needed to correct and prevent the quality issue, and update SOPs.

- Learn from the experience; communicate and reinforce expectations when it comes to what is correct, safe and consistent to other staff members who are involved in similar tasks.
- Recipient(s) sign off when the issue is resolved.
- Share information about the CAR and how it was resolved with other groups in the agency and with other agencies who are involved in similar work.
- Send CAR response back to issuing staff (QA).

Example 1

as issued/ field

AQMD CORRECTIVE ACTION REQUEST

To:	Rene Bermudez	**Date:**	4/14/2016	**Assessor:**	Mike Hamdan
Location:	Rubidoux	**Assessment Date:**	3/30/2016	**CAR #:**	20160002
Expected Deadline:	5/17/2016	**Instrument:**	Sitting	**S/N:**	NA

FINDINGS: Trees on the N. side of the PM sampling area at Rubidoux are growing and close to the PM samplers (924 and others), may have an impact on PM air samples.

RECOMMENDATIONS: 1. confirm finding and resolve the issue.

Example 1
cont.

Please indicate the corrective action taken below, save, and return this form to:

Quality Assurance Senior AQ Chemist or Instrument Specialist

and also copy this CAR electronically to your supervisor and manager

CORRECTIVE ACTION TAKEN INCLUDING REOCCURRANCE PREVENTION/MINIMIZATION:

By: _____ **Date:** _____

REVIEWER/QA MANAGER COMMENTS

QA Reviewer (Title): _____ **Date:** _____

QA Manager: _____ **Date:** _____

QA Questions: Contact QA Senior AQ Chemist or Instrument Specialist or QA Manager

Template: (CAR_Template_v.2.0_092612.xls)

Example 2

as completed/ lab

AQMD CORRECTIVE ACTION REQUEST

To:	Teffera/ Saucedo	**Date:**	8/31/2016	**Assessor:**	K. Kasza
Location:	Diamond Bar	**Assessment Date:**	NA	**CAR #:**	20160012
Expected Deadline:	10/31/2016	**Instrument:**	NA	**S/N:**	NA

FINDINGS:

Per 2016 South Coast Air Quality Management District's PM10/PM2.5 mass analysis performance audit August 11, 2016

1. Weight comparisons between the primary and working weights should be conducted quarterly for both the PM10 and PM2.5 laboratory. No records were available for PM10.

RECOMMENDATIONS:

1. conduct quarterly weight comparisons between the primary and working weights for the PM10 laboratory. Comment: PM10 quarterly intercomparison between weights is not a Federal requirement. Please note that the long time period between checks may create problematic values. If that happens, please issue a QAA related to this CAR 20160012 for better resolution.

Example 2
cont

Please indicate the corrective action taken below, save, and return this form to:

Quality Assurance Senior AQ Chemist or Instrument Specialist

and also copy this CAR electronically to your supervisor and manager

CORRECTIVE ACTION TAKEN INCLUDING REOCCURRANCE PREVENTION/MINIMIZATION:

The lab has began PM10 Quarterly weight comparisons between the primary and the working weights. This was performed on 08/17/2016 and is being recorded in the calibrations notebook for PM10 for Quarter 3 2016. This will be a continued practice for every quarter and changes to the SOP has been made to show this as standard practice.

By: Laura Saucedo **Date:** 9/8/2016

REVIEWER/QA MANAGER COMMENTS

QA Reviewer (Title): K. Kasza **Date:** 9/14/2016

QA Manager: A. Polidori **Date:** 9/22/2016

QA Questions: Contact QA Senior AQ Chemist or Instrument Specialist or QA Manager

Template: (CAR_Template_v.2.0_092612.xls)

Example 3

as issued long-term/ lab

AQMD CORRECTIVE ACTION REQUEST

To:	Teffera/ Dutz	**Date:**	9/3/2015	**Assessor:**	Kasza
Location:	Diamond Bar	**Assessment Date:**	8/13/2015	**CAR #:**	201500016
Expected Deadline:	9/3/2016	**Instrument:**	PM2.5 cond room	**S/N:**	NA

FINDINGS: The PM2.5 room experiences rapid swings in humidity (and to a lesser extent temperature) and upward drift of the 24 mean humidity (and to a lesser extent temperature) which require constant monitoring and repair calls. (see graphs on sheets 3 and 4)

RECOMMENDATIONS:
1. continue diligence to maintain system within bounds
2. investigate repair, reconfiguration,and/ or replacement to ensure a more stable, reliable system

Example 3
cont

Please indicate the corrective action taken below, save, and return this form to:

Quality Assurance Senior AQ Chemist or Instrument Specialist

and also copy this CAR electronically to your supervisor and manager

CORRECTIVE ACTION TAKEN INCLUDING REOCCURRANCE PREVENTION/MINIMIZATION:

By: _____ **Date:** _____

REVIEWER/QA MANAGER COMMENTS

QA Reviewer (Title): _____ **Date:** _____

QA Manager: _____ **Date:** _____

QA Questions: Contact QA Senior AQ Chemist or Instrument Specialist or QA Manager

Template: (CAR_Template_v.2.0_092612.xls)

Example 3

cont

This is an example of a long-term response to a CAR. It requires re-evaluation of the PM2.5 weigh room basic design as part of the improvement process, to create a more stable, rugged weighing environment.

CAR Instructions

Attached is a Corrective Action Request (CAR) from the Quality Assurance Branch. Please follow the instructions below:

1) Open CAR (the attached Excel File)

2) Review Finding(s), Recommendation(s), and Proposed Deadline

3) Select Option using the Buttons Above:

   a. ACCEPT: CAR findings are correct and action(s) including cause identification and preventative/minimization actions taken or recommendations made will be accomplished to resolve finding and prevent/minimize its reoccurrence by the proposed deadline
   b. PROPOSE NEW TIME <also insert a new date>: CAR findings are correct and action(s) including cause identification and preventative/minimization actions taken or recommendations made will be accomplished to resolve finding and prevent/minimize its reoccurrence but by an alternative deadline.
   c. DECLINE <also insert explanation>: CAR finding is not valid and there are no plans for further action.

CAR Instructions

cont.

If option 3a or 3b is selected, forward to the appropriate lead staff <Alt+F> or *Actions -> Forward* as applicable, and follow up with (a) progress report(s) on corrective action(s).

4) Inform the QA Branch when a proposed deadline cannot be achieved including the reason for the delay and provide a new deadline date.

5) Upon completion, summarize the corrective action taken in the CAR form and include the cause determination and preventative/minimization actions taken or recommendations made to prevent/minimize reoccurrence under the "Corrective Action Taken" field. The person performing the corrective action is to sign, date, save it electronically, and email it to the Senior AQ Chemist or Senior AQ Instrument Specialist in the QA Branch as appropriate

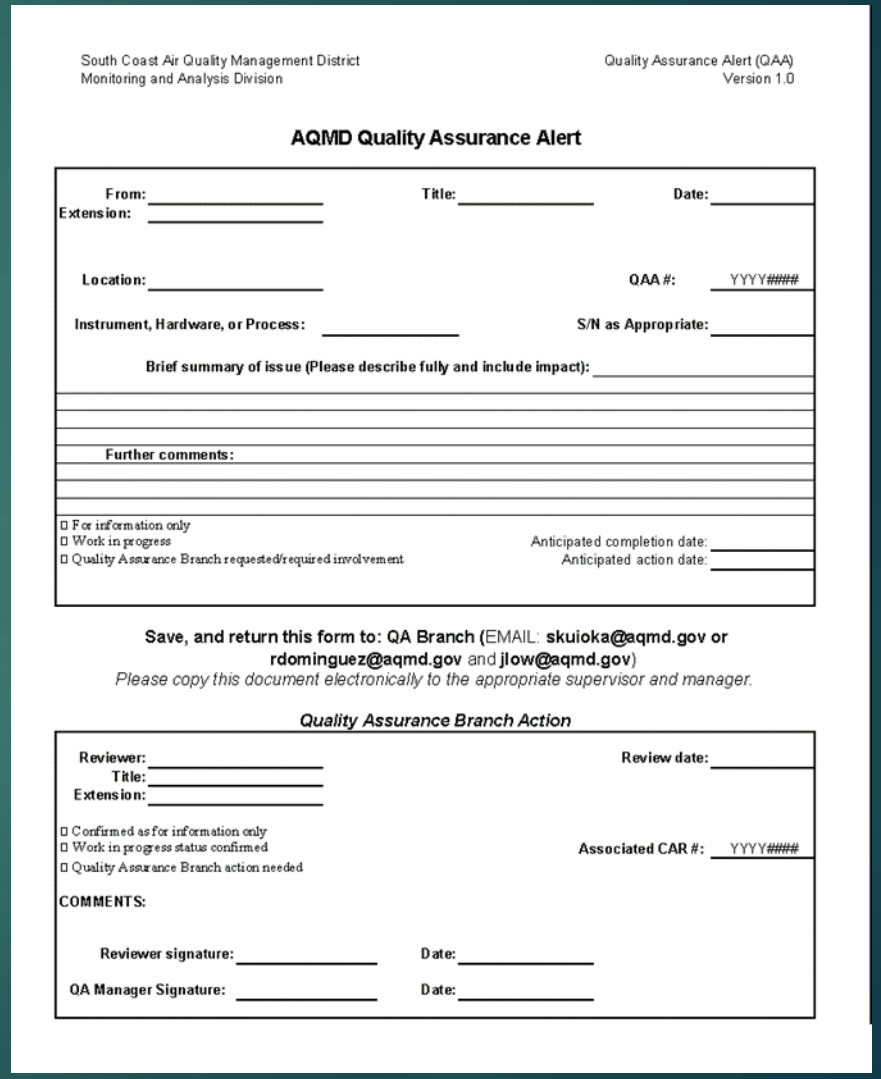
6) Under normal circumstances, the QA Branch will acknowledge receipt of the completed CAR within 4 working days.

Room for Improvement

- The CAR process doesn't adequately track problems that are complex, protracted, or evolving, and/ or that require involvement from multiple areas of the District (e.g. legal, purchasing, facilities management, field investigators), or outside entities (e.g. gas vendors) that aren't directly required to follow the CAR process.

Quality Assurance Alert (QAA)

- Mechanism for staff to communicate an issue(s) or problem to the Quality Assurance Branch
  - Repeated systematic technical issue that will affect data quality or completeness (over 2 weeks)
  - Safety Concern
- Not used for typical QC adjustments or routine troubleshooting
- 3 Levels of QA Involvement-
  - Information only
  - Work in Progress
  - Quality Assurance Branch requested/required involvement



South Coast Air Quality Management District
Monitoring and Analysis Division

Quality Assurance Alert (QAA)
Version 1.0

AQMD Quality Assurance Alert

From: _____ Title: _____ Date: _____
Extension: _____

Location: _____ QAA #: YYYY#####

Instrument, Hardware, or Process: _____ S/N as Appropriate: _____

Brief summary of issue (Please describe fully and include impact): _____

Further comments:

☐ For information only
☐ Work in progress
☐ Quality Assurance Branch requested/required involvement

Anticipated completion date: _____
Anticipated action date: _____

Save, and return this form to: QA Branch (EMAIL: **skuioka@aqmd.gov or rdominguez@aqmd.gov** and **jlow@aqmd.gov**)
Please copy this document electronically to the appropriate supervisor and manager.

Quality Assurance Branch Action

Reviewer: _____ Review date: _____
Title: _____
Extension: _____

☐ Confirmed as for information only
☐ Work in progress status confirmed
☐ Quality Assurance Branch action needed

Associated CAR #: YYYY#####

COMMENTS:

Reviewer signature: _____ Date: _____

QA Manager Signature: _____ Date: _____

Conclusions

The corrective action process is the means by which the SCAQMD ensures that Data Quality Objectives and data completeness requirements are being met.

Everyone is involved in continuously identifying deviations and non-conformances.

QA centrally evaluates the problems that are uncovered, issues formal calls for action when appropriate, tracks progress, documents the solutions, evaluates the outcome, and is the repository for documentation.

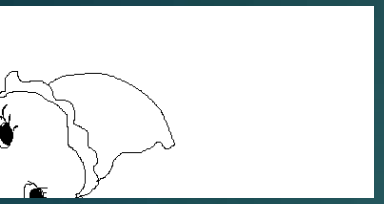
Like any other process, the corrective action process is itself a work in progress!

Thank You!

Raul Dominguez, Jr. Ph.D.
Senior Air Quality Chemist
SCAQMD

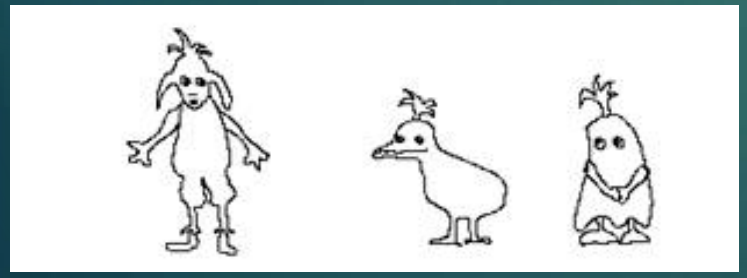
Contact: rdominguez@aqmd.gov
Phone: (909) 396-3283

“Oh dear” said that Who.
”Is there more
than papers to write,
And files to store?”

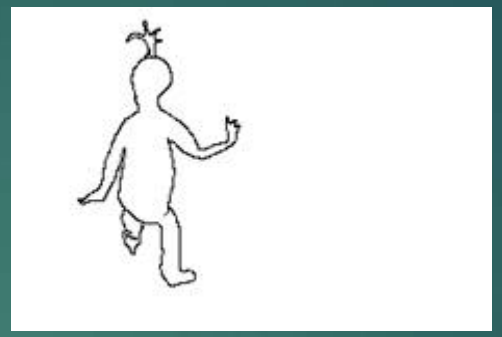


“There’s versions and
visions,
Signatures! Decisions!
And audits that peep
And results to keep!”

“There’s QMPs, and QAPPS,
and SOPs galore.



There’s QAs and things
To not ignore!



And TADs and CARs
Come by the score!
QA goes on - forevermore.
:
Forevermore.”

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And that my friends,
is why this thread
Was left unfinished –
Yet is ever said.
~~~~~~~~~~~~~~~~~~~~~~