

# Standard Operating Procedure for Corrective Action for the PM<sub>2.5</sub> Chemical Speciation Program

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\* RTI International is a trade name of Research Triangle Institute.

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## Standard Operating Procedure for Corrective Action for the PM<sub>2.5</sub> Chemical Speciation Program

### 1.0 Introduction and Background

The Corrective Action Request (CAR) system for the Chemical Speciation Program is used to document major changes made to procedures, systems, instruments, and computer programs that occur after the system has been completed and accepted. A good corrective action process is an invaluable management tool that can be used to improve client communications, control deadlines and costs, and provide input for project reports. The CAR file provides information about why, when, and how a change was made and provides a secure place to archive information generated during the corrective action process, including design documents and acceptance testing results.

**Note:** The CAR system does not supersede any other RTI or EPA policies, requirements, or procedures, including purchasing, accounting, quality assurance (QA), health and safety, and administration.

Typical situations in which the CAR process can be used include the following:

- Correcting a major “bug” in software, especially after that software has been used to deliver data outside RTI
- Developing improved procedures and making the corresponding changes to approved standard operating procedures (SOPs), the Quality Assurance Project Plan (QAPP), and other affected documents
- Purchasing, installing, and testing new equipment intended to solve specific performance problems
- Developing new training materials to remedy specific staff performance deficiencies
- Investigating and correcting systematic data quality problems in the laboratory.

A CAR should always be used when any of the following conditions apply:

- A substantial planned effort is necessary to solve a specific operational or data quality problem
- Significant costs (i.e., labor hours or purchased materials) are involved
- Corrected data will have to be redelivered to the client
- The client is aware of the problem and is expecting status updates
- The correction is expected to take a relatively long period of time (more than about two weeks) and deadlines need to be monitored by management
- Previously approved validation or QA criteria are affected

- Information about the corrective action needs to be preserved in a controlled file.

A CAR is optional when none of the above conditions apply and the area supervisor agrees that the corrective action can be handled within the normal scope of operations. Isolated problems that normally arise during routine operations should not generate CARs; however, a CAR would be appropriate when a procedural change is necessary to address a chronic operational problem.

## 2.0 Procedure

Administration. CAR forms will be issued and logged by the project administrator (currently Diane Haas). The project administrator will assign numbers to the CARs and distribute them as requested. The project administrator will also be responsible for updating the log sheet and for filing the CAR forms and any other information that may be included with the form.

Initiation. Any project staff member may report a problem that initiates a CAR. The CAR originator should work with the area supervisor to complete the first two sections of the CAR form.

Assignment and Approval. The supervisor for the affected area is responsible for assigning personnel, setting the completion deadline, and approving the CAR to be acted upon. The supervisor may assign one of the laboratory staff, him/herself, or other qualified project personnel to lead the CAR. CARs requiring significant additional labor hours or other costs must be approved by the Program Manager (PM).

Tracking. After the CAR has been scheduled and approved, copies of the CAR form should be distributed as indicated at the bottom of the form. The project administrator will enter the information onto the log sheet and will start a new file folder for the CAR. The PM and Quality Assurance Officer (QAO) should review each CAR regularly and provide any necessary input to the process. The CAR log will be reviewed each month by the PM or QAO as part of monthly reporting. The QAO and/or PM will follow up on CARs that are overdue for completion.

Implementation and Acceptance. The assigned staff member is responsible for carrying out the corrective action, along with the area supervisor. A CAR file should be updated whenever significant modifications to the approach, costs, or deadlines become necessary. Successful completion of each CAR should be witnessed and approved by the area supervisor, QAO, or PM.

Completion and Archiving. When the corrective actions have been completed and accepted, the approved CAR form, copies of planning materials, test data, and other significant documentation should be archived in the CAR file.