

**DRI STANDARD OPERATING PROCEDURE**

**Corrective Action**

**DRI SOP #6-017r1  
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## **1. GENERAL DISCUSSION**

### **1.1 Purpose of Procedure**

This procedure outlines the corrective action system and use of the Corrective Action Request (CAR) system within the Environmental Analysis Facility (EAF). CAR documents root cause investigation for nonconforming work or departures from the policies and procedures, subsequent corrective actions, and effectiveness.

### **1.2 Measurement Principle**

Not applicable

### **1.3 Measurement Interferences and Their Minimization**

Not applicable

### **1.4 Ranges and Typical Values**

Not applicable

### **1.5 Typical Lower Quantifiable Limits, Precision, and Accuracy**

Not applicable

### **1.6 Personnel Responsibilities**

All EAF employees are responsible for being aware of the potential for operational and data quality issues and to report any problems to their supervisors, including those that may initiate a CAR.

The supervisor/coordinator for the affected operation is responsible for assigning personnel, assisting in setting completion deadlines, and reviewing and approving the CAR to be acted upon. The EAF Executive Director and Quality Assurance (QA) Officer may need to be included in allocating resources and establishing deadlines, especially when a major, costly effort involving multiple groups may be indicated.

The responsible personnel is responsible for address root cause, carry out and complete corrective and preventive actions.

The EAF QA Officer or designee acts as the administrator for CARs, reviews each regularly, provides assistance as needed, tracks the progress of each, and follows up if a CAR's completion is overdue.

### **1.7 Definitions**

Corrective Action Request (CAR) system – A process by which specified operational and data quality issues are addressed, especially if major resources or time or data has been delivered to a client.

**1.8 Related Procedures**

None

**2. APPARATUS, MATERIALS, AND FORMS**

**2.1 Apparatus and Instrumentation**

Not applicable

**2.2 Reagents**

Not applicable

**2.2 Forms**

EAF Corrective Action Request (CAR) Form (Figure 2-1).

**3. CALIBRATION PROCEDURES**

Not applicable

**4. PROCEDURES**

**4.1 Applicability**

4.1.1 Typical circumstances in which the CAR process may be used may include the following:

- Correcting major bugs in software (especially if the software has been used to deliver data to EAF clients)
- Making major changes to improve procedures and corresponding SOPs or other quality documents (especially when the revisions involve equipment, facility, or software revisions)
- Purchasing, installing, and testing new equipment or software to solve specific performance deficiencies
- Developing new training materials to remedy specific staff performance issues
- Investigating and correcting systematic data quality or quality system deficiencies in the EAF
- Addressing nonconforming work or departures from the policies and procedures identified from internal or external audits

Title: Corrective Action

<b>CAR No.:</b>	<b>Initiation Date:</b>
<b>To:</b>	
<b>From:</b>	
<b>How Identified:</b>	
<b>Reported (Nonconformance) Conditions:</b>	
<b>Answer Due Date:</b>	
<b>Root Cause:</b>	
<b>Corrective Action (Give Steps &amp; Expected Completion Dates):</b>	
<b>Preventive Action:</b>	
<b>Completed by:</b>	<b>Date:</b>
<b>Accepted by:</b>	<b>Date:</b>
<b>Follow-up Results:</b>	
<b>Performed by:</b>	<b>Date:</b>
<b>Closed Out (Y/N):</b>	If not closed out on follow-up, issue a new CAR
<b>New CAR No.:</b>	<b>Date</b>

Figure 2-1. EAF Corrective Action Request (CAR) Form

4.1.2 A CAR must be used if any of the following conditions apply:

- A major effort is needed to solve a specific operational or data quality issue
- Significant costs (e.g., labor hours, equipment, or materials) are involved
- Corrected data needs to be redelivered to the client
- A client is aware of the issue and expects status updates
- The corrective effort will take a relatively long period of time (i.e., more than about two weeks)
- Approved validation and QA criteria are affected
- Information about the corrective action needs to be formally documented

4.1.3 A CAR may be used when none of the circumstances in 4.1.2 apply and the laboratory supervisor/coordinator agrees that the corrective action can be handled within the normal scope of operations. Isolated, limited problems that typically arise during routine operations should not require CARs.

## 4.2 Procedure

4.2.1 Administration – The CAR forms are issued and logged by the EAF Quality Assurance (QA) Officer or a designee. Numbers are assigned to the CARs and are distributed as requested. CARs are logged in the EAF CAR Log Form for review and tracking.

4.2.2 Initiation – Any EAF personnel may report a problem that initiates a CAR. Often, CARs may arise from internal EAF audit, external audits, and ongoing data validation and QA/QC review. The originator of the CAR works with the supervisor/coordinator and EAF QA Officer (or designee) to complete the first two sections of the CAR form, within one week of initiation.

4.2.3 Assignment and Approval – The supervisor/coordinator for the affected operation is responsible for assigning personnel, working with the EAF QA Officer or designee to set a completion deadline and approving the CAR to be acted upon. CARs requiring significant resources or time to complete must be approved by the EAF Executive Director and the EAF QA officer.

4.2.4 Tracking – Once the CAR has been scheduled and approved, copies of the form are distributed to the initiator, assigned personnel, and supervisor/coordinator. The CAR form is maintained by the EAF QA Officer or designee, who enters due dates into a tracking calendar. The QA Officer or designee reviews the CAR log and each CAR regularly, provides input as necessary, and reports delays or concerns to the EAF Executive Director and QA Officer.

4.2.5 Implementation – Assigned personnel and the area supervisor/coordinator are responsible for carrying out the corrective action and implementing preventive actions. The CAR file

is updated whenever significant modifications to the approach, costs, resources, or deadlines are necessary.

- 4.2.6 Completion – When the corrective actions are completed, the successful completion of a CAR should be approved by the area supervisor/coordinator, QA Officer or designee, or the EAF Executive Director.
- 4.2.6 Effectiveness Verification – The QA Officer should review CARs during internal audit and verify the effectiveness of corrective and preventive actions. Such verification will be documented in the CAR form.
- 4.2.7 Archiving – When the corrective action has been completed and approved, the approved CAR form and copies of related material and documentation shall be archived with their location on the DRI server or the CAR log book.

**5. QUANTIFICATION**

Not applicable

**6. QUALITY CONTROL**

Expected due dates and completion are tracked using a schedule calendar.

**7. QUALITY ASSURANCE**

Not applicable

**8. REFERENCES**

None

**9. DOCUMENT CHANGES**

08/15/12: New SOP – r0.

11/19/21: r1 – Added role of responsible personnel for implementing corrective and preventive actions. Added effective verification procedure. Updated CAR form.