

Subject: Re: Interim Change to Management Procedure 3.1, Rev. 6, CARs

Date: Tue, 26 Mar 2002 08:14:27 -0700

From: Steve Zappe <Steve_Zappe@nmenv.state.nm.us>

Organization: NMED Hazardous Waste Bureau

To: "Sena, Gloria - DOE" <Gloria.Sena@wipp.ws>



Gloria -

I received MP 3.1, but there was no difference between it and the one we received on January 23. Please clarify whether the interim changes were actually incorporated into the MP, or if the March 20 memorandum is the only new information.

If there is a newer version of MP 3.1 that incorporates the interim changes identified in the March 20 memo, please provide that to me. Thanks!

Steve

"Sena, Gloria - DOE" wrote:

> I will get that mailed out to you.

>

> -----Original Message-----

> From: Steve Zappe [mailto:Steve_Zappe@nmenv.state.nm.us]

> Sent: Wednesday, March 20, 2002 11:11 AM

> To: Sena, Gloria - DOE

> Cc: Paul Ritzma; James Bearzi; Meg.Milligan@wipp.ws

> Subject: Re: Interim Change to Management Procedure 3.1, Rev. 6, CARs

>

> Gloria -

>

> Please provide me with a copy of Management Procedure 3.1, Rev 6 with these

> interim changes incorporated into it for our records. This procedure was an

> integral part of the settlement of the recent compliance order by NMED

> against

> CBFO and WTS. Thanks!

>

> Steve Zappe

> NMED

>

> "Sena, Gloria - DOE" wrote:

>

>> Name: 02-0692 memo to

> Distribution.doc

>> 02-0692 memo to Distribution.doc Type: WINWORD File

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CBFO MANAGEMENT PROCEDURE
Carlsbad Field Office

MP No. 3.1 Page 1 of 16

Revision 6



Title: **CORRECTIVE ACTION REPORTS**

Manager, Carlsbad Field Office

Ines Tray

Date: *1/23/02*

1.0 PURPOSE

This procedure establishes responsibilities and defines the method for initiating and processing corrective action reports (CARs) to ensure that effective measures are implemented to correct Carlsbad Field Office (CBFO) and participant deficiencies identified by CBFO. CARs are used to identify and correct conditions adverse to quality.

2.0 SCOPE

This procedure applies to CBFO personnel who initiate, track, and verify the completion of corrective actions, and close CARs issued by CBFO. It also applies to those CBFO personnel who investigate, correct, and prevent recurrence of the deficiencies identified in the CARs. This procedure shall be used when CBFO identifies a condition adverse to quality involving a CBFO or participant's process, service, or product. This procedure also provides instructions related to tracking CARs initiated by transuranic (TRU) waste sites. This procedure supercedes MP 3.1, revision 5 Corrective Action Reports."

3.0 REFERENCES AND DEFINITIONS

3.1 References

- 3.1.1 DOE CBFO-94-1012, *CBFO Quality Assurance Program Document (QAPD)*
- 3.1.2 CBFO Management Procedure, (MP) 1.2, *Selection of Quality Levels*
- 3.1.3 CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Project Records*
- 3.1.4 CBFO MP 4.9, *Quality Assurance Records*
- 3.1.5 CBFO MP 10.2, *Surveillances*
- 3.1.6 CBFO MP 10.3, *Audits*
- 3.1.7 CBFO Team Procedure (TP) 3.2, *Trend Identification and Reporting*
- 3.1.8 *WIPP Hazardous Waste Facility Permit*

- 3.2.15 Work Suspension Recommendation - A recommendation provided to a project or organization to suspend work until such time as corrective measures are implemented. A work suspension recommendation may be issued as a result of a significant condition adverse to quality. The formality of notification depends on the specific contractual arrangements.
- 3.2.16 WIPP Operating Record - Records maintained at the WIPP facility as required by 20.4.1.500 NMAC (incorporating 40 CFR §264.73) and the WIPP Hazardous Waste Facility Permit.

4.0 RESPONSIBILITIES

4.1 CBFO Manager

- 4.1.1 The CBFO Manager maintains overall responsibility for the implementation of the process described in this procedure.
- 4.1.2 The CBFO Manager is also responsible for evaluating and approving requests to extend corrective action completion dates for CARs related to CBFO certified processes at the TRU waste sites.

4.2 CBFO Assistant Managers (AMs)

The CBFO assistant managers (AMs) are responsible for ensuring that CAR resolution is accomplished in a timely and effective manner, and concurring with the method of work suspension recommendations. When a CAR is initiated outside of a CBFO assessment activity and there is no associated assessment team leader or initiating team leader, the AM who supervises or exercises oversight of the CAR initiator shall ensure that the responsibilities contained in sections 4.3 and 4.4 below are fulfilled.

4.3 Initiating Team Leader

The CBFO initiating team leader is responsible for performing the following corrective action activities:

- 4.3.1 Ensuring that the CAR process responsibilities of the assessment team leader are fulfilled whenever an assessment is led by someone other than a CBFO staff member.
- 4.3.2 Ensuring that all assessment team personnel receive adequate familiarization and training on this management procedure.

4.4 Assessment Team Leaders

CBFO assessment team leaders are responsible for the following CAR process activities. If the assessment team leader is not a CBFO staff member, or is no longer available, the initiating team leader shall ensure that these responsibilities are fulfilled:

- 4.4.1 Reviewing, approving, and transmitting CARs that result from their assessments.
- 4.4.2 Approving the proposed corrective actions for CARs.
- 4.4.3 Monitoring the corrective action process for CARs resulting from their assessments.
- 4.4.4 Evaluating and approving requests for extension of the response due date and the corrective action completion dates (see Section 4.1 for additional information).

4.9 Corrective Action Verifier

Responsible for verifying corrective action completion and assigning the appropriate trend cause code (block 19b).

5.0 PROCEDURE

Note: Instructions for completing the CAR forms are included in attachment V.

5.1 Corrective Action Report Initiation

A CAR form (attachment I) shall be initiated to document conditions adverse to quality.

- 5.1.1 Individuals identifying a condition adverse to quality shall discuss the condition with the appropriate members of the responsible organization (CAR block 7) and shall initiate a CAR, using the CAR form and the continuation sheet (attachment I).
 - 5.1.2 The CAR initiator shall complete CAR blocks 2 through 13 (excluding 11b) and forward the CAR to the assessment team leader.
 - 5.1.3 The assessment team leader shall review the condition and determine if the CAR is valid.
 - 5.1.4 If the assessment team leader determines the CAR is not valid, the CAR shall be returned, unsigned, to the initiator along with an explanation of the determination.
 - 5.1.5 The assessment team leader shall determine if accelerated corrective action is required. Accelerated corrective action is required if the CAR documents a significant condition adverse to quality or RCRA-related deficiency in a process currently certified by CBFO at a TRU waste site. Accelerated corrective action is not mandatory for transportation-related deficiencies except at the discretion of the CBFO Manager. CARs not related to processes currently certified by CBFO at the TRU Waste Sites shall not be marked for accelerated corrective action.
 - 5.1.6 The assessment team leader will determine if a corrective action plan is required. Corrective action plans are required for RCRA-related deficiencies and significant conditions adverse to quality. They are optional for all other deficiencies.
 - 5.1.7 When the assessment team leader determines the CAR is valid, the assessment team leader shall indicate, in CAR block 11b, whether a work suspension recommendation is required, and assign a response due date in CAR block 14, allowing the responsible organization a maximum of thirty (30) days after receipt of the CAR. If block 11d is marked "yes", a corrective action completion date no more than 30 days from receipt of the CAR by the responsible organization shall be assigned.
 - 5.1.8 The assessment team leader shall indicate concurrence with the CAR content by signing in CAR block 15.
- NOTE:** A. Deficiencies determined to be significant or RCRA-related require a corrective action response that addresses all four types of actions indicated in CAR block 12.

- I. Date response accepted (CAR block 17)
- J. Date actions are expected to be completed
- K. Date verified (CAR block 19a)
- L. Cause code (CAR block 19b)
- M. Date closed (CAR block 20)
- N. RCRA related
- O. Accelerated Corrective Action Required

5.3 Corrective Action Response

- 5.3.1 A corrective action response shall be prepared by the responsible organization addressing each checked item in block 12.
- 5.3.2 If the responsible organization cannot provide an acceptable corrective action response before the response due date, the responsible organization shall respond with an expected completion date. The assessment team leader shall approve the extension if warranted. Verbal extension requests shall be followed up by a written extension request. If the extension request is approved, the assessment team leader shall notify the responsible organization in writing, with a copy to the CAR coordinator, who shall update the CAR Log.
- 5.3.3 If a response is not received by the response due date, the CAR coordinator shall notify the assessment team leader and the responsible organization of the overdue status.
- 5.3.4 If a corrective action plan is not required, as indicated in Block 14 of the CAR form, the responsible organization shall notify the Assessment Team Leader of the anticipated corrective action completion date.

5.4 Response Evaluation

- 5.4.1 Upon receipt of the corrective action response from the responsible organization, the assessment team leader shall transmit the response to the CAR initiator (or another staff member knowledgeable of the condition) for review, with a copy to the CAR coordinator. The CAR initiator, or designee, shall evaluate the proposed actions to ensure that the plan properly addresses the deficiency, contains expected completion dates, and assigns responsibilities for the completion of the corrective actions. Once the review is completed, the CAR initiator, or designee, shall provide to the assessment team leader a recommendation for acceptance or rejection of the proposed actions.
- 5.4.2 The assessment team leader shall review the CAR response and the recommendations from the CAR initiator. If acceptable, the assessment team leader shall sign block 17 of the CAR.
- 5.4.3 If the response is complete and acceptable, the assessment team leader shall issue a response acceptance transmittal to the responsible organization, with a copy to the CAR coordinator.
- 5.4.4 If the response is not acceptable, the assessment team leader shall document the reason for non-acceptance on a CAR continuation sheet, and prepare a memo to the responsible organization along with a new response due date, with a copy to the CAR coordinator.
- 5.4.5 The CAR coordinator shall update the CAR log with the new information.

B. Document the verification in CAR block 18 or on a CAR continuation sheet and identify the specific areas investigated, the objective evidence reviewed, and the results of the verification. Indicate acceptable verification by signing and dating the CAR in block 19a. If the verification is not acceptable, the verifier shall document, on a CAR continuation sheet, the corrective actions that were unacceptable, incomplete, or why corrective action could not be verified, and what further actions are required.

C. Assign a cause code in block 19b per TP 3.2.

5.6.2 If the corrective action verifier does not accept the corrective actions, a transmittal requesting additional actions shall be issued by the assessment team leader to the responsible organization with a new expected completion date identified with a copy to the CAR coordinator.

5.7 CAR Closure

5.7.1 The assessment team leader shall review verification information and, if closure is justified, obtain the Quality Assurance Manager's signature in CAR block 20 and provide a copy to the CAR coordinator.

5.7.2 The CAR coordinator shall update the CBFO CAR log to reflect the CAR status.

5.7.3 The assessment team leader shall issue a transmittal to the responsible organization informing them of the CAR closure and ensure that CAR records are prepared and submitted in accordance with section 6.0, Records.

5.7.4 The CAR coordinator shall perform a semi-annual review of CARs to identify potentially adverse trends over the previous six months, in accordance with TP 3.2.

5.8 Site-Generated CARs

5.8.1 RCRA-related corrective action reports, generated by the TRU waste sites during their internal assessments, are also transmitted to the CBFO CAR coordinator for inclusion in the CBFO CAR tracking database.

5.8.2 Upon receipt of a site-generated CAR, the CAR coordinator shall assign a CBFO CAR number in the CAR identification block.

5.8.3 Site-generated CARs shall be uniquely identified by their site identification letters (LANL=LA, RFETS=RF, ORNL=OR, etc.) within the CAR number, i.e., 99-LA-00.

5.8.4 The CBFO CAR log database entries will be restricted to (reference paragraph 5.2.4) items A, C, D, F, J, L, M, N.

5.8.5 Upon closure of the site-generated CARs, the site shall transmit a copy of the closed CAR to the CBFO CAR coordinator.

5.8.6 The CBFO CAR coordinator will update the CBFO CAR log.

5.8.7 The CBFO CAR coordinator shall transmit site-generated CARs and CAR closure documentation to the WIPP operating record after the information is entered in the tracking database.

EXAMPLE OF A CORRECTIVE ACTION REPORT

1. CAR No.:	2. Activity Report No.:	3. Page ___ of ___
4. Controlling Document:		5. CBFO Assessment Team Leader:
6. Responsible Organization:		7. CAQ was Discussed With:
8. Requirement that was violated:		
9. Condition Adverse to Quality:		
10. Suggested Actions (Optional):		
11a. Significant CAQ (Yes or No):		
11b. Work Suspension Recommended (Yes or No):		
11c. RCRA Related (Yes or No):		
11d. Accelerated Corrective action Required? (Yes or No):		
12. Types of Actions: Remedial: ___ Investigative: ___ Root Cause: ___ Actions to Preclude Recurrence: ___		
13. CAR Initiator: _____ Date: _____		
14. Response Due Date _____ Corrective Action Response Required YES <input type="checkbox"/> NO <input type="checkbox"/>		
Required Corrective Action Completion Date: _____		
15. a. Concurrence: _____ b. _____		
Assessment Team Leader	Date	Responsible Assistant Manager
Date		Date
c. _____		
Quality Assurance Manager	Date	
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:		

Assessment Team Leader	Date	
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____		
Name	Date	
19b. Trend Cause Code: _____		
20. Closure: _____		
Quality Assurance Manager	Date	

INSTRUCTIONS FOR PROVIDING CORRECTIVE ACTION RESPONSE

WASTE ISOLATION PILOT PLANT
U.S. DEPARTMENT OF ENERGY
Carlsbad Field Office

CAR NO: _____
PAGE _____ OF _____

**INSTRUCTIONS FOR COMPLETING A CORRECTIVE ACTION PLAN IN
RESPONSE TO A CAR ADDRESSING A CONDITION ADVERSE TO QUALITY**

You are requested to provide a corrective action in response to this corrective action report (CAR) by the due date identified in block 14 of the CAR. If this date cannot be met, provide a written request for extension to the assessment team leader (block 5). This request must include justification for the delay and must be provided prior to the due date.

The response shall address the corrective actions indicated in block 12. As appropriate, develop the response in accordance with the following sequence and format:

In order to develop the CAR response, perform an investigative action to determine the extent and impact of the deficiency and to identify the root cause. Next, determine the actions required to correct the adverse condition. The response shall include the following information, as appropriate to block 12.

1. Corrective action response for CAR # _____
 - A. **Remedial Action**-Describe actions required or taken to correct the specific conditions noted and any similar conditions identified during the investigations.
 - B. **Extent and Impact of the Deficiency**-Describe the investigative actions performed to determine the extent and impact of the condition and the results. This will include a determination of the acceptability of any data generated prior to resolution of the deficiency.
 - C. **Root Cause Determination**-Identify the root cause of the condition as determined through investigative action.
 - D. **Corrective Action to Preclude Recurrence**-Identify the actions required to address the root cause of the condition in order to preclude recurrence.
2. For each action above, identify the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.
3. The response must identify the individual having the overall responsibility for completion of the corrective actions.

CORRECTIVE ACTION REPORT PROCESS

