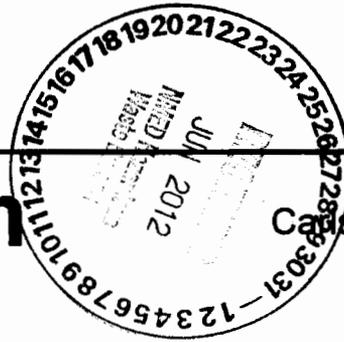




United States Government

Department of Energy

memorandum

 Carlsbad Field Office
 Carlsbad, New Mexico 88221


DATE: JUN 29 2012

REPLY TO
ATTN OF: CBFO:OQA:RU:CC:12-1439:UFC 2300.00

SUBJECT: Issuance of CARs 12-023 through 12-025 from Audit A-12-19, CBFO Quality Assurance Program Implementation

TO: David Garcia, Director, Office of Business

Carlsbad Field Office (CBFO) Audit A-12-19 of CBFO Quality Assurance (QA) Program implementation of Nuclear Quality Assurance (NQA-1) Criteria 1 through 9 requirements was performed May 22-31, 2012. Attached are Corrective Action Reports (CARs) 12-023 through 12-025, which address the conditions adverse to quality identified during the audit. The three CARs focus on aspects of the CBFO QA Program administered by the Office of Business (OOB), and CAR identification numbers with brief descriptions of the concern being addressed are listed below:

- CAR 12-023 – Inadequate implementation of Management Procedure (MP) 5.4, *Orders Compliance Program*.
- CAR 12-024 – Improper implementation of CBFO Quality Assurance Program Document (QAPD) records maintenance and control requirements.
- CAR 12-025 – Inadequacies were identified in MPs which cover development/preparation, review, approval, and issuance of CBFO procedures.

Please prepare a Corrective Action Plan (CAP) response for each CAR, ensuring that each required action indicated in Block 12 is addressed, including a schedule for completion of corrective actions. Please provide me with the resulting CAPs addressing each CAR, respectively, on or before July 30, 2012, the due date identified in Block 14a of the CAR Forms.

If you have any comments or questions regarding the subject CARs, please contact Richard Farrell at (575) 725-7214 or me at (575) 234-7065.

Randy Unger, Director
Office of Quality Assurance

Attachments



David Garcia

-2-

cc: w/attachments

J. Franco, CBFO	*ED
E. Ziemianski, CBFO	ED
M. Milligan, CBFO	ED
J.R. Stroble, CBFO	ED
A. Cooper, CBFO	ED
G. Basabilvazo, CBFO	ED
R. Farrell, CBFO	ED
E. Preciado, CBFO	ED
D. Gadbury, CBFO	ED
C. Fesmire, CBFO	ED
O. Vincent, CBFO	ED
R. Nelson, CBFO	ED
M. Eagle, EPA	ED
T. Kesterson, NMED/DOE OB	ED
J. Marple, NMED/DOE OB	ED
D. Winters, DNFSB	ED
N. Frank, CTAC	ED
P. Hinojos, CTAC	ED
G. White, CTAC	ED
WIPP Operating Record	ED
CBFO QA File	
CBFO M&RC	

*ED denotes electronic distribution

CORRECTIVE ACTION REPORT

1. CAR No.: 12-023	2. Activity Report No.: A-12-19	3. Page 1 of 2
4. Controlling document:	CBFO MP 5.4, Rev. 1, <i>Orders Compliance Program</i> ; CBFO MP 4.5, Rev. 5; CBFO MP 4.1, Rev. 9	5. CBFO Assessment Team Leader: Richard Farrell
6. Responsible organization: CBFO		
7a. CAQ/CAR Owner (Office Director):	David Garcia, OOB	7b. CAQ was discussed with: Andrea Cooper, Patty Crockett, Dennis Miehl
8. Requirement that is involved: See attached Continuation Sheet		
9. Condition Adverse to Quality (CAQ): See attached Continuation Sheet		
10. Suggested actions (Optional): N/A		
11a. Significant CAQ? (If 'Yes', go to block 15b) Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 11b. Work Suspension recommended? (If 'Yes', go to block 15b) Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 11c. RCRA related? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 11d. Accelerated corrective action required? (If 'Yes', go to block 15b) Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 11e. Does this CAQ affect waste streams BNINW216 or BNINW218? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		12. Type of actions required: Remedial? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Investigative? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Root Cause Determination? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Actions to Preclude Recurrence? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
13a. Trend Code: RM-05	13b. CAR Initiator: <i>R. Castillo</i> (printed name) Rick Castillo	Date: 6/21/12
14a. Response due date: 30 July 12		
14b. Required corrective action completion date: NA		
15. Concurrence:		
a. Assessment Team Leader (if applicable): <i>Richard V. Farrell</i> (printed name) Richard V. Farrell		Date: 6-27-2012
b. CBFO Quality Assurance Director: <i>R. W. Unger</i> (printed name) RANDY UNGER		Date: 29 Jun 12
16. Acceptance of Proposed Corrective Actions: (printed name) _____		Date: _____
17. Acceptance of Corrective Action Completion: (printed name) _____		Date: _____
18. Closure: (printed name) _____		Date: _____

CAR CONTINUATION SHEET

1. CAR No: 12-023

2. Activity No: A-12-19

3. Page 2 of 2.

Requirement that is involved (Section #8):**Item 1:**

CBFO MP 4.1, *Preparation and Maintenance of CBFO Procedures*, section 5.3.2 [A] states, "Forms to be used in the execution of a procedure shall be numbered based upon the procedure number (e.g., MP 4.1 has three forms, only one of which is completed as a result of this procedure [the procedure template, CBFO Form 4.1-1])."

Item 2:

CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Program Records*, section 5.3.1 states, "Employees shall protect completed or in-process records they generate and maintain in the work area through the following activities...."

CBFO MP 5.4, *Orders Compliance Program*, section 6.0 lists the following records as being generated and maintained according to this procedure: "Directive Review Log" and "Directive Applicability Review Checklist."

Item 3:

MP 5.4, *Orders Compliance Program*, section 5.1.2 states, "Reviewers evaluate the draft directive in accordance with the review criteria provided in Attachment II..."

MP 5.4, *Orders Compliance Program*, section 5.3.3 states, "The assigned reviewers evaluate the approved directive for applicability to the WIPP mission in accordance with the criteria in Attachment II, and transmit the completed form to the Directives Coordinator by the assigned due date."

Condition Adverse to Quality (Section #9):

Three issues pertaining to MP 5.4, *Orders Compliance Program*, Attachment II, Example Directive Applicability Review Checklist, have been identified:

1. There is a contradiction with the use of a required form number for Attachment II. This attachment was assigned a form number; however, the words "Example" and "Sample" are both listed on the form.
2. Attachments I and II are listed as quality assurance records generated by the use of this procedure, but are not being maintained as records.
3. Documentation (meeting minutes) does not capture all required review criteria listed on Attachment II, as required by the procedure.

CORRECTIVE ACTION REPORT

1. CAR No.: 12-024	2. Activity Report No.: A-12-19	3. Page 1 of 2
4. Controlling document:	DOE/CBFO-94-1012, Rev. 11, <i>Quality Assurance Program Document</i>	5. CBFO Assessment Team Leader: Richard Farrell
6. Responsible organization:	CBFO	
7a. CAQ/CAR Owner (Office Director):	David Garcia, OOB	7b. CAQ was discussed with: David Garcia
8. Requirement that is involved: See attached Continuation Sheet		
9. Condition Adverse to Quality (CAQ): See attached Continuation Sheet		
10. Suggested actions (Optional): None		
11a. Significant CAQ? (If 'Yes', go to block 15b) Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 11b. Work Suspension recommended? (If 'Yes', go to block 15b) Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 11c. RCRA related? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 11d. Accelerated corrective action required? (If 'Yes', go to block 15b) Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 11e. Does this CAQ affect waste streams BNINW216 or BNINW218? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		12. Type of actions required: Remedial? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Investigative? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Root Cause Determination? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Actions to Preclude Recurrence? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
13a. Trend Code: RM-05	13b. CAR Initiator: <i>Norman C. Frank</i> (printed name) Norman C. Frank	Date: 6/21/12
14a. Response due date: 30 July 12		
14b. Required corrective action completion date: NA		
15. Concurrence:		
a. Assessment Team Leader (if applicable): <i>Richard F. Farrell</i> (printed name) Richard F. Farrell		Date: 6-27-2012
b. CBFO Quality Assurance Director: <i>R. Minger</i> (printed name) RANDY MINGER		Date: 29 July 12
16. Acceptance of Proposed Corrective Actions: _____ (printed name)		Date: _____
17. Acceptance of Corrective Action Completion: _____ (printed name)		Date: _____
18. Closure: _____ (printed name)		Date: _____

CAR CONTINUATION SHEET**1. CAR No: 12-024****2. Activity No: A-12-19****3. Page 2 of 2.****8. Requirement that is involved:**

CBFO QAPD

Section 1.5A, "Records shall be...maintained."

Section 1.5B, "QA Records shall be controlled..."

9. Condition Adverse to Quality (CAQ):

Some QA records are not reaching the QA records files. For example:

- The WBS numbers for Science and International Programs added to the Master Quality Level Determination form in September 2010 are not on file in QA records.
- Two of the four audit files reviewed are incomplete in the CBFO QA records. A-12-03 was missing the Final Audit Report and A-12-04 was missing the Audit Plan.
- Several records listed on the current DOE/CBFO/Office of the National TRU Program (ONTP) Records Inventory and Disposition Schedule (RIDS) are no longer maintained in the ONTP office.
- The records package for revision 3 of CBFO MP 1.2 is missing from the records file.
- Management assessment plans and reports are not being maintained as non-permanent Quality Assurance records. Two of four management assessment reports and plans assessed (MA-11-07 and MA-11-09) were not entered into the CBFO QA Records Center.

CORRECTIVE ACTION REPORT

1. CAR No.: 12-025	2. Activity Report No.: A-12-19	3. Page 1 of 2
4. Controlling document: DOE/CBFO-94-1012, Rev. 11, Quality Assurance Program Document	5. CBFO Assessment Team Leader: Richard Farrell	
6. Responsible organization: CBFO		
7a. CAQ/CAR Owner (Office Director): David Garcia	7b. CAQ was discussed with: Meg Milligan and Richard Farrell <i>RMF</i> 6-29-12	
8. Requirement that is involved: See attached Continuation Sheet		
9. Condition Adverse to Quality (CAQ): See attached Continuation Sheet		
10. Suggested actions (Optional): As part of the investigative actions, the audit team recommends that older CBFO implementing procedures be reviewed and updated. Ten out of 31 procedures have effective dates more than three years old (from April 2009).		
11a. Significant CAQ? (If 'Yes', go to block 15b) Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	12. Type of actions required:	
11b. Work Suspension recommended? (If 'Yes', go to block 15b) Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Remedial? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
11c. RCRA related? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Investigative? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
11d. Accelerated corrective action required? (If 'Yes', go to block 15b) Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Root Cause Determination? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
11e. Does this CAQ affect waste streams BNINW216 or BNINW218? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Actions to Preclude Recurrence? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
13a. Trend Code: DC-01	13b. CAR Initiator: <i>Laurie Smith</i> (printed name) Laurie Smith	Date: 6/21/12
14a. Response due date: 30 July 12		
14b. Required corrective action completion date: NA		
15. Concurrence:		
a. Assessment Team Leader (if applicable): <i>Richard F. Farrell</i> (printed name) Richard F. Farrell	Date: 6-27-2012	
b. CBFO Quality Assurance Director: <i>R. Unger</i> (printed name) R. UNGER	Date: 29 July 12	
16. Acceptance of Proposed Corrective Actions: _____ (printed name) _____ Date: _____		
17. Acceptance of Corrective Action Completion: _____ (printed name) _____ Date: _____		
18. Closure: _____ (printed name) _____ Date: _____		

CAR CONTINUATION SHEET

1. CAR No: 12-025

2. Activity No: A-12-19

3. Page 2 of 2.

8. Requirement that is involved:

CBFO QAPD section 1.4:

1.4 Documents

- A. "Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.
- B. Documents that specify requirements, prescribe processes, or establish design important to the compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility, such as instructions, procedures, drawings, test plans, management plans, technical reports, performance reports, and test reports, shall be controlled according to the requirements listed below to ensure that the correct documents are being used."

2.1.2 Implementing Procedures

- A. "Implementing procedures shall be developed, reviewed, and approved by technically competent personnel."

9. Condition Adverse to Quality (CAQ)

There are adequacy issues with procedures CBFO MP 4.1, Rev. 9, Preparation and Maintenance of CBFO Procedures; CBFO MP 4.2, Rev. 7, Document Review; and CBFO MP 4.4, Rev. 8, Document Preparation and Control, which do not address two requirements from the CBFO QAPD. In addition, MP 4.2 has conflicting requirements that need to be addressed.

1. QAPD section 1.4.1 H, "The appropriate quality assurance organization shall review documents that translate CBFO QAPD or other CBFO requirements." This was flowed into the procedures, but with "should" instead of "shall."
2. QAPD section 1.4.2 A, "Documents shall be distributed to affected personnel and used at the work location." For program documents, this was not found in the procedures.
3. Procedure MP 4.2, Rev. 7 has conflicting steps that could potentially cause confusion during implementation and subsequently result in noncompliance with the QAPD. Section 5.2.4 B states "Changes made using the Track Changes option will be printed out in full..." Section 5.5.1 needs to change the word "should" to "shall" to ensure changes are documented and become records per the procedure.