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CCP-QP-004

Revision 10

CCP
Corrective Action
Management

EFFECTIVE DATE: 12/29/2010

Larry Porter

PRINTED NAME

APPROVED FOR USE

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RECORD OF REVISION

Revision Number	Date Approved	Description of Revision
4	02/13/2003	Total re-write to address issues identified in CAR-CCP-0512-02, revision 0, First Quarter 2002, Trend Report (ref; Inter-Office Correspondence TP:02:04131), WTS Audit I 02-07 and to comply with format requirements of CCP-QP-010.
5	07/01/2003	Minor revision to separate electronically fIllable forms and update references in procedure.
6	03/18/2005	This revision deletes the trending requirements that are now addressed with the new CCP-QP-014, *CCP Data Analysis and Trending* procedure, also made minor changes to procedure for consistency. Added attachments back into this procedure. Addressed CBFO comments.
7	11/16/2006	Revised to implement the Waste Isolation Pilot Plant Hazardous Waste Facility Permit requirements resulting from the Section 311/Remote-Handled (RH) Permit Modification Request (PMR). Addressed Carlsbad Field Office (CBFO) Document Review Record (DRR).
8	04/25/2007	Revised to delete reference to CCP-QP-009 and replace it with CCP-QP-005.
9	09/21/2007	Revised to incorporate 5-day notification changes initiated in Standing Order CCP-SO-024.
10	12/29/2010	Revised to implement the revision of the *Waste Isolation Pilot Plant Hazardous Waste Facility Permit*.

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1.0 PURPOSE

This procedure establishes the management controls and processes for Central Characterization Project (CCP) to ensure that identified deficiencies and conditions adverse to quality are analyzed and resolved. This procedure identifies the process for evaluation of nonconformances to determine significant conditions adverse to quality.

1.1 Scope

This procedure, used in conjunction with CCP-QP-006, *CCP Corrective Action Reporting and Control*, and CCP-QP-005, *CCP TRU Nonconforming Item Reporting and Control*, applies to CCP personnel who are responsible for the identification, classification, control, and correction of conditions adverse to quality, and nonconforming items, activities, and processes associated with the CCP, including one or more of the following:

- Regulatory compliance
- Nuclear safety
- Waste characterization
- Waste isolation
- CCP programmatic compliance

Additionally, this procedure provides the controls to identify recurring conditions adverse to quality to determine effectiveness of corrective action implementation.

Control of conditions adverse to quality for hardware (items) and Batch Data Report (BDR) deficiencies are addressed in CCP-QP-005.

Control of conditions adverse to quality related to programmatic or process failures, malfunctions, and deficiencies are addressed in CCP-QP-006.

2.0 REQUIREMENTS

2.1 References

Baseline Documents

- DOE/CBFO-94-1012, *U.S. Department Of Energy Carlsbad Field Office Quality Assurance Program Document*

- DOE/WIPP-02-3214, *Remote-Handled TRU Waste Characterization Program Implementation Plan*

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- CCP-PO-001, *CCP Transuranic Waste Characterization Quality Assurance Project Plan*

- CCP-PO-002, *CCP Transuranic Waste Certification Plan*

Referenced Documents

- *Waste Isolation Pilot Plant (WIPP) Hazardous Waste Facility Permit,* Attachment C*, Waste Analysis Plan (WAP)*

- CCP-QP-005, *CCP TRU Nonconforming Item Reporting and Control*

- CCP-QP-006, *CCP Corrective Action Reporting and Control*

- CCP-QP-008, *CCP Records Management*

- CCP-QP-014, *CCP Quality Assurance Trend Analysis and Reporting*

2.2 Conditions Adverse to Quality

2.2.1 Processes will be established and implemented to detect and prevent conditions adverse to quality and to ensure continuous improvement.

2.2.2 Conditions adverse to quality will be classified with regard to their significance. Corrective actions will be developed accordingly. The following categories have been established:

[A] Conditions adverse to quality

[B] Significant conditions adverse to quality

2.2.3 Conditions adverse to quality are identified, documented, controlled, and corrected. Documentation will clearly identify and describe the characteristics that do not conform to specified criteria. Controlled changes to CCP project plans or procedures that affect the *Waste Isolation Pilot Plant (WIPP) Hazardous Waste Facility Permit,* Attachment C*, Waste Analysis Plan (WAP),* requirements, by either creating a condition that is not in compliance with the requirements, or as the result of a corrective action plan (CAP) for a documented condition adverse to quality, will be addressed as part of the nonconformance and corrective action process.

2.3 Significant Conditions Adverse to Quality

2.3.1 Significant conditions adverse to quality are reported to and evaluated by the responsible quality assurance (QA) organization, other relevant regulatory compliance functions (e.g., environmental and safety), and the Responsible Management to determine if a Stop Work order is necessary.

2.3.2 A significant condition adverse to quality is a condition that, if not corrected, could have a serious effect on:

[A] Health and safety of employees, the public, or the environment

[B] Ability to characterize waste

2.3.3 All violations of the WIPP Hazardous Waste Facility Permit (HWFP) shall be evaluated as a significant condition adverse to quality.

2.3.4 The CCP notifies the Department of Energy (DOE) Carlsbad Field Office (CBFO) (the permittee) of all Corrective Action Reports (CAR) affecting waste that will be shipped to the WIPP, that are programmatic in nature, and that relate to violations of the WIPP HWFP for tracking. Management of the responsible organization is notified and provided with the results of the subject evaluations.

2.3.5 CAPs are required for all significant and recurring conditions adverse to quality. CAPs for significant conditions adverse to quality are documented using Attachment 1, CCP Deficiency Evaluation Form (DEF), and Attachment 2, CCP Deficiency Evaluation Form (DEF) Continuation Sheet, if needed, and shall address the following:

[A] Stop work consideration

[B] Root cause

[C] Immediate/compensatory actions

[D] Extent and impact

[E] Action(s) to preclude recurrence

[F] Expected completion dates for each item and responsible individuals

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2.3.6 CAPs for recurring conditions adverse to quality are documented using Attachment 3, CCP Corrective Action Plan (CAP), and Attachment 4, CCP Corrective Action *Plan* (CAP) Continuation Sheet, if needed, and shall address the following:

[A] The cause of the deficiency

[B] Immediate/compensatory actions

[C] Extent and impact; including effectiveness of corrective actions previously taken.

[D] Corrective Actions

[E] Action(s) to preclude recurrence

2.4 Corrective Action Tracking and Follow-up

2.4.1 Conditions adverse to quality are tracked using the Corrective Action Reporting Module (CARM). This system facilitates the effective implementation of scheduled corrective actions, trending for quality improvement, and the timely completion of corrective actions.

2.4.2 As a minimum, nonconformance reports (NCRs), will be tracked in the Nonconformance Reporting Module (NCRM) and CARs will be tracked in the CARM.

2.5 Effectiveness of Action Implementation

2.5.1 Where determined necessary due to the nature of identified problems, the corrective action management program shall provide provisions to determine the effectiveness of previous corrective action implementation.

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3.0 RESPONSIBILITIES

3.1 CCP QA

3.1.1 Ensures consistent application of the Corrective Action Management Program (CAMP), and provides support to the CCP Site Project Manager (SPM) and Responsible Managers.

3.1.2 Screens CARs for significant and recurring conditions adverse to quality.

3.1.3 Participates in the evaluation of significant conditions adverse to quality.

3.1.4 Reviews NCRs for significant conditions adverse to quality.

3.2 CCP SPM

3.2.1 Serves as authority for determining deficiency owners and/or corrective action owners, if necessary.

3.2.2 Participates in the evaluation of significant conditions adverse to quality.

3.2.3 Initiates Stop Work, if applicable.

3.2.4 Notifies Vendor Project Manager (VPM) in case of an event or occurrence.

3.2.5 Reviews quality performance analyses and initiates corrective action as appropriate.

3.3 Responsible Manager

3.3.1 Prepares CAPs in accordance with this procedure, and ensures that actions to resolve identified problems are completed in a timely manner.

3.4 CCP QA Manager

3.4.1 Makes the final determination whether CAR conditions and NCR conditions represent significant conditions adverse to quality.

4.0 PROCEDURE

NOTE
When initiating a CAR, Attachment 1, and Attachment 2 (when needed), of CCP-QP-006, *CCP Corrective Action Reporting and Control,* are used.

4.1 Screen CARs for Significant Conditions Adverse to Quality and Recurring Conditions Adverse to Quality.

CCP QA

Significant Conditions Adverse to Quality

NOTE
The CCP QA Manager makes the final determination whether CAR and NCR conditions represent significant conditions adverse to quality.

4.1.1 Make an initial determination as to whether or not a significant condition adverse to quality exists by determining the following:

[A] Does the noncompliance adversely impact the capability to characterize, certify, and/or ship waste?

[B] Is the noncompliance a violation of the HWFP?

[C] Could the noncompliance have a serious effect on Health and Safety of employees, the public, and/or the environment?

4.1.2 **IF** the answer is YES to any of the criteria in step 4.1.1,
THEN check YES in Block 4a of the CAR, **AND** proceed to Section 4.3.

4.1.3 **IF** the answer is NO to all of the criteria in step 4.1.1,
THEN search the CARM to determine if there are previous violations of the same requirement/condition (recurring conditions adverse to quality).

Recurring Conditions Adverse to Quality

4.1.4 **IF** multiple occurrences are identified (three or more within the last 12 months),
THEN discuss with the CCP QA Manager, who will determine whether the recurring nature of the condition represents a significant condition adverse to quality, **AND** document the determination in an email to the CAR/NCR Coordinator, who will include it as part of the QA record file for the CAR.

4.1.5 **IF** multiple occurrences are identified (three or more within the last 12 months), **AND** the CCP QA Manager has determined the recurring nature of the condition represents a significant condition adverse to quality,
THEN check YES in Block 4a of the CAR, **AND** proceed to Section 4.3.

4.1.6 **IF** there have been any previous CARs (less than three) citing the same condition and requirement within the last six months
THEN check NO in Block 4a of the CAR, check YES is Block 4b of the CAR, Corrective Action Plan Required, **AND** list the previous CAR(s) in the space provided.

4.1.7 **IF** there are no previous occurrences,
THEN check NO in Block 4b of the CAR.

4.1.8 Identify the Trend Code in accordance with CCP-QP-014, *CCP Trend Analysis and Reporting*, Attachment 6*,* Trend Codes, enter the appropriate code in Block 4c of the CAR, and continue processing CAR per CCP-QP-006.

NOTE

NCRs required by CCP technical procedures to be written to document CCP characterization and/or certification activities that do not reflect upon the adequacy of the CCP QA program, and therefore do not reflect a significant and/or recurring condition adverse to quality, will not be screened in accordance with Section 4.2. Examples are: prohibited items, out of calibration range. When initiating an NCR, Attachment 1, and Attachment 2 (when needed), of CCP-QP-005 are used.

4.2 Review NCRs for Significant Conditions Adverse to Quality and Recurring Conditions Adverse to Quality During Trend Reporting.

4.2.1 Make an initial determination as to whether or not the NCRs represent a significant condition adverse to quality by reviewing in accordance with step 4.1.1.

4.2.2 **IF** the initial determination is YES to any of the criteria in step 4.1.1,
THEN discuss with the CCP QA Manager, **AND** if directed, initiate a CAR in accordance with CCP-QP-006, process as a “Significant” condition, **AND** reference the NCR number and revision in the CAR, **AND** document the determination in an email to the NCR/CAR Coordinator, who will include it as part of the QA record file for the NCR.

4.2.3 **IF** the answer is NO to all of the criteria in step 4.1.1,
THEN search the CARM and NCRM to determine if there are previous violations of the same requirement/condition (recurring conditions adverse to quality).

Recurring Conditions Adverse to Quality

4.2.4 **IF** multiple occurrences are identified (three or more within the last 12 months),
THEN discuss with the CCP QA Manager, who will determine whether the recurring nature of the condition represents a significant condition adverse to quality, **AND** document the determination in an email to the NCR/CAR Coordinator, who will include it as part of the QA record file for the NCR.

4.2.5 **IF** multiple occurrences are identified (three or more within the last 12 months), **AND** the CCP QA Manager has determined the recurring nature of the condition represents a significant condition adverse to quality,
THEN check YES in Block 10 of the NCR, **AND** process as "Significant" condition as required in step 4.2.2.

4.2.6 **IF** there have been any previous NCRs (less than three) citing the same condition and requirement within the last six months,
THEN discuss with the CCP QA Manager, who will determine whether the recurring nature of the condition requires a CAP, **AND** document the determination in an email to the NCR/CAR Coordinator, who will include it as part of the QA record file for the NCR.

4.2.7 **IF** multiple occurrences are identified (three or more within the last 12 months), **AND** the CCP QA Manager has determined the recurring nature of the condition represents a significant condition adverse to quality,
THEN check YES in Block 11 of the NCR, initiate a CAR with CAP, **AND** reference the NCR number(s) and revision in the CAR.

4.3 Deficiency Evaluation Prerequisites

CCP SPM

4.3.1 Notify the VPM by memo in the case of an event or occurrence report.

4.3.2 Identify the need for Subject Matter Experts (SMEs) to assist in the evaluation.

4.3.3 Ensure appropriate personnel are present to assist in the evaluation.

4.3.4 Establish an understanding of the potential deficiency, including knowledge of applicable requirements the potential deficiency did not meet, to successfully perform the evaluation.

4.4 Deficiency Evaluation

CCP QA/CCP SPM/CCP QA Manager/Responsible Manager

NOTE

STOP WORK processing (if applicable) will be in accordance with Section 4.6.

Attachment 5 provides guidance on performing Direct Derivation Root Cause Analysis. Items [B], [F], [G], and [H] may be deferred if the information is not available when the CAR is otherwise ready for issuance. If deferred, the information shall be documented on the CAR form, or elsewhere in the CAR documentation, in lieu of being entered on Attachment 1. Attachment 1 will be annotated to state where the information will be included in the CAR documentation.

NOTE

Senior management may decide to subcontract for the root cause analysis services when analysis beyond direct derivation is determined appropriate. In this case, the subcontractor must be capable of performing the root cause analysis to an acceptable industry standard for this purpose.

4.4.1 Conduct the evaluation and document the results on Attachment 1 and Attachment 2, if needed to include the following:

[A] Document the logic for Stop Work decisions, as applicable.

[B] Determine Appropriate Root Cause and document Trend/Code in the Block 4c of the CAR.

[C] Determine responsible manager (if not previously addressed in CAR).

[D] Document immediate/compensatory action(s), or provide justification if not applicable.

[E] Evaluate extent and impact of the deficiency.

[F] Document Corrective Actions.

[G] Enter actions to be taken to preclude recurrence of the problem.

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[H] Identify expected completion dates for each corrective action (if required) and responsible individuals (if not the Responsible Manager).

CCP QA/CCP SPM/Responsible Manager

4.4.2 Print name, sign, and date Attachment 1.

CCP QA

4.4.3 Attach Attachments 1 and 2, if needed, to the CAR, and submit the CAR to the CCP QA Manager for approval in accordance with CCP-QP-006.

4.5 CAP Preparation

Responsible Manager

4.5.1 When a CAP is required, evaluate the recurring conditions to the following:

[A] Determine the events leading to the deficiencies.

[B] Develop an understanding of the technical and work activities associated with the conditions adverse to quality.

[C] Ascertain any generic implications.

[D] Determine the extent to which similar quality problems or precursors to the problem have been recognized by responsible management.

[E] Determine the effectiveness of any corrective actions that were taken, and identify any generic implications and impacts on completed work.

4.5.2 Summarize the results of step 4.5.1 to determine the cause and document in Section 1 of Attachments 3 and 4, if needed.

4.5.3 Complete Sections 2 through 5 of Attachments 3 and 4, if needed.

4.5.4 Submit Attachments 3 and 4, if applicable, to the CCP QA Manager for approval in accordance with CCP-QP-006.

4.6 Stop Work Processing

CCP SPM

4.6.1 **IF** a Stop Work order is necessary,
THEN perform the following:

[A] Initiate appropriate notifications to other relevant regulatory compliance functions (e.g., environmental and safety) and to responsible management.

[B] Issue the Stop Work order to the project/facility technical supervisor in accordance with CCP-QP-005, *CCP TRU Nonconforming Item Reporting and Control*.

[C] Take appropriate action to lift and close (in part or in total) the Stop Work order based on the resolution of the related condition.

CCP QA

4.6.2 Verify and validate the completion of applicable corrective actions prior to any action releasing the Stop Work order.

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5.0 RECORDS

5.1 Records generated during the performance of this procedure are maintained as QA records in accordance with CCP-QP-008, *CCP Records Management.* The records are the following:

5.1.1 <u>QA/Nonpermanent Records</u>

- CCP Deficiency Evaluation Form (DEF), Attachment 1
- CCP Deficiency Evaluation Form (DEF) Continuation Sheet (if applicable), Attachment 2
- CCP Corrective Action Plan (CAP), Attachment 3
- CCP Corrective Action Plan (CAP) Continuation Sheet (if applicable), Attachment 4
- SPM Memo – Notification of Occurrence
- Email documentation of significance and recurrence determinations made by the CCP QA Manager

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Attachment 1 – CCP Deficiency Evaluation Form (DEF)

CAR No._____ Revision No._____Attachment #_____Page_____ of_____

1. Document the logic for Stop Work decisions (as applicable). (Use DEF Continuation Sheet, if necessary)

2. Determine Appropriate Root Cause. (Use DEF Continuation Sheet, if necessary)

3. Determine Responsible Manager(s) if not already identified in CAR.

   Responsible Manager_____

4. Document immediate/compensatory action(s) (as applicable). (Use DEF Continuation Sheet, if necessary)

5. Evaluate the extent and impact of the deficiency. (Use DEF Continuation Sheet, if necessary)

6. Document Corrective Actions. (Use DEF Continuation Sheet, if necessary)

7. Document actions to be taken to preclude recurrence of the problem. Identify expected completion dates (for each item) and responsible individuals.

APPROVALS:

CCP SPM:

Print	Signature	Date

CCP QA:

Print	Signature	Date

RESPONSIBLE MANAGER:

Print	Signature	Date

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Attachment 2 – CCP Deficiency Evaluation Form (DEF) Continuation Sheet

CAR No._____Revision No._____ Attachment # _____ Page _____of___
Continuation from DEF Section(s)#_____

Attachment 3 – CCP Corrective Action Plan (CAP)

CAR No. _____Revision No._____Attachment #_____Page_____of____

1. Document Cause. (Use CAP Continuation Sheet, if necessary)

2. Document Immediate/Compensatory Actions (as applicable). (Use CAP Continuation Sheet, if necessary)

3. Evaluate and document the Extent and Impact of the Deficiency. (Use CAP Continuation Sheet, if necessary)

4. Document Corrective Actions. (Use CAP Continuation Sheet, if necessary)

5. Document action(s) taken to preclude recurrence of the deficiency. (Use CAP Continuation Sheet, if necessary)

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Attachment 4 – CCP Corrective Action Plan (CAP) Continuation Sheet

CAR No._____Revision No._____Attachment # _____Page_____of_____
Continuation from CAP Section(s)#_____

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Attachment 5 – Guidance for Performing Direct Derivation Root Cause Analysis

This attachment provides guidance for performing a Direct Derivation Root Cause Analysis (RCA) of a deficiency considered a significant condition adverse to quality.

The Table A-1 summarizes the information that may be used for Direct Derivation RCA. The codes used to classify the trend codes of deficiencies are contained in CCP-QP-014.

1.0 PROCESS

1. Review the accumulated data on the deficiency being examined. Consider the information that may represent relevant factors from the topics listed below in Table A-1, Information for Direct Derivation Root Cause Analysis.

2. Perform a Direct Derivation RCA.

3. Determine the trend code, in accordance with CCP-QP-014 for the deficiency.

4. Document the results of the Direct Derivation RCA on the Attachments 1 and 2, as applicable.

Table A-1. Information For Direct Derivation Root Cause Analysis
The following information is useful in the investigation and evaluation of a condition when conducting root cause analysis.
1. Deficiency documentation describing the condition
2. Situation before and after occurrence or event
3. Personal interviews
4. Personnel statements as to conditions before and after the time of the occurrence and perceived cause
5. Procedure and drawings being employed
6. Physical equipment being employed
7. Environmental factors at the time
8. Operating logs
9. Training and qualification records
10. Background information on personnel involved
11. Recommendations for corrective actions
12. Recommendations for corrective actions

Attachment 6 – CBFO Notification Process Requirements

This attachment provides reporting notification requirements for CCP-generated Nonconformance Reports (NCR) which meet the condition identified in CCP-PO-001, Section C3-13.

WIPP e-mail Address: wipp.notify@wipp.ws

NCR Process

The electronic process is strongly encouraged for this notification. If electronic process is used, the following criteria is required:

On the subject line, preceding the subject, [ncr]. The term “ncr” in brackets [ ] allows the automatic transfer into the proper folder of the receiving system.

NOTE: The notification must include the NCR number, description of the deficiency and the date identified.

The thirty (30) day notification requires CCP to send the NCR form, containing CCP’s procedurally required information.

NOTE: If CCP chooses, the NCR form can be transmitted within the required time period, and satisfy both notification requirements, provided the following information is submitted:

- Site NCR #
- Responsible organization
- Date initiated
- Individual who identified the NCR
- Deficiency
- Requirement violated
- Actions
- Date closed, if applicable

General Notification

If CCP does not choose to or does not have the capability of electronically transmitting documents via e-mail, hard-copy transmittal may be utilized. Correspondence must be sent to the following address:

[Assigned CBFO Contact]
Carlsbad Field Office
U.S. Department of Energy
P.O. Box 3090
Carlsbad, NM 88221-3090