

3.0 REFERENCES AND DEFINITIONS

3.1 References

- 3.1.1 DOE Order 226.1B, *Implementation of Department of Energy Oversight Policy*
- 3.1.2 DOE Order 227.1, *Independent Oversight Program*
- 3.1.3 DOE Order 232.2, *Occurrence Reporting and Processing of Operations Information*
- 3.1.4 DOE Order 414.1D, *Quality Assurance*
- 3.1.5 DOE Guide 414.1-2B, *Quality Assurance Program Guide*
- 3.1.6 DOE/CBFO-94-1012, *CBFO Quality Assurance Program Document (QAPD)*
- 3.1.7 DOE/CBFO-04-3299, *CBFO Contractor Oversight Plan*
- 3.1.8 DOE/CBFO-14-3533, *Issues Collection and Evaluation User Manual*
- 3.1.9 CBFO MP 3.2, *Deficiency Trending and Reporting*
- 3.1.10 CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Program Records*
- 3.1.11 CBFO MP 4.9, *Quality Assurance Records*
- 3.1.12 CBFO MP 10.3, *Audits*
- 3.1.13 CBFO MP 10.9, *Surveillance, Operational Awareness, and Issues Management*
- 3.1.14 CBFO OP 10.1, *Qualification of Audit Personnel and Certification of Lead Auditors*
- 3.1.15 CBFO OP 10.4, *Surveillances*
- 3.1.16 Waste Isolation Pilot Plant (WIPP) Hazardous Waste Facility Permit (HWFP) NM4890139088-TSDF
- 3.1.17 New Mexico Environment Department Compliance Order HWB 01-08, *Settlement Agreement*

3.2 Definitions

- 3.2.1 **Accelerated Corrective Action** – Process used to achieve timely closure of significant conditions adverse to quality (SCAQ) and WIPP HWFP Waste Analysis Plan (WAP) deficiencies involving a currently certified transuranic (TRU) waste site characterization program.
- 3.2.2 **Action to Preclude Recurrence** – Action(s) required to correct the cause(s) of a CAQ in order to preclude recurrence.
- 3.2.3 **Assessment Team Leader** – The leader of a CBFO quality assurance, environmental, or safety and health independent assessment activity.

- 3.2.4 **Auditor** – An individual who is qualified to perform assigned portions of an independent assessment in accordance with CBFO OP 10.1, *Qualification of Audit Personnel and Certification of Lead Auditors*.
- 3.2.5 **CAR Coordinator** – The individual assigned responsibility for administration of the CBFO CAR tracking and reporting system.
- 3.2.6 **Causal Analysis** – Identification of the direct and/or contributing cause(s), which led to a CAQ based on the results of investigative action(s).
- 3.2.7 **Condition Adverse to Quality (CAQ)** – An all-inclusive term used in reference to any of the following: findings, failures, malfunctions, deficiencies, defective items, nonconformances, and technical inadequacies. Examples include:
- A. A condition rendering a structure, system or component indeterminate in fulfilling its intended function
 - B. Noncompliance with a program document or implementing procedure requirement
 - C. Failure of a program document or implementing procedure to adequately address applicable governing (upper-tier) requirements
 - D. A weakness in a prescribed process which renders the results suspect
- 3.2.8 **Corrective Actions** – A measure that is taken to rectify CAQs and, where necessary, to preclude recurrence.
- 3.2.9 **Corrective Action Report (CAR)** – A document used to identify a CAQ and track the associated corrective actions. A CAR addresses a CAQ that is primarily programmatic in nature, as opposed to a nonconformance report, which addresses a CAQ relating to a specific item such as a piece of hardware or data.
- 3.2.10 **Corrective Action Report Initiator** – The individual identifying a CAQ and reporting that condition on a CAR form for resolution.
- 3.2.11 **Corrective Action Verifier** – The individual (or designee) responsible for verification of corrective action completion.
- 3.2.12 **Currently Certified TRU Waste Site Process** – A process for which a TRU waste site has received formal, written approval from the CBFO for characterization, certification, and/or transportation of TRU waste to the WIPP, including inter-site shipments.
- 3.2.13 **HWFP Deficiency** – A deficiency that constitutes a violation of the requirements of the Hazardous Waste Facility Permit.
- 3.2.14 **Investigative Action** – Investigation performed to identify the direct and/or contributing causes(s), as well as the extent and impact of a CAQ.
- 3.2.15 **Participant** – A contractor or laboratory organization that directly supports the CBFO mission and supporting work scope (i.e., CBFO Technical Assistance Contractor, Los Alamos National Laboratory – Carlsbad Operations, Sandia National Laboratories – Carlsbad Operations, WIPP management and operating contractor) or TRU waste generator site that has responsibility for complying with CBFO-authorized TRU waste site certification requirements.

- 3.2.16 **Quality Assurance Representative (QAR)** – A CBFO representative from the Office of Quality Assurance (OQA) designated by the OQA Director with the responsibility for overall management of quality assurance (QA) independent assessments.
- 3.2.17 **Remedial Action** – Immediate action(s) taken to control/correct a CAQ.
- 3.2.18 **Responsible Organization** – The organization responsible for correcting the CAQ (CBFO or participant).
- 3.2.19 **Significant Condition Adverse to Quality (SCAQ)** – A CAQ is considered significant when any of the following apply:
- A. If uncorrected, the CAQ could have a serious effect on safety, operability, waste isolation, TRU waste site certification, regulatory compliance demonstration, or effective implementation of the QA program.
 - B. The CAQ requires immediate notification of regulatory entities (e.g., 10 CFR Part 21; HWFP Part 1.7.13).
 - C. The CAQ indicates a significant failure or breakdown in the implementation of QA program requirements.
 - D. Repeated attempts to resolve a CAQ have been unsuccessful
 - E. The CAQ is identified in items or activities important to safety or waste isolation and compromises the ability to prevent or mitigate the consequences of an accident, thereby presenting a significant hazard to the safety and health of workers and/or the public.
- 3.2.20 **Technical Specialist** – An individual assigned to an assessment team when the scope, complexity, or special nature of the work to be examined warrants assessment of the technical adequacy of the work or the effectiveness of the technical process.
- 3.2.21 **Transportation-Related Deficiency** – Any nonconformance to procedures or requirements related to the packaging and transportation of waste.
- 3.2.22 **Waste Analysis Plan (WAP)-Related Audit** – An audit activity performed for purposes of determining the degree of compliance with the requirements contained in the WIPP HWFP related to characterization and certification of TRU waste.
- 3.2.23 **WAP Deficiency** – A deficiency that constitutes a violation of the requirements of the HWFP WAP related to characterization and certification of TRU waste.
- 3.2.24 **WIPP Operating Record** – Records maintained at the WIPP facility as required by 20.4.1.500 New Mexico Administrative Code (incorporating 40 CFR 264.73) and the WIPP HWFP.
- 3.2.25 **Work Suspension** – A formal directive issued by management that work must be stopped until the related SCAQ or nonconformance has been resolved.

4.0 RESPONSIBILITIES

NOTE: CBFO responsibilities can be delegated to other individuals using the CBFO delegation of authority process.

4.1 CBFO Manager/Deputy Manager

- 4.1.1 Maintain overall responsibility for the implementation of the process described in this procedure.
- 4.1.2 Review the CAR status report.
- 4.1.3 Arbitrate, if necessary, disagreements regarding CARs and associated corrective action plans (CAPs).

4.2 CBFO Assistant Managers/Division Directors/Office Directors

- 4.2.1 Review CARs initiated in their area of responsibility prior to submittal to the OQA Director.
- 4.2.2 Review the CAR status report.
- 4.2.3 Determine whether CAQs identified in their area of responsibility are significant or are related to compliance with 40 CFR 194 and therefore must be tracked using a CAR, or whether the issue will be entered into the Issue Collection and Evaluation (ICE) system.
- 4.2.4 Review and validate CARs self-initiated for conditions within their organization.
- 4.2.5 Ensure that the requirements of this procedure, as applicable, are fulfilled when a CAR that is not associated with an assessment is initiated.
- 4.2.6 Provide assistance in determining methods of work suspension when necessary.

4.3 CBFO Office of Quality Assurance (OQA) Director

- 4.3.1 Ensure the requirements of this procedure are fulfilled.
- 4.3.2 Manage assessment activities to ensure that assessments are performed in compliance with the CBFO QAPD.
- 4.3.3 Review and determine the classification of concerns.
- 4.3.4 Determine whether a work suspension is required, concur with SCAQ determination, and sign the CAR form, if necessary.
- 4.3.5 Recommend work suspension when necessary.
- 4.3.6 If a work suspension is required, notify the CBFO Manager, Deputy Manager, and appropriate Assistant Manager or Office/Division Director.
- 4.3.7 Arbitrate, if necessary, disagreements regarding issues/concerns.
- 4.3.8 Review, validate, approve and/or reject CARs.

4.3.9 Evaluate and approve or reject requests to extend response due dates as well as corrective action completion or closure dates for CARs.

NOTE: Requests for extension must be submitted in writing at least seven calendar days prior to the due date and sufficient justification for the extension must be presented in the request.

4.3.10 Provide copies of extension requests and their disposition to the QAR and CAR Coordinator.

4.4 Quality Assurance Representative

4.4.1 Review and determine the classification of concerns.

4.4.2 Concur with SCAQ determination, and sign the CAR form, if necessary.

4.4.3 Recommend work suspension when necessary.

4.4.4 Review, validate, approve and/or reject CARs.

4.4.5 Evaluate and approve or reject requests to extend response due dates as well as corrective action completion or closure dates for CARs.

4.5 Assessment Team Leaders

4.5.1 Review CARs that result from an assessment.

4.5.2 Determine if CARs require work suspension and/or accelerated corrective action and make recommendation to the QAR as appropriate.

4.5.3 In conjunction with the OQA Director or QAR, determine if the deficiency is a SCAQ or WAP-related deficiency, using Attachment V.

4.5.4 Based on review, recommend approval or rejection of proposed corrective actions for CARs.

4.5.5 Monitor the corrective action process for CARs.

4.5.6 Evaluate and recommend approval or rejection of requests for extension of the response due date and the corrective action completion dates.

4.5.7 Review and recommend approval or rejection of CAR closure, based on verification information.

4.5.8 Ensure that the CAR Coordinator receives copies of all hardcopy and electronic correspondence related to the processing and resolution of CARs.

4.5.9 If necessary, recommend to the OQA Director or QAR that TRU waste site certification should be suspended for untimely corrective action in response to CARs requiring accelerated corrective action.

4.5.10 Sign and transmit CARs, as necessary.

4.5.11 Review the CAR status report.

- 4.5.12 Transmit copies of CARs to the New Mexico Environment Department (NMED) for CAQs related to the HWFP.
- 4.5.13 Evaluate concerns and issues resulting from external audits and inspections (e.g., Environmental Protection Agency [EPA], DOE Headquarters).
- 4.6 TRU Sites and Transportation Division (TSTD) Director

Evaluate, in writing, the impact of a CAR requiring accelerated corrective action on TRU waste received at WIPP or proposed for shipment to WIPP.
- 4.7 CAR Initiator
 - 4.7.1 Interface with the responsible organization through the OQA Director or QAR for CAR issuance, response evaluations, and corrective action verifications.
 - 4.7.2 Complete a CBFO Corrective Action Report (CBFO Form 3.1-1) when a CAQ is identified and justifies a CAR (see section 2.0, Scope, and Attachment I). If additional space is needed to complete the report, use a CAR Continuation Sheet (CBFO Form 3.1-2, see Attachment II).
 - 4.7.3 Review proposed CAPs and make recommendations to the OQA Director or QAR concerning their acceptability.
 - 4.7.4 Ensure that the CAR Coordinator receives copies of all hardcopy and electronic correspondence related to the processing and resolution of CARs.
- 4.8 CAR Coordinator
 - 4.8.1 Provide a CAR number, when requested.
 - 4.8.2 Administer the CBFO CAR reporting and tracking system.
 - 4.8.3 Transmit a monthly CAR status report to the CBFO Manager and Deputy Manager, OQA Director, QAR, Assistant Managers, Office/Division Directors, and appropriate assessment team leaders.
 - 4.8.4 Prepare a letter or memorandum to the responsible organization for issuance by the OQA Director when CAR responses or corrective actions are due or overdue.
 - 4.8.5 Prepare the CAR records package in accordance with section 6.0, Records.
- 4.9 Corrective Action Verifier

Independently verify corrective action completion and make recommendations to the OQA Director or QAR concerning the appropriateness of CAR closure.
- 4.10 Responsible Organization
 - 4.10.1 Prepare a CAP addressing the actions indicated in CAR block 11 and submit it by the due date indicated in CAR block 13a.
 - 4.10.2 Submit objective evidence demonstrating that all corrective actions have been fulfilled to the OQA Director or QAR.

- 4.10.3 When necessary, submit due date extension requests to the OQA Director (or QAR) for responding to CARs or when additional time is needed to fulfill corrective actions.
- A. Extension requests shall be made in writing, and shall provide sufficient justification for the request.
 - B. Extensions are preferably requested at least seven calendar days prior to the due date.
 - C. The QAR and CAR Coordinator shall be on courtesy-copy distribution for all extension requests.

5.0 PROCEDURE

NOTE: Instructions for completing the CAR forms are included in Attachment IV. Discussion between the CAR initiator and QAR may be necessary to determine the appropriate entries for CAR blocks 10 and 11.

5.1 Corrective Action Report Initiation

- 5.1.1 Individuals identifying a CAQ involving a CBFO or participant's process, service, or product, which requires the use of a CAR to manage the CAQ, shall discuss the condition with the appropriate member(s) of the responsible organization and shall initiate a CAR using a Corrective Action Report form (CBFO Form 3.1-1, see Attachment I) and a CAR Continuation Sheet (CBFO Form 3.1-2; see Attachment II), if extra space is needed. CBFO forms are available electronically on the WIPP Intranet CBFO home page at <http://bellview/cbfo/forms.html>.
- 5.1.2 Complete CAR blocks 2 through 9 and 12b, and transmit the CAR to the appropriate management of the responsible organization.
- 5.1.3 If the CAR is not issued to the CBFO, then the CAR initiator enters "N/A" (for "not applicable") in block 5.
- 5.1.4 The individual who identifies a CAQ as a potential WAP-related deficiency or SCAQ shall brief the OQA Director or QAR using the Deficiency Classification Determination form (see Attachment V).
- 5.1.5 The OQA Director or QAR shall review the condition and determine if the CAR represents a noncompliant condition.
- 5.1.6 If the OQA Director or QAR determines the CAR does not represent a noncompliant condition, then the unsigned CAR is returned to the CAR initiator with an explanation and the CAR initiator shall submit the issue in the ICE system per CBFO MP 10.9.
- 5.1.7 Disagreements regarding the validity of a CAR shall be elevated to successive levels of management for resolution.
- 5.1.8 Upon verification that conditions in the CAR represent a noncompliant condition, the CAR initiator shall obtain a CAR number from the CAR Coordinator and enter it in CAR block 1.
- 5.1.9 The OQA Director or QAR shall complete CAR blocks 10a through 10d as follows:
 - A. If the condition represents a SCAQ (see Attachment V), then check "Yes" in block 10a. Otherwise check "No."

- B. If the condition warrants work suspension, then check “Yes” in block 10b and notify, orally or in writing, the CBFO Manager, CBFO Deputy Manager, OQA Director, and appropriate management of the responsible organization to determine the appropriate method for implementing a work suspension. Otherwise check “No.”
 - C. If the condition is a WAP-related deficiency, then check “Yes” in block 10c. Otherwise check “No.”
 - D. If the condition is a WAP-related deficiency and affects a process currently certified by CBFO at a TRU waste generator/storage site, then check “Yes” in block 10d, indicating accelerated corrective action required. Otherwise check “No.”
- 5.1.10 The OQA Director or QAR shall complete CAR blocks 11a through 11d as follows (blocks 11a through 11d shall ALL be checked for SCAQ or WAP-related deficiency CARs):
- A. Check “Yes” or “No” for remedial action(s) in block 11a as applicable.
 - B. Check “Yes” or “No” in block 11b to indicate whether investigative action(s) are required (required if other similar/same condition(s) may exist elsewhere).
 - C. Check “Yes” or “No” in block 11c to indicate whether a causal analysis of a condition is required.
 - D. Check “Yes” or “No” in block 11d to indicate whether actions to preclude recurrence are required and described in the CAP.
- 5.1.11 The OQA Director or QAR shall identify the appropriate Trend Code per CBFO MP 3.2, *Deficiency Trending and Reporting*, for the condition by completing CAR block 12a.
- 5.1.12 The OQA Director or QAR shall assign a response due date in CAR block 13a, allowing the responsible organization a maximum of 30 calendar days after issuance of the CAR to respond.
- 5.1.13 If CAR block 10d is marked “Yes,” then a required corrective action completion date shall be assigned of no more than 30 calendar days from issuance of the CAR in block 13b.

NOTE: The accelerated corrective action process was initiated in response to NMED Compliance Order HWB 01-08, Settlement Agreement.

- 5.1.14 The OQA Director or QAR shall ensure the CAR form blocks are complete and shall indicate concurrence with the CAR content by signing in CAR block 14a.
- 5.1.15 For SCAQ, work suspension or accelerated CARs, the OQA Director shall sign and date CAR block 14b.

NOTE 1: All CARs require a CAP that addresses the types of actions marked “Yes” in CAR block 11. The deficiencies determined to be SCAQs, or any WAP-related deficiencies, require a CAP that addresses all four types of actions indicated in CAR block 11.

NOTE 2: The CAR serves as the tracking document for a work suspension.

5.2 CAR Issuance

- 5.2.1 When the CAR is approved for issuance, then the OQA Director or QAR shall ensure preparation of a transmittal package containing:
- A. A copy of the CAR
 - B. Attachment III, Instructions for Providing a Corrective Action Plan
 - C. A CAR transmittal letter if the responsible organization is external to the DOE, or a CAR transmittal memorandum if the responsible organization is internal to the DOE
- 5.2.2 The OQA Director shall distribute the CAR in accordance with the current CAR distribution list.
- 5.2.3 Upon issuance, CARs requiring accelerated corrective action (i.e., CAR block 10d is marked "Yes") shall also be transmitted via memorandum to the TSTD Director for impact evaluation as described in section 5.9, and to the NMED, as appropriate.
- 5.2.4 The CAR Coordinator shall maintain the CBFO CAR database. The CAR database shall contain the following status and tracking information:
- A. CAR number (CAR block 1)
 - B. Description of the condition adverse to quality (CAR block 9)
 - C. Activity report number (i.e., surveillance or audit number), if applicable (CAR block 2)
 - D. Responsible organization (CAR block 6)
 - E. Responsible CBFO Manager (CAR block 5)
 - F. HWFP or WAP Deficiency (CAR block 10c)
 - G. Trend Code (CAR block 12a)
 - H. Date issued (CAR transmittal date)
 - I. Date response due (CAR block 13a)
 - J. Date response received
 - K. Date response accepted (CAR block 15)
 - L. Date actions are expected to be completed
 - M. Acceptance of corrective action completion date (CAR block 16)
 - N. Date closed (CAR block 17)
 - O. Accelerated Corrective Action Required (CAR block 10d)

5.3 Corrective Action Plan

NOTE: A CAP template is provided on the CBFO Bellview site, under “Forms,” to help with CAP development, as needed.

5.3.1 A CAP shall be prepared and submitted by the responsible organization to the OQA Director or QAR, addressing each checked item in CAR block 11.

5.3.2 If the responsible organization cannot provide an acceptable CAP before the response due date, then the responsible organization shall submit a written extension request to the QAR, with justification, preferably seven calendar days prior to the due date. The OQA Director shall be on courtesy-copy distribution for all extension requests. The QAR shall notify the responsible organization of extension approval or rejection, with a copy to the OQA Director and the CAR Coordinator.

5.4 Corrective Action Plan Evaluation

5.4.1 Upon receipt of the CAP from the responsible organization, the OQA Director or QAR shall transmit the CAP to the CAR initiator for review, with a copy to the CAR Coordinator.

5.4.2 The CAR initiator shall evaluate the proposed actions to ensure that the CAP properly addresses the deficiency, contains expected completion dates, and assigns responsibilities for the completion of the corrective actions.

5.4.3 When the review is completed, then the CAR initiator shall provide to the OQA Director a recommendation on a CAR Continuation Sheet describing the justification for acceptance or rejection of the proposed actions.

5.4.4 The OQA Director shall review the CAP and recommendations from the CAR initiator. If the CAP is acceptable, then the OQA Director or QAR shall sign CAR block 15.

5.4.5 The OQA Director shall notify the responsible organization that the CAP has been accepted, and include the completed CAR Continuation Sheet (see step 5.4.3), with a copy to the CAR Coordinator.

5.4.6 If the CAP is not acceptable, then the OQA Director shall prepare a rejection justification, and include the completed CAR Continuation Sheet (see step 5.4.3) and notify the responsible organization, with a copy to the CAR Coordinator.

5.4.7 If issues with CAP evaluation and approval cannot be resolved, then they shall be elevated to successive levels of management until resolution is attained.

5.5 Corrective Action Completion

5.5.1 The responsible organization shall:

A. Complete the actions in the approved CAP.

B. If necessary, submit a written request for extension to the OQA Director or QAR. Requests should be submitted seven calendar days prior to the due date to allow for review and approval. The request shall include a justification for the extension. The QAR shall be on courtesy-copy distribution for all extension requests.

- C. Transmit the evidence of corrective action completion to the OQA Director on or before the completion due date.
- 5.5.2 If the CAR requires accelerated corrective action (block 10d is marked "Yes") and the responsible organization cannot complete corrective actions by the due date indicated in CAR block 13b, then the responsible organization shall submit a written, detailed justification and request for extension of the due date to the CBFO Manager, preferably within seven calendar days before the original due date, with a copy to the OQA Director and QAR.
- 5.5.3 The QAR shall monitor the status of the responsible organization's corrective actions.
- 5.5.4 For CARs that require accelerated corrective action, if corrective actions are not completed by the due date indicated in CAR block 13b, then the OQA Director or QAR shall recommend to the CBFO Manager/Deputy Manager that TRU waste site certification be suspended.
- A. If the CBFO Manager/Deputy Manager determines that TRU waste site certification should be suspended, then the waste site shall be notified in writing.
 - B. If TRU waste site certification is not suspended as determined by CBFO Manager/Deputy Manager, then the CBFO Manager/Deputy Manager will notify the OQA Director.
- 5.5.5 The NMED and/or EPA, as appropriate, shall be notified of the decision to suspend or not suspend TRU waste site certification, with a copy to the CAR Coordinator.
- 5.6 Verification of Corrective Action Completion
- 5.6.1 CARs issued to address technical deficiencies shall be verified by a qualified technical specialist. CARs resulting from QA deficiencies shall be verified by a QA auditor.
- 5.6.2 The corrective action verifier shall:
- A. Perform a verification to determine that approved corrective actions have been completed. Verification shall be accomplished as soon as practicable.
 - B. Document the verification on a CAR Continuation Sheet and identify the specific areas investigated, the objective evidence reviewed, and the results of the verification.
 - C. Document how each of the actions required in CAR Block 11 were accomplished and list the objective evidence reviewed to determine that the actions were completed.
 - D. Indicate verification by signing and dating the CAR Continuation Sheet and submit to the QAR.
 - E. If the verification review indicates the corrective actions were unacceptable, incomplete, or cannot otherwise be verified, then the verifier shall document the results of the review on a CAR Continuation Sheet, including any additional actions that are required, and submit to the QAR.

5.6.3 If the corrective action verifier does not accept the corrective actions, then a transmittal requesting additional actions shall be issued by the QAR to the responsible organization (with a copy to the CAR Coordinator) identifying the new expected completion date.

5.7 CAR Closure

5.7.1 The OQA Director or QAR shall review verification information and, if closure is justified, sign CAR block 17.

5.7.2 The OQA Director or QAR shall notify the responsible organization of the CAR closure, in writing, with a copy to the CAR Coordinator.

5.8 TRU Waste Generator Site CARs

5.8.1 Upon receipt of a site-generated CAR, the CAR Coordinator shall assign a tracking number and enter the CAR information in the site-generated CAR database.

5.8.2 Site-generated CARs shall be uniquely identified by site identification letters (e.g., Hanford = RL, AMWTP = IA, ORNL= OR) within the CBFO assigned CAR number (e.g., 09-IA-10).

5.8.3 The CBFO site-generated CAR database shall contain the following items:

- A. CBFO-assigned CAR Tracking Number
- B. Site-assigned CAR Activity Report Number
- C. Responsible Organization
- D. Condition Adverse to Quality
- E. CAP Due Date
- F. Corrective Action(s)
- G. CAR Initiator/Name
- H. CAR Initiation Date
- I. CAR Closure Approval/Name
- J. CAR Closure Date

5.8.4 The CAR Coordinator shall transmit site-generated WAP-related deficiency CAR information reports (updated as appropriate) as QA records to the WIPP Records Archive.

5.9 Evaluation of Impact for CARs Requiring Accelerated Corrective Action

5.9.1 The TSTD Director shall evaluate the impact of CARs requiring accelerated corrective action. This evaluation should be completed within 10 working days of receiving the CAR.

5.9.2 The evaluation shall address waste received by WIPP and waste awaiting shipment.

- 5.9.3 The evaluation will include a determination of whether waste shipments from the TRU waste site should be suspended.
- 5.9.4 The evaluation shall be documented in writing and transmitted to the CBFO Manager/Deputy Manager, OQA Director, the Environmental Protection Division Director, the responsible organization, as appropriate, and the CAR Coordinator for inclusion in the CAR files.
- 5.9.5 Results of the evaluation shall be forwarded to NMED and/or EPA, as appropriate.

6.0 RECORDS

- 6.1 Records generated during the performance of this procedure are maintained in accordance with CBFO MP 4.5 and CBFO MP 4.9. QA records comprise the following, as applicable:
 - 6.1.1 Issued CBFO Corrective Action Report
 - 6.1.2 Completed CBFO CAR Continuation Sheet(s)
 - 6.1.3 Transmittal letters
 - 6.1.4 CAR responses
 - 6.1.5 Response evaluations
 - 6.1.6 Extension requests and approvals
 - 6.1.7 Closure package submittals
 - 6.1.8 Verification documentation
 - 6.1.9 Closure letters and memoranda
 - 6.1.10 TSTD evaluations of CAR impact related to CBFO-certified processes at the TRU waste sites
 - 6.1.11 Work suspension letters and associated documentation

7.0 ATTACHMENTS

- Attachment I: CBFO Corrective Action Report form (CBFO Form 3.1-1)
- Attachment II: CBFO CAR Continuation Sheet form (CBFO Form 3.1-2)
- Attachment III: Instructions for Providing a Corrective Action Plan
- Attachment IV: Instructions for Completing the CAR Form
- Attachment V: Deficiency Classification Determination

CBFO Form 3.1-1
December 2015

CBFO CORRECTIVE ACTION REPORT

1. CAR No.:	2. Activity Report No.:	3. Page 1 of
4. Controlling document:		5. Responsible CBFO Manager:
6. Responsible organization:		7. CAQ discussed with:
8. Requirement:		
9. Condition Adverse to Quality (CAQ):		
10a. Significant CAQ? (If "Yes", go to block 14b)	Yes <input type="checkbox"/> No <input type="checkbox"/>	11. Type of actions required:
10b. Work Suspension recommended? (If "Yes", go to block 14b)	Yes <input type="checkbox"/> No <input type="checkbox"/>	11a. Remedial? Yes <input type="checkbox"/> No <input type="checkbox"/>
10c. WAP-related Deficiency?	Yes <input type="checkbox"/> No <input type="checkbox"/>	11b. Investigative? Yes <input type="checkbox"/> No <input type="checkbox"/>
10d. Accelerated corrective action required? (If "Yes", go to block 14b)	Yes <input type="checkbox"/> No <input type="checkbox"/>	11c. Causal Analysis? Yes <input type="checkbox"/> No <input type="checkbox"/>
12a. Trend Code:		12b. CAR Initiator:
		<i>Printed Name:</i> _____ <i>Date</i> _____
13a. Response due date:		
13b. Required corrective action completion date:		
14. Concurrence:		
a. Quality Assurance Representative (if applicable):		
<i>Printed Name:</i> _____		<i>Date</i> _____
b. CBFO Office of Quality Assurance Director: (If SCAQ, work suspension, or accelerated corrective action; otherwise mark as "N/A")		
<i>Printed Name:</i> _____		<i>Date</i> _____
15. Acceptance of Proposed Corrective Actions:		
<i>Printed Name and Title:</i> _____		<i>Date</i> _____
16. Acceptance of Corrective Action Completion:		
<i>Printed Name:</i> _____		<i>Date</i> _____
17. Closure:		
<i>Printed Name:</i> _____		<i>Date</i> _____

CAR CONTINUATION SHEET

1. CAR No:	2. Activity No:	3. Page of

INSTRUCTIONS FOR PROVIDING A CORRECTIVE ACTION PLAN

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

INSTRUCTIONS FOR PROVIDING A CORRECTIVE ACTION PLAN

You are requested to provide a corrective action plan (CAP) in response to this corrective action report (CAR) by the completion date identified in block 13b of the CAR. If this date cannot be met, provide a written request for extension to the Quality Assurance Representative with courtesy copy to the Office of Quality Assurance Director. This request must include justification for the delay and must be provided seven calendar days prior to the response due date (CAR block 13a).

The CAP shall address the corrective actions indicated in CAR block 11. As appropriate, develop the plan in accordance with the following sequence and format:

In order to develop the CAP, perform an investigative action to determine the extent and impact of the deficiency and to identify the causal factors. Next, determine the actions required to correct the adverse condition. The plan shall include the following information, as appropriate to CAR block 11.

1. Corrective action response for CAR # _____
 - A. **Remedial Actions**-Describe actions required or taken to correct the specific conditions noted and any similar conditions identified during discovery.
 - B. **Investigative Actions**-Describe the investigative actions performed to determine the extent and impact of the deficiency and the results of the investigation. This will include a determination of the acceptability of any data generated prior to resolution of the deficiency.
 - C. **Causal Analysis**-Identify the causal factors of the condition as determined through investigative actions. (Refer to DOE Order 232.2.)
 - D. **Actions to Preclude Recurrence**-Identify the corrective actions required to address the causal factors of the condition in order to preclude recurrence.

NOTE: Schedule for completion of corrective actions is always required.
2. For each action above, identify 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.

NOTE: A CAP Template is provided on the CBFO Bellview site, under FORMS, to help with CAP development, as needed

INSTRUCTIONS FOR COMPLETING THE CAR FORM

<u>Block No.</u>	<u>Performed By</u>	<u>Action</u>
1	CAR Initiator	Enter the sequential CAR identification number obtained from the CAR Coordinator.
2	CAR Initiator	Identify any activity report number (Assessment, Operational Evaluation, etc., Number) associated with the identified deficiency (i.e., Surveillance #, Audit #). Otherwise, mark block "N/A."
3	CAR Initiator	Enter page numbers.
4	CAR Initiator	Identify the applicable requirements document and revision.
5	CAR Initiator	CAR initiator enter "N/A" if the CAR is not issued to CBFO. If issued to CBFO, identify the responsible manager/director.
6	CAR Initiator	Enter the organization responsible for responding/correcting the CAR condition.
7	CAR Initiator	Enter the individual with whom the CAQ was discussed.
8	CAR Initiator	Identify the specific requirement(s) that were violated.
9	CAR Initiator	Clearly describe the condition adverse to quality, including representative examples (use the CAR Continuation Sheet if necessary).
10a	OQAD/QAR	Determine if the CAR condition is a significant condition adverse to quality (see Attachment V).
10b	OQAD/QAR	Indicate if a work suspension is recommended.
10c	QAR	Determine if the deficiency represents a violation of WIPP Hazardous Waste Facility Permit requirements.
10d	QAR	Determine if the deficiency meets the criteria for accelerated corrective action required (see Attachment V), i.e., a deficiency in a CBFO certified process at a TRU waste site that is a SCAQ or WAP-related deficiency.
11a	OQAD/QAR	Check "Yes" for Remedial Action(s) (required for any CAR). NOTE: Actions 11a through 11d shall all be checked "Yes" for CARs that are SCAQ or WAP-related deficiency.
11b	OQAD/QAR	Indicate whether Investigative Actions are required or not by checking "Yes" or "No." (Check "Yes" if it is apparent that other similar or same conditions exist elsewhere.)
11c	OQAD/QAR	Indicate whether a Causal Analysis of the condition should be determined or not by checking either "Yes" or "No." (Required for CARs that are SCAQ or WAP-related.)
11d	OQAD/QAR	Check "Yes" to require the identification of Action(s) to Preclude Recurrence. (Check "No" if only remedial action(s) are necessary to resolve the CAR condition).
12a	OQAD/QAR	Assign Trend Code per MP 3.2.
12b	OQAD/QAR	Name and Date.
13a	OQAD/QAR	Enter the Response Due Date, allowing the responsible organization a maximum of 30 calendar days from CAR issuance.
13b	OQAD/QAR	For CARs requiring accelerated corrective action, enter a required corrective action completion date no more than 30 calendar days from CAR issuance. Otherwise, mark the required corrective action completion date "N/A."
14a	OQAD/QAR	Sign and date indicating concurrence with CAR validity and completion of blocks 1 through 12b.
14b	OQAD, if applicable	Sign, if SCAQ, work suspension, or accelerated corrective action indicating concurrence with CAR validity and completion of blocks 1 through 12b.
15	OQAD/QAR	Sign and date indicating acceptance of proposed corrective action.
16	OQAD/QAR	Sign and date, indicating CAR closure.
17	OQAD/QAR	Sign and date indicating acceptance of proposed corrective action.

QAR = Quality Assurance Representative
 SCAQ = Significant Condition Adverse to Quality
 OQAD = Office of Quality Assurance Director

DEFICIENCY CLASSIFICATION DETERMINATION

Considerations to Determine if a Deficiency is a SCAQ

- If uncorrected, could the condition adverse to quality have a **serious** effect on safety, operability, waste isolation, TRU waste site certification, regulatory compliance demonstration, or effective implementation of the QA Program?
- Does the condition adverse to quality require immediate notification of regulatory entities?
- Does the condition adverse to quality indicate a significant failure or breakdown in the implementation of QA Program requirements?
- Have repeated attempts to resolve the condition adverse to quality been unsuccessful?
- Does the condition adverse to quality affect items or activities important to safety or waste isolation and compromise the ability to prevent or mitigate the consequences of an accident, thereby presenting a significant hazard to safety and health of workers and/or the public?

If the answer to ALL of these questions is “No,” the deficiency **is not** a significant condition adverse to quality. Mark block 10a on the CAR form “No.”

If the answer to ANY of these questions is “Yes,” the deficiency **is** a significant condition adverse to quality. Do the following:

- Mark block 10a on the CAR form “Yes.”
- Mark all four actions as “Yes” in block 11 on the CAR form.
- Obtain concurrence of the Quality Assurance Representative or Office of Quality Assurance Director in block 14a on the CAR form AND of the Office of Quality Assurance Director in block 14b on the CAR form.

Considerations to Determine if a Deficiency is a WAP-Related Deficiency

- Does the deficiency potentially constitute a violation of a provision of the HWFP WAP?
- Is the Responsible Organization identified in block 6 of the CAR form a TRU waste generator/storage site?

If the answer to EITHER question is “No,” the CAR **is not** WAP-related. Mark block 10c on the CAR form “No.”

If the answer to BOTH questions is “Yes,” the CAR **is** WAP-related. Mark block 10c on the CAR form “Yes” and mark “Yes” for each action type in block 11 on the CAR form.

Considerations to Determine if a CAR Requires Accelerated Corrective Action

- Is the CAR WAP-related?
- Is the deficiency written against a process that is currently certified by CBFO at a TRU waste generator/storage site?

If the answer to EITHER question is “No,” the CAR **does not** require accelerated corrective action. Mark block 10d on the CAR form “No.”

If the answer to BOTH questions is “Yes,” the CAR **does** require accelerated corrective action. Mark block 10d on the CAR form “Yes.”