



Department of Energy
Carlsbad Field Office
P. O. Box 3090
Carlsbad, New Mexico 88221

October 19, 2004



Tim Hedahl
Washington TRU Solutions
P.O. Box 2078
Carlsbad, NM 88331-2078

Re: Issuance of Corrective Action Reports 05-001 through 05-004 from Audit
A-05-02 of the NTS/CCP

Dear Mr. Hedahl:

The Carlsbad Field Office (CBFO) performed Audit A-05-02 of the Nevada Test Site (NTS) Central Characterization Project (CCP) characterization activities on October 05-08, 2004. CBFO Corrective Action Reports (CARs) 05-001 through 05-004 are enclosed.

Please document on the attached CAR continuation sheets your proposed corrective actions and a schedule for completion then forward to me prior to the response due date identified in CAR block 14. CARs 05-003 and 05-004 require accelerated corrective action.

Attached are the instructions for providing corrective action responses for your use in preparing the required responses.

If you have any questions or comments, contact me at (505) 234 -7491.

Sincerely,

Dennis S. Miehl
Quality Assurance Specialist

Enclosures



cc w/enclosures:

A. Holland, CBFO *ED
K. Watson, CBFO *ED
R. McCallister, CBFO *ED
J. Norton, NSO *ED
M. Eagle, EPA *ED
B. Shroff, EPA *ED
E. Feltcorn, EPA *ED
R. Joglekar, EPA *ED
S. Zappe, NMED *ED
D. Winters, DNFSB *ED
L. Greene, WRES *ED
D. Haar, WTS *ED
A. Fisher, WTS *ED
C. Riggs, CTAC *ED
A. Pangle, CTAC *ED
WIPP Operating Record, MS 486-06
CBFO QA File
CBFO M&RC

CORRECTIVE ACTION REPORT

1. CAR No.: 05-001	2. Activity Report No.: A-05-02	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: DOE-WIPP-02-3122		5. CBFO Assessment Team Leader: Dennis Miehl
6. Responsible Organization: NTS/CCP		7. CAQ Was Discussed With: B. Gillespie, G. Westick
8. Requirement that was violated: DOE-WIPP-02-3122, Appendix A, Section A.4.2 and Table A-4.2, (see continuation sheet)		
9. Condition Adverse to Quality: On 07/14/04 the Cs-137 Daily Performance Check was outside of the 3 sigma action limit. CCP-TP-051, Rev 7, Section 4.1.4 requires that an NCR be written and the system removed from service, neither of which was done. The actual problem was not instrument related but was caused by the use of the wrong date for decay correcting the source which produced an artificially low result. Upon rerunning the performance check with the correct decay correction the system was within the acceptance criteria.		
10. Suggested Actions (Optional): 		
11a. Significant CAQ (Yes or No): No		
11b. Work Suspension Recommended (Yes or No): No		
11c. RCRA-Related (Yes or No): No		
11d. Accelerated Corrective Action Required (Yes or No): No		
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>P. Kelly</u> <i>Ass. T. R. F.</i> Date: <u>10/18/04</u>		
14. Response Due Date: <u>11-17-04</u> Corrective Action Plan Required: YES Required Corrective Action Completion Date: <u>N/A</u>		
15. a. Concurrence: <u>D. J. Mills</u> <u>10-18-04</u> b. <u>N/A</u> <u>N/A</u> Assessment Team Leader Date Responsible Assistant Manager Date c. <u>N/A</u> <u>N/A</u> 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		

CBFO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No.: 05-001	2. Activity No.: A-05-02	3. Page ___ of ___
<p>Block # <u>8</u></p> <p>From DOE/WIPP-02-3122, Section A.4.2: "Data Checks; ... If daily performance check result in data that are outside the acceptable range, the required responses in table A-4.2 shall be followed."</p> <p>Table A-4.2 states for daily performance check data that exceed 3 sigma, "Work shall stop and the occurrence shall be documented and appropriately dispositioned (e.g., initiating a non-conformance report). The radioassay system shall be removed from service pending successful resolution of all necessary actions, and all assays performed since the last acceptable performance check are suspect, pending satisfactory resolution. Recalibration or calibration verification is required prior to returning the system back to service."</p>		

CORRECTIVE ACTION REPORT

1. CAR No.: 05-002	2. Activity Report No.: A-05-02	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: DOE-CBFO-94-1012		5. CBFO Assessment Team Leader: Dennis Miehlis
6. Responsible Organization: NTS/CCP		7. CAQ Was Discussed With: Dave Haar
<p>8. Requirement that was violated: QAPD, DOE-CBFO-94-1012, Section 1.5.2.B states, "QA records shall be legible, accurate, and completed appropriate to the work accomplished."</p>		
<p>9. Condition Adverse to Quality: Three of four visual examination batch data reports reviewed contained erroneous container number entries, totaling 5 errors. Three appear to be typographical errors; one was a number missing from the batch data report cover sheet; one was the entry of an untraceable container number on the package inventory report.</p>		
10. Suggested Actions (Optional):		
<p>11a. Significant CAQ (Yes or No): No</p> <p>11b. Work Suspension Recommended (Yes or No): No</p> <p>11c. RCRA-Related (Yes or No): No</p> <p>11d. Accelerated Corrective Action Required (Yes or No): No</p>		
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>A. Axinn</u> <u>Man. T. Rep. E.</u> Date: <u>10/12/04</u>		
<p>14. Response Due Date: <u>11-17-04</u> Corrective Action Plan Required: YES</p> <p>Required Corrective Action Completion Date: <u>N/A</u></p>		
<p>15. a. Concurrence: <u>D. J. Muelko</u> <u>10-18-04</u> b. <u>N/A</u> <u>N/A</u></p> <p style="text-align: center;">Assessment Team Leader Date Responsible Assistant Manager Date</p> <p>c. <u>N/A</u> <u>N/A</u></p> <p style="text-align: center;">Quality Assurance Manager Date</p>		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:		
<p>_____</p> <p>Assessment Team Leader Date</p>		
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	

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 05-002

2. Activity No.: A-05-02

3. Page ___ of ___

Block #_

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 05-003

2. Activity No.: A-05-02

3. Page ___ of ___

Block # _

CORRECTIVE ACTION REPORT

1. CAR No.: 05-004	2. Activity Report No.: A-05-02	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: WAP B3-1, equation B3-4	5. CBFO Assessment Team Leader: D. Miehlis	
6. Responsible Organization: NTS/CCP	7. CAQ Was Discussed With: Terri Groover, D. Haar	
<p>8. Requirement that was violated: WAP B3-1, equation B3-4 states that in instances where precision is associated with analytical equipment calibration, the percent difference (%D) between multiple measurements of an equipment calibration standard shall be calculated as follows: $\%D = \frac{C_1 - C_2}{C_1} \times 100$</p> <p>Where C_1 is the initial measurement and C_2 is the second or other additional measurement.</p>		
<p>9. Condition Adverse to Quality: The % D calculated for the continuing calibration verification (CCV) in the Batch Data Reports CCV Report/QAO is incorrect, when calculated using the information given on the CCV Report/QAO Form.</p>		
10. Suggested Actions (Optional):		
<p>11a. Significant CAQ (Yes or No): Yes</p> <p>11b. Work Suspension Recommended (Yes or No): No</p> <p>11c. RCRA-Related (Yes or No): Yes</p> <p>11d. Accelerated Corrective Action Required (Yes or No): Yes</p>		
12. Types of Actions: Remedial: <u>X</u> Investigative: <u>X</u> Root Cause: <u>X</u> Actions to Preclude Recurrence: <u>X</u>		
13. CAR Initiator: Verret/Rodriguez <u>Ann. J. Rodriguez</u> Date: <u>10/12/04</u>		
<p>14. Response Due Date: <u>11-1-04</u> Corrective Action Plan Required: <u>YES</u></p> <p>Required Corrective Action Completion Date: <u>11-17-04</u></p>		
<p>15. a. Concurrence: <u>D. J. Miehlis</u> <u>10-18-04</u> b. <u>N/A</u> <u>N/A</u></p> <p style="text-align: center;"> <small>Assessment Team Leader Date Responsible Assistant Manager Date</small> <u>Ann. J. Rodriguez</u> <u>10/18/04</u> </p> <p style="text-align: center;"> <small>Quality Assurance Manager Date</small> </p>		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:		
<p>_____</p> <p style="text-align: center;"><small>Assessment Team Leader Date</small></p>		
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	

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 05-004

2. Activity No.: A-05-02

3. Page ___ of ___

Block #

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 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.