

United States Government

Department of Energy

memorandumCarlsbad Field Office
Carlsbad, New Mexico 88221

DATE: October 25, 2001

REPLY TO
ATTN OF: CBFO:QA:TJR:KJB 01-1489 UFC 2300

SUBJECT: Issuance of Corrective Action Reports (CARs); 02-003 through 02-006

TO: Farok Sharif, WTS/CCP



The Carlsbad Field Office (CBFO) performed Audit A-02-09 of the Westinghouse TRU Solutions (WTS) Central Characterization Project (CCP) on October 15-19, 2001. The audit team identified four (4) conditions adverse to quality, which have been documented in CARs 02-003 through 02-006.

Please document on the attached CAR Continuation Sheets your proposed corrective actions and a schedule for completion and forward to me prior to your agreed upon response due date identified in CAR Block 14 of each CAR.

If you have any questions or comments, please contact me at (505) 234-7311.

/s/ signature on file

Thomas J. Reese
Acting Quality Assurance Manager

Attachments

cc: w/attachments

L. Chism, CBFO	
B. Bennington, CBFO	*ED
K. Watson, CBFO	*ED
J. Schuetz, CTAC	*ED
T. Bowden, CTAC	
M. Eagle, EPA	*ED
S. Monroe, EPA	*ED
S. Zappe, NMED	*ED
B. Walker, EEG	*ED
D. Winter, DNFSB	*ED
M. Gerle, WTS (Operating Record)	

*ED denotes Electronic Distribution



CORRECTIVE ACTION REPORT

1. CAR No.: 02-003	2. Activity Report No.: A-02-09	3. Page <u>1</u> of <u>2</u>
4. Controlling Document:	5. CBFO Assessment Team Leader: Thomas J. Reese	
6. Responsible Organization: Central Characterization Project	7. CAQ Was Discussed With: D. Killingsworth, Adela Cantu	
8. Requirement that was violated: (See Continuation Sheet)		
9. Condition Adverse to Quality: (See Continuation Sheet)		
10. Suggested Actions (Optional): 		
11a. Significant CAQ	(Yes or No): Yes	
11b. Work Suspension Recommended	(Yes or No): No	
11c. CCA-Related	(Yes or No): Yes	
11d. RCRA-Related	(Yes or No): Yes	
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: <u>Steve Davis / Dorothy Gill</u>		Date: <u>October 19, 2001</u>
14. Response Due Date: <u>November 26, 2001</u>		Corrective Action Plan Required: YES
15. Concurrence: <u>/s/ signature on file</u> Assessment Team Leader	<u>10-25-01</u> Date	<u>/s/ signature on file</u> Responsible Assistant Manager
<u>10-25-01</u>	<u> </u> Date	<u>10-25-01</u> Date
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions: _____ Date _____ Assessment Team Leader		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____		
19b. Trend Cause Code: _____		
20. Closure: _____ Quality Assurance Manager		
		_____ Date

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 02-003

2. Activity No.: A-02-09

3. Page 2 of 2

Block # 8 Requirement that was violated:

CCP-TP-029, Sec. 4.10.1(L), "The concentration of the tentatively identified compounds shall be estimated using the internal standard analyte nearest the retention time of the TIC (free of interferences). Quantification shall use the total ion response area and a response factor of 1. Quantification is performed by dividing the area count of the TIC by the response factor of the internal standard. The resulting concentration shall be reported to identify which internal standard compound was used to determine the TIC concentration."

QAPD, Sec.; 1.3.2.3.A, "Nonconforming items shall be identified by marking, tagging, or other methods that do not adversely affect their end use. The identification shall provide for traceability to the related adverse condition....."

CCP-QP-022, Sec. 4.5.2[I], "If software was modified to correct a problem to the baseline, the code sponsor ensures that the SPR process (Section 4.8) has been initiated. In the event the problem is a material attribute to a nonconformance or may result in a condition adverse to quality, the code sponsor shall address this in accordance with CCP-QP-005, CCP TRU Nonconforming Item and Reporting and Control System".

Block # 9 Condition Adverse to Quality:

- A) While performing generation level data review of a HSG Batch Data Report #101001B, in accordance with CCP procedure CCP-TP-029, the Operator discovered errors in a computer spreadsheet calculation utilized for determination of TIC concentration and manually corrected the data. The Operator accepted the data package and did not evaluate or address the reason for the discrepant condition. Further investigation of the problem identified obvious problems inherent with the selected software. Various computer software controls and testing techniques had not been utilized to verify functional operation or acceptability of the revised software.
- B) The accuracy performance data recorded in the spreadsheet for the target analyte, Bromoform, is out-side of acceptance criteria and needs to be properly addressed.

CORRECTIVE ACTION REPORT

1. CAR No.: 02-004	2. Activity Report No.: A-02-09	3. Page <u>1</u> of <u>2</u>
4. Controlling Document:	5. CBFO Assessment Team Leader: Thomas J. Reese	
6. Responsible Organization: : Central Characterization Project	7. CAQ Was Discussed With: Julia Whitworth, Sheila Bickerstaff	
8. Requirement that was violated: (See Continuation Sheet)		
9. Condition Adverse to Quality: (See Continuation Sheet)		
10. Suggested Actions (Optional): 		
11a. Significant CAQ	(Yes or No): Yes	
11b. Work Suspension Recommended	(Yes or No): No	
11c. CCA-Related	(Yes or No): Yes	
11d. RCRA-Related	(Yes or No): Yes	
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: <u>Dick Blauvelt & Schuetz</u> Date: <u>October 19, 2001</u>		
14. Response Due Date: <u>November 26, 2001</u> Corrective Action Plan Required: <u>YES</u>		
15. Concurrence: _____ /s/ signature on file _____ 10-25-01 _____ Assessment Team Leader Date Responsible Assistant Manager Date	/s/ signature on file _____ 10-25-01 _____ Responsible Assistant Manager Date	
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions: _____ Date _____ Assessment Team Leader Date		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____		
19b. Trend Cause Code: _____		
20. Closure: _____ Date _____ Quality Assurance Manager Date		

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 02-004

2. Activity No.: A-02-09

3. Page 2 of 2

Block # 8 Requirement that was violated:

QAPD, Sec. 1.5.2.5.D, "Procedures for receipt and inspection of incoming records, including verification that the QA records received are in agreement with the transmittal document and that the records are legible."

CCP-QP-008, Section 4.9.7[B], "Use of Attachment 2 – CCP Records Transmittal/Receiving Form to transmit....."

Block # 9 Condition Adverse to Quality

- A) The Transmittal of AK documents (QA records) to the CCP Records Custodian is not formally documented on a Records Transmittal Form. AK records are required to be maintained as "Auditable Records".
- B) Records generated (Attachments) while performing Project Level V&V are not transmitted to the CCP Records Custodian using the required Records Transmittal/Receiving Form. In addition, records generated while preparing the test drum in accordance with CCP-TP-028 (Attachment A) was not transmitted using the required Records Transmittal/Receiving Form.

CORRECTIVE ACTION REPORT

1. CAR No.: 02-005	2. Activity Report No.: A-02-09	3. Page <u>1</u> of <u>2</u>
4. Controlling Document:	5. CBFO Assessment Team Leader: Thomas J. Reese	
6. Responsible Organization: : Central Characterization Project	7. CAQ Was Discussed With: Steve Klover, Steve Muse, Ava Holland, A. J. Fisher	
8. Requirement that was violated: (See Continuation Sheet)		
9. Condition Adverse to Quality: (See Continuation Sheet)		
10. Suggested Actions (Optional):		
11a. Significant CAQ	(Yes or No): Yes	
11b. Work Suspension Recommended	(Yes or No): No	
11c. CCA-Related	(Yes or No): No	
11d. RCRA-Related	(Yes or No): Yes	
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input checked="" type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>Porf Martinez</u> Date: <u>October 19, 2001</u>		
14. Response Due Date: <u>November 26, 2001</u>		Corrective Action Plan Required: YES
15. Concurrence: _____/s/ signature on file_	10-25-01_	/s/ signature on file_____ 10-25-01_
Assessment Team Leader	Date	Responsible Assistant Manager
_____ /s/ signature on file _____	10-25-01_	
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: _____		
19b. Trend Cause Code: _____		
20. Closure: _____		
Quality Assurance Manager	Date	

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 02-005

2. Activity No.: A-02-09

3. Page 2 of 2

Block # 8 Requirement that was violated:

QAPD, Section 2.3.2.7.B.5, "Receiving inspection shall include a review of the adequacy and completeness of any required supplier documentation"

CCP-QP-015, Section 4.10, States in part, "Prepare the inspection plan for the procedure in accordance with CCP-QP-026, CCP Inspection Control. Determine applicable needs for source inspection, receipt inspection, and/or hold points"

CCP-QP-026, Section 4.1.2, States in part, "CCP SPQAO/FQAO: Develop inspection plans/instructions for inclusion in applicable work documents. Include description of the characteristics to be inspected and reference to the applicable acceptance criteria document"

CCP-QP-026, Section 4.1.2[E], States in part, "Review of adequacy and completeness of any required supplier documentation"

CCP-QP-026, Section 4.3.2, (Inspector functions), States in Part, "perform a records review to ensure adequacy and completeness"

Block # 9 Condition Adverse to Quality:

Purchase requisition (BPO 501127) for calibration gases, specified that the gases be traceable to NIST. The following conditions were identified:

A) There was no objective evidence in procurement files to support verification of this requirement.

B) The receipt inspection plan utilized for verification of this procurement action, did not request verification of the NIST traceability certification and the supplied gas certification document received, did not include the "NIST traceability statement".

Note: Requisition #BPO 501127, Dated 8/28/01, Release 1, Item 3, Was for procurement of Calibration Gases for the GC/MS On-line Control Standard (OSC) and the Continuing Calibration Verification (CCV) for Hydrogen and Methane. The gas cylinder provided was No. ALM012203, Cylinder size – AL, Certification Date 9/18/2001, Expiration Date 9/18/2002.

CORRECTIVE ACTION REPORT

1. CAR No.: 02-006	2. Activity Report No.: A-02-09	3. Page <u>1</u> of <u>2</u>																
4. Controlling Document:		5. CBFO Assessment Team Leader: Thomas J. Reese																
6. Responsible Organization: : Central Characterization Project		7. CAQ Was Discussed With: Dave Haar, Dutch Conrad, Farok Sharif																
8. Requirement that was violated: (See Continuation Sheet)																		
9. Condition Adverse to Quality: (See Continuation Sheet)																		
10. Suggested Actions (Optional): 																		
11a. Significant CAQ (Yes or No): No 11b. Work Suspension Recommended (Yes or No): No 11c. CCA-Related (Yes or No): No 11d. RCRA-Related (Yes or No): No																		
12. Types of Actions: Remedial: <u>X</u> Investigative: <u> </u> Root Cause: <u> </u> Actions to Preclude Recurrence: <u> </u>																		
13. CAR Initiator: <u>Calvert / Arceo</u> Date: <u>October 19, 2001</u>																		
14. Response Due Date: <u>November 26, 2001</u> Corrective Action Plan Required: <u>No</u>																		
<table style="width: 100%; border: none;"> <tr> <td style="width: 33%; text-align: center;"> /s/ signature on file Assessment Team Leader </td> <td style="width: 10%; text-align: center;"> Date </td> <td style="width: 33%; text-align: center;"> /s/ signature on file Responsible Assistant Manager </td> <td style="width: 10%; text-align: center;"> Date </td> </tr> <tr> <td style="text-align: center;"> 10-25-01 </td> <td style="text-align: center;"> 10-25-01 </td> <td style="text-align: center;"> 10-25-01 </td> <td style="text-align: center;"> 10-25-01 </td> </tr> <tr> <td style="text-align: center;"> /s/ signature on file Quality Assurance Manager </td> <td style="text-align: center;"> Date </td> <td colspan="2"></td> </tr> <tr> <td style="text-align: center;"> 10-25-01 </td> <td style="text-align: center;"> Date </td> <td colspan="2"></td> </tr> </table>			/s/ signature on file Assessment Team Leader	Date	/s/ signature on file Responsible Assistant Manager	Date	10-25-01	10-25-01	10-25-01	10-25-01	/s/ signature on file Quality Assurance Manager	Date			10-25-01	Date		
/s/ signature on file Assessment Team Leader	Date	/s/ signature on file Responsible Assistant Manager	Date															
10-25-01	10-25-01	10-25-01	10-25-01															
/s/ signature on file Quality Assurance Manager	Date																	
10-25-01	Date																	
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet																		
17. Acceptance of Proposed Corrective Actions:																		
<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; text-align: center;"> _____ Assessment Team Leader </td> <td style="width: 40%; text-align: center;"> _____ Date </td> </tr> </table>			_____ Assessment Team Leader	_____ Date														
_____ Assessment Team Leader	_____ Date																	
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)																		
19a. Verified By: _____																		
19b. Trend Cause Code: _____																		
20. Closure: _____																		
Quality Assurance Manager		Date																

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 02-006

2. Activity No.: A-02-09

3. Page 2 of 2

Block # 8 Requirement that was violated:

CCP-PO-004, Sec. 4.13.1, "Any new procedures developed by CCP will be evaluated by the STR to determine if the procedure shall be added to the SRS review lists noted below".

NQA-1, Supplement 1S-1, Section 2.1, The organizational structure and the responsibility assignments shall be such that: (a) quality is achieved and maintained by those who have been assigned responsibility for performing work; and (b) quality achievement is verified by persons or organizations not directly responsible for performing the work.

Block # 9 Condition Adverse to Quality:

The SRS Site Technical Representative (STR) has not reviewed and concurred with the last three revisions of the CCP Training and Qualification Plan as required by the CCP Interface Document.

The Organization Chart in the CCP/SRS Interface Document shows the CCP QA Officer (SPQAO) reporting solely to the CCP Project Manager. This condition is not consistent with actual management practices, where the SPQAO does indeed, have access to a higher level of management.

NOTE: During assessment of the CCP/SRS Interface Document per audit A-02-09, two observations (Concerns 001 and 002) were identified that explained conditions, that if left uncorrected, could result in future discrepant conditions. In addition, there was one recommendation for improvement of the document. In addition to the two observations and the recommendation, the EPA expressed a concern that the WAP identified position of Facility QA Officer, and the related functions this individual performs, is inconsistent with the intent of NQA-1. QA and QC functions are defined within NQA-1 as independent functions where the individual performing these functions is totally independent of the work being performed. It is suggested that CCP management evaluate these concerns and consider making the necessary changes to the Interface document that will address these issues.