



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



May 12, 2005

Mr. Farok Sharif  
Washington TRU Solutions  
P.O. Box 2078  
Carlsbad, NM 88221-2078

Subject: Issuance of CARs 05-031 and 05-032 from Audit A-05-12 of the ICP/CCP

Dear Mr. Sharif:

The Carlsbad Field Office (CBFO) performed Audit A-05-12 of the Idaho Completion Project (ICP) Central Characterization Project (CCP) characterization activities on May 2 - 6, 2005. CBFO Corrective Action Reports (CARs) 05-031 and 05-032 are enclosed.

Please document on the enclosed CAR continuation sheets your proposed corrective actions and a schedule for completion and forward to me prior to the response due date identified in CAR block 14.

Enclosed with each CAR are the instructions for providing corrective action responses for your use in preparing the required responses.

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

Sincerely,

Dennis S. Miehl  
Senior Quality Assurance Specialist

Enclosures



Mr. Farok Sharif

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May 12, 2005

cc: w/enclosures

A. Holland, CBFO \*ED

K. Watson, CBFO ED

A. Fisher, CBFO ED

J. Perry, DOE-ID 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

D. Haar, WTS ED

J. Wilburn, CTAC ED

A. Pangle, CTAC ED


CBFO QA File

CBFO M&RC

WIPP Operating Record, MS 486-06

\*ED denotes electronic distribution

## CORRECTIVE ACTION REPORT

1. CAR No.: <u>05-031</u>	2. Activity Report No.: <u>A-05-12</u>	3. Page <u>1</u> of <u>3</u>
4. Controlling Document: <u>CCP-QP-022, CCP TRU Software Quality Assurance</u>	5. CBFO Assessment Team Leader: <u>Dennis Miehl</u>	
6. Responsible Organization: <u>Idaho Completion Project / Central Characterization Project</u>	7. CAQ Was Discussed With: <u>A. J. Fisher and Sinisa Djordjevic</u>	
8. Requirement that was violated: <u>CCP-QP-022, CCP TRU Software Quality Assurance and the QAPD, Section 6. See Section 9 below for identification of specific sections of these documents.</u>		
9. Condition Adverse to Quality: <u>See Continuation Sheet.</u>		
10. Suggested Actions (Optional): <ul style="list-style-type: none"> <li>• Either re-write procedure CCP-QP-022 so that it reflects CCP implementation and remains adequate regarding flowdown of the QAPD requirements, or implement the procedure as written.</li> <li>• Clarify terms such as the SIL/CIS. This document is called a SIL in some procedure sections, and the CIS in others, although it is titled the CIS.</li> </ul>		
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
11e. Waste Stream BNINW216 or BNINW218?	(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>Laurie Sparks</u> Date: <u>May 11, 2005</u>		
14. Response Due Date: <u>5-26-05</u> Corrective Action Plan Required: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> Required Corrective Action Completion Date: <u>N/A</u>		
15. a. Concurrence: <u></u>	<u>5-12-05</u>	b. <u>N/A</u>
Assessment Team Leader	Date	Responsible Office Director
c. <u>N/A</u>		Date
Quality Assurance Manager	Date	
16. Corrective Actions Proposed by the Responsible Organization: <u>Use CAR Continuation Sheet</u>		
17. Acceptance of Proposed Corrective Actions:  _____ Date _____ Assessment Team Leader		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ Date _____ Name		
19b. Trend Code: <u>SW-01</u>		
20. Closure: _____ Date _____ Quality Assurance Manager		

# CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

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## Block #9. Condition Adverse to Quality:

CCP-QP-022, CCP TRU Software Quality Assurance is not implemented as written. Deficiencies are:

- Section 4.3.1 contains a bullet list of required SQAP contents. Review of the SQAPs for Antech and Canberra software indicate that these SQAPs lack some of the items in the bullet list of Section 4.3.1. Specifically, the information from bullets 1, 2, and 5 is not contained in the Canberra SQAP. Finally, bullet 7 of Section 4.3.1 requires SPM involvement in SQAP development and there is no indication SPMs were involved in the development of these SQAPs.
- An equivalency memo was issued for the Canberra SQAP indicating that the Canberra SQAP is compliant with Procedure CCP-QP-022. However, as stated above, the SQAP does not contain all of the items required to be in a SQAP as listed in Section 4.3.1 of the procedure.
- Section 4.4.1 contains a bullet list of required Software Information Listing / Code Information Summary (SIL/CIS) contents, but the SIL/CIS lacks some of the items in the bullet list. Specifically, the information from bullets 5, 6, 8, 9, and 10 is not contained in the SIL/CIS.
- This procedure does not completely flow down the QAPD requirements. Specifically, there are no documented criteria for retiring software (QAPD Section 6.6.2.7) and technical adequacy and completeness for the design document are not addressed in the design document review checklist (QAPD Section 6.7.2.3).
- Section 4.2.2 conflicts with Table 1 and Attachment 13 regarding the necessity for a SQAP. The QAPD requires a SQAP (Section 6.3.2).
- The software requirements are only marginally traceable throughout the software development cycle (QAPD Section 6.6.2.1).

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**INSTRUCTIONS FOR COMPLETING A CORRECTIVE ACTION PLAN IN  
RESPONSE TO A CAR ADDRESSING A CONDITION ADVERSE TO QUALITY**

You are requested to provide a corrective action plan 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 (CAR block 5). This request must include justification for the delay and must be provided prior to the response due date (CAR block 14).

The corrective action plan shall address the corrective actions indicated in CAR block 12. As appropriate, develop the plan in accordance with the following sequence and format:

In order to develop the corrective action plan, 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 plan shall include the following information, as appropriate to CAR block 12.

1. Corrective action response for CAR # 05-031
  - A. **Remedial Actions**-Describe actions required or taken to correct the specific conditions noted and any similar conditions identified during the investigations.
  - 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. **Root Cause Determination**-Identify the root cause of the condition as determined through investigative actions.
  - D. **Actions to Preclude Recurrence**-Identify the corrective 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.

## CORRECTIVE ACTION REPORT

1. CAR No.: 05-032	2. Activity Report No.: A-05-12	3. Page <u>1</u> of <u>3</u>
4. Controlling Document: DOE/CBFO 94-1012, R6 & CCP-QP-022, Section 4.2, R3	5. CBFO Assessment Team Leader: Dennis Michls	
6. Responsible Organization: : Idaho Completion Project/Central Characterization Project	7. CAQ Was Discussed With: S. Djordjevic, Ed Gulbransen, T. Donohoue & A. J. Fisher	
<b>8. Requirement that was violated:</b> DOE/CBFO-94-1012 Rev 6, Section 6.5.1 States:  "Software that has not been developed or approved in accordance with this QAPD shall be evaluated to determine its adequacy to perform intended functions. The evaluation shall be documented. The software shall be uniquely identified and controlled prior to the evaluation, clearly traceable to the software requirements, accepted by the sponsoring organization, and placed under configuration control prior to use."		
<b>9. Condition Adverse to Quality:</b> The software QA Requirements of the CBFO QAPD and CCP procedure have not been effectively implemented on the NDA software, NDA 2000 V4.0, Genie 2000 V3.0, Antech Master Scan V5.1.5, Antech Master Analysis V4.1.4, Report Generator V2.2.6, and Batch Generator V2.1.5, as follows: (See Continuation Sheet)		
10. Suggested Actions (Optional):		
11a. Significant CAQ? (Yes or No): YES 11b. Work Suspension Recommended? (Yes or No): NO 11c. RCRA-Related? (Yes or No): NO 11d. Accelerated Corrective Action Required? (Yes or No): NO 11e. Waste Stream BNINW216 or BNINW218? (Yes or No): NO		
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>Jeff May</u> Date: <u>May 11, 2005</u>		
14. Response Due Date: <u>5-26-05</u> Corrective Action Plan Required: YES Required Corrective Action Completion Date: <u>N/A</u>		
15. a. Concurrence: <u>[Signature]</u> <u>5-12-05</u> b. <u>N/A</u> <small>Assessment Team Leader Date Responsible Office Director Date</small>  <u>[Signature]</u> <u>5/12/05</u> <small>Quality Assurance Manager Date</small>		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:		
_____ <small>Assessment Team Leader Date</small>		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ <small>Name Date</small>		
19b. Trend Code: <u>SW-05</u>		
20. Closure: _____ <small>Quality Assurance Manager Date</small>		

**CBFO CORRECTIVE ACTION REPORT**  
(continuation sheet)

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**Block # 8 (Continued)**

**CCP –QP-022, Section 4.2 states:**

“Software developed under other QA programs consists of software that was not developed or approved under a QA program consistent with the QAPD. This includes commercial (off-the-shelf) and legacy software. The process of qualifying such software for production is provided below (Figure 2, located at the end of this procedure before the appendix and attachments). Several documents may be produced from this section in addition to the SQAP (see Section 4.3.1): a primitive baseline memorandum and primitive baseline review memorandum, documents associated with Sections 4.3.2 through 4.3.5, and/or equivalent documentation. Software is documented for installation and checkout in accordance with Section 4.3.6.”

**Block # 9 (Continued)**

- 1) The Genie 2000 V3.0B software is installed on the HENC, as stated by the NDA SME, while the software Code Management: Code Information Summary states that the Genie 2000 software version under configuration management is version 3.0.
  
- 2) The SQA package for Genie 2000 V3.0 has not been approved by the CCP QA Manager and CCP started to assay waste on the systems as follows:  
WAGS - 4/2/05  
SGRS - 4/2/05  
HENC – 4/14/05
  
- 3) The SQA packages for the following software were approved by the Software Configuration Management Coordinator on 5/2/05, after CCP started to assay waste on 4/2/05 for the WAGS and SGRS systems and 4/14/05 for the HENC and the TGS systems.

NDA 2000 V4.0	Antech Master Scan V5.1.5	Batch Generator V2.2.6
Genie 2000 V3.0	Antech Master Analysis V4.1.4	Report Generator V2.1.5
  
- 4) CCP performed software installation and checkout testing on the following dates and CCP started to assay waste on 4/2/05 for the WAGS and SGRS systems and 4/14/05 for the HENC and the TGS systems.

WAGS – Testing started on 4/20/05, approved on 5/2/05  
SGRS – Testing started on 4/14/05, approved on 5/2/05  
HENC – Testing started on 4/18/05, approved on 5/2/05  
TGS Master Scan – Testing started on 4/27/05  
TGS Master Analysis – Testing started on 4/27/05  
TGS Batch Generator - Testing started on 4/27/05  
TGS Report Generator - Testing started on 4/27/05
  
- 5) NDA notified AK that the U234 equation should be modified and as a result revised the U234 equation script within the NDA 2000 V4.0 software. This revision took place on 4/14/2005 and the software SQA packages were not approved until 5/2/2005 and testing was not performed until 4/14/05 and approved on 5/2/05. BDR INNDAS050005 (three containers) and INNDAS050004 (two containers) were processed through the system utilizing the pre 4/14/05 U234 equation and had gone through expert review without this fact being documented. The use of the software prior to completing the required software QA resulted in the data within the BDR INNDAS050005 and INNDAS050004 being inconsistent with other BDRs. BDR INNDAS050001 (one container) was processed utilizing the post 4/14/04 U234 equation.

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RESPONSE TO A CAR ADDRESSING A CONDITION ADVERSE TO QUALITY**

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The corrective action plan shall address the corrective actions indicated in CAR block 12. As appropriate, develop the plan in accordance with the following sequence and format:

In order to develop the corrective action plan, 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 plan shall include the following information, as appropriate to CAR block 12.

1. Corrective action response for CAR # 05-033
  - A. **Remedial Actions**-Describe actions required or taken to correct the specific conditions noted and any similar conditions identified during the investigations.
  - 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. **Root Cause Determination**-Identify the root cause of the condition as determined through investigative actions.
  - D. **Actions to Preclude Recurrence**-Identify the corrective 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.