



**Department of Energy**

Carlsbad Area Office  
P. O. Box 3090  
Carlsbad, New Mexico 88221

June 9, 2000



Steve Zappe, Project Leader  
Hazardous & Radioactive Materials Bureau  
New Mexico Environment Department  
P.O. Box 26110  
Santa Fe, NM 87502-6110


Subject: Corrective Active Report (CAR) Closure Documentation for Carlsbad Area Office CARs 00-25 and 00-27 for the Final Audit Report for the Idaho National Engineering and Environmental Laboratory (A-00-06)

Dear Mr. Zappe:

This letter transmits copies of closure documentation for CAO CARs 00-25 and 00-27. This documentation should have been included in TABs CAR1 and CAR2 of the Final Audit Report for the Idaho National Engineering and Environmental Laboratory. Please include this information in your copies of the Final Audit Report.

Please contact the CAO Quality Assurance Manager, Sam Vega, at 505-234-7423 should you have any questions concerning this documentation.

Sincerely,

  
Dr. Inés R. Triay  
Manager

Enclosure

CAO:QA:SAV:NM 00-0816 UFC 2300.00



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Zappe

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cc w/o enclosure

T. Harms, DOE-HQ

I.R. Triay, CAO

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S. Vega, CAO

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C. Zvonar, CAO

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L. Steven, WID

cc: w/enclosure

W. Most, WID

# CORRECTIVE ACTION REPORT

1. CAR No.: 00-027	2. Activity Report No.: A-00-06	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: PLN-582 TRIPS SCMP, Rev.0, PLN-583 TRIPS SQAP Rev. 0, PLN-584 TRIPS SVVP, PLN-585 TRIPS STP		5. CAO Assessment Team Leader: Samuel Vega
6. Responsible Organization: : DOE-ID, BBWI		7. CAQ Was Discussed With: S. Teller, S. Krusch
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. RCRA-Related (Yes or No): No		
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>Mario Chavez</u> Date: <u>May 1, 2000</u>		
14. Response Due Date: _____ Corrective Action Plan Required: YES		
15. Concurrence: <u>Samuel Vega</u> <u>5/5/00</u> <u>N/A</u> _____ <small>Assessment Team Leader Date Responsible Assistant Manager Date</small> <u>N/A</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: <u>Samuel Vega</u> <u>5/11/00</u> <small>Assessment Team Leader Date</small>		
1. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: <u>SEE ATTACHED CONTINUATION SHEET</u>		
19b. Trend Cause Code: _____		
21. Closure: <u>Samuel Vega</u> <u>6/9/00</u> <small>Quality Assurance Manager Date</small>		

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## Block # 8. Requirement that was Violated:

1. PLN-583, (TRIPS Software QA Plan) Rev.0, Section 3.2 "Mini Designs are modified as needed to reflect the design."
2. PLN-584 (TRIPS Software Verification and Validation Plan), Rev.0, Section 4.2 (Figure 1) "TRIPS V&V Task Summary" requires the SQ Lead to report the status of the software to the project manager; Section 4.4.2 "Technical Documentation Review" A review of requirements and design documentation to ensure they are synchronized with the product. The SQ Lead or their delegate will perform this review; PLN-583 (TRIPS SQAP), Rev.0, Section 4.2.3.1, "Customers and TRIPS Software quality personnel have reviewed these documents (i.e., SDD and IDD) for completeness."
3. PLN-584 (TRIPS SVVP), Section 4.4.2, Technical Documentation Review – A review of requirements and design documentation to ensure they are synchronized with the product. The SQ Lead or their delegate will perform this review.
4. PLN-582 (TRIPS SCMP), Rev. 0, Section 3.1 Configuration Identification (CI) Table 3 TRIPS CI and Change Methods: Test Reports, RWMC Equipment List, and Software CI identifies the configuration item, type, identification, and change management method to be used for configuration management; PLN-585 (TRIPS Software Test Plan), Rev. 0, Section 10, Deliverables provides a list of the information the test will contain for major releases.
5. PLN-582 (TRIPS SCMP), Rev. 0, Section 3.1 Configuration Identification: Software CI identifies the configuration item, type, identification, and change management method to be used for configuration management.

## Block # 9. Condition Adverse to Quality:

1. Several TRIPS Change Request did not identify which Mini Design or Business Process Requirement is impacted by the modification.
2. There was no review of the TRIPS Implementation phase (i.e., a review of the source code against the design).
3. The number of TRIPS Change Requests (TCRs) identified in the INEEL/INT-99-00710 TRIPS Software Test Report Abstract did not match the number of TCRs in the TRIPS TCR Test Summary Log.
4. The Version numbers for the Operating System, Oracle Application Software, and the Uniface Application software were not documented as configuration items and were not reported as part of the test configuration.
5. The TRIPS Build Scripts were not identified on the CI list or mapped to the proper configuration management method.

**CORRECTIVE ACTION REPORT**  
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1. CAR No.: 00-026

2. Activity No.: A-00-06

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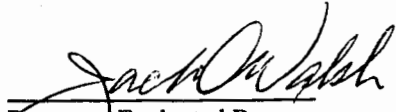
Block # 17

**Evaluation of Proposed Corrective Actions:**

The following is an evaluation of the response to CAO CAR 00-026 (identified during Audit A-00-06) as submitted via DOE ID letter EM-WMO-00-040, L. L. Fritz to Samuel A. Vega, dated May, 10, 2000.

The proposed corrective actions (remedial, investigative/extent and impact of the deficiency, root cause and actions to preclude recurrence) for the Condition Adverse to Quality described within the CAR are acceptable.

Your response indicates all corrective actions will be completed by May 12, 2000. Verification of corrective actions will be performed during subsequent follow-up activities.

  
Response Evaluated By:  
Jack Walsh

5/11/00  
Date

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**Block 18 Verification of Corrective Action Completion**

The corrective actions taken and implemented for this CAR were verified during an on-site visit and follow-up audit (A-00-06) at Idaho, on May 17, 2000. The corrective actions and objective evidence reviewed, and found to be acceptable are as follows:

- The TRIPS Change Request (TCR) system was modified (date: 4/25/00), to include a decision button to be set during the review of the change request to indicate if any Mini Design or Business Process Requirements have been impacted by the requested change. Fields were also added to allow for the identification of the specific Mini Design or Business Process Requirements that are impacted by the request.

Fields added to the TCR system are:

Requirement/Design Change?:   N     Y    
 Requirement/Design Document: \_\_\_\_\_

- The TRIPS QA documents were changed to specify that, a formal review of the Mini Design documents be made by the cognizant tester – with the documents being signed off by the developer and tester.

Additionally, a formal review of the TRIPS release 4.0 Mini Design documents was completed, (date: 4/28/00), to review all of the Mini Design documents in question, and to log and track to closure any issues found in the documents.

- 69 issues were logged during the formal review of the TRIPS mini-designs against the released software. The issues have all been closed, and the Mini Designs signed off.

One new TCR (TRIPS Change Request), was issued (TCR 928) that addressed a minor error discovered during the review of the Payload Assembly Mini Design. The design document has been modified so that the design reflects the released software. The change completed testing, and was put in production (date: 5/11/00).

Two additional TCR's were referenced on the issues page. TCR 611 is a TCR related to SPO Reporting and is still in testing. TCR 700 was referenced because the Mini Design for certification did not reflect the table changes specified within this TCR. This has been corrected and the Mini Design has been signed off.

Additionally, 18 editorial comments were logged that did not have any impact to the design as reflecting the current system, and as it relates to the currently released software.

# CAO CORRECTIVE ACTION REPORT

(Continuation Sheet)

1. CAR No. 00-027

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## Block 18 Verification of Corrective Action Completion (cont.)

- The TRIPS QA plans were modified to specify that all mini designs will be formally reviewed and signed off by the designer and cognizant tester for major releases.

Document Action Requests (DARs) were prepared to implement the modifications to the TRIPS QA Plans. Actions requested on the DARs include:

DAR No.: EO-RS-5633 – revise/modify the SQAP ... as depicted in this CAR response.

DAR No.: EO-RS-5634 – revise/modify the SVVP ... as depicted in this CAR response.

DAR No.: EO-RS-5632 – revise/modify the SCMP ... as depicted in this CAR response.

The format of the Test Report was modified during the audit to exclude redundant listing of TCR numbers in the abstract paragraph of the TRIPS Test Report. This change has been incorporated into the document, reviewed for correctness, and re-issued (date: 4/25/00)

- The TRIPS Test Plan (PLN-585) was modified to require that all version numbers associated with the Operation System, Database Management System, Application Software, and Network Protocol, be specified for the server-side configuration. In addition, the TRIPS Test Plan was modified to specify that the Operating System, Application Software, Network Protocol, Hardware CPU, Hardware Memory and the Hardware disk space, be specified for the client-side configuration.

The TRIPS Release 4.0 Test Report was modified to reflect the incorporation of version numbers (along with the changes specified above). The Test Report was reviewed for correctness and released as Rev. 1

The TRIPS Test Plan was modified to require that this information be reported at the time of major releases of the TRIPS system. A Document Action Request (DAR) was submitted to include the following instructions:

DAR No.: EO-RS-5635 - revise/modify the STP ... as depicted in this CAR response.

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1. CAR No. 00-027

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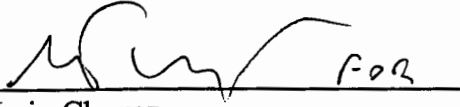
3. Page 4 of 3

**Block 18 Verification of Corrective Action Completion (cont.)**

- Changes to the TRIPS Configuration Management Plan were made to include the CVS method for managing the TRIPS Build Scripts. A DAR was submitted with the following instructions:

DAR No.: EO-RS-5633 – revise/change the SCMP, table 3, for Software CI

Based upon the above information, the recommendation is for closure of this CAR.

Verified by:  FOR Date: 5/22/00  
Mario Chavez

**Block 19b Trend Cause Code: 6.5, Policy not adequately defined, disseminated or enforced**



# CORRECTIVE ACTION REPORT

1. CAR No.: 00-025	2. Activity Report No.: A-00-06	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: WIPP WAP; NT-AP-03, R/10; HFEF-OI-6890, R/4a	5. CAO Assessment Team Leader: Samuel Vega	
6. Responsible Organization: : DOE-ID, BBWI, ANL-W	7. CAQ Was Discussed With: F. Dunhour, C. Dwight	
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. 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>Karen Gaydosh</u> Date: <u>May 1, 2000</u>		
14. Response Due Date: <u>May 15, 2000</u> Corrective Action Plan Required: <u>YES</u>		
15. Concurrence: <u>Samuel Vega</u> Assessment Team Leader	<u>5/5/00</u> Date	<u>Samuel Vega</u> Responsible Assistant Manager
<u>Samuel Vega</u> Quality Assurance Manager	<u>5/5/00</u> Date	<u>5/5/00</u> Date
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions: <u>Samuel Vega</u> <u>5/11/00</u> Assessment Team Leader Date		
1. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: <u>SEE ATTACHED CONTINUATION SHEET</u>		
19b. Trend Cause Code: _____		
21. Closure: <u>Samuel A. Vega</u> <u>6/9/00</u> Quality Assurance Manager Date		

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## Block # 8. Requirement that was Violated:

1. WIPP WAP Attachment B2, section B2-1 states in part: "The data obtained from the visual examination shall also be used to determine, with acceptable confidence, the percentage of miscertified waste containers from the radiographic examination..."
2. HFEF-OI -6890, Rev. 4a, paragraph 6.6 states in part: "All visual examination activities... results must be documented on visual examination data forms (Ref. Appendix A, HFEF WCA drum VE record sheet..."
3. NT-AP-03, Rev. 10, paragraph 3.1.b states in part: "Review each container using the Independent Technical Review (ITR)" checklist (Appendix A) in accordance with the instruction in this checklist..."
4. NT-AP-09, Rev. 2, paragraph 4.3(c) states in part: "The VEE prepares ANL-W, TWCP Initial Deficiency Report (IDR) as necessary to document WIPP WAC prohibited items..." Also, HFEF-OI-6890, Rev. 4a, paragraph 8.2.2. (3). (g) states in part: "Inspect... visible area of this drum and each item for the presence of liquid and record..."
5. HFEF-OI-689, Rev. 4a, paragraph 6.6 states in part: "All Visual Examination activities must be documented on video/audio tapes..."

## Block # 9. Condition Adverse to Quality:

1. Contrary to the requirement, the miscertification rate in place at INEEL was calculated using data acquired prior to the issuance of the WIPP WAP. The data used has not been evaluated to the requirements of the WIPP WAP.
2. Contrary to the requirement, the raw data for drum 032356 was not entered on the visual examination record sheet.
3. Contrary to the requirement, the Independent Technical Review of VE was not completed for drum 032256.
4. Contrary to the requirements, liquid was found and absorbent added, at SPO direction before an IDR was initiated.
5. Contrary the requirement, the complete visual examination process is not being recorded on audio/video tape.

**ORRECTIVE ACTION REPORT**  
(continuation sheet)

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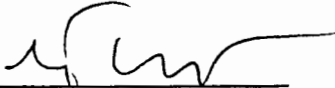
Block # 17

**Evaluation of Proposed Corrective Actions:**

The following is an evaluation of the response to CAO CAR 00-025 (identified during Audit A-00-06) as submitted via DOE ID letter EM-WMO-00-040, L. L. Fritz to Samuel A. Vega, dated May, 10, 2000.

The proposed corrective actions (remedial, investigative/extent and impact of the deficiency, root cause and actions to preclude recurrence) for the Condition Adverse to Quality described within the CAR are acceptable.

Your response indicates all corrective actions will be completed by May 15, 2000. Verification of corrective actions will be performed during subsequent follow-up activities.



Response Evaluated By:  
Trey Greenwood & Steve Calvert

5/11/00  
Date

# CAO CORRECTIVE ACTION REPORT

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## Block 18 Verification of Corrective Action Completion

The corrective actions taken and implemented for this CAR were verified during an on-site visit and follow-up audit (A-00-06) at Idaho, on May 17, 2000. The corrective actions and objective evidence reviewed, and found to be acceptable are as follows:

- The "WAP Compliance Evaluation" was examined to verify that an evaluation against the requirements of the WIPP WAP was performed by INEEL, to ensure that the data were collected and validated in a manner compliant with the WAP. This document examined data generation level collection, data generation level validation, and the Project level validation requirements that applied when the data supporting the miscertification rate calculation was generated for both VE and RTR, and it evaluates them against current WAP requirements. The evaluation/document specifies verification activities for documenting objective evidence, and identifies corrective actions for cases where WAP requirements were not specifically addressed during data generation and validation activities.
- The "WAP Compliance Evaluation" document includes an appropriate "impact on quality of TWCP data" statement, including the conclusion(s)/results of the evaluation with appropriate technical justification.
- Verified that miscertification rates will henceforth be determined in accordance with Engineering Design File (EDF) 363.
- The data package (WCV-032356) was corrected to include the visual data forms generated during the examination.
- Examined a sampling of data forms (out of the "nearly 500 drums characterized for this program at ANL-W"), to ensure/verify raw data inclusion, in packages(s).
- Clarifications were made to HFEF-01-6890 (Rev. 4b, Effective: 4/28/00), to emphasize that all raw data be included on the data forms from the procedure, and that all forms be completed during characterization.
- The ITR Checklist (WCV-032356) was corrected on 04/27/00, to complete the item, which was inadvertently left blank.
- Verified that lessons learned training, was provided on 05/16/00 to ANL-W data reviewers (ITR, TS & QADR).

Cont.

# CAO CORRECTIVE ACTION REPORT

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## Block 18 Verification of Corrective Action Completion (Cont.)

- The IDR-032356, Remedial action item #4, and the resulting INEEL (ICARE) NCR (#HF-00-31), were revised to add documentation of the phone call to Dr. Rod Arbon.
- NT-AP-04 (Rev. 5, Effective: 04/28/00), was revised to add an initiator signature and date to the IDR form. HFEF-01-6890 (Rev. 4b, Effective: 04/28/00), has been revised to provide a routine method for absorption of liquids and to provide for completion of drum characterization regardless of the prohibited items encountered.
- Procedure HFEF-01-6890 (Rev. 4b, Effective 04/28/00), has also been revised to clarify that videotaping should include the actual weighing process.

Based upon the above information, the recommendation is for closure of this CAR.

Verified by:

  
Trey Greenwood/Jack Walsh

Date: 5/17/00

Block 19b Trend Cause Code: 6.1