

United States Government


Department of Energy

memorandum

Carlsbad Field Office
Carlsbad, New Mexico 88221

DATE: May 24, 2001
REPLY TO
ATTN OF: CBFO:QA:SAV:VW:01-1125:UFC:2300
SUBJECT: Issuance of Corrective Action Reports (CARs)
TO: James Nunz, LAAO



The Carlsbad Field Office (CBFO) performed Audit A-01-11 of the LANL site on May 8-9 and 14-16, 2001. The audit team identified three conditions adverse to quality, which have been documented in CARs.

Please have cognizant management of the LANL TWCP document on the attached CAR Continuation Sheets their proposed corrective actions with a schedule for completion and forward them to me prior to the response due date identified in CAR Block 14.

If you have any questions or comments, please contact me at (505) 234 -7423.


Samuel A. Vega
Quality Assurance Manager

Attachments

cc: w/attachments
T. Harms, DOE-HQ
K. Watson, CBFO
L. Chism, CBFO
M. Eagle, EPA
B. Walker, EEG
D. Winters, DNFSB
S. Zappe, NMED
M. Gerle, WTS Operating Record
J. Schuetz, CTAC
E. Bradford, CTAC

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CORRECTIVE ACTION REPORT

1. CAR No.: 01-038	2. Activity Report No.: A-01-11	3. Page <u>1</u> of <u>3</u>
4. Controlling Document: CAO 94-1012, Rev. 3, QAPD, Sections 6.2.1.1 A, Software Inventory and 6.7.1, Software Configuration Management LANL Procedure QA-SQAP-COMP-R01.1, Software Quality Assurance Plan, Sections 3.8 and 6.8.2	5. CBFO Assessment Team Leader: Sam Vega	
6. Responsible Organization: Los Alamos National Laboratory (LANL)	7. CAQ Was Discussed With: Manual Martinez, Doris Poteet and Dave Anderson	
8. Requirement that was violated: (See CAR continuation sheet)		
9. Condition Adverse to Quality: (See CAR continuation sheet)		
10. Suggested Actions (Optional): Revise Procedures to delete references to retired software programs. Revise procedures and appendices to describe current method of software change and change controls.		
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): 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>James R. Schuetz</u> <i>James R. Schuetz</i> Date: <u>May 8, 2001</u>		
14. Response Due Date: <u>June 15, 2001</u> Corrective Action Plan Required: Yes		
15. Concurrence: <u><i>Samuel A. Vega</i></u> <u>5/24/01</u> <u>N/A</u> Assessment Team Leader Date Responsible Assistant Manager Date <u><i>Samuel A. Vega</i></u> <u>5/24/01</u> Quality Assurance Manager 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: _____ Date _____		
19b. Trend Cause Code: _____		
20. Closure: _____ Date _____ Quality Assurance Manager		

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 01-038

2. Activity No.: A-01-11

3. Page 2 of 3

Block # 8 Requirement that was violated:

Quality Assurance Program Document, CAO 94-1012 Rev. 3, Section 6 - SOFTWARE

6.2 Applicability

6.2.1 Inventory and Classification of Software

6.2.1.1 General Requirements

A. An inventory of all applicable software shall be maintained that identifies the software name, version, classification, exemption status, operating environment, and the person and organization responsible for the software.

6.7 Software Configuration Management

6.7.1 General Requirements

(Paragraph 2)

Software configuration controls shall be planned, including the identification of organizational positions that are authorized to make changes and the methods, procedures, and instructions to be used to control the identification of, access to, changes to, and the status of computer software. Configuration control documents shall indicate how changes will be validated, including regression testing, and how the tests will be documented. These planning documents shall be formally reviewed, approved, and in place before the release of the software for use.

Block # 9 Condition Adverse to Quality:

Reference is made, in LANL Procedure QA-SQAP-COMP-R01.1, Software Quality Assurance Plan, to the NETLOG data base for software inventory and configuration information. This program has recently been retired and procedure references have not been revised.

The method for implementation (coding) of a WMS software change has recently been revised for ease of programming and to accommodate the change from a multi-server system to a single server/storage system. LANL procedures do not include a description of the process of copying, modifying and publishing a software change.

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 01-038

2. Activity No.: A-01-11

3. Page 3 of 3

Block 19b Trend Cause Code: 2.1 (Inadequate Procedure)

Block 18 Verification of Corrective Action Completion

By: _____

_____ Date

CORRECTIVE ACTION REPORT

1. CAR No.: 01-040	2. Activity Report No.: A-01-11	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: WIPP HAZARDOUS WASTE FACILITY PERMIT NM4890139088; TWCP-PLAN-0.2.3-001,R.5; TWCP-QP-1.1-021, R.5	5. CBFO Assessment Team Leader: Samuel Vega	
6. Responsible Organization: Los Alamos National Laboratory (LANL)	7. CAQ Was Discussed With: S. Kosiewicz	
8. Requirement that was violated: (See CAR Continuation Sheet)		
9. Condition Adverse to Quality: OSR Sealed Sources Acceptable Knowledge Report (OSR-MISC-003, Revision 1) does not reference all supplemental source documents used to establish the conclusions documented in the report.		
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: <u>X</u> Investigative: <u>X</u> Root Cause: <u>X</u> Actions to Preclude Recurrence: <u>X</u>		
13. CAR Initiator: <u>Steven D. Calvert</u> <i>S. Calvert</i> <i>W. Burkhead</i> Date: <u>5/17/01</u>		
14. Response Due Date: <u>June 15, 2001</u> Corrective Action Plan Required: YES		
15. Concurrence:	<i>Samuel A. Vega</i> <u>5/24/01</u> Assessment Team Leader Date	<u>N/A</u> _____ Responsible Assistant Manager Date
	<i>Samuel A. Vega</i> <u>5/24/01</u> Quality Assurance Manager 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.: 01-040

2. Activity No.: A-01-11

3. Page 2 of 2

Block # 8 Requirement that was violated:

WIPP HAZARDOUS WASTE FACILITY PERMIT NM4890139088, Waste Analysis Plan (WAP)

B4-2c Supplemental Acceptable Knowledge Information

The generator/storage sites shall obtain supplemental acceptable knowledge information. The amount and type of supplemental information is site-specific and cannot be mandated, but sites shall collect information as appropriate to support required information.

All specific, relevant supplemental acceptable knowledge documentation assembled and used in the acceptable knowledge process, whether it supports or contradicts any required acceptable knowledge documentation, shall be identified and an explanation provided for its use (e.g., identification of a toxicity characteristic).

TWCP-PLAN-0.2.3-001,R.5: LOS ALAMOS NATIONAL LABORATORY TRANSURANIC WASTE QUALITY ASSURANCE PROJECT PLAN

B4-2c Supplemental Acceptable Knowledge Information

Supplemental AK information, as appropriate, is collected to support required TRU waste stream information. LANL includes this information in the AK written record.

Specific, relevant supplemental AK documentation assembled and used in the AK process, whether it supports or contradicts any required AK documentation, is identified and an explanation provided for its use (e.g., identification of a toxicity characteristic).

QP 1.1-021, R5: ACCEPTABLE KNOWLEDGE DOCUMENTATION

6.1.2

Identify and obtain supplemental information, as appropriate, to support the required information. The specific, relevant information must be identified and justification provided for its use.

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 01-039

2. Activity No.: A-01-11

3. Page 2 of 2

Block # 8 Requirement that was violated

1. The WIPP Hazardous Waste Facility Permit (HWFP) Section B3-10 requires in part that, *"All raw data shall be signed and dated in reproducible ink by the person generating it. Alternately, unalterable electronic signatures may be used."*

Section B-3d(1) of the HWFP requires, in part, that... *"the VE technique for newly generated waste (or repackaged retrievably stored waste) uses a second operator, who is equally trained to the requirements stipulated in Permit Attachment B1, to provide additional verification by reviewing the contents of the waste container to ensure correct reporting."*
2. Procedure NMT7-WI3-SOP-TA55-013, Section 4.1.5, requires the operators to use information from a "Raw Data Collection Form".
3. The HWFP, Section B-4a(4) requires, in part, concerning the format of Batch Data Reports, *"This format will be included in the generator/storage site QAPjP, controlled electronic databases, or procedures referenced in the QAPjP (Permit Attachment B5) and will include all of the elements required by this WAP for Batch Data Reports (Permit Attachment B3)."*
4. The Carlsbad Field Office (CBFO) Quality Assurance Program Document (QAPD), Section 2.1.2.B.9 requires that, *"B. Implementing procedures shall include the following information as appropriate to the work to be performed: ... 9. Identification and classification of QA records to be generated by the implementing procedure"*

Block # 9 Condition Adverse to Quality

1. When waste items are packaging into the final drum, TA55 personnel note in the comments field in WMS the identity of the two VE personnel that packaged and verified the waste in the drum. The electronic approval of the form in WMS is performed by only one of the VE personnel. Using the comments field to document the two VE personnel does not meet the requirement for an unalterable electronic signature. Both of the VE personnel must approve the packaging information using an electronic signature.
2. Procedure NMT7-WI3-SOP-TA55-013 does not identify or reference how the "Raw Data Collection Form" is generated.
3. The LANL procedures for VE technique in TA-55 do not identify the format or content of a VE technique batch report.
4. The LANL procedures for VE technique in TA-55 do not identify the records generated by the procedures or specify their classification (ie. Lifetime or Non Permanent).