

United States Government

Department of Energy

memorandumCarlsbad Area Office
Carlsbad, New Mexico 88221

DATE: August 26, 1997

REPLY TO
ATTN OF: CAO:NTP:DEW 97-1509 (UFC 2300.00)

SUBJECT: Corrective Action Reports (CARs) 97-113 through 97-117

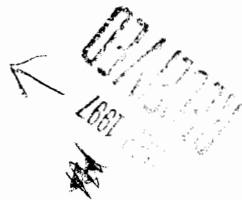
TO: Bruce LeBrun, Radioactive Waste Manager, LAAO


During the Carlsbad Area Office (CAO) Audit of the LANL QA Program (A-97-07), the enclosed Corrective Action Reports (CARs) were identified. Please determine and document the proposed corrective actions, investigative actions, root cause determinations, and the actions to preclude recurrence as required by Block 12 of the CAR forms. Also include an identification of responsible individuals and a schedule for completing the corrective actions.

Please transmit the CAR responses to the CAO Quality Assurance Manager for review and concurrence no later than the date indicated in Block 14.

Attached to this letter is a blank "CAR Continuation Sheet" and "Instructions for Completing Corrective Action Responses."

If you have any questions or require additional information concerning these CARs, please contact me at (505) 234-7478.



For 
Don Watkins
Team Leader
National TRU Waste Program

Attachments

cc:

K. Hunter, CAO
D. Brown, CAO
B. Stroud, CAO
M. Gavett, LANL
P. Rogers, LANL
L. Chism, CAC
T. Bowden, C. AC

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CORRECTIVE ACTION REPORT

1. CAR No.:97-113	2. Activity Report No.:A-97-07	3. Page <u>1</u> of <u>1</u>	
4. Controlling Document:QP-1.1-006, R.5		5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: DOE-LAAO/Los Alamos National Laboratory (LANL)		7. Discussed With: D. Janecky, D. Taggert	
8. Requirement: TWCP-QP-1.1-006, R.5, Section 4.2 requires that software developed under other QA program requirements be evaluated and that the activities necessary to validate and accept the software for its intended use be defined.			
9. Condition Adverse to Quality: The evaluations of software qualification documentation for PC/FRAM v2.3, PAN v1.0 and MAESTRO v3.00 determined that the documents did not define sufficient requirements, test cases, or acceptance criteria to fully validate the software for its intended use. Software requirements, test cases, and/or test results did not fully demonstrate the ability of the FRAM and PAN software to support measurement of total alpha activity and the activity of all individual isotopes present.			
10. Suggested Actions: Complete the documentation of requirements, test cases, and/or test results, to fully validate the software.			
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>			
12. Applicable Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input type="checkbox"/>			
13. CAR Initiator: <u>S. Ailes</u>		Date: <u>8/22/97</u>	
14. Response Due Date: <u>Sept. 3, 1997</u>			
15. Concurrence: <u>Michael K. Brown</u> <u>8/26/97</u> for Don ^{LANL} Responsible Team Leader Date		<u>R. Dennis Brown</u> <u>9/26/97</u> Assurance Team Leader Date	
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet			
17. Acceptance of Proposed Corrective Actions:			
_____ Responsible Team Leader	_____ Date	_____ Assurance Team Leader	_____ Date
18. Verification of Corrective Action:			
19. Verified By (Signature): _____		_____	
Verifier		Date	
20. Closure: _____			
_____ Responsible Team Leader	_____ Date	_____ Assurance Team Leader	_____ Date

CORRECTIVE ACTION REPORT

1. CAR No.: 97-114	2. Activity Report No.: A-97-07	3. Page <u>1</u> of <u>1</u>				
4. Controlling Document: CAO-94-1010, QAPP, Interim Change, 11/15/96	5. Affected CAO Team Leader: Don Watkins					
6. Responsible Organization: DOE-LAAO/Los Alamos National Laboratory (LANL)	7. Discussed With: P. Rogers, S. Wander					
<p>8. Requirement: QAPP, Section 4, Para 4.2.1 "...If a toxic characteristic contaminant is identified and is not included as a listed waste, assign the toxicity characteristic EPA hazardous waste number...When analytical data is not available, the toxicity characteristic EPA hazardous waste number for the identified hazardous constituent must be applied to the waste stream...In the case of discrepancies in information, no judgment may be made regarding the quality of the information. Sites must ensure that all potential EPA hazardous waste numbers are assigned to the waste stream."</p>						
<p>9. Condition Adverse to Quality: Based on a review of (one) acceptable knowledge (AK) summary report for waste stream TA55-20A.001, EPA Hazardous Waste Codes are not being assigned consistently with the requirements of the QAPP. As a result of discrepancies in AK information, LANL personnel were required to assign numerous EPA hazardous waste codes for this waste stream. This requirement was not being met.</p>						
<p>10. Suggested Actions: The appropriate EPA Hazardous Waste Code must be assigned for any listed wastes identified as being present in the AK documentation. In the absence of sampling and analysis data for the particular waste stream, LANL must, prior to shipment to WIPP, assign the EPA hazardous waste codes for all toxicity characteristic contaminants which were identified as being in the waste. No judgement may be made about the quality of the information which identified the presence of the toxicity characteristic contaminant or the concentrations.</p>						
<p>11. Significant Condition Adverse to Quality (Yes or No)?: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/></p>						
<p>12. Applicable Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input type="checkbox"/></p>						
<p>13. CAR Initiator: <u>R. Vann Bynum</u> Date: <u>8/18/97</u></p>						
<p>14. Response Due Date: <u>Sept. 3, 1997</u></p>						
<p>15. Concurrence: <u>Michael R. Brown</u> <u>8/26/97</u> <u>R. Dennis Brown</u> <u>8/26/97</u> <small>for Don Watkins</small> Responsible Team Leader Date Assurance Team Leader Date</p>						
<p>16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet</p>						
<p>17. Acceptance of Proposed Corrective Actions:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 33%; border-top: 1px solid black; text-align: center;">Responsible Team Leader</td> <td style="width: 15%; border-top: 1px solid black; text-align: center;">Date</td> <td style="width: 33%; border-top: 1px solid black; text-align: center;">Assurance Team Leader</td> <td style="width: 15%; border-top: 1px solid black; text-align: center;">Date</td> </tr> </table>			Responsible Team Leader	Date	Assurance Team Leader	Date
Responsible Team Leader	Date	Assurance Team Leader	Date			
<p>18. Verification of Corrective Action:</p>						
<p>19. Verified By (Signature): _____ <div style="display: flex; justify-content: space-around; width: 100%;"> Verifier Date </div> </p>						
<p>20. Closure: _____ <div style="display: flex; justify-content: space-around; width: 100%;"> Responsible Team Leader Date Assurance Team Leader Date </div> </p>						

CORRECTIVE ACTION REPORT

1. CAR No.: 97-115	2. Activity Report No.: A-97-07	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: CAO-94-1012, Revision 1, April 1996		5. Affected CAO Team Leader: D. Watkins
6. Responsible Organization: DOE-LAAO/Los Alamos National Laboratory (LANL)		7. Discussed With: G. Vigil, D. Taggart, M. Gavett
8. Requirement: CAO QAPD, Rev. 1, Section 1.1.1.5.B.2.b states that "participant QA management shall be sufficiently independent from cost and schedule considerations."		
9. Condition Adverse to Quality: The TWCP organization chart dated 8/18/97 indicates that the same two individuals report functionally to the Site Project Manager (Database Data Flow) <u>and</u> to the Site QA Officer (Software QA). The Operations Leader for NDA is performing the Level 1 QA review of FRAM data. Based on review of completed FRAM data packages, the same individual is performing data reduction activities for the FRAM system.		
10. Suggested Actions: Review each TWCP functional assignment and ensure that independence is maintained for any individual performing quality management activities.		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
12. Applicable 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>D. Brown</u> Date: <u>8/18/97</u>		
14. Response Due Date: <u>Sept. 3, 1997</u>		
15. Concurrence: <u>Michael B. [Signature]</u> <u>8/26/97</u> <u>R.D. Dennis [Signature]</u> <u>8/26/97</u> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> Responsible Team Leader Date Assurance Team Leader Date </div> <small>for D.W. Watkins</small>		
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet		
17. Acceptance of Proposed Corrective Actions:		
_____ Responsible Team Leader	_____ Date	_____ Assurance Team Leader
_____ Date		
18. Verification of Corrective Action:		
19. Verified By (Signature):		
_____ Verifier	_____ Date	
20. Closure:		
_____ Responsible Team Leader	_____ Date	_____ Assurance Team Leader
		_____ Date

CORRECTIVE ACTION REPORT

1. CAR No.:97-116	2. Activity Report No.:A-97-07	3. Page <u>1</u> of <u>1</u>	
4. Controlling Document: LANL QAPJP R.1, DTP-1.2-029 R.0		5. Affected CAO Team Leader: D. Watkins	
6. Responsible Organization: DOE-LAAO/Los Alamos National Laboratory (LANL)		7. Discussed With:D. Taggart, H. Poths	
8. Requirement: LANL QAPJP, TWCP-PLAN-0.2.3-001, R.1, Section 1.9 and 1.9.1 states in part that "TWCP personnel follow approved DTPs...Each TWCP operations leader ensures that TWCP activities are controlled and conducted in accordance with controlled procedures.			
9. Condition Adverse to Quality: During the observation of FRAM system operations, it was determined that procedure TWCP-DTP-1.1-029 was not implemented exactly as written and that the procedure did not include some necessary instructions. Alternate methods from those in the procedure were used for calibrations and daily system checks, and the (one) completed FRAM System Control Chart Form did not contain all required entries. In addition, the procedure did not provide instructions for the set up of the FRAM equipment relative to the waste drums, shielding of the FRAM detector and shielding of the target drums from background and adjacent storage areas.			
10. Suggested Actions: Update the procedure as necessary to reflect current operations and train effected personnel.			
11. Significant Condition Adverse to Quality (Yes or No?): YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>			
12. Applicable Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input type="checkbox"/>			
13. CAR Initiator: <u>R. Paedon</u>		Date: <u>8/18/97</u>	
14. Response Due Date: <u>Sept. 3, 1997</u>			
15. Concurrence: <u>Michael Rowan</u>	<u>For D. Watkins</u>	<u>8/26/97</u>	
Responsible Team Leader	Date	Assurance Team Leader Date	
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet			
17. Acceptance of Proposed Corrective Actions:			
_____	_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader	Date
18. Verification of Corrective Action:			
19. Verified By (Signature): _____			
Verifier		Date	
20. Closure: _____			
Responsible Team Leader	Date	Assurance Team Leader	Date

CORRECTIVE ACTION REPORT

1. CAR No.:97-117	2. Activity Report No.:A-97-07	3. Page <u>1</u> of <u>1</u>	
4. Controlling Document: QP-1.1-028, R.1		5. Affected CAO Team Leader:D. Watkins	
6. Responsible Organization: DOE-LAAO/Los Alamos National Laboratory (LANL)		7. Discussed With: P. Rogers	
<p>8. Requirement: TWCP-QP-1.1-028, R.1, Section 8.8.1 states: "Review the radioassay data to ensure that the value of the TRU activity reported demonstrates with a 95-percent probability that the waste is TRU waste and not low-level radioactive waste. Check to see that the average mass and activity of each radionuclide is listed for each waste container." Section 8.9 states: "Review the gas sampling and analysis data to ensure that the concentrations of hydrogen, methane, and flammable VOCs meet the flammability and waste acceptance criteria were not met, file a nonconformance report...and document required remedial action..."</p>			
<p>9. Condition Adverse to Quality: Checks of radioassay data to distinguish between TRU and low-level radioactive waste were not performed as required. Sampling and analysis data were in the package reviewed but the results of the review were not documented and the check was not listed in the DQO checklist. Documentation of the review of the gas sampling and analysis data to ensure that the concentrations of flammable gases meets the flammability and waste acceptance criteria was not available. The data to perform such a review was in the data package, but the results of the review, if performed, was not documented and was not listed in the DQO checklist.</p>			
<p>10. Suggested Actions: Document and include in the data package the review of the radioassay data to distinguish between TRU and low-level waste, and the review of the concentrations of flammable gases to ensure that the flammability and waste acceptance criteria were met. Include these two reviews on the DQO checklist.</p>			
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>			
12. Applicable Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input type="checkbox"/>			
13. CAR Initiator: <u>R. Vann Bynum</u>		Date: <u>8/18/97</u>	
14. Response Due Date: <u>Sept. 3 1997</u>			
15. Concurrence: <u>Michael Howards</u> Sor Don Watkins Responsible Team Leader		<u>R. D. Lemme Brown</u> Assurance Team Leader	
Date: <u>8/26/97</u>		Date: <u>8/26/97</u>	
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Date _____		Date _____	
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Date _____		Date _____	