

United States Government

memorandum

 Carlsbad Area Office
 Carlsbad, New Mexico 88221

DATE: July 6, 1999

REPLY TO
ATTN OF: CAO:QA:MLC 99-0876 UFC 2300.00

SUBJECT: Issuance of CARs 99-083 Through 99-088 from CAO Audit A-99-14

TO: Gary Young, Manager, ES&H Integration



The Carlsbad Area Office (CAO) performed audit A-99-14 of the Waste Isolation Division (WID) June 28 – July 2, 1999. The audit team identified six conditions adverse to quality which have been identified on Corrective Action Reports (CARs) 99-083 through 99-088.

Please advise the audit team leader, prior to the response due date identified in CAR block 14, of the expected date for completion of corrective actions. Also, please formally notify the audit team leader as soon as corrective actions have been completed and are ready to be verified.

If you have any questions or comments, please contact Lea Chism (505) 234-7442 or Wayne Ledford at (505) 234-3219.

Lea Chism
 For Marc A. Italiano
 CAO Quality Assurance Manager

Attachments

cc w/original attachments:
 L. Chism, CAO

cc w/attachments:
 M. Lipscomb, WID
 T. Ferguson, WID
 B. Allen, WID
 L.J. Dalton, WID
 K. Hunter, CAO
 W. Walker, CAO
 M. Eagle, EPA
 B. Walker, EEG
 S. Zappe, NMED
 W. Ledford, CTAC
 T. Bowden, CTAC

990704



CORRECTIVE ACTION REPORT

1. CAR No.: 99-083	2. Activity Report No.: A-99-14	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: WP13-QA.03, <i>Quality Assurance Department Assessment Program</i> , CAO 94-1012, <i>CAO QAPD</i>	5. CAO Assessment Team Leader: M. Italiano	
6. Responsible Organization: : WID	7. CAQ Was Discussed With: Tom Ferguson	
8. Requirement that was violated: Paragraph 5.3.3 of WP13-QA.03 requires that WID internal audit reports include an Executive Summary. Section 3.2.4.8 of the CAO QAPD requires, in part, that audit reports include a statement of the QA program adequacy, implementation and effectiveness; and that the reports include a summary of the documents reviewed, and the specific results of the reviews and interviews (i.e., a summary of checklist contents).		
9. Condition Adverse to Quality: The audit reports reviewed (including 199-01, 199-02, 199-03, 199-04) did not contain an summary statement of QA Program adequacy, implementation, and effectiveness. The audit reports also did not contain a summary of the checklist contents.		
10. Suggested Actions (Optional):		
11. Significant Condition Adverse to Quality (Yes or No)?: YES NO <input checked="" type="checkbox"/>		
12. 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>L. David Kimbro</u> <i>W.D.K.</i> Date: <u>7/6/99</u>		
14. Response Due Date: <u>7-28-99</u> Corrective Action Plan Required: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		
15. Trend Cause Code: _____		
16. Concurrence: <u>Lea Chism</u> <u>7-7-99</u> <i>for</i> Assessment Team Leader Date		
17. Corrective Actions Proposed by the Responsible Organization (for SCQA only): Use CAR Continuation Sheet		
18. Acceptance of Proposed Corrective Actions (for SCAQ only):		
_____ Assessment Team Leader	_____ Date	_____ Quality Assurance Manager Date
19. Verification of Corrective Action Completion:		
20. Verified By: _____ _____ Name Date		
21. Closure: _____ _____ Assessment Team Leader Date		

CORRECTIVE ACTION REPORT

1. CAR No.: 99-084	2. Activity Report No.: A-99-14	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: WP02-PC.01, <i>WIPP RCRA-Specific Generator Site Waste Screening and Acceptance Program Plan</i>	5. CAO Assessment Team Leader: M. Italiano	
6. Responsible Organization: : WID	7. CAQ Was Discussed With: Steve Kouba/John Gram	
8. Requirement that was violated: Section 4.7 of WP02-PC.01 details numerous responsibilities of the Environmental Compliance and Support Manager. See attached continuation sheet for identification of specific requirements.		
9. Condition Adverse to Quality: None of the requirements of Section 4.7 of WP02-PC.01 are being implemented.		
10. Suggested Actions (Optional):		
11. Significant Condition Adverse to Quality (Yes or No)?: YES NO <input checked="" type="checkbox"/>		
12. 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>L. David Kimbro</u> <i>Ward J Kimbro</i> Date: <u>7/6/99</u>		
14. Response Due Date: <u>7-28-99</u> Corrective Action Plan Required: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		
15. Trend Cause Code: _____		
16. Concurrence: <u><i>Dea Chism</i></u> Date: <u>7-7-99</u> <i>for</i> Assessment Team Leader		
17. Corrective Actions Proposed by the Responsible Organization (for SCQA only): Use CAR Continuation Sheet		
18. Acceptance of Proposed Corrective Actions (for SCAQ only):		
_____ Assessment Team Leader	_____ Date	_____ Quality Assurance Manager
19. Verification of Corrective Action Completion:		
20. Verified By: _____ Date: _____ Name Date		
21. Closure: _____ Date: _____ Assessment Team Leader Date		

CAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 99-084

2. Activity No.: A-99-14

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Block # 8

WP02-PC.01, Section 4.7 , contains, in part, the following requirements:

The WID RCRA permitting manager shall:

- Track RCRA related audit results, and any RCRA specific CARs.
- Maintain RCRA auditor/technical specialist training and qualification records
- Review, approve, and submit the DOE/CAO all final WID RCRA audit reports
- Review generator site corrective action responses
- Review, approve and issue trend reports
- Submit the WID RCRA audit report to DOE/CAO within 30 days of completion of the audit
- Maintain QA records including, RCRA CARs, deficiency resolutions, WID RCRA audit reports, trend reports

CORRECTIVE ACTION REPORT

1. CAR No.: 99-085	2. Activity Report No.: A-99-14	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: WP10-AD3029, Revision 0, Chg. 1, Calibration and Control of Monitoring and Data Collection Equipment		5. CAO Assessment Team Leader: M. Italiano
6. Responsible Organization: : WID		7. CAQ Was Discussed With: Stewart Jones, Ron Richardson, and Melvin Balderrama
8. Requirement that was violated: WP10-AD3029, "Calibration and Control of Monitoring and Data Collection Equipment" Paragraphs 1.2 and 5.0. See continuation sheet for details.		
9. Condition Adverse to Quality: Trending of calibration data is not performed by all M&DC equipment owners in accordance with the noted paragraphs.		
10. Suggested Actions (Optional):		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input type="radio"/> NO <input checked="" type="radio"/>		
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: ___ Actions to Preclude Recurrence: ___		
13. CAR Initiator: <u>A. E. Bradford</u> <i>A.E. Bradford</i> Date: <u>July 6, 1999</u>		
14. Response Due Date: <u>7-28-99</u> Corrective Action Plan Required: <input checked="" type="radio"/> YES <input type="radio"/> NO		
15. Trend Cause Code: _____		
16. Concurrence: <u><i>Lea Chiam</i></u> <u>7-7-99</u> <i>for</i> Assessment Team Leader Date		
17. Corrective Actions Proposed by the Responsible Organization (for SCQA only): Use CAR Continuation Sheet		
18. Acceptance of Proposed Corrective Actions (for SCAQ only):		
_____	_____	_____
Assessment Team Leader	Date	Quality Assurance Manager
19. Verification of Corrective Action Completion:		
20. Verified By: _____		
Name	Date	
21. Closure: _____		
Assessment Team Leader	Date	

CORRECTIVE ACTION REPORT

1. CAR No.: 99-086	2. Activity Report No.: A 99-14	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: WP 15-PS3103, Rev. 3, <i>Document Distribution</i> ; WP 15-PR, Rev. 1, <i>Records Management Program</i>	5. CAO Assessment Team Leader: M. Italiano	
6. Responsible Organization: : WID	7. CAQ Was Discussed With: Craig Suggs	
8. Requirement that was violated: See attached continuation sheet.		
9. Condition Adverse to Quality: See attached continuation sheet.		
10. Suggested Actions (Optional):		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input checked="" type="radio"/> NO		
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>Amelia I. Arceo</u> Date: <u>7/6/99</u>		
14. Response Due Date: <u>7-28-99</u> Corrective Action Plan Required: <input checked="" type="radio"/> YES NO		
15. Trend Cause Code: _____		
16. Concurrence: <u>Dea Chiam</u> <u>7-7-99</u> <small>Assessment Team Leader Date</small>		
17. Corrective Actions Proposed by the Responsible Organization (for SCQA only): Use CAR Continuation Sheet		
18. Acceptance of Proposed Corrective Actions (for SCAQ only):		
_____ Assessment Team Leader	_____ Date	_____ Quality Assurance Manager _____ Date
19. Verification of Corrective Action Completion:		
20. Verified By: _____ <small style="margin-left: 100px;">Name</small> <small style="margin-left: 150px;">Date</small>		
21. Closure: _____ <small style="margin-left: 100px;">Assessment Team Leader</small> <small style="margin-left: 150px;">Date</small>		

CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.:99-086

2. Activity No.: A 99-14

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Block # 8

- A. WP 15-PS3103, Rev. 3, *Document Distribution*, Section 4.0 requires that Operator Handbooks be checked to verify that current revision/change number of each controlled procedure is available and usable.
- B. WP 15-PR, Rev. 1, *Records Management Program*, Section 4.0 requires that records be identified in the implementing procedures.

Block # 9

Contrary to the above requirements:

- A. The Operator Handbooks (OHBs) in the following locations were not current:
1. OHB 101, Building 384, SH Hoist Control Room has Procedure WP 12- ER4911, Revision 0, Change 9. Current revision is Revision 0, Change 11. This procedure was not listed on the Distribution Log dated 6/29/99.
 2. OHB 104, Room 204, WH Hoist Control Room has Procedure WP 12-ER4911, Revision 0. Current revision is Revision 0, Change 11. This procedure was not listed on the Distribution Log dated 6/29/99.
 3. OHB 107, Building 362, AIS Handling Hoist Control Room has Procedure WP 12-ER4911, Revision 0. Current revision is Revision 0, Change 11. This procedure was not listed on the Distribution Log dated 6/29/99.
 4. OHB 111, Support Building, Room 116 has:
 - a) Procedure WP 04-CM1304, Revision 2, Change 5. Current revision is Revision 3. This procedure was not listed on the Distribution Log dated 6/29/99.
 - b) Procedure WP 04-ED2306, Revision 0. This procedure should not be in the binder per Larry Porter of Document Services.
 5. OHB 113, WH Building, Room 208 has Procedure WP 04-HV1021, Revision 2, Change 3. Current revision is Revision 2, Change 4. This procedure was not listed on the Distribution Log dated 6/29/99.
- B. The following documents do not have records identified:
1. WP 09-SU.01, Revision 0, PCN 2, *WIPP Startup Test Program*
 2. WP 10-2, Revision 2, *Maintenance Operations Instructions Manual*

CORRECTIVE ACTION REPORT

1. CAR No.: 99-087	2. Activity Report No.: A-99-14	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: <i>CAO QAPD, CAO-94-1012</i>	5. CAO Assessment Team Leader: M. Italiano	
6. Responsible Organization: : WID	7. CAQ Was Discussed With: W. W. Allen	
8. Requirement that was violated: See attached continuation sheet for adequacy issues related to the WID QAPD.		
9. Condition Adverse to Quality: See attached continuation sheet.		
10. Suggested Actions (Optional):		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input checked="" type="radio"/> NO		
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: ___ Actions to Preclude Recurrence: ___		
13. CAR Initiator: <u>Wayne Ledford</u> <i>WLF</i> Date: <u>7/6/99</u>		
14. Response Due Date: <u>7-28-99</u> Corrective Action Plan Required: <input checked="" type="radio"/> YES NO		
15. Trend Cause Code: _____		
16. Concurrence: <u><i>Lea Chism</i></u> <u>7-7-99</u> <small>Assessment Team Leader Date</small>		
17. Corrective Actions Proposed by the Responsible Organization (for SCQA only): Use CAR Continuation Sheet		
18. Acceptance of Proposed Corrective Actions (for SCAQ only):		
_____	_____	_____
Assessment Team Leader	Date	Quality Assurance Manager Date
19. Verification of Corrective Action Completion:		
20. Verified By: _____		
Name	Date	
21. Closure: _____		
Assessment Team Leader	Date	

CAO CORRECTIVE ACTION REPORT

(continuation sheet)

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Block # 8

1. The CAO QAPD lists, among others, the following regulatory requirements documents:
ASME NQA-1-1989
ASME NQA-2a-1990 addenda Part 2.7
ASME NQA-3-1989, excluding Section 2.1 (b) and (c) and Section 17.1
2. The CAO QAPD, Section 2.2.2.1.D requires that design inputs based on assumptions that require reverification be identified and controlled.
3. The CAO QAPD, Section 3.2.4.6 contains requirements for the verifiable evidence of lead auditor education and experience.
4. The CAO QAPD, Section 2.2.2.5.B requires that the use a particular design verification method be justified.
5. The CAO QAPD, Section 3.2.4.8 requires that audit team leaders sign the audit report.
6. The CAO QAPD, Section 3.2.4.8 states in part that, "The audit report shall include the following as appropriate:..."
7. The CAO QAPD, Section 3.2.4.10 requires that certain audit records be maintained as QA records.

Block #9

1. The WID QAPD lists the following as source documents:
ASME NQA-1, (1989, with 1992 addenda)
ASME NQA-2, Part 2.7 (1989)
ASME NQA-3 (1989) Parts 2.2, 2.3, 2.4, 3.1, 3.2, 3.3, 17.3, 18, and 3SW-1
2. The WID QAPD does not specify that design inputs based on assumptions that require reverification be identified and controlled.
3. The WID QAPD does not specify requirements for the verifiable evidence of lead auditor education and experience.
4. The WID QAPD does not require that the use a particular design verification method be justified.
5. The WID QAPD does not require that audit team leaders sign the audit report.
6. The WID QAPD does not require the audit report content as specified by Section 3.2.4.8 of the CAO QAPD.
7. The WID QAPD does not specify that certain audit records are QA records as identified in Section 3.2.4.10 of the CAO QAPD.

CORRECTIVE ACTION REPORT

1. CAR No.: 99-088	2. Activity Report No.: A-99-14	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: WP09-CN3018, <i>Design Verification</i>		5. CAO Assessment Team Leader: M. Italiano
6. Responsible Organization: : WID		7. CAQ Was Discussed With: Wayne Treadway
8. Requirement that was violated: Sections 2.2, 2.3, 2.4 of WP09-CN3018 contains requirements for documentation of design verification. See attached continuation sheet for details of the requirements.		
9. Condition Adverse to Quality: See attached continuation sheet.		
10. Suggested Actions (Optional):		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <u>NO</u>		
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: _____ Actions to Preclude Recurrence: _____		
13. CAR Initiator: <u>L. David Kimbro</u> <i>W. J. Kimbro</i> Date: <u>7/6/99</u>		
14. Response Due Date: <u>7-28-99</u> Corrective Action Plan Required: <u>YES</u> NO		
15. Trend Cause Code: _____		
16. Concurrence: <u><i>Lee Chion</i></u> <u>7-7-99</u> <div style="display: flex; justify-content: space-between; width: 100%;"> Assessment Team Leader Date </div>		
17. Corrective Actions Proposed by the Responsible Organization (for SCQA only): Use CAR Continuation Sheet		
18. Acceptance of Proposed Corrective Actions (for SCAQ only):		
_____ Assessment Team Leader	_____ Date	_____ Quality Assurance Manager
_____ Date		
19. Verification of Corrective Action Completion:		
20. Verified By: _____ <div style="display: flex; justify-content: space-between; width: 100%;"> Name Date </div>		
21. Closure: _____ <div style="display: flex; justify-content: space-between; width: 100%;"> Assessment Team Leader Date </div>		

CDM CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 99-088

2. Activity No.: A-99-14

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Block # 8

1. Section 2.2.3 of WP09-CN3018 requires that a design verification memo to file be generated that contains documentation of the basis and conclusion of the design verification and a signature blank for CDM concurrence.
2. Section 2.2.4.[B] of WP09-CN3018 requires that design verification documentation include resumes or other statements of reviewer technical qualifications.
3. Section 2.0, Note of WP09-CN3018 and WID QAPD, Section 2.2.5.D requires that when the CDM performs design reviews the determination to use the CDM is documented and approved in advance.
4. Section 5.0 of WP09-CN3018 requires that for designs verified by the formal design review method; a design review plan is prepared and a design review report is generated.

Block # 9

1. The design review memo to file for ECO 9282 did not contain the basis and conclusion, nor a signature blank for CDM concurrence.
2. The design verification documentation for ECO 9282 did not include resumes/statements related to qualification of the independent reviewers.
3. The CDM (acting) also signed ECO 9136 as the independent reviewer, with no evidence of a documented/approved determination.
4. ECO 8705 had no design review plan, nor was there a design review report prepared.