

United States Government

Department of Energy

memorandum

Carlsbad Area Office
Carlsbad, New Mexico 88221

DATE: May 6, 1997

REPLY TO
ATTN OF: CAO:NTP:MRB 97-1110 UFC 2300

SUBJECT: Issuance of CAO Corrective Action Reports from April 1997 Certification Audit

TO: Joel Case, ID

The Carlsbad Area Office (CAO) performed Audit A-97-02 from April 21-25, 1997, of Idaho National Engineering and Environmental Laboratories (INEEL) waste characterization, transportation, and certification activities. The audit team identified ten conditions adverse to quality which initiated Corrective Action Reports (CARs) 97-039 through 97-048.

Please provide the information and the schedule for completing the actions requested in block 12 of the CAR. Continuation sheets have been provided for your use. The proposed actions and completion schedule are due by the date specified in block 14 of each CAR.

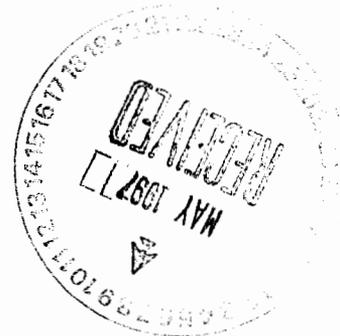
If you have any questions or comments, please contact Butch Stroud at (505) 234-7483 or Dennis Brown at (505) 234-7484.

for Michael R B
Don Watkins
Team Leader
National TRU Waste Program

Attachments

cc: w/attachments:

J. Wells, ID
K. Hunter, CAO
B. Stroud, CAO
D. Brown, CAO
T. Clements, INEEL/LMITCO
G. Hayes, INEEL/LMITCO
C. Dwight, ANL-W
M. Horseman, CTAC
✓ S. Zappe, NMED
M. Eagle, EPA/ORIA



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CORRECTIVE ACTION REPORT

1. CAR No.: 97-039	2. Activity No.: A 97-02	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: CAO QAPD, Rev. 1 and ANL-W TPM 3.3.4, Rev. 5 & 6, HFEF WAC Initial and Continuing Training Plan	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: DOE-ID/INEEL/ANL-W	7. Discussed With: Carla Dwight, Klayne Coburn	
Requirement: 1.) CAO QAPD, Rev. 1, Section 1.2.2 states in part that "...participant personnel performing activities important to ... waste characterizationshall receive related training in accordance with the following requirements.....B.1. general criteria, including, applicable QA Plans, codes, regulations and standards; and B2. specific criteria, including applicable QAPjPs and implementing procedures...". 2.) CAO QAPD, Rev. 1, Section 1.2, states that "personnel be qualified to perform assigned tasks." (continued)		
Condition Adverse to Quality: Contrary to the above requirements: 1. There was no documentation of training for management personnel for Quality Assurance programmatic documents such as the CAO QAPD, CAO QAPP or ANL-W QAPjP 2. There was no current documentation of qualification and training for HFEF personnel Subject Matter Experts. 3. A supervisor for HFEF Sampling Operators has not been trained and the training documented (also, no objective evidence for written exam) to the level required by the controlling procedure.		
10. Suggested Actions:		
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>M. E. Bennington</u>		Date: <u>4/24/97</u>
14. Response Due Date: <u>May 30, 1997</u>		
15. Concurrence: <u>Michael RB for Don Watkins</u>	<u>5/6/97</u>	<u>Dennis Brown</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

(continuation sheet)

1. CAR No.: 97-039

2. Activity Report No.: A-97-02

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3.) TMP 3.3.4, Section 7.1 and 7.2; the procedure and complete initial and continuing training through self study and oral examination; and, that each person who works in the HFEF WCA complete a biennial written exam.

CORRECTIVE ACTION REPORT

1. CAR No: 97-040	2. Activity Report No.: A-97-02	3. Page <u>1</u> Of <u>1</u>
4. Controlling Document: MCP-1805, Rev. 0, Document Preparation, Review, Control and Release	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: DOE-ID/INEEL/RWMC	7. Discussed With: Craig Kvamme	
8. Requirement: Paragraph 4.2.1.7 states: "Update manuals at designated work stations located within RWMC when documents issued and discard replaced document. Paragraph 4.2.4.2. E. Instructions to mark off issue number from issue record sheet in the front of controlled manuals."		
9. Condition Adverse to Quality: Three manual sets (out of 19 manual sets) of MCPs and TPRs were reviewed for completeness and to ensure that current documents were in the manuals. It was discovered that in several incidents, deleted procedures were still contained in the manuals. Also, superseded procedures were discovered to be in the manuals along with the current procedure version. The issue record sheet in two of the MCP manual sets reviewed did not have the current issue(#65) initialed and dated.		
10. Suggested Actions: Review all RWMC controlled manual sets to ensure that they contain the correct and current documents. Also ensure that the issue record sheets for all manuals reflect the current issue.		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
12. Applicable 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>Bruce Langsteiner</u> Date: <u>4/24/97</u>		
14. Response Due Date: <u>May 30 1997</u>		
15. Concurrence: <u>Michael R. Broder for Don Watkins 5/6/97</u> <u>RD Dennis Brown</u> <u>5/5/97</u>		
Affected 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.: 97-041	2. Activity Report No.: A-97-02	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: MCP-1805, Rev. 0, "Document Preparation, Review, Control and Release"	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: DOE-ID/INEEL/RWMC	7. Discussed With: Arturo Flores	
<p>8. Requirement: Section 4.3.3, <u>RWMC Reviewers</u>: Review document. Section 4.3.3.1.C, Assist in preparation of a Comment Resolution Copy (prepared by the Coordinator) of each document reviewed. This copy shall; (1) Identify incorporation of all resolutions made during the review, (2) Provide a record of review results.</p>		
<p>9. Condition Adverse to Quality: Contrary to the above, two procedures (DOP-RO-2.5.1 and TPR-1726) were issued which did not incorporate all the changes and/or comments agreed to on the applicable Document Revision Requests (DRRs). The team reviewed records for seventeen (17) documents.</p>		
<p>10. Suggested Actions: Correct identified documents; review an additional representative sample of the total population to determine the extent of the problem; evaluate the document review, comment resolution/incorporation, and approval process to determine the root cause of this problem; and initiate required corrective actions to preclude recurrence of this condition.</p>		
<p>11. Significant Condition Adverse to Quality (Yes or No)?: YES <u>X</u> NO <u> </u></p>		
<p>12. Applicable Types of Actions: Remedial:<u>X</u> Investigative:<u>X</u> Root Cause:<u>X</u> Actions to Preclude Recurrence: <u>X</u></p>		
13. CAR Initiator: <u>S. Davis</u>		Date: <u>4/24/97</u>
14. Response Due Date: <u>May 30, 1997</u>		
15. Concurrence: <u>Michael R. Bro for Don Watkins</u> <u>5/6/97</u>		<u>R. Dennis Brown</u> <u>5/5/97</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.: 97-042	2. Activity Report No.: A-97-02	Page 1 of 2	
4. Controlling Document: MCP-1809, Rev. 1, Record Management		5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: DOE-ID/INEEL/RWMC		7. Discussed With: Janice Gilman	
8. Requirement: Paragraphs 4.1.2.1 and 4.1.2.2 require RWMC personnel to identify file locations and retention periods for QA records. Paragraph 4.1.3.3 requires records to be legible, traceable, and accurately reflect completed work.			
9. Condition Adverse to Quality: Numerous RWMC QA records were not designated "lifetime" or "nonpermanent". QA records were not validated by the originating organization. Revisions to QA records were not properly approved or validated. Document Action Requests (DARs) were not being completed properly to accurately reflect completed work. (Details on page 2)			
10. Suggested Action: 1. Provide training to personnel who generate QA records on records requirements and records validation.. 2. Alter the records transmittal form to provide specific information blanks for required retention times and file designations.			
11. Significant Condition Adverse to Quality (Yes or No)?: Yes _____ No <u> X </u>			
12. Applicable 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: Ava Holland		Date: 4/24/97	
14. Response Due Date: <u> May 30, 1997 </u>			
15. Concurrence: <u> Michael E. Bro... for Don Watkins </u>		<u> R. Dennis Brown </u>	
Responsible Team Leader		Assurance Team Leader	
Date		Date	
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet			
17. Acceptance of Proposed Corrective Actions:			
_____		_____	
Responsible Team Leader		Assurance Team Leader	
Date		Date	
18. Verification of Corrective Action:			
19. Verified By (Signature): _____			
Verifier		Date	
20. Closure: _____			
Responsible Team Leader		Assurance Team Leader	
Date		Date	

CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 97-042	2. Activity Report No.: A-97-02	Page 2 of 2
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- A. Unprocessed document transmittals received at the record center were reviewed and found incorrect.
- 8 transmittals of QA records had no classification as "lifetime" or "nonpermanent."
 - 3 transmittals of QA records had no file designation, no validation, and no "lifetime" or "nonpermanent" classification.
 - 1 transmittal of QA records used the non-QA transmittal form and had no validation, but did classify the records as "permanent".
 - 1 transmittal of non-QA records used the right form and was correct.
- B. Document Action Requests (DARs) were not properly completed to accurately reflect completed work.
- Information on 4 DARs in the record center was marked through without any initial and date.
 - Reviewer's block on 5 DARs did not identify the reviewer's discipline.
 - Review blocks on 2 DARs were not signed and dated.

CORRECTIVE ACTION REPORT

1. CAR No.: 97-043	2. Activity Report No.: A-97-02	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: AWP 4.14, Rev. 0, Procurement Document Preparation	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: DOE-ID/TNEEL/ANL-W	7. Discussed With: D. Brynglson, JuDee Mortensen, C. Dwight	
8. Requirement: Section 7.3.2 requires receipt inspection of all Level B procurements.		
9. Condition Adverse to Quality: For one of three purchase orders sampled, the receiving inspection was not performed (purchase order 63051007, ACL/QA-B, AMERIND, INC.)		
10. Suggested Actions: Perform investigative actions to determine the extent and impact of the deficiency and identify the root cause. Determine the remedial actions required to correct the adverse condition and describe the actions to be taken to preclude recurrence.		
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>Pete V. Rodriguez</u> Date: <u>4/24/97</u>		
14. Response Due Date: <u>May 30, 1997</u>		
15. Concurrence: <u>Michael R. Bo</u> for Don Watkins <u>5/6/97</u> <u>R. Dennis Brown</u> <u>5/5/97</u> <small>Affected Team Leader Date Assurance Team Leader Date</small>		
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet		
17. Acceptance of Proposed Corrective Actions: _____ <small>Responsible Team Leader Date Assurance Team Leader Date</small>		
18. Verification of Corrective Action:		
19. Verified By (Signature): _____ <small>Verifier Date</small>		
20. Closure: _____ <small>Responsible Team Leader Date Assurance Team Leader Date</small>		

CORRECTIVE ACTION REPO

1. CAR No.: 97-044	2. Activity Report No.: A-97-02	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: Quality Assurance Program Document (QAPD), Rev. 1	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: DOE-ID/INEEL/RWMC	7. Discussed With: Elvin Dumas	
8. Requirement: Section 6.3 requires that vendor software be evaluated to verify the acceptability of supporting documentation. Section 6.4 requires that existing software be evaluated to determine the adequacy of software documentation to support operation and maintenance. Section 6.8 requires that software design, implementation and user documentation be developed.		
9. Condition Adverse to Quality: MCP-1803, Rev. 1, "Configuration Control of RWMC Hardware/Software" does not fully address the specified QAPD requirements for qualification or documentation of existing RWMC software. The development of the life-cycle documentation for Drum Vent System (DVS) and Data Management System (DMS) did not include design, implementation, or user documentation.		
10. Suggested Actions: Issue and implement draft procedure (MCP-1803, Rev. 2) to identify and grade SQA requirements for existing RWMC software including DVS, DMS, RGA, and FTTR.		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
12. Suggested Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input type="checkbox"/> Root Cause: <input checked="" type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>Sid Ailes</u> Date: <u>4/24/97</u>		
14. Response Due Date: <u>May 30, 1997</u>		
15. Concurrence: <u>Michael R. Brown</u> <u>5/6/97</u> <u>R. Dennis Brown</u> <u>5/5/97</u> Affected 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: _____ Date _____ Date Responsible Team Leader Assurance Team Leader		
18. Verification of Corrective Action:		
19. Verified By (Signature): _____ Date _____ Verifier Date		
20. Closure: _____ Date _____ Date Responsible Team Leader Assurance Team Leader		

CORRECTIVE ACTION REPO

1. CAR No.: 97-045	2. Activity Report No.: A-97-02	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: ACL SOP R.1.29, Rev. 1, Software Control in the Analytical Chemistry Section	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: DOE-ID/INEEL/ACL	7. Discussed With: Shelly Sailer	
8. Requirement: Section 5.7.1 requires that computer personnel making changes to software document what was done and why it was done. This requirement is also included in MCP-2009, Section 4.7.2, which replaced SOP R.1.29 on April 17, 1997.		
9. Condition Adverse to Quality: The software used for the Mercury analysis (Method 7802) was modified without documenting what was done and why it was done. Of three additional modules checked (M8100, M7016, and M3950), M8100 and M3950 had been modified without the required documentation file entry or time stamp. Although the new system automatically controls changes to software by identifying the personnel making changes and the date of the change, no documentation was available in the file or in the internal code documentation describing what change was made or why it was made.		
10. Suggested Actions: Establish a separate change control form for MCP-2009 to clearly identify the purpose for proposed changes to software and to provide evidence of approval for the change prior to modifying affected software. Modify MCP-2009 to include in the internal code documentation a title block that identifies the revision history of the code, including changes made and affected modules or sub-routines.		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
12. Suggested 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>Sid Ailes</u> Date: <u>4/24/97</u>		
14. Response Due Date: <u>May 30, 1997</u>		
15. Concurrence: <u>Michael Rounbo for Don Watkins</u> <u>5/6/97</u> <u>R. Dennis Brown</u> <u>5/5/97</u> Affected Team Leader Date Assurance Team Leader Date		
16. Corrective Actions Porposed by the Responsible Organization: See attached CAR continuation sheet		
17. Acceptance of Proposed Corrective Actions: _____ Date _____ Date Responsible Team Leader Assurance Team Leader		
18. Verification of Corrective Action:		
19. Verified By (Signature): _____ Date _____ Verifier		
20. Closure: _____ Date _____ Date Responsible Team Leader Assurance Team Leader		

CORRECTIVE ACTION REPORT

1. CAR No.: 97-046	2. Activity Report No. A-97-02	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: HFEF-OI-6890, Rev 1g, Waste Characterization, and HFEF-OI-6892, Rev. 1, Waste Characterization Data Package	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: DOE-ID/INEEL/ANL-W	7. Discussed With: Carla C. Dwight	
8. Requirement: HFEF-OI-6890, Rev 1g, Paragraph 4.2.3 [7] Waste characterization activities must be performed at temperatures in the range of 18 degrees C to 29 degrees C (65 to 84 degrees F) HFEF-OI-6892, Appendix D requires not only recording temperature data, but verifying it is within tolerances.		
9. Condition Adverse to Quality: Four drum data packages 024311, 005427, 014170 and 021442 had been submitted with temperature data outside the acceptable ranges. The activities on one package were completed at 16 degrees C, others at 17 degrees C. Three of the packages had been through all the ANL-W and SPO reviews. The fourth package had completed the generator review and independent technical review. The data and activities had not been identified as having temperatures outside the acceptable range.		
10. Suggested Actions: 1) Review all completed drum data packages to identify any other packages that were completed at temperatures outside of the acceptable range. 2) Complete and document a technical evaluation of the data to determine the acceptability of the data.		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input checked="" type="checkbox"/> NO <input 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>Michael R. Brown</u> Date: <u>4/24/97</u>		
14. Response Due Date: <u>May 30 1997</u>		
15. Concurrence: <u>Michael B. for Don Watkins 5/6/97</u> <u>RD Dennis Brown 5/5/97</u>		
Affected 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: _____ <div style="display: flex; justify-content: space-between; width: 100%;"> Responsible Team Leader Date Assurance Team Leader Date </div>		
18. Verification of Corrective Action:		
19. Verified By (Signature): _____ <div style="display: flex; justify-content: space-between; width: 100%;"> Verifier Date </div>		
20. Closure: _____ <div style="display: flex; justify-content: space-between; width: 100%;"> Responsible Team Leader Date Assurance Team Leader Date </div>		

CORRECTIVE ACTION REPORT

1. CAR No.: 97-047	2. Activity Report No.: A-97-02	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: INEEL Quality Program Plan, Rev. 0 INEEL QAPJP, Rev. 0	5. Affected CAO Team Leader: Don Watkin	
6. Responsible Organization: DOE-ID/INEEL/SPO	7. Discussed With: R. Arbon, K. Peters, S. Hailey	
8. Requirement: QPP, Section 5.1.4, first paragraph: "Documents are prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design."		
9. Condition Adverse to Quality: The WASTREN (INEEL subcontractor) procedure for assembling and evaluating acceptable knowledge documentation was not approved for use by TWCP personnel. In addition, it does not contain all the information required by the QAPJP. The following information was missing: 1) Site waste management operations and mission (continued)		
10. Suggested Actions:		
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. D. Brown</u> Date: <u>4/24/97</u>		
14. Response Due Date: <u>May 30, 1997</u>		
15. Concurrence: <u>Michael R. Brown for Don Watkins 5/6/97</u> <u>R. Dennis Brown</u> <u>5/5/97</u> <div style="display: flex; justify-content: space-around; font-size: small;"> Affected Team Leader Date Assurance Team Leader Date </div>		
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet		
17. Acceptance of Proposed Corrective Actions: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%; text-align: center;"> _____ Responsible Team Leader </div> <div style="width: 10%; text-align: center;"> _____ Date </div> <div style="width: 45%; text-align: center;"> _____ Assurance Team Leader </div> <div style="width: 10%; text-align: center;"> _____ Date </div> </div>		
18. Verification of Corrective Action:		
19. Verified By (Signature): _____ <div style="display: flex; justify-content: space-around; font-size: small;"> Verifier Date </div>		
20. Closure: _____ <div style="display: flex; justify-content: space-between; font-size: small;"> Responsible Team Leader Date Assurance Team Leader Date </div>		

CAR CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No: 97-047

2. Activity Report No.: A-97-02

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Block # 9

- 2) Waste generating process history (dates)
- 3) Physical form of waste
- 4) Radionuclides present in waste
- 5) Identify hazardous wastes and assign EPA HWNs

CAR CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.:

2. Activity Report No.:

3. Page ____ of ____

Block # _____

C O CORRECTIVE ACTION F O R T

(continuation sheet)

1. CAR No.:	2. Activity Report No.:	3. Page ____ of ____
<p>Block # _____</p>		