

United States Government

Department of Energy

memorandum

Carlsbad Area Office
Carlsbad, New Mexico 88221

DATE: July 30, 1997

REPLY TO
ATTN OF: CAO:NTP:DEW 97-1192 UFC 2300

SUBJECT: Issuance of CAO Corrective Action Reports A-97-03

TO: Keith Klein, RFFO

The Carlsbad Area Office (CAO) performed Audit A-97-03 from July 14-18, 1997, of Rocky Flats Environmental Technology Site (RFETS) waste characterization, transportation, and certification activities. The audit team identified 18 conditions adverse to quality which initiated Corrective Action Reports (CARs) 97-083 through 97-100.

Please determine and document on each CAR the extent of the deficiencies, the proposed corrective action(s) to preclude recurrence, and the schedule for completing those actions.

Please transmit the CARs with the proposed actions and completion schedule to me by the due 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.



Don Watkins
Manager
National TRU Program

Attachments



printed on recycled paper

970718



Keith Klein

- 2 -

July 30, 1997

cc w/attachments:

G. Dials, CAO
D. Brown, CAO
L. Chism, CAO
B. Stroud, CAO
D. Watkins, CAO
T. Bowden, CTAC
M. Horseman, CTAC
D. Winters, DNFSB
B. Walker, EEG
M. Eagle, EPA
✓ S. Zappe, NMED
A. Flewelling, RFETS
G. O'Leary, RFETS



CORRECTIVE ACTION REPORT

1. CAR No.:97-083	2. Activity Report No.:A-97-03	3. Page <u>1</u> of <u>1</u>								
4. Controlling Document: CAO-94-1012, Quality Assurance Program Document, Revision 1	5. Affected CAO Team Leader: Don Watkins									
6. Responsible Organization: RFETS	7. Discussed With: Art Flewelling, J. O'Leary									
8. Requirement: Paragraph 3.1 states in part, "Managers at every level shall periodically assess the performance of their organization to determine the effectiveness of QA program provisions that enable the organization to meet customer requirements and expectations."										
9. Condition Adverse to Quality: RFETS Management Assessments were conducted by management personnel to verify compliance to procedures. RFETS personnel did not provide evidence that management assessments were being used to evaluate QA program effectiveness. This has been previously identified (by NTS), but a corrective action plan is not in place to correct this condition adverse to quality.										
10. Suggested Actions:										
11. Significant Condition Adverse to Quality (Yes or No)?: YES <u>X</u> NO <u> </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: R.D. Brown <i>Mary E. Bennington for</i> Date: 7/18/97										
14. Response Due Date: 8/14/97										
15. Concurrence: <i>[Signature]</i> 7/30/97 <i>Mary E. Bennington</i> 7/30/97 Responsible Team Leader Date for Assurance Team Leader Date										
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet										
17. Acceptance of Proposed Corrective Actions: <table style="width: 100%; border: none;"> <tr> <td style="width: 33%; border: none;">_____</td> <td style="width: 17%; border: none;">Date</td> <td style="width: 33%; border: none;">_____</td> <td style="width: 17%; border: none;">Date</td> </tr> <tr> <td style="border: none; text-align: center;">Responsible Team Leader</td> <td style="border: none;"></td> <td style="border: none; text-align: center;">Assurance Team Leader</td> <td style="border: none;"></td> </tr> </table>			_____	Date	_____	Date	Responsible Team Leader		Assurance Team Leader	
_____	Date	_____	Date							
Responsible Team Leader		Assurance Team Leader								
18. Verification of Corrective Action:										
19. Verified By (Signature): <table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;">_____</td> <td style="width: 40%; border: none;">Date</td> </tr> <tr> <td style="border: none; text-align: center;">Verifier</td> <td style="border: none;"></td> </tr> </table>			_____	Date	Verifier					
_____	Date									
Verifier										
20. Closure: <table style="width: 100%; border: none;"> <tr> <td style="width: 33%; border: none;">_____</td> <td style="width: 17%; border: none;">Date</td> <td style="width: 33%; border: none;">_____</td> <td style="width: 17%; border: none;">Date</td> </tr> <tr> <td style="border: none; text-align: center;">Responsible Team Leader</td> <td style="border: none;"></td> <td style="border: none; text-align: center;">Assurance Team Leader</td> <td style="border: none;"></td> </tr> </table>			_____	Date	_____	Date	Responsible Team Leader		Assurance Team Leader	
_____	Date	_____	Date							
Responsible Team Leader		Assurance Team Leader								

CORRECTIVE ACTION REPORT

1. CAR No.: 97-084	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: DOE/WIPP/CAO - 94-1010, Interim Change, 11/15/96; CAO - 94-1012, Quality Assurance Program Document, Revision 1, 1-MAN-001-SDRM, Revision 0, Site Document Requirements Manual	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: RFETS	7. Discussed With: Dorothy Davidson, Greg Ward, Frank Grady, Art Flewelling	
8. Requirement: - see continuation sheet -		
9. Condition Adverse to Quality: - see continuation sheet -		
10. Suggested Actions: Document the RFETS/RMRS review and approval of the <i>Canberra Nuclear NDA Implementation Plan for RFETS Transuranic Waste Characterization Program</i> , SQM011.		
11. Significant Condition Adverse to Quality (Yes or No)?: YES ___ NO <u>X</u>		
12. Applicable Types of Actions: Remedial: <u>✓</u> / Investigative: ___ Root Cause: ___ Actions to Preclude Recurrence: ___		
13. CAR Initiator: <u>Amber Clay</u> <i>Amber Clay</i>		Date: <u>7/18/97</u>
14. Response Due Date: 8/14/97		
15. Concurrence: <u><i>Don Watkins</i></u> <u>7/20/97</u> Affected Team Leader Date	<u><i>Mary E. Cunningham</i></u> <u>7/30/97</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

CAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No:97-084

2. Activity Report No.:A-97-03

Page 2 of 2

Block # 8 (Cont.)

Requirements

CAO - 94-1012, Quality Assurance Program Document, Revision 1, Sections 1.4.2.1, 1.4.2.2 & 1.4.2.3 state in part that: "Documents shall be reviewed for adequacy... prior to approval and issuance... that participants shall identify the individuals or organizations responsible for the preparation, review, approval, and issuance... The organization or technical discipline affected by the document shall review the document according to established review criteria. The cognizant QA organization shall review documents that translate CAO QAPD or QAPP requirements... Controls shall be established and maintained to identify the current status or revision of controlled documents... Changes to documents...shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated in accordance with approved procedures."

DOE/WIPP/CAO - 94-1010, Interim Change, 11/15/96, Section 1.2.3 states in part that: "All quality documents for the Program shall be reviewed prior to approval and issuance by qualified and independent individual... and that whenever the QA documents are revised, review and approval of the revision shall be conducted by the same level of approval."

RFETS QAPjP, Section 2.2 states in part that: "Site compliance to document review, approval and control begins with the RFETS Site QA Manual...and that the *Site Document Requirements Manual*, 1-MAN-001-SDRM, defines the development, review, and approval of site documents."

Sections 2I and 2B of RFETS procedure 1-MAN-001-SDRM state in part that: "...after the document draft review, comment disposition, and concurrence by the reviewing organizations, and before being issued, the document shall be approved by a level of management that has overall responsibility for the task identified in the document... Approval documentation shall be included in the DHF."

Block # 9 (Cont.)

Condition Adverse to Quality

The *Canberra Nuclear NDA Implementation Plan for RFETS Transuranic Waste Characterization Program*, SQM-011, was revised and issued on 6/25/97, however, no objective evidence was available to demonstrate a review and approval by RFETS. Note: A transmittal sheet which acknowledged RFETS receipt of the Canberra Plan was provided, however, this acknowledgment does not constitute review and approval of the document.

CORRECTIVE ACTION REPORT

1. CAR No.: 97-085	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: CAO-94-1012, Quality Assurance Program Document, Revision 1 and 96-RF/T&Q-0005, Training and Qualification Program, Revision 0, 5-NDT-TC-1A, Revision 0, Training, Qualification and Certification of Metrology/Nondestructive Testing Personnel	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: RFETS	7. Discussed With: D. Reinhart, S. Tallman, S. Fischer, L. Williams	
8. Requirement: CAO-94-1012, Section 1.2.2 states: "CAO and participant personnel... shall receive related training... in general criteria, including, applicable QA plans, codes, regulations, and standards... specific criteria, including QAPjPs and implementing procedures... records generated... shall be collected and maintained as QA records."		
9. Condition Adverse to Quality: Training requirements associated with the TWCP project are not properly implemented. The following are examples of training deficiencies:		
10. Suggested Actions:		
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>Sam Vega</u> <i>Mary E. Seemington for</i> Date: <u>7/18/97</u>		
14. Response Due Date: 8/14/97		
15. Concurrence: <u><i>Don W. Fisher</i></u> <u>7/30/97</u> <u><i>Mary E. Seemington for</i></u> <u>7/30/97</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
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader
18. Verification of Corrective Action:		
19. Verified By (Signature): _____		
Verifier	Date	
20. Closure: _____		
Responsible Team Leader	Date	Assurance Team Leader
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader

CAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No:97-085

2. Activity Report No.:A-97-03

Page 2 of 2

Block # 8 (Cont.)

Requirement:

96-RF/T&Q-0005, Section 1, Subsection 3 states: " Within 120 days of... October 1, 1996, each affected company shall develop subordinate (company-specific) procedures for training and services to meet the manual's requirements... During the 120 day development period, affected companies shall adopt the Kaiser-Hill Training Oversight and Integration (K-H TO&I) subordinate procedures..."

Block # 9 (Cont.)

Condition Adverse to Quality:

- 1.) The majority of the companies associated with TWCP activities do not have the required company-specific training procedures in place as required (examples: RMRS, Dyncorp, and Canberra). In most instances, company representatives responsible for training of personnel did not know they were to satisfy K-H OT&I procedures in the interim.
- 2.) 5-NDT-TC-1A, Training, Qualification and Certification of Metrology/Nondestructive Testing Personnel, Revision 0; 4-X07-WP-4716, Qualification, Training, and Indoctrination for WIPP TWCP Project Officers and Managers; and RFQ-TC-1A, Qualification of NDA Personnel, do not designate resultant training records to be QA records, nor do they require them to be maintained as such.
- 3.) TWCP personnel are not all required to be trained in project-specific or site-specific requirements and procedures associated with the TWCP or the work that they perform (some examples: QAPD, QAPP, QAPjP, WAC, or procedures related to QA activities such as NCRs, corrective actions, procedure development, document control, and records management).
- 4.) The CAR Records Coordinator/Custodian does not have documented evidence of completing training required for that position.

CORRECTIVE ACTION REPORT

1. CAR No.: 97-086	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: CAO-94-1012, Quality Assurance Program Document, Revision 1	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: RFETS	7. Discussed With: K. Lenaric, L. Williams	
8. Requirement: Section 1.2.1 states: "Qualification Requirements... Shall be established...the evaluation shall be documented... the responsible organization shall analyze each job position to determine the tasks and responsibilities of the position... personnel selected... shall have education, experience and training commensurate with the minimum requirements."		
9. Condition Adverse to Quality: See continuation sheet.		
10. Suggested Actions: Revise/develop procedures that address the requirements in Section 1.2 of the CAO QAPD. Education, experience, qualification, and certification requirements need to be established and documented for <u>all</u> TWCP associated positions. A review to determine if TWCP personnel meet requirements needs to be performed, and records maintained. RFETS must be able to verify education, experience, qualification and certification status of each TWCP employee.		
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>Sam Vega</u> <i>Mary E. Benington</i> Date: <u>7/18/97</u>		
14. Response Due Date: <u>8/14/97</u>		
15. Concurrence: <u><i>Don U. Jochen</i></u> <u>7/30/97</u> <u><i>Mary E. Benington</i></u> <u>7/30/97</u> <div style="display: flex; justify-content: space-around; width: 100%;"> Affected Team Leader Date for 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: 25%; border-bottom: 1px solid black; text-align: center;">Responsible Team Leader</div> <div style="width: 25%; border-bottom: 1px solid black; text-align: center;">Date</div> <div style="width: 25%; border-bottom: 1px solid black; text-align: center;">Assurance Team Leader</div> <div style="width: 25%; border-bottom: 1px solid black; text-align: center;">Date</div> </div>		
18. Verification of Corrective Action:		
19. Verified By (Signature): _____ <div style="display: flex; justify-content: space-around; width: 100%;"> Verifier Date </div>		
20. Closure: _____ <div style="display: flex; justify-content: space-between; width: 100%;"> <div style="width: 25%; text-align: center;">Responsible Team Leader</div> <div style="width: 25%; text-align: center;">Date</div> <div style="width: 25%; text-align: center;">Assurance Team Leader</div> <div style="width: 25%; text-align: center;">Date</div> </div>		

CA CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No:97-086

2. Activity Report No.:A-97-03

Page 2 of 2

Block # 9

Condition Adverse to Quality:

QAPD qualification/certification requirements are not being properly implemented for TWCP related positions. The following are examples:

1. TWCP Project Data Control Officer does not have sufficient evidence to show that TWCP project officers satisfy the experience and education requirements for their positions as stated in 4-X07-WIP-4716, Revision 0, Qualification, training, and indoctrination for WIPP TWCP Project Officers and Managers. Also, the procedure does not provide the direction to maintain such documentation.
2. Education, experience, training, qualification, and certification requirements have not been established for many TWCP related job positions. Examples include:
 - a. the training procedures and certification/qualification documentation for those performing acceptable knowledge activities were not provided.
 - b. transportation Waste Certification Official (WCO) - Procedure 1-Pro-X05-WC-4018, Revision 0, Transuranic Waste Certification, makes reference to the requirements that the WCO and operators are to be qualified, but does not mention what those qualifications should be. Qualification requirements, could not be determined, but operator certification documentation was located in the Training Records Center.
 - c. the statement: "Employees who perform transportation-related activities shall have completed training as required by the following regulatory agencies: Department of Energy (DOE)..." A specific description of the types and content of training were not provided in procedures: 4-J02-TPO-WO-5030, Revision 0; 4-K14-TPO-WO-5032, Revision 0; 4-H39-TPO-WO-5033, Revision 0; and 4-H81-TPO-WO-5034, Revision 0). This statement is too vague to satisfy QAPD requirements. The Site Training Records Center did contain certification records for the operators included in the sample, but because specific training requirements were not identified in the procedures, the auditor could not determine if they were appropriate for the TWCP activities that the operators supported.
 - d. procedures 4-182-WI-4012, Revision 1, and 4-M63-WI-4013, Revision 1 indicate that the Waste Inspection Technical Lead and the Waste Inspectors are to be qualified, but do not mention what the qualifications should be.

CORRECTIVE ACTION REPORT

1. CAR No.:97-087	2. Activity Report No.:A-97-03	3. Page <u>1</u> of <u>1</u>								
4. Controlling Document: DOE/WIPP/CAO-94-1010, Interim Change, 11/15/96, Quality Assurance Program Plan and RFETS 95-QAPjP - 0050, Revision 1	5. Affected CAO Team Leader: Don Watkins									
6. Responsible Organization: RFETS	7. Discussed With: David Prochnow, Linda Williams									
<p>8. Requirement: DOE/WIPP/CAO-94-1010, Paragraph 1.7 states in part, "An appropriate records inventory and disposition schedule (RIDS) shall be prepared and approved by appropriate site personnel."</p> <p>Rocky Flats Environmental Technology Site TRU Waste Characterization Program Quality Assurance Project Plan, 95-QAPjP - 0050. Revision 1, Paragraph 2.4.1 states in part, "Individuals responsible for project records maintain a records inventory and disposition schedule (RIDS) in accordance with site procedure 1-V41-RM-001. The applicable RIDS reflect the requirements of 1-V41-RM-001 and the WIPP QAPP."</p>										
<p>9. Condition Adverse to Quality: RFETS has no Records Inventory and Disposition Schedule (RIDS). The requirement was removed from 1-V41-RM-001, Revision 0 by the Document Modification Request No. 97-DMR-000545, Effective date 7/30/97.</p>										
<p>10. Suggested Actions: Reinstate the requirement to prepare, approve, and maintain the RIDS.</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: _____</p>										
<p>13. CAR Initiator: <u>Amelia I. Arceo</u> Date: <u>7/18/97</u></p>										
<p>14. Response Due Date: 8/14/97</p>										
<p>15. Concurrence: <u>Don Watkins</u> <u>7/30/97</u> <u>Mary E. Bennett</u> <u>7/30/97</u> 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: none;">_____</td> <td style="width: 15%; border: none;">_____</td> <td style="width: 33%; border: none;">_____</td> <td style="width: 15%; border: none;">_____</td> </tr> <tr> <td style="text-align: center; border: none;">Responsible Team Leader</td> <td style="text-align: center; border: none;">Date</td> <td style="text-align: center; border: none;">Assurance Team Leader</td> <td style="text-align: center; border: none;">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): _____ _____ Verifier Date</p>										
<p>20. Closure: _____ _____ _____ _____ Responsible Team Leader Date Assurance Team Leader Date</p>										

CORRECTIVE ACTION REPORT

1. CAR No.: 97-088	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: CAO-97-1012, Quality Assurance Program Document, Revision 1		5. Affected CAO Team Leader: Don Watkins
6. Responsible Organization: RFETS		7. Discussed With: David Pochnow, Linda Williams
8. Requirement: <p>Paragraph 1.5.2.2 C states in part, "Individuals handling documents intended to become QA records, shall provide reasonable protection for the records from damage or loss until the records are submitted to the records system (this includes documents generated during field operations)." (See Continuation Sheet Page 2)</p>		
9. Condition Adverse to Quality: (See Continuation Sheet Page 2)		
10. Suggested Actions: Since these conditions are pervasive throughout the RFETS, a detailed plan and investigation should be implemented to correct the site-wide deficiencies.		
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>Amelia Arceo</u> <small>Amelia Arceo</small>		Date: <u>7/18/97</u>
14. Response Due Date: 8/14/97		
15. Concurrence: <u>Don Watkins</u> <small>Responsible Team Leader</small>		<u>7/30/97</u> <small>Date</small>
<u>Mary E. Bunnigton</u> <small>for Assurance Team Leader</small>		<u>7/30/97</u> <small>Date</small>
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet		
17. Acceptance of Proposed Corrective Actions:		
Responsible Team Leader _____ <small>Date</small>	Assurance Team Leader _____ <small>Date</small>	
18. Verification of Corrective Action:		
19. Verified By (Signature): _____ <small>Verifier</small>		_____ <small>Date</small>
20. Closure:		
Responsible Team Leader _____ <small>Date</small>	Assurance Team Leader _____ <small>Date</small>	

CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.:97-088

2. Activity Report No.:A-97-03

3. Page 2 of 2

Block # 8

Requirement:

Paragraph 1.5.2.2 E states in part, "Once authenticated, QA records shall be submitted to the records system, as described above, for either permanent or temporary storage. Upon completion of a project or other discrete task or activity, responsible management shall verify that the contents of the applicable QA records package are stored in the records system."

Paragraph 1.5.2.6 B states in part, "The records storage arrangement shall provide for adequate protection of records, including special processed records (such as radiographs,...microfilm,...) To preclude damage from moisture, temperature,...as appropriate for the type of record being stored."

Block # 9

Condition Adverse to Quality:

The following QA records were not provided with reasonable protection from damage or loss until the records are submitted to the records system, not submitted to the records system for either permanent or temporary storage, not temporarily stored at dual facilities nor one-hour fire rated container, or not provided with the necessary protection to preclude damage from moisture and temperature.

- a) Records of auditor qualification and certification were not stored in a fire-rated cabinets nor submitted to Records Management. (Kaiser-Hill, RMRS, DynaCorp).
- b) The L-5000 series procedures' master copies and Document History Files at Building 881 in R. Cichorz office were not stored in a fire-rated cabinet nor submitted to Records Management.
- c) Microfilms (master and duplicates) were stored in the same room (Room 115, Building 881) without temperature and humidity controls. The microfilms were removed from a vault in anticipation for a move to another vault this month; however, the vault is not yet ready and the estimated schedule of completion is August 1997.
- d) Waste Quality Action Reports were not stored in a fire-rated cabinet nor submitted to Records Management.*
- e) Document History Files of Traffic Department Procedures were not stored in a fire-rated cabinet nor submitted to Records Management.*
- f) Document History File for Procedure 1-77000-RM-001 was not submitted to Records Management.**
- g) Not all the training records (e.g., Indoctrination and Visual Examination Cards) were available at the Training Center. In addition, those that were there, were not arranged by individual in records package; hence, the status of training per individual could not be ascertained.
- h) Software Quality Assurance (SQA) documents - the SIN Log, SQA Change Requests, and Test Results were not maintained as QA records.

NOTE:

* These were corrected during the audit by moving the files to fire-rated cabinets.

** This was corrected during the audit by submitting the file to Records Management.

CORRECTIVE ACTION REPORT

1. CAR No.: 97-089	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>2</u>								
4. Controlling Document: CAO - 94-1012, Quality Assurance Program Document, Revision 1, DOE/WIPP/CAO - 94-1010, Interim Change, 11/15/96, RFETS QAPjP, Procedure 1-W36-APR-111 - Acquisition Procedure for Requisitioning Commodities and Services, et. al.,	5. Affected CAO Team Leader: Don Watkins									
6. Responsible Organization: RFETS	7. Discussed With: Dorothy Davidson, Greg Ward, Frank Grady									
8. Requirement: QAPD, Section 1.2.2 B. & C. states in part that: "...personnel are to receive indoctrination in general criteria, including applicable QA plans, codes, regulations... specific criteria, including applicable QAPjPs and implementing procedures... and that records generated during qualification... shall be collected and maintained as QA records." QAPP, Section 1.6 states in part that: "Before performing activities that affect quality, all personnel are required to receive indoctrination into the scope, purpose, and objectives of the program and the specific QAOs of the assigned task " QAPP, Section 9.3.3 states in part that: "Requalification of operators must be based upon evidence of continued satisfactory performance and must be done at least every two years. " Section 4.5 of procedure 1-W36-APR-111 states that Procurement QA (PQA) evaluates supplier QA Programs...										
9. Condition Adverse to Quality: - see continuation page -										
10. Suggested Actions: Revise or amend the RFETS/RMRS contract and SOW to Canberra and pass on all the applicable and specific RFETS implementing procedures as cited in the RFETS QAPD Matrix. SOW should specify which QA Program requirements will be satisfied by or through RFETS procedure(s) or Canberra procedure. Additional suggested actions include the review, evaluation and audit of Canberra's program by the PQA.										
11. Significant Condition Adverse to Quality (Yes or No)?: YES <u>X</u> NO <u> </u>										
12. Applicable Types of Actions: Remedial: <u>✓</u> Investigative: <u>✓</u> Root Cause: <u>✓</u> Actions to Preclude Recurrence: <u>✓</u>										
13. CAR Initiator: <u>Pete V. Rodriguez</u> <i>P.V. Rodriguez</i> Date: <u>7/18/97</u>										
14. Response Due Date: 8/14/97										
15. Concurrence: <u>Don Watkins</u> <i>Don Watkins</i> <u>7/30/97</u> Affected Team Leader Date <u>Mary E. Bennington</u> <i>Mary E. Bennington</i> <u>7/30/97</u> Assurance Team Leader Date										
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet										
17. Acceptance of Proposed Corrective Actions: <table style="width: 100%;"><tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td style="text-align: center;">Responsible Team Leader</td><td style="text-align: center;">Date</td><td style="text-align: center;">Assurance Team Leader</td><td style="text-align: center;">Date</td></tr></table>			_____	_____	_____	_____	Responsible Team Leader	Date	Assurance Team Leader	Date
_____	_____	_____	_____							
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										

CA CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No:97-089

2. Activity Report No.:A-97-03

Page 2 of 2

Block # 9 (Cont.)

(Condition Adverse to Quality)

RFETS procurement documents/procedural requirements as cited in the RFETS QAPD Matrix were not passed on to the subcontractor (Canberra). Procurement documents to the subcontractor, do not define the specific QA program requirements and responsibilities to be performed. Additionally, the subcontractor's program did not meet the requirements of specific QAPP/QAPD and RFETS QA program requirements as follows:

- The RFETS Statement of Work (SOW) for the Mobile NDA services is indistinct with regard as to how Canberra is to satisfy the RFETS implementing procedures as cited in the QAPD matrix (i.e., will Canberra work to RFETS QA and technical procedures, to the Canberra QA procedures, or to both?). The SOW was also noted as inappropriately requiring CAO review and approval of a Canberra developed QAPjP, and a CAO audit of the subcontractor.
- Canberra operators have not been trained to perform site specific activities relative to NCR's, corrective actions, records management, document control, etc.
- Canberra operator training does not include the documentation of objective evidence showing that they have received training or have read operating procedures for the mobile units.
- Individuals acting for the Canberra Project Manager had not received site specific training.
- Canberra Certification Documentation requires recertification every year, but the procedures do not explain how recertification is accomplished.
- Documentation was not available to demonstrate that Procurement QA (PQA) has evaluated the supplier Canberra.

CORRECTIVE ACTION REPORT

1. CAR No.: 97-090	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: 4-F72-WEM-WP1205, Revision 2, WEMS Software Quality Assurance Compliance	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: RFETS	7. Discussed With: Dwan Franks	
8. Requirement: Section 6.3.3, Step 14 requires that the Software Change Record (SCR) Tracking System be updated when the SCR Form is completed.		
9. Condition Adverse to Quality: The SCR Tracking System is not being maintained current with the status of software changes. A review of 6 SCR packages indicated that all of the requested changes were implemented and in production, yet the SCR Tracking System still indicated that 5 out of 6 (SCR 1130, 1141, 1142, 1153, 1155, and 1186) were still in progress. A review of 21 SCRs (SCR 1140-1160) indicated that the changes were approved and the priority status had been assigned, although the Tracking System did not reflect the change status.		
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>S.B. Ailes</u> <u>Mary E. Bennington for</u> Date: <u>7/18/97</u>		
14. Response Due Date: <u>8/14/97</u>		
15. Concurrence: <u>Don Watkins</u> <u>7/30/97</u> <u>Mary E. Bennington for</u> <u>7/30/97</u> Responsible Team Leader Date Assurance Team Leader Date		
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Verifier	Date	Date
20. Closure: _____		
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader

CORRECTIVE ACTION REPORT

1. CAR No.:97-091	2. Activity Report No.:A-97-03	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: 4-F72-WEM-WP1205, Revision 2, WEMS Software Quality Assurance Compliance	5. Affected CAO Team Leader: D. Watkins	
6. Responsible Organization: RFETS	7. Discussed With: Dwan Franks	
8. Requirement: 4-F72-WEM-WP1205, Revision 2, Section 6.3.2, Step 18, requires that a reviewer, independent of the Administration Validator, review the SCR package for completeness, accuracy and clarity.		
9. Condition Adverse to Quality: There is no evidence that the review of SCR package for completeness, accuracy and clarity was performed. A review of 10 out of 20 SCR packages installed in the production environment indicated that the packages were missing some signatures or dates, missing checklist items, and contained incomplete exception packages. In addition, completed documents contained multiple examples of incorrect data corrections (e.g. white-outs and "black-outs").		
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 checked="" type="checkbox"/>		
13. CAR Initiator: <u>S. B. Ailes</u> <i>Mary E. Bennett for</i> Date: <u>7/18/97</u>		
14. Response Due Date: <u>8/14/97</u>		
15. Concurrence: <u><i>Dwan Franks</i></u> <u>7/30/97</u> <u><i>Mary E Bennett for</i></u> <u>7/30/97</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:		
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18. Verification of Corrective Action:		
19. Verified By (Signature): _____		
_____	_____	_____
Verifier	Date	Date
20. Closure: _____		
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader

CORRECTIVE ACTION REPORT

1. CAR No.: 97-092	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>3</u>
4. Controlling Document: CAO-94-1012, Quality Assurance Program Document, Revision 1		5. Affected CAO Team Leader: Don Watkins
6. Responsible Organization: RFETS		7. Discussed With: Art Flewelling, Steve Chestnut
8. Requirement: See continuation sheet.		
9. Condition Adverse to Quality: See continuation sheet.		
10. Suggested Actions: Completely re-develop an effective independent audit program that meets CAO QAPD requirements. This should be done at the site level. Implement the audit program and then audit the effectiveness of implementation.		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <u>X</u> NO <u> </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: <u>Marlin Horseman</u> <i>Mary E. Bennington for</i>		Date: <u>7/18/97</u>
14. Response Due Date: <u>8/14/97</u>		
15. Concurrence: <u><i>Don Watkins</i></u>	<u>7/30/97</u>	<u><i>Mary E. Bennington</i></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:		
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19. Verified By (Signature): _____		
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Verifier	Date	
20. Closure: _____		
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader Date

C O CORRECTIVE ACTION R O RT

(continuation sheet)

1. CAR No.: 97-092

2. Activity Report No.: A-97-03

3. Page 2 of 3

Block # 8

Lead Auditor Certification

The CAO-94-1012, Quality Assurance Program Document, Revision 1, Section 3.2.4.6 requires that lead auditor certification be based upon education, experience, professional competence, and rights of management. Specific points are allocated for various backgrounds and capabilities. In addition, the certification is based upon communication skills, examination results, and five audits in the three years prior to certification, with at least one nuclear audit in the year prior to certification. Also, the lead auditor must maintain proficiency on an annual basis.

Audit Scheduling

The CAO-94-1012, Quality Assurance Program Document, Revision 1, Section 3.2.4.1 requires that an annual evaluation of audit needs (internal and external) to be developed and incorporated into an audit schedule.

Reporting Audit Results

The CAO-94-1012, Quality Assurance Program Document, Revision 1, Section 3.2.4.8 requires that the audit report provide a summary of the details contained on the checklist. Also, the report is to include a statement of the QA program adequacy implementation, and effectiveness, as appropriate to the scope.

Block # 9

Lead Auditor Certification

Site and company-specific procedures and practices do not meet the requirements of the CAO QAPD and RFETS procedures. Examples include:

- A review of five lead auditor certifications revealed:
 - Kaiser-Hill Lead Auditor certification dated 12/20/90 (Form SQA-056, Revision 0) and another on 10/26/94 (same lead auditor) did not meet the QAPD requirements for certification of lead auditors.
 - 10 points were provided for experiences (maximum allowed is 9). Note: The extra point was not needed for certification.
 - Only four of the required five audits in the three years prior to the lead auditor certification were identified on the certification form.
- Note: The lead auditor certification was properly revised and verified. The completion of the five audits was also verified. For this CAR, the remedial actions have been completed.
- Kaiser-Hill lead auditor certification dated 8/7/96 indicated that the lead auditor applicant received four points for education, even though he had a B.S. in marketing (should be two points). Also the experience points were incorrect. Also the audits listed in Section IV of the form do not demonstrate 5 audits in the last three years.
- Other generic cases included incorrect forms and the use of the same audit twice to justify the five audit criteria.
- None of the site nor any of the company specific audit procedures agreed with each other nor did any of them meet the requirements of the QAPD.

CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 97-092

2. Activity Report No.: A-97-03

3. Page 3 of 3

Block # 9 (Cont.)

Audit Scheduling

- The RFETS Integrated Audit Schedule is not being maintained up-to-date. Audits have been canceled (e.g., The audit of the "Log-out/Tag-out in Building 771) and the schedule not updated nor a rationale provided. Numerous entries were incorrect.

Note: RFETS is about to issue site procedure 1-W37-IA-002, Revision 0, which may help to bring this process into compliance with requirements, provided that a uniform implementation is achieved.
- The required annual evaluation for RFETS audit activities is not being performed in accordance with QAPD requirements.

Reporting Audit Results

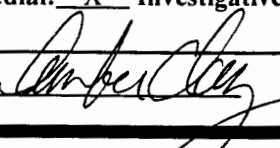
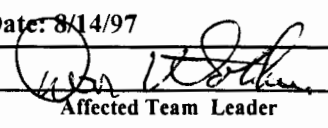
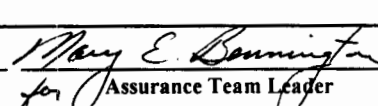
Based upon a review of five audit reports at the various organizations, the following deficiencies were noted:

- The audit results do not have a statement of adequacy, implementation, nor effectiveness.
- Some audit reports do not address the audit scope nor the audit plan.
- In general, deficiencies are not being documented as findings. Some are identified as concerns, but do not require rigorous correction.
- Some reports identify conditions adverse to quality and ask (within the report) "Is this OK?"
- Some reports are based on checklists where the objective evidence has not been recorded nor the results of the evaluation of an area indicated.

CORRECTIVE ACTION REPORT

1. CAR No.: 97-093	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>1</u>								
4. Controlling Document: CAO-94-1012, Quality Assurance Program Document, Revision 1	5. Affected CAO Team Leader: Don Watkins									
6. Responsible Organization: RFETS	7. Discussed With: Charlie Turner, Art Flewelling, Jim Valenzuela									
<p>8. Requirement: The RFETS QAPjP refers to procedures 1-A65-ADM-15.01, Control Nonconforming Items, and U76-WC-4030, Control of Waste Nonconformances, as procedures used to complete tracking of nonconformances. Procedure 1-A-65-ADM-15.01 states in Section 1.0 that "this procedure does not specify details for tracking and trending of nonconforming items and does not address nonconforming programs, services or processes. Site deficiency tracking and trending and control of nonconforming program...are governed by 1-E93-ADM-16.18, Performance Indication and Trend Analysis."</p>										
<p>9. Condition Adverse to Quality: Contrary to the requirements, procedure 1-E93-ADM-11.18 is not being implemented for nonconformances issued for the RFETS TWCP analytical laboratory activities and the Waste Certification and Oversight group (WCO). The current trending performed for TRU waste nonconformances by the WCO group is based on the type of nonconformance issued and not the cause of the nonconforming condition.</p>										
<p>10. Suggested Actions: Develop a procedure for the TWCP specific activities at RFETS, so that participating organizations can provide adequate and relevant information to the PQA for trending.</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 checked="" type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/></p>										
<p>13. CAR Initiator: <u>Beth Bennington</u> <i>Mary E. Bennington</i> Date: <u>7/18/97</u></p>										
<p>14. Response Due Date: <u>8/14/97</u></p>										
<p>15. Concurrence: <u><i>Don Watkins</i></u> <u>7/30/97</u> <u><i>Mary E. Bennington</i></u> <u>7/30/97</u> Responsible Team Leader Date for Assurance Team Leader Date</p>										
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Responsible Team Leader	Date	Assurance Team Leader	Date							
<p>18. Verification of Corrective Action:</p>										
<p>19. Verified By (Signature): _____ _____ Verifier Date</p>										
<p>20. Closure: _____ _____ _____ _____ Responsible Team Leader Date Assurance Team Leader Date</p>										

CORRECTIVE ACTION REPORT

1. CAR No.: 97-094	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: CAO-94-1045, Revision 0, PDP Plan for NDA	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: RFETS	7. Discussed With: Dorothy Davidson, Greg Ward, Frank Grady, Art Flewelling	
<p>8. Requirement: Sections 7.1.2 through 7.1.5, and 5.2.1 through 5.2.3 state in part that: On initial receipt the Assay Coordinator will inspect the condition of the drum seals by checking the tamper-indicating devices (TIDs) on each Performance Demonstration Program (PDP) sample ... that the Assay Coordinator shall confirm the accuracy of each Custody Form... that the Assay Coordinator will review, sign, and date each form... that the Sample Preparation Team (SPT) will pull two copies of each Custody Form...and that all subsequent transfers of the drums within the measurement group (interpreted as RFETS/RMRS and Canberra) and ultimate return of the drums to the SPT will be documented on the PDP Sample Custody Form accompanying the drum.</p> <p>Immediately on receipt of PDP standards matrix drums, the SPT will locate the shipping manifest...The SPT will verify that the standards and matrix drums actually received match those listed on the shipping manifest... and if required, the SPT will return the signed shipping manifest to the designated addressee.</p>		
9. Condition Adverse to Quality: NDA PDP Sample Acceptance/Chain of Custody process was not followed when the NDA PDP Drums were transferred from RMRS to Canberra. It was also noted that the SPT does not sign & return the shipping manifest to the Program Coordinator as required.		
10. Suggested Actions: Develop a new or revised implementing procedure that includes the necessary provisions and requirements for the transfer and interface between RFETS/RMRS and Canberra.		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <u>X</u> NO <u> </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: <u>Amber Clay</u> 		Date: <u>7/18/97</u>
14. Response Due Date: <u>8/14/97</u>		
15. Concurrence:  <u>7/20/97</u>		 <u>7/30/97</u>
Affected Team Leader		Date for Assurance Team Leader
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet		
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Verifier	Date	
20. Closure: _____		
Responsible Team Leader	Date	Assurance Team Leader
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Responsible Team Leader	Date	Assurance Team Leader

CORRECTIVE ACTION REPORT

1. CAR No.: 97-095	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>1</u>								
4. Controlling Document: DOE/WIPP/CAO - 94-1010, Interim Change, 11/15/96	5. Affected CAO Team Leader: Don Watkins									
6. Responsible Organization: RFETS	7. Discussed With: Pam Edrich									
<p>8. Requirement: Section 4.2.1 states: "If a toxicity characteristic contaminant is identified and is not recorded as a listed waste, assign the toxicity characteristic EPA hazardous waste number. Unless data is available from the sampling and analysis of a representative sample of the waste stream that demonstrates that the concentration of the constituent in the waste is less than the toxicity characteristic regulatory level, no judgement may be made regarding the concentration of the constituent. 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."</p>										
<p>9. Condition Adverse to Quality: RFETS personnel, in generating Acceptable Knowledge, utilize a form titled "Underlying Hazardous Constituents Worksheet". This sheet lists hazardous constituents that are reasonably expected to be present in the waste stream. In the review of the waste process, it was discovered that RFETS personnel are not assigning EPA codes consistent with this worksheet and do not have analytical data to support the exclusion.</p>										
<p>10. Suggested Actions:</p> <p>1) Assign codes consistent with the requirements of the QAPP.</p> <p>2) Review the basis for including constituents on the underlying Hazardous Constituents Worksheet and revise as appropriate.</p>										
<p>11. Significant Condition Adverse to Quality (Yes or No)?: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p>										
<p>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"/></p>										
<p>13. CAR Initiator: <u>R. V. Bynum</u> <u>Mary E. Bennington for</u> Date: <u>7/18/97</u></p>										
<p>14. Response Due Date: <u>8/14/97</u></p>										
<p>15. Concurrence:</p> <table style="width: 100%; border: none;"> <tr> <td style="text-align: center; width: 33%;"><u>Don Watkins</u></td> <td style="text-align: center; width: 15%;"><u>7/24/97</u></td> <td style="text-align: center; width: 33%;"><u>Mary E. Bennington</u></td> <td style="text-align: center; width: 15%;"><u>7/30/97</u></td> </tr> <tr> <td style="text-align: center;">Responsible Team Leader</td> <td style="text-align: center;">Date</td> <td style="text-align: center;">Assurance Team Leader</td> <td style="text-align: center;">Date</td> </tr> </table>			<u>Don Watkins</u>	<u>7/24/97</u>	<u>Mary E. Bennington</u>	<u>7/30/97</u>	Responsible Team Leader	Date	Assurance Team Leader	Date
<u>Don Watkins</u>	<u>7/24/97</u>	<u>Mary E. Bennington</u>	<u>7/30/97</u>							
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<p>20. Closure:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 25%; border-top: 1px solid black;">Responsible Team Leader</td> <td style="width: 25%; border-top: 1px solid black;">Date</td> <td style="width: 25%; border-top: 1px solid black;">Assurance Team Leader</td> <td style="width: 25%; border-top: 1px solid black;">Date</td> </tr> </table>			Responsible Team Leader	Date	Assurance Team Leader	Date				
Responsible Team Leader	Date	Assurance Team Leader	Date							

CORRECTIVE ACTION REPORT

1. CAR No.:97-096	2. Activity Report No.:A-97-03	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: Quality Assurance Program Plan DOE/WIPP/CAO-94-1010, Interim Change, 11/15/96, and RFETS QAPjP and Procedure 4-H19-WSRIC-001, Revision 0, WSRIC Field Verification	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: RFETS	7. Discussed With: Jim Schoen and Pam Edrich	
8. Requirement: Procedure 4-H19-WSRIC-001, provides instructions for gathering and preparing the information required to create and update the WSRIC Building Books, which are a major component of the RFETS Acceptable Knowledge (AK) activities.		
9. Condition Adverse to Quality: The procedure is not being properly implemented and is not reflective of current practice. The procedure is missing steps, missing necessary forms, lacks references to other inter-related procedures, and does not specify required approvals of the results from execution of the procedure.		
10. Suggested Actions: Revise the procedure to accurately reflect current practice and requirements. Incorporate all necessary forms and specify required approvals.		
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 checked="" type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>R. V. Bynum</u> <i>Mary E. Baumigter for</i> Date: <u>7/18/97</u>		
14. Response Due Date: 8/14/97		
15. Concurrence: <u><i>Don W. Watkins</i></u> <u>7/31/97</u> <u><i>Mary E. Baumigter for</i></u> <u>7/30/97</u> Responsible Team Leader Date Assurance Team Leader Date		
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet		
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Responsible Team Leader	Date	Assurance Team Leader

CORRECTIVE ACTION REPORT

1. CAR No.: 97-097	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: DOE/WIPP/CAO - 94-1010, Interim Change, 11/15/96	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: RFETS	7. Discussed With: Bill Simmons, Greg Ward, Frank Grady	
<p>8. Requirement: Section 7.0 requires that standard gases be traceable to the manufacture's certification.</p> <p>Section 7.2.1 states in part that cylinders of field reference standard gases must be certified by the manufacturer to contain known analytes at known concentrations.</p>		
<p>9. Condition Adverse to Quality: Field reference gas cylinders could not be traced to the manufacturer's certification records for one gas cylinder. This was an aluminum cylinder marked with analytical results and a RFETS bar code. The cylinder is stored in the MS lab.</p>		
<p>10. Suggested Actions: Establish traceability of gas cylinder if possible and submit documented objective evidence along with the response and investigative action(s) statement to this CAR. If traceability can not be established, determine the impact and the disposition of previous headspace gas sampling that utilized the subject gas cylinder.</p> <p>NOTE: If the investigative actions can not determine that the QAO's described in section 7.0 of the QAPP and QAPjP have been met, a nonconformance report must be prepared and resolved.</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: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input checked="" type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/></p>		
<p>13. CAR Initiator: <u>Mark Doherty</u> Date: <u>7/18/97</u></p>		
<p>14. Response Due Date: <u>8/14/97</u></p>		
<p>15. Concurrence: <u></u> <u>7/30/97</u> <u></u> <u>7/30/97</u> Affected 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> <p style="text-align: center;">_____</p> <p style="text-align: center;">Responsible Team Leader Date Assurance Team Leader Date</p>		
<p>18. Verification of Corrective Action:</p>		
<p>19. Verified By (Signature): _____ Verifier Date</p>		
<p>20. Closure: _____ Responsible Team Leader Date Assurance Team Leader Date</p>		

CORRECTIVE ACTION REPORT

1. CAR No.: 97-098	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: DOE/WIPP/CAO - 94-1010, Interim Change, 11/15/96	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: RFETS	7. Discussed With: Dorothy Davidson, Greg Ward, Frank Grady	
8. Requirement: Section 9.5 states that "Each site must determine and document the range of waste types to which it will apply any given calibration and set of correction factors."		
9. Condition Adverse to Quality: At the time of the audit, RMRS/Canberra had not clearly documented the range of waste types that the passive neutron and IQ-3 gamma systems were intended to measure.		
10. Suggested Actions: RMRS/Canberra should clearly document the range of waste types (or waste properties) that each instrument can validly assay. This should include the permitted range of plutonium mass values for each instrument.		
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>Kenneth Coop</u> <i>Mary E. Bennington for</i> Date: <u>7/18/97</u>		
14. Response Due Date: <u>8/14/97</u>		
15. Concurrence: <u><i>Don Watkins</i></u> <u>7/30/97</u> <u><i>Mary E. Bennington</i></u> <u>7/30/97</u> Affected Team Leader Date Assurance Team Leader Date		
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet		
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CORRECTIVE ACTION REPORT

1. CAR No.: 97-099	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>1</u>								
4. Controlling Document: DOE/WIPP/CAO - 94-1010, Interim Change, 11/15/96	5. Affected CAO Team Leader: Don Watkins									
6. Responsible Organization: RFETS	7. Discussed With: Dorothy Davidson, Greg Ward, Frank Grady									
8. Requirement: Section 9.5 states in part that: "Primary calibration standards shall be obtained from NIST, the New Brunswick Laboratory, or from suppliers maintaining measurement systems traceable to NIST, whenever such standards are available. When standards are not available from such suppliers, the actual standards used shall be calibrated against primary standards obtained from NIST or from suppliers maintaining measurement systems traceable to NIST. The documentation of this cross-calibration shall be retained as a QA record."										
9. Condition Adverse to Quality: Calibration certifications, traceable to NIST, were not available. The Canberra mobile WM3100 Drum Assay System (WDAS) was calibrated at Los Alamos National Laboratories (LANL) using plutonium sources fabricated by LANL. LANL has written a letter stating that these calibration sources are traceable to NIST; however, LANL has yet to issue certifications for these standards, which provide the necessary traceability for the standards used. Note: The calibration certifications were requested during the audit by Canberra/RMRS, and LANL has promised to send them.										
10. Suggested Actions: Obtain calibration certifications from LANL that provide the necessary cross-calibration information and NIST traceability, for the standards used in the calibration of the Canberra mobile Waste Drum Assay System.										
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"/>										
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17. Acceptance of Proposed Corrective Actions: <table style="width: 100%; border: none;"> <tr> <td style="width: 33%; border: none;">_____</td> <td style="width: 16%; border: none;">_____</td> <td style="width: 33%; border: none;">_____</td> <td style="width: 18%; border: none;">_____</td> </tr> <tr> <td style="text-align: center; border: none;">Responsible Team Leader</td> <td style="text-align: center; border: none;">Date</td> <td style="text-align: center; border: none;">Assurance Team Leader</td> <td style="text-align: center; border: none;">Date</td> </tr> </table>			_____	_____	_____	_____	Responsible Team Leader	Date	Assurance Team Leader	Date
_____	_____	_____	_____							
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.: 97-100	2. Activity Report No.: A-97-03	3. Page <u>1</u> of <u>1</u>
4. Controlling Document: DOE/WIPP/CAO - 94-1010, Interim Change, 11/15/96, RFETS QAPjP, Procedure L-4111-I	5. Affected CAO Team Leader: Don Watkins	
6. Responsible Organization: RFETS	7. Discussed With: John Jennings, Bill Simmons, San Goade, Greg Ward, Frank Grady	
<p>8. Requirement: The QAPP and QAPjP, Sections 3.1 through 3.1.1, state in part that: Data validation confirms that the data reported satisfy the requirements defined by the user and is accompanied by signature release... that individuals conducting this data review, validation, and verification must use checklists that address all of the items included in this section...that One-hundred percent of the data must receive independent technical review, and technical supervisory and QA officer review, and signature release. Section 12.6 of the QAPjP also specifies the information that is required on the analysis form. Section 10.6 of the QAPP states that each radiography facility is required to submit testing batch data report for each testing batch to the site project office on approved standard forms.</p>		
<p>9. Condition Adverse to Quality: The checklist required for Level 1 data validation and verification have not been prepared for H₂CH₄, VOC, and RTR. The VOC analysis form must also include the date sampled and the method number. RTR testing batch reports have not been completed. The RTR and lab procedures need to be revised to include the checklists. RTR procedures need to address testing batch data reports.</p>		
<p>10. Suggested Actions: Individuals conducting this review must: 1) Use checklists that address all of the items in section 3.1.1 of the QAPP. 2) Perform and document the required Level 1 data validation and verifications. 3) Revise the VOC analysis form to include the date sampled and the method number. 4) Revise the RTR and lab procedures to include the checklists. 5) Revise the RTR procedures to address testing batch data reports.</p>		
<p>11. Significant Condition Adverse to Quality (Yes or No)?: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p>		
<p>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"/></p>		
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