



United States Government

Department of Energy

memorandum

Carlsbad Field Office
Carlsbad, New Mexico 88221



DATE: February 20, 2002
 REPLY TO
 ATTN OF: CBFO:QA:MLC:GS:02-0672:UFC 2300.00
 SUBJECT: Issuance of Corrective Action Reports Initiated During Audit A-02-07
 to: John Schneider, Assistant Manager for Environment and Compliance

The Carlsbad Field Office (CBFO) performed Audit A-02-07 of the Rocky Flats Environmental Technology Site (RFETS) on February 4-8, 2002. CBFO Corrective Action Reports (CARs) 02-044 through 02-052 are attached.

Please document on the attached CAR continuation sheets your proposed corrective actions and a schedule for completion and forward to me prior to the response due date identified in CAR block 14. The corrective actions for the CARs requiring accelerated corrective action must be completed within thirty days of the receipt of this memorandum.

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

/Signature on File/
 Ava L. Holland
 Quality Assurance Manager

Attachments

- cc w/attachments:
- L. Chism, CBFO
- M. Gerle, WTS
- J. Schuetz, CTAC
- R. Knerr, CBFO *ED
- K. Watson, CBFO *ED
- J. Jefferies, RFFO *ED
- C. Ferrera, RFETS *ED
- J. O'Leary, RFETS *ED
- R. A. Eschenbaum, RFETS *ED
- M. Eagle, EPA *ED
- S. Monroe, EPA *ED
- E. Feltcorn, EPA *ED
- S. Zappe, NMED *ED
- B. Walker, EEG *ED
- D. Winters, DNFSB *ED
- A. Pangle, CTAC *ED
- CBFO Mailroom

020230



CORRECTIVE ACTION REPORT

1. CAR No.: 02-044	2. Activity Report No.: A-02-07	3. Page <u>1</u> of
4. Controlling Document: EPA Method SW-846	5. CBFO Assessment Team Leader: Ava Holland	
6. Responsible Organization: RFETS Radiological Laboratories	7. CAQ Was Discussed With: M. Harris, D. Guthrie	
8. Requirement that was violated: U.S. EPA Reference SW-846, "Test Methods for Evaluating Solid Waste," Method 8000B, Section 7.4.2.2, Internal standard calibration procedures, 3 rd paragraph, requires the analyst to demonstrate that "the measurement of the internal standard is not affected by method analytes and surrogates, or by the matrix interferences".		
9. Condition Adverse to Quality: At present, only retention time (RT) and area of the Internal Standard (IS), in the daily calibration standard, are reported on Form 8B of the data package. This does not address the requirement to demonstrate that the measurement of the internal standard is not affected by sample matrix.		
10. Suggested Actions (Optional):		
11a. Significant CAQ	(Yes or No): Yes	
11b. Work Suspension Recommended	(Yes or No): No	
11c. RCRA-Related	(Yes or No): Yes	
11d. Accelerated Corrective Action Required	(Yes or No): Yes	
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input checked="" type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>Dorothy Gill / Porf Martinez</u> Date: <u>02/08/02</u>		
14. Response Due Date: <u>3/4/02</u> Corrective Action Plan Required: YES Required Corrective Action Completion Date: <u>03/25/02</u>		
15. a. Concurrence: <u>A. L. Holland</u> <u>02/23/02</u>	b. <u>N/A</u> <u>N/A</u>	Responsible Assistant Manager Date
Assessment Team Leader	Date	Date
c. <u>A. L. Holland</u> <u>02/23/02</u>	Quality Assurance Manager Date	
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:		
_____	_____	_____
Assessment Team Leader	Date	Date
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____	_____	_____
Name	Date	Date
19b. Trend Cause Code: _____		
20. Closure: _____		
Quality Assurance Manager		Date

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

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

CORRECTIVE ACTION REPORT

1. CAR No.: 02-045	2. Activity Report No.: A-02-07	3. Page <u>1</u> of
4. Controlling Document: L-4006-J, Chain-Of-Custody And Sample Administration For Headspace Sample Canisters, WIPP WAP, Section B1-1(b) & Table B1-1	5. CBFO Assessment Team Leader: Ava Holland	
6. Responsible Organization: : RFETS Radiological Laboratories	7. CAQ Was Discussed With: Charles Turner	
8. Requirement that was violated: (See Continuation Sheet)		
9. Condition Adverse to Quality: (See Continuation Sheet)		
10. Suggested Actions (Optional): 		
11a. Significant CAQ	(Yes or No): Yes	
11b. Work Suspension Recommended	(Yes or No): No	
11c. RCRA-Related	(Yes or No): Yes	
11d. Accelerated Corrective Action Required	(Yes or No): Yes	
12. Types of Actions: Remedial: <u> X </u> Investigative: <u> X </u> Root Cause: <u> X </u> Actions to Preclude Recurrence: <u> X </u>		
13. CAR Initiator: <u> John Gray/B J Verret </u> Date: <u> 02/12/02 </u>		
14. Response Due Date: <u> 3/4/02 </u> Corrective Action Plan Required: YES Required Corrective Action Completion Date: <u> 03/25/02 </u>		
15. a. Concurrence: <u> A. L. Holland </u> <u> 02/23/02 </u>	b. <u> N/A </u> <u> N/A </u>	Assessment Team Leader Date Responsible Assistant Manager Date
c. <u> A. L. Holland </u> <u> 02/23/02 </u>	Quality Assurance Manager Date	
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions: _____ Assessment Team Leader _____ Date		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ Name _____ Date		
19b. Trend Cause Code: _____		
20. Closure: _____ Quality Assurance Manager _____ Date		

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 02-045	2. Activity No.: A-02-07	3. Page <u>2</u> of <u> </u>
<p>Block # <u>8</u></p> <ul style="list-style-type: none">a) L-4006-J-7, Section 3.6, requires that each sample be assigned a unique fourteen-digit WIPP sample identification number in a specified format on the Sample Canister Information Document (SCID).b) L4006-J-11, Section 4.2.1.5, requires that the sample logbook information for canister sampling carts includes: sampling data, sampling time, Drum number, sample tag number, canister number, sample type, Gelman results, volume removed, sampler's initials, Batch number, RF number for pressure gauge, RF number for vacuum gauge, RF number for temperature sensor, PID span readings, and comments.c) WIPP WAP Section B1-1b states in part "Holding temperatures and container requirements for gas sample containers are contained in Table B1-1." <p>Block # <u>9</u></p> <ul style="list-style-type: none">a) A Sample Canister Information Document (page 276 of Field Sample Information, pages 266 through 305, of Batch Data Report HVOC-DP-00556) was missing the "BB" designation, rendering the field sample number out of compliance with the required format for canister B237.b) Sample Logbooks for canister HSG Sampling Carts #3 and #4 had recent entries where sampler initials were missing and pressure gauge, vacuum gauge, and/or temperature sensor RF numbers were inconsistent (some listed two of the three RF numbers, one listed one out of three RF numbers). Logbook pages involved were: Cart #3, pages 106 through 129, and Cart #4 pages 104 through 119.c) Data packages for Canister HSG Sampling and Analysis, HVOC-DP-00556 and HVOC-DP-00559, contained copies of temperature recorder charts for the sample storage area in Building 561. These charts are not labeled with the chart recorder information allowing direct traceability to the calibrated sample storage temperature recorder from which they originated. This does not allow for verification of sample storage conditions of 0° – 40° C as required by the WIPP WAP, Section B1-1(b) and Table B1-1.		

CORRECTIVE ACTION REPORT

1. CAR No.: 02-046	2. Activity Report No.: A-02-07	3. Page <u>1</u> of
4. Controlling Document: L-4215-D, L-4165-L, WAP Attachment B3	5. CBFO Assessment Team Leader: Ava Holland	
6. Responsible Organization: RFETS Radiological Laboratories	7. CAQ Was Discussed With: M. Harris, D. Guthrie	
8. Requirement that was violated: See Continuation Sheet		
9. Condition Adverse to Quality: See Continuation Sheet		
10. Suggested Actions (Optional):		
11a. Significant CAQ	(Yes or No): Yes	
11b. Work Suspension Recommended	(Yes or No): No	
11c. RCRA-Related	(Yes or No): Yes	
11d. Accelerated Corrective Action Required	(Yes or No): Yes	
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input checked="" type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>Dorothy Gill / Porf Martinez</u> Date: <u>02/08/02</u>		
14. Response Due Date: <u>3/4/02</u> Corrective Action Plan Required: YES Required Corrective Action Completion Date: <u>03/25/02</u>		
15. a. Concurrence: <u>A. L. Holland</u> Assessment Team Leader	<u>02/23/02</u> Date	b. <u>N/A</u> Responsible Assistant Manager <u>N/A</u> Date
c. <u>A. L. Holland</u> Quality Assurance Manager	<u>02/23/02</u> Date	
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions: _____ Date _____ Assessment Team Leader		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ Name	_____ Date	
19b. Trend Cause Code: _____		
20. Closure: _____ Date _____ Quality Assurance Manager		

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 02-046

2. Activity No.: A-02-07

3. Page 2 of

Block # 8. Requirement that was violated:

The acceptance criteria for LCS recovery found in Table 3 of procedure L-4215-D are different to those required by WAP Table B3-6.

WAP, B3-1. In accordance with SW-846 convention, identification of compounds detected by gas chromatography/mass spectrometry methods that are not on the list of target analytes shall be reported. Both composited and individual container headspace gas, volatile Analysis (TCLP/Totals), and semi-volatile (TCLP/Totals) shall be subject to tentatively identified compound (TIC) reporting. These TICs for GC/MS Methods are identified in accordance with the following SW-846 criteria:

- Relative intensities of major ions in the reference spectrum (ions greater than 10% of the most abundant ion) should be present in the sample spectrum.
- The relative intensities of the major ions should agree within ± 20 percent.
- Molecular ions present in the reference spectrum should be present in the sample spectrum.
- Ions present in the sample spectrum but not in the reference spectrum should be reviewed for possible background contamination or presence of coeluting compounds.
- Ions present in the reference spectrum but not in the sample spectrum should be reviewed for possible subtraction from the sample spectrum because of background contamination or coeluting peaks.
- The reference spectra used for identifying TICs shall include, at minimum, all of the available spectra for compounds that appear in the 20.4.1.200 NMAC (incorporating 40 CFR Part 261) Appendix VIII list.

SW-846, Method 8270C, section 7.6.2 and Method 8260B, section 7.6.2

Block # 9. Condition Adverse to Quality:

L-4215-D, Table 3 of the procedure provides acceptance limits of 80-120%R for LCS, which are not in accordance with Table B3-6 of the WAP.

L-4215-D does not describe the criteria used for identification of TICs, hence compliance to WAP section B3-1 requirements could not be demonstrated.

It is not possible to determine from the text of procedure L-4165-L if the TIC criteria, provided in Section 5.3.6.3, comply with WAP requirements (WAP Section B3-1).

CORRECTIVE ACTION REPORT

1. CAR No.: 02-047	2. Activity Report No.: A-02-07	3. Page <u>1</u> of
4. Controlling Document: L-4214-E , L-4215-D, L-4165-L, L-4151-J, EPA Method SW-846	5. CBFO Assessment Team Leader: Ava Holland	
6. Responsible Organization: RFETS Radiological Laboratories	7. CAQ Was Discussed With: M. Harris, Y. Mazza, D. Guthrie, P. Castillo, P. Womble	
8. Requirement that was violated: See Continuation Sheet		
9. Condition Adverse to Quality: See Continuation Sheet		
10. Suggested Actions (Optional):		
11a. Significant CAQ	(Yes or No): Yes	
11b. Work Suspension Recommended	(Yes or No): No	
11c. RCRA-Related	(Yes or No): Yes	
11d. Accelerated Corrective Action Required	(Yes or No): Yes	
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input checked="" type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>Dorothy Gill / Porf Martinez</u> Date: <u>February 8, 2002</u>		
14. Response Due Date: <u>3/4/02</u> Corrective Action Plan Required: YES Required Corrective Action Completion Date: <u>03/25/02</u>		
15. a. Concurrence: <u>A. L. Holland</u> Assessment Team Leader	<u>02/23/02</u> Date	b. <u>N/A</u> Responsible Assistant Manager
c. <u>A. L. Holland</u> Quality Assurance Manager	<u>02/23/02</u> Date	<u>N/A</u> Date
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions: _____ _____ Assessment Team Leader Date		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ Name	_____ Date	
19b. Trend Cause Code: _____		
20. Closure: _____ Quality Assurance Manager		
		_____ Date

CBO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 02-047

2. Activity No.: A-02-07

3. Page 2 of

Block # 8 Requirement that was violated:

L-4214-E, Section 4.2.1 "Purchase certified stock standard solutions commercially. Replace a stock standard on or before its expiration date, or sooner if comparison with quality control check samples indicate a problem."

L-4214-E, Section 8.1, "All data are to be recorded in black ink, directly in the *Semivolatiles Standards Preparation Logbook* or *WIPP Total SVOCs Sample Preparation Logbook*."

L-4215-D, Section 4.2.1 "Purchase certified stock standard solutions commercially. Replace a stock standard on or before its expiration date, or sooner if comparison with quality control check samples indicate a problem."

L-4165-L, Section 4.1.1.1 "Certified Standards utilized in this procedure are purchased from commercial vendors. These certified stock standards are stored in the original sealed ampule at or below -10 degrees C. This standards are disposed of when the vendor's expiration date is past."

U.S. EPA Reference SW-846, "Test Methods for Evaluating Solid Waste," Method 7000A, Section 8.2

Block # 9 Condition Adverse to Quality:

No record of Surrogate Spiking Solution, Lot # 120301, was found in the Standards Preparation Logbook, although it was available for use in a glove box.

Stock standards B0110212 (expiration date 11/14/01), and B0120271 (expiration date 12/19/01), were stored with current, unexpired standards. Dilutions from these stock standards were considered valid until April, 2002, after the stock standard expiration dates.

Dilutions from volatiles stock standard "Alcohol MSE", expiration date 7/31/01, were made on 7/13/01, and valid until 10/11/01, after the stock standard expiration date.

Initial Calibration (ICAL) and Initial Calibration Verification (ICV) standards for Selenium calibrations, dated 1/9/02 and 1/11/02, were made from the same stock standard.

CORRECTIVE ACTION REPORT

1. CAR No.: 02-048	2. Activity Report No.: A-02-07	3. Page <u>1</u> of
4. Controlling Document: DOE/WIPP 93-1001, Rev. 4.5	5. CBFO Assessment Team Leader: Ava Holland	
6. Responsible Organization: RFETS	7. CAQ Was Discussed With: Leslie Lewis	
<p>8. Requirement that was violated: DOE/WIPP 93-1001, Revision 4.5, <i>TRUPACT-II Operating and Maintenance Instructions</i>, Section 2.4, states in part: "All components will be furnished by the WID National TRU Programs to user sites. The parts package will be labeled with part number, description, WIPP purchase order number, and shelf-life expiration, if applicable."</p>		
<p>9. Condition Adverse to Quality: RFETS split the parts located in the Building 664 loading facility to obtain spare parts for the new Building 440 loading facility. The following part numbers in Building 440 TRUPACT-II parts cabinet do not have a purchase order number on the package:</p> <ul style="list-style-type: none"> - Part number 2077-160-28 - Part number 2077-180-06 - Part number 2077-180-10 - Part number 2077-180-25 - Part number 2077-180-20 - Part number 2077-180-23 <p>Tracibility to the purchase order has not been maintained as a result of the repackaging of the parts listed above.</p>		
10. Suggested Actions (Optional):		
11a. Significant CAQ	(Yes or No): Yes	
11b. Work Suspension Recommended	(Yes or No): No	
11c. RCRA-Related	(Yes or No): No	
11d. Accelerated Corrective Action Required	(Yes or No): No	
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input checked="" type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>L. Dee Scott</u> Date: <u>February 8, 2002</u>		
14. Response Due Date: <u>03/04/02</u> Corrective Action Plan Required: YES Required Corrective Action Completion Date: <u>N/A</u>		
15. a. Concurrence: <u>A. L. Holland</u> <u>02/23/02</u>	b. <u>N/A</u> <u>N/A</u>	
Assessment Team Leader	Date	Responsible Assistant Manager Date
c. <u>A. L. Holland</u> <u>02/23/02</u>		
Quality Assurance Manager	Date	
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:		
_____	_____	
Assessment Team Leader	Date	
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____		
Name	Date	
19b. Trend Cause Code: _____		
20. Closure: _____		
Quality Assurance Manager	Date	

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.:	2. Activity No.:	3. Page ___ of ___
<p>Block #_</p>		

CORRECTIVE ACTION REPORT

1. CAR No.: 02-049	2. Activity Report No.: A-02-07	3. Page <u>1</u> of																
4. Controlling Document: CAO-94-1012, Quality Assurance Program Document; PRO-077-WIPP-005, Management of Waste Information Prior to Transmittal to the Waste Records Center		5. CBFO Assessment Team Leader: Ava Holland																
6. Responsible Organization: : RFETS		7. CAQ Was Discussed With: Mike Wolfe, John Tressell, and Doyle Gillespie																
8. Requirement that was violated: CBFO QAPD section 1.5.2.2.B states in part "QA Records are legible, accurate, and completed appropriate to the work accomplished." PRO-077-WIPP-005, section 4.2 states in part "ensures that records prepared and received are ... completed appropriate to the work accomplished..."																		
9. Condition Adverse to Quality: Record packages for PATS 2001-000087, PATS 2001-000101, and PATS 2001-000664 have (17) specific instances of entries missing and/or not completed on the "PATS Identification Form – CAP Appendix 2" and the "Status Revision/Completion Form."																		
10. Suggested Actions (Optional):																		
<table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">11a. Significant CAQ</td> <td>(Yes or No): No</td> </tr> <tr> <td>11b. Work Suspension Recommended</td> <td>(Yes or No): No</td> </tr> <tr> <td>11c. RCRA-Related</td> <td>(Yes or No): No</td> </tr> <tr> <td>11d. Accelerated Corrective Action Required</td> <td>(Yes or No): No</td> </tr> </table>			11a. Significant CAQ	(Yes or No): No	11b. Work Suspension Recommended	(Yes or No): No	11c. RCRA-Related	(Yes or No): No	11d. Accelerated Corrective Action Required	(Yes or No): No								
11a. Significant CAQ	(Yes or No): No																	
11b. Work Suspension Recommended	(Yes or No): No																	
11c. RCRA-Related	(Yes or No): No																	
11d. Accelerated Corrective Action Required	(Yes or No): 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>Jack Walsh</u> Date: <u>02/08/02</u>																		
14. Response Due Date: <u>3/4/02</u> Corrective Action Plan Required: NO Required Corrective Action Completion Date: <u>N/A</u>																		
<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">15. a. Concurrence: <u>A. L. Holland</u></td> <td style="width: 33%;"><u>02/23/02</u></td> <td style="width: 33%;">b. <u>N/A</u></td> <td style="width: 33%;"><u>N/A</u></td> </tr> <tr> <td style="text-align: center;">Assessment Team Leader</td> <td style="text-align: center;">Date</td> <td style="text-align: center;">Responsible Assistant Manager</td> <td style="text-align: center;">Date</td> </tr> <tr> <td colspan="2" style="padding-top: 10px;">c. <u>N/A</u></td> <td colspan="2"><u>N/A</u></td> </tr> <tr> <td colspan="2" style="text-align: center;">Quality Assurance Manager</td> <td colspan="2" style="text-align: center;">Date</td> </tr> </table>			15. a. Concurrence: <u>A. L. Holland</u>	<u>02/23/02</u>	b. <u>N/A</u>	<u>N/A</u>	Assessment Team Leader	Date	Responsible Assistant Manager	Date	c. <u>N/A</u>		<u>N/A</u>		Quality Assurance Manager		Date	
15. a. Concurrence: <u>A. L. Holland</u>	<u>02/23/02</u>	b. <u>N/A</u>	<u>N/A</u>															
Assessment Team Leader	Date	Responsible Assistant Manager	Date															
c. <u>N/A</u>		<u>N/A</u>																
Quality Assurance Manager		Date																
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet																		
17. Acceptance of Proposed Corrective Actions: _____ Assessment Team Leader _____ Date																		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)																		
19a. Verified By: _____ Name _____ Date																		
19b. Trend Cause Code: _____																		
20. Closure: _____ Quality Assurance Manager _____ Date																		

CBO CORRECTIVE ACTION REPORT

(continuation sheet)

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

CORRECTIVE ACTION REPORT

1. CAR No.: 02-050	2. Activity Report No.: A-02-07	3. Page <u>1</u> of <u>3</u>
4. Controlling Document: CBFO Quality Assurance Program Document (QAPD) and RFETS procedure PRO-548-SSOC-SQA, R2, <i>Software Management for Nondestructive Assay Systems</i>	5. CBFO Assessment Team Leader: Ava Holland	
6. Responsible Organization: RFETS	7. CAQ Was Discussed With: D. Dahl, L. McInroy, C. Baldwin	
8: Requirement that was violated: See Page 2 continuation sheet		
9. Condition Adverse to Quality: The NDA software management procedure is not being implemented. See Page 2 continuation sheet for details.		
10. Suggested Actions (Optional):		
11a. Significant CAQ	(Yes or No): Yes	
11b. Work Suspension Recommended	(Yes or No): No	
11c. RCRA-Related	(Yes or No): No	
11d. Accelerated Corrective Action Required	(Yes or No): Yes	
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input checked="" type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>N. Frank</u> Date: <u>02/08/02</u>		
14. Response Due Date: <u>3/4/02</u> Corrective Action Plan Required: YES Required Corrective Action Completion Date: <u>03/25/02</u>		
15. a. Concurrence: <u>A. L. Holland</u> Assessment Team Leader	<u>02/23/02</u> Date	b. <u>N/A</u> Responsible Assistant Manager <u>N/A</u> Date
c. <u>A. L. Holland</u> Quality Assurance Manager	<u>02/23/02</u> Date	
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions: _____ _____ Assessment Team Leader Date		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ Name	_____ Date	
19b. Trend Cause Code: _____		
20. Closure: _____ Quality Assurance Manager Date		

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 02-050

2. Activity No.: A-02-07

3. Page 2 of 3

Block # 8 Requirement that was violated: (continued from Page 1)

General Requirements

- CBFO QAPD, Introduction: "The CAO QAPD is the document that describes and establishes the CAO QA program. The provisions of this QAPD apply to all programs and projects managed by the CAO which require a QA program, including activities related to waste isolation, waste characterization, regulatory compliance, and nuclear safety."
- CBFO QAPD, 1.1.2.1: "Program participants shall develop and follow plans and procedures that effectively implement the requirements described within this QAPD..." (emphasis added).
- CBFO QAPD Section 6.1: "This section of the QAPD establishes software quality assurance (SQA) requirements for CAO participants who develop, procure, maintain, or use computer software that is important to compliance application and waste characterization."

Specific Requirements

- RFETS PRO-548-SSOC-SQA, Section 1: "This procedure provides instruction to Kaiser Hill (KH) Nondestructive Assay (NDA) personnel who procure, test, protect, maintain, administer and control the software that runs NDA package counting systems."

Block # 9 Condition Adverse to Quality: (continued from Page 1)

Note: Initially only eight Software Change Requests (SCRs) were included in the audit sample. Because of the problems noted the sample size was increased to 20. There were approximately 120 SCRs in the portion of the population included within the audit scope.

In the examples below, the paragraph numbers refer to the RFETS procedure PRO-548-SSOC-SQA, Rev. 2. Examples of specific requirements that were not being met at the time of the audit include, but are not limited to the following:

- The unique software name and number, which is assigned by the NDA Software Custodian, is not being added to the software procurement documents by the Technical SME. (Paragraph 5.2[6])
- SuperHENC SGEAS V2.68 was installed on 10/31/01 via SCR 2001-115. No evidence of a Test Plan or Test Report could be found during the audit. Only check was to verify that the stated version was actually on the machine. Final Software Release Note was SRN-006, dated 10/31/01, which allowed use of V2.68 for production. (Procedure 5.4[2])
- Software Change Request (SCR) numbers are being assigned before the SCR has been approved in violation of the procedure. Procedure does not cover how to "VOID" an SCR number after it has been assigned. SCRs 2001-122 and 2001-126 had been found to be void. SCR 2002-002 has a number assigned, but had not been approved. (5.7.2[3] through [5])
- The NDA Software Documentation File is not maintained current. (Paragraph 5.7[1]) Example SCRs include:
 - 2001-072: No documentation in file. V2.1.7 is actually on TGS03, but SCR Log and file say it is not complete.
 - 2001-081: No documentation in file. SCR Log shows as complete.
 - 2001-095: No documentation in file. SCR Log shows as complete.
 - 2001-112: No documentation in file. SCR only says "New Software" and "Urgent" as the description.
 - 2001-124: No Test Plan or results in file. TGS05 has V3.1.5 installed, so this should be complete.
- SCR 2001-013 has a K-H Software Qualification Report that includes signatures of Technical SME, QA Software Custodian, and NDA Method Supervisor. This does not meet the intent of the procedure of having the Test Plan reviewed and approved prior to performing the tests. There is no clear statement that the review used Subsection 5.6 as the basis for the review. (Paragraph 5.4[2], [3], [4], [6], [8], and [9], 5.6[1], and 5.2[8])

(Continued on Page 3 continuation sheet)

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 02-050

2. Activity No.: A-02-07

3. Page 3 of 3

Block # 9 Condition Adverse to Quality: (continued from Page 2 of 3)

- NDA Quality Engineers are not reviewing documentation as required by the procedure.
 - 2001-013: Software Qualification Report not signed as reviewed (Paragraph 5.3[5])
 - 2001-098: Application Package not signed as required (Paragraph 5.5[5])
 - 2001-107, 2001-079, 2001-064, and 2001-065: Test Plan results not signed as required (Paragraph 5.4[3] and [8])
- SCR 2001-013 for SuperHENC V1.03 had Block #10 checked "Yes" that there is an adverse impact on previous production data, but no Non-Conformance Report Number is provided. The "By:" and "Date:" spaces are not filled in. (Paragraph 5.7.2[6][D])
- SCRs are not being completed to clearly state what changes were made. (Paragraph 5.7.2[1] through [4])
 - 2001-076, block #4 says "see attached letter", but no letter was attached or sent to QA records. Further investigation showed that only IDC 370 was changed, not all. The letter was determined to be #JDB-029-01, dated 5/22/01.
 - 2002-014 stated that the MDA had been changed. Further investigation showed that only the ²³⁹PU MDA had been changed.
 - 2001-112: SCR only says "New Software" and "Urgent" as the description
- Applications developed for Excel and Access were not controlled as required by the procedure.
 - 2001-098, 2001-076, 2002-014 did not have hand calculations or other means validating correct results (Paragraphs 2.1 and 5.5[3])
 - 2001-107, 2001-098, 2001-079, 2001-076, 2001-065, 2001-064, 2002-010, and 2002-014 did not have a review by the NDA Quality Engineer for the test plan or test results (Paragraphs 5.5[5])
- The Master List of Software Baseline documentation was not current. The list did not include applications or Application Packages, Software Qualification Reports, Software Test Plans, or Software Test Reports. In at least three cases Installation and Checkout was not listed. (Paragraphs 5.3[4], 5.3[10], 5.4[6], 5.7.2[11], 5.7.1[3], and 5.7.2[17])
- The NDA Software Inventory was not current at the time of the audit. Not all the Software change Request information had been entered. The last signed (by the NDA Method Supervisors) inventory was dated September 10, 1999. (Paragraphs 5.1, Note 2 and 5.1[3])

CORRECTIVE ACTION REPORT

1. CAR No.: 02-051	2. Activity Report No.: A-02-07	3. Page <u>1</u> of
4. Controlling Document: DOE/WIPP-069, Waste Acceptance Criteria for the Waste Isolation Pilot Plant		5. CBFO Assessment Team Leader: Ava Holland
6. Responsible Organization : RFETS NDA		7. CAQ Was Discussed With: P. Carson, J. Stewart, M. Clapham, P. Hyman
8. Requirement that was violated: DOE/WIPP-069 Section A.8 states in part "There is no numerical limit for TMU, but it must be properly calculated and documented.		
9. Condition Adverse to Quality: The Neutron Multiplicity Counters (NMC) 01 and 02 are approved for 2 IDCs, 312 and 370. A TMU Report has not been prepared for IDC 312. IDC 312 and 370 are similar (graphite and LECO crucibles) with respect to neutron-related properties. They have been applying the TMU value for IDC 370 to IDC 312 samples, which is expected to be similar or equivalent.		
10. Suggested Actions (Optional):		
11a. Significant CAQ (Yes or No): No 11b. Work Suspension Recommended (Yes or No): No 11c. RCRA-Related (Yes or No): No 11d. Accelerated Corrective Action Required (Yes or No): 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>Patrick Kelly</u> Date: <u>02/08/02</u>		
14. Response Due Date: <u>03/22/02</u> Corrective Action Plan Required: NO Required Corrective Action Completion Date: <u>N/A</u>		
15. a. Concurrence: <u>A. L. Holland</u> <u>02/23/02</u> b. <u>N/A</u> <u>N/A</u> <small>Assessment Team Leader Date Responsible Assistant Manager Date</small> c. <u>N/A</u> <u>N/A</u> <small>Quality Assurance Manager Date</small>		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions:		
<hr style="width: 100%;"/> <small>Assessment Team Leader Date</small>		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ Date _____ <small>Name Date</small>		
19b. Trend Cause Code: _____		
20. Closure: _____ Date _____ <small>Quality Assurance Manager Date</small>		

CBO CORRECTIVE ACTION REPORT

(continuation sheet)

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

CORRECTIVE ACTION REPORT

1. CAR No.: 02-052	2. Activity Report No.: A-02-07	3. Page <u>1</u> of
4. Controlling Document: DOE/WIPP-069, Waste Acceptance Criteria for the Waste Isolation Pilot Plant	5. CBFO Assessment Team Leader: Ava Holland	
6. Responsible Organization: : RFETS NDA	7. CAQ Was Discussed With: J. Stewart, D. Draher, N. Stoner, M. Clapham, P. Carson	
8. Requirement that was violated: See Continuation Sheet		
9. Condition Adverse to Quality: See Continuation Sheet		
10. Suggested Actions (Optional): 		
11a. Significant CAQ (Yes or No): Yes 11b. Work Suspension Recommended (Yes or No): No 11c. RCRA-Related (Yes or No): No 11d. Accelerated Corrective Action Required (Yes or No): No		
12. Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input checked="" type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>Patrick Kelly</u> Date: <u>02/08/02</u>		
14. Response Due Date: <u>03/22/02</u> Corrective Action Plan Required: YES Required Corrective Action Completion Date: <u>N/A</u>		
15. a. Concurrence: <u>A. L. Holland</u> <u>02/23/02</u> b. <u>N/A</u> <u>N/A</u> <small>Assessment Team Leader Date Responsible Assistant Manager Date</small> c. <u>A. L. Holland</u> <u>02/23/02</u> <small>Quality Assurance Manager Date</small>		
16. Corrective Actions Proposed by the Responsible Organization: Use CAR Continuation Sheet		
17. Acceptance of Proposed Corrective Actions: _____ <small>Assessment Team Leader</small> _____ <small>Date</small>		
18. Verification of Corrective Action Completion: (Use CAR Continuation Sheet)		
19a. Verified By: _____ <small>Name</small> _____ <small>Date</small>		
19b. Trend Cause Code: _____		
20. Closure: _____ <small>Quality Assurance Manager</small> _____ <small>Date</small>		

CBFO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 02-052

2. Activity No.: A-02-07

3. Page 2 of

Block # 8 Requirement that was violated:

DOE/WIPP-069 Section A.3 states in part "The minimum detectable concentration (MDC) for each assay method must be determined."

DOE/WIPP-069 Section A.6 states in part "The range of applicability of system calibrations must be specified in site procedures.

DOE/WIPP-069 Section A.8 states in part "There is no numerical limit for TMU, but it must be properly calculated and documented.

Block # 9 Condition Adverse to Quality:

The minimum detectable concentration (MDC) for the SuperHENC drum operation has not been determined.

The SuperHENC WIPP Qualification Report (KH-NDA2001-SHENC QUAL-001, Rev. 0) does not specify the range of "waste types or relevant waste matrix characteristics" for drums. This information is included in a RFETS Safeguards Report (KH-NDA2001-SHNEC-SFGRD-QUAL-001, Rev. 0), but it is not clear this report is a WIPP document.

The Total Measurement Uncertainty (TMU) report LA-13786-MS, Rev. May 2001 does not adequately represent TMU relative to 55 gallon (208L) Drums. Another report was provided by M. Clapham, but this is not a formal report.