memorandum

DATE: July 1, 1999

REPLY TO ATTN OF: CAO:QA:MLC 99-0871

SUBJECT: Issuance of Corrective Action Report (CAR) 99-041 Revision 1

TO: Joe Legare, RFFO

The Carlsbad Area Office (CAO) performed Audit A-99-21 June 15-18, 1999 at Rocky Flats Environmental Technology Site (RFETS) for the RCRA Draft Permit, Appendix B6 Evaluation. The audit team identified nine (9) conditions adverse to quality which have been identified on Corrective Action Report (CAR) 99-041 Revision 1.

The adverse conditions were in the area of Chain-of-Custody. Since there is an open CAR (99-041) from the Salts Certification Audit (A-99-09), concerning the same subject area, that CAR was revised to include the additional adverse conditions.

Please notify me, prior to the response due date identified in CAR block 14, of the expected date for completion of corrective actions. Also, please formally notify me as soon as the corrective actions are complete and ready to be verified.

If you have any questions or comments, please contact me at (505) 234-7484.

Marc A. Italiano
CAO Quality Assurance Manager

Attachments
Joe Legare

cc: w/original attachment:
L. Chism, CAO

cc w/attachment:
M. Castagneri, RFETS
G. O'Leary, RFETS
B. Stroud, CAO
B. Bennington, CAO
S. Vega, CAO
M. Eagle, EPA
S. Monroe, EPA
S. Zappe, NMED
B. Walker, EEG
D. Winters, DNFSB
T. Bowden, CTAC
C. Riggs, CTAC
B. Weston, WID (RCRA CAR)

July 1, 1999
Corrective Action Report

1. CAR No.: 99-041 Revision 1
3. Page 1 of 3

4. Controlling Document: L-4028-1 and J (effective 5/25/99), Sample administration for the Radiological laboratory, 4-W84-RS-0114, Rev 3, Salt Residue Stabilization, Bldg 707, CAO-94-1010, Quality Assurance Program Plan, Rev 0, and 95-QAPjP-0050, Rev 3, RFETS Quality Assurance Project Plan

5. CAO Assessment Team Leader: Marc A. Italiano

6. Responsible Organization: DOE RFFO

7. CAQ Was Discussed With: J. Reynolds, Y. Mazza, D. Goade, P. Carlson, and M. Johnson

8. Requirement that was violated: A. Procedure L-4028-1, Section 3.1.5.3, bullets 1, 2, 3, 7, and 8; Section 3.1.5.4; and Section 3.1.5.5. The Chain-of-Custody (COC) form is to be signed by the person relinquishing the sample and by the person receiving the sample. The condition of the sample and the agreement of COC and Samples is to be shown on the COC. (see continuation sheet)

9. Condition Adverse to Quality: A. The person receiving the sample has not signed the COC indicating unbroken Chain-of-Custody for the sample. The condition of the sample is not noted, nor is there any indication that sample label and COCs are in agreement. The Tamper Indicating Device or glovebox designation is being used in lieu of a signature. (see continuation sheet)

10. Suggested Actions (Optional):

11. Significant Condition Adverse to Quality (Yes or No)?: YES NO X


13. CAR Initiator: William J. Verret/Kerry Watson Date: April 15, 1999/June 18, 1999

14. Response Due Date: July 22, 1999 Corrective Action Plan Required: YES

15. Trend Cause Code:

16. Concurrence: Assessment Team Leader Date: 7/1/99

17. Corrective Actions Proposed by the Responsible Organization (for SCQA only): Use CAR Continuation Sheet

18. Acceptance of Proposed Corrective Actions (for SCAQ only):

19. Verification of Corrective Action Completion:

20. Verified By: Name Date

21. Closure: Assessment Team Leader Date
CORRECTIVE ACTION REPORT

1. CAR No.: 99-041 Rev 1
2. Activity No.: A-99-09/A-99-21
3. Page 2 of 3

Block #8

B.

QAPP Section 6.3: “Whenever a transfer of custody takes place, both parties must sign and date a COC form, with the relinquishing party retaining a copy of the form.”

QAPP Section 6.4.3: “The sample COC forms must be placed in a waterproof plastic bag and taped to the underside of the shipment container lid.”

QAPP Section 6.3: “The original COC forms shall be maintained in the site project files.” QAPP Section 6.3.2: “Sample custody must be maintained until the associated analyses are completed and the data have been validated at the project level.”

QAPP Section 6.0: “In order to ensure that the Program generated data meet accepted standards for legal admissibility and defensibility, field logs, sample labels, and chain-of-custody (COC) forms must be maintained and samples properly handled throughout the waste characterization process. These practices shall be documented in QAPJPs, implemented by SOPs, and must be in accordance with EPA guidelines as prescribed in NEIC policies and procedures.”

QAPP Section 6.3: “Any discrepancies in information, signs of damage, or tampering must be documented on a nonconformance report and on the COC form by the receiving custodian.”

QAPP Section 6.3: “A waste container or sample will be considered under effective custody control if it is sealed (i.e., unopened) with the custody seal intact,...”

QAPP Section 6.3.2: “... include a copy of the sample COC form; this form shall include provisions for each of the following:
• Documentation of sample numbers for each sample under custody
• Description of final waste container disposition, along with signature of individual removing waste container from custody.

QAPP Section 6.2.4: “The sample identification number must have the following format: 12 alpha-numeric characters; two alpha characters must designate the sampling site (zz), and the remaining ten numeric characters must indicate the chronological sequence of homogenous solids and soil/gravel sample collection (##########).”

QAPP Section 6.3.2: “Site QAPJPs must include a copy of the sample COC form;...”

Block #9

B.

Following a transfer of sample custody, the requirement for the relinquishing party to retain a copy of the COC form is not captured in RFETS procedures.

COC forms are not secured inside the shipping container. They are sent with the container.

Procedure L-4028-J does not include provisions to ensure sample custody is adequately maintained until sample disposition, i.e. COC is released to TID, Lab receives custody from TID, new COC is generated, lab COC does not become part of the Project Record.

RFETS procedures reviewed (L-4028-J and 4-W84-RS-1010) do not ensure that the custody information will be maintained in accordance with EPA NEIC guidance as required per QAPP Section 6.0.
C.J CORRECTIVE ACTION REPORT

(continuation sheet)

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**Block # 9**

Procedure L-4028-J does not specify that discrepant sample information, indications of damage, or indications of tampering are documented on a nonconformance report.

For Pyro-oxidized salts, no custody seals are placed on sample containers. RFETS QAPJP section 6.4.1 does not reflect the requirements specified in CAO QAPP 6.3. **Note:** The requirement to place custody seals on sample containers is not exempted by QAPP Rev. 0 Interim Change Table AC-1 6.4 item 4.

The COC form for solids samples (4-W84-RS-0114, Rev 3, Appendix 11) does not meet the requirements of QAPP 6.3.2:

- Documentation of sample numbers for each sample under custody
- Description of final waste sample disposition, along with signature of individual removing sample from custody
- Chain of Custody form does not include provisions for shipping information (date, time, shipper, mode)

For Pyro-oxidized salts:

- The sample number used on the COC is RIN # + Event # + Bottle #
- Sample identification numbers marked on the sample container labels are not in the format specified in the QAPP Section 6.2.4
- Sample labels do not include information of 1) Type and number of sample containers, and 2) analysis requested
- Procedure 4-W84-RS-0114 10[3][F] does not require that the sample number be recorded in the sample logbook

The QAPJP does not include a sample COC form for solid samples as required by Section 6.3.2 of the QAPP.