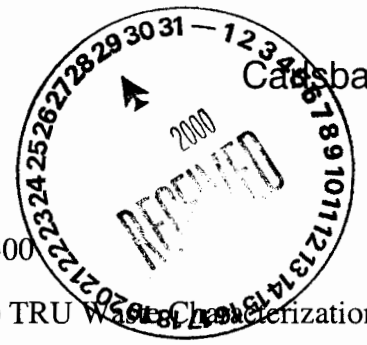
DOE F 1325.8

United States Government **Department of Energy**

memorandum

Carlsbad Field Office
Carlsbad, New Mexico 88221



DATE: November 22, 2000

REPLY TO ATTN OF: CBFO:QA:SAV:VW:00-1341 UFC:2300

SUBJECT: Issuance of Savannah River Site (SRS) TRU Waste Characterization, Corrective Action Reports 01-002 through 01-006

TO: Dale Ormond, DOE-SR

During the period of November 7 through 16, Certification Audit A-01-01 was conducted at the Savannah River Site. As a result of this audit five conditions adverse to quality were identified which have resulted in the issuance of Corrective Action Reports (CARs) 01-002 through 01-006, attached.

Please determine and document on the attached CAR continuation sheet, your proposed corrective action plan for the CAR. Please forward the proposed corrective action plan and schedule for completion to me prior to the response due date identified in CAR block 14.

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

Samuel A. Vega
Quality Assurance Manager

Attachment

cc: w/attachment
K. Watson, CBFO
L. Chism, CBFO
B. Crapse, DOE-SR
J. D'Amelio, SRS
M. Mason, SRS
M. Eagle, EPA
S. Zappe, NMED
B. Walker, EEG
J. May, CTAC
J. Schuetz, CTAC
M. Gerle, WID
D. Winter, DNFSB

001128

CORRECTIVE ACTION REPORT

1. CAR No.: CAR 01-002	2. Activity Report No.: CBFO A-01-01	3. Page 1 of 4
4. Controlling Document: CBFO Quality Assurance Program Document (QAPD), CAO-94-1012	5. CAO Assessment Team Leader: S. Vega	
6. Responsible Organization: Savannah River Site	7. CAQ Was Discussed With: D. Ormond, J. D'Amelio, M. Mason and J. Riddle	

8. Requirement that was violated: (See Continuation Page)

9. Condition Adverse to Quality:

SRS "Ship to WIPP" Quality Assurance Department procedures for oversight of software packages are not properly implemented in the following areas:

- Classification of WIPP related software is addressed in two separate site procedures that can result in a classification that does not address all WIPP software life-cycle requirements, (requirements phase, design phase, implementation phase, testing phase, installation phase and in-use test), and QA oversight requirements.

  The WIPP Software Quality Assurance Plan references the site procedure QAP 20-1 for procurement of software and baselining existing software. The QAP 20-1 software classification method classifies WIPP software as GS, which applies insufficient documentation and configuration control to meet the NQA standard.

(See Continuation Page)

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**

12. Types of Actions: Remedial: X **Investigative:** X **Root Cause:** X **Actions to Preclude Recurrence:** X

13. CAR Initiator: J. Schuetz James R. Schuetz **Date:** 11/21/00

14. Response Due Date: 12/22/00 **Corrective Action Plan Required: YES**

15. Concurrence:

Samuel A. Vega	11/21/00	N/A	
Assessment Team Leader	Date	Responsible Assistant Manager	Date
Samuel A. Vega	11/21/00		
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: _____ _____

19b. Trend Cause Code: _____

20. Closure: _____ _____
Quality Assurance Manager Date

CAR CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: CAR 01-002	2. Activity No.: CBFO A-01-01	3. Page 2 of 4

Block # 8

- NQA-1, 1989 part 2 requires that the QA program shall provide control over activities affecting quality to an extent consistent with their importance.

- NQA-2a-1990 part 2.7 requires in section 2.1 that the requirements set forth in part 2.7 apply to computer software used to produce or manipulate data which is used directly in the operation of structures systems, and components. In addition, section 10.2 requires that software not developed using this standard shall be placed under configuration controls required by this part prior to use.

- NQA-2a-1990 Part 2.7 requires in section 5.2 that changes to software be formally documented, that only authorized changes be made to software baselines, and that changes are reflected in documentation to ensure that document traceability is maintained.

- CAO QAPD Section 6.2.1.1 B states, in part, that "software governed by this section of the QAPD shall be categorized. The criteria for classification shall be documented in the inventory and shall address the purpose of the software relative to its us in engineering, scientific, testing, data collection, design, analysis, and operations activities as well as its importance to safety or its significance in managing information and augmenting mission-essential decisions."

- CAO QAPD Section 6.2.2.2 C states in part, that "Plan (s) for ensuring software quality shall be prepared for each software project at the start of the software life-cycle. For procured software, the software quality plan shall be prepared before the software enters the purchaser organization. Plan (s) may be prepared individually for each software project, may exist as a generic documents to be applied to software prepared within or procured by an organization, or may be incorporated in the overall quality assurance program. The plan shall identify:
  C. The organization responsible for performing the work and achieving software quality and their tasks and responsibilities..."

- CAO QAPD Section 6.3.2 Additional Requirements (Software Procurement) states in part "A. The procurement of software and related services shall be performed in accordance with Section 2.3 of this QAPD."

- CAO QAPD Section 6.6.2.1 Verification (additional Requirements states in part, "... Verification activities shall be clearly documented including the identification of those performing and approving the verification..."

- CAO QAPD Section 6.7.2.2 Configuration Change Control states in part, "...All changes shall be formally evaluated and approved by the organization responsible for the original design...."

Block # 9

- Site procedures do not require Quality Assurance department review and/or approval of software life-cycle plans and documentation

  The WIPP SQAP does not incorporate quality assurance review or approval in the software quality program beyond approving the SQAP and reviewing the system requirements documents, and the audit schedule for the next year contained no plans for performing software quality assurance audits. Additionally the required quality assurance review of the system requirements specification document for the TRUPACT-II software was not performed, and no signature line for the CQF was included on the review form.

- Review and acceptance of quality assurance items for purchased software, by the quality assurance department, is not implemented

- Vendor audits or Supplier Verifications of software quality assurance items are performed using NQA-1 checklist items as opposed to NQA-2 Part 2.7

- Internal and vendor quality audits and/or surveillances of software are not adequately specified in procedures and are not implemented

- Software changes are not adequately evaluated for compliance with change request descriptions and are not reviewed by the quality assurance department (Cognizant Quality Function (CQF))

  A review of Software Modification Traveler (SMT) 08 for the TRUPACT-II software showed that changes to the TRUPACT-II source code were made outside the SMT process. The undocumented changes were generally seen to be minor, but no process is in place to capture minor changes, and not guidelines exist for classifying changes as major or minor.

- Verification and validation of software quality assurance items is not performed by the quality assurance department

CAR CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: CAR 01-002	2. Activity No.: CBFO A-01-01	3. Page 4 of 4

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CORRECTIVE ACTION REPORT

1. CAR No.: CAR 01-003	2. Activity Report No.: CBFO A-01-01	3. Page 1 of 2
4. Controlling Document: Hazardous Waste Facility Permit Waste Isolation Plant EPA No. NM4890139088-TSDF and SW18-WP-AP-0002, R4, IPC1 "WIPP Disposal Program Acceptable Knowledge"	5. CAO Assessment Team Leader: S. Vega	
6. Responsible Organization: Savannah River Site	7. CAQ Was Discussed With: D. Ormond, J. D'Amelio and M. Mason	

8. Requirement that was violated:
WAP B4-3d states: "The permittees shall require sites to establish a program for reevaluating AK if RTR or VE results in the assignment of a different waste matrix code."
WAP B4-3e states: "Sites also shall assess and documents the limitations of the AK information used to assign hazardous waste codes."
WP-AP-002, R4, Para 4.4-2 states: Any limitations associated concerning use of the information are described."

9. Condition Adverse to Quality:
SRS's Acceptable Knowledge Program is not being implemented as required by the WAP and the SRS internal procedure, WP-AP-0002, in the following areas:

- Reassignment of waste matrix codes has not been performed as required by the WAP. Waste matrix code S5440 has been applied to containers that are designated as S5300, S5420, and S5190 for waste stream SR-T001-221F-HET.
- The limitations of the AK documentation has not been documented as required by the WAP and WP-AP-0002, Para 4.4-2

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**

12. Types of Actions: Remedial: X **Investigative:** X **Root Cause:** X **Actions to Preclude Recurrence:** X

13. CAR Initiator: S. Calvert _____ **Date:** 11/21/00

14. Response Due Date: 12/22/00 **Corrective Action Plan Required:** YES

15. Concurrence:

Samuel A. Vega	11/21/00	N/A	
Assessment Team Leader	Date	Responsible Assistant Manager	Date
Samuel A. Vega	11/21/00		
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: _____ _____

19b. Trend Cause Code: _____

20. Closure: _____ _____
Quality Assurance Manager Date

CAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: CAR 01-003	2. Activity No.: CBFO A-01-01	3. Page 2 of 2

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CORRECTIVE ACTION REPORT

1. CAR No.: CAR 01-004	2. Activity Report No.: CBFO A-01-01	3. Page 1 of 2
4. Controlling Document: DOE/WIPP-069 Waste Acceptance Criteria, Appendix A, Section A.2 and WSRC-RP-01095, R0 "SRS WIPP Disposal Program Waste Certification Plan"		5. CAO Assessment Team Leader: S. Vega
6. Responsible Organization: Savannah River Site		7. CAQ Was Discussed With: D. Ormond, J. D'Amelio and M. Mason

8. Requirement that was violated:

DOE/WIPP-069 WAC, Appendix A, Section A.2 Accuracy states in part:

"The minimum detectable concentration (MDC) for each assay method must be determined. In addition to being a function of the particular instrument and assay method, the MDC is also dependent on the radiation background, characteristics of the waste type being measured, and other factors. The MDC is defined here as that radioactivity concentration which, if present, yields a measured value greater than the critical level with 95% probability, where the critical level is defined as that value which measurements of the background will exceed with 5% probability."

9. Condition Adverse to Quality:

The calculation for MDC in SRS calculations E-CLC-E-00013 and E-CLC-E-00014 in Table 1 & 2 is incorrect. Specifically, L_c and $L_{-K\sigma}$ do not include the term "K" as defined in the NBS procedure SP456 attached to calculation E-CLC-E-00014. Consequently SRS is not calculating the MDC at 95 % confidence level.

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**

12. Types of Actions: Remedial: X **Investigative:** X **Root Cause:** X **Actions to Preclude Recurrence:** X

13. CAR Initiator: S. Davis Steve Davis **Date:** 11/21/00

14. Response Due Date: 12/22/00 **Corrective Action Plan Required:** YES

15. Concurrence:

Samuel A. Vega — Assessment Team Leader — 11/21/00 — Date

N/A — Responsible Assistant Manager — Date

Samuel A. Vega — Quality Assurance Manager — 11/21/00 — 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: _____ _____

19b. Trend Cause Code: _____

20. Closure: _____ _____

Quality Assurance Manager — Date

CAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: CAR 01-004	2. Activity No.: CBFO A-01-01	3. Page 2 of 2

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CORRECTIVE ACTION REPORT

1. CAR No.: CAR 01-005	**2. Activity Report No.:** CBFO A-01-01	**3. Page** 1 **of** 3
4. Controlling Document: 40 CFR 191 & 194, CCA & DOE/WIPP-069, Waste Acceptance Criteria for the WIPP Isolation Pilot Plant (WAC)	**5. CAO Assessment Team Leader:** S. Vega	
6. Responsible Organization: Savannah River Site	**7. CAQ Was Discussed With:** D. Ormond, J. D'Amelio and M. Mason	

8. Requirement that was violated: (See Continuation Page)

9. Condition Adverse to Quality:

Contrary to the requirements listed in Section 8 of this CAR, SRS is not in compliance with 40 CFR 194.22, which specifies that all data and information collected prior to the implementation of an approved QA program be qualified by one of 4 methods. SRS uses AK to assign values for plutonium isotopes to waste drums without performing confirmation of the AK values.

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**

12. Types of Actions: Remedial: X **Investigative:** X **Root Cause:** X **Actions to Preclude Recurrence:** X

13. CAR Initiator: S. Davis Steve Davis **Date:** 11/21/00

14. Response Due Date: 12/22/00 **Corrective Action Plan Required:** YES

15. Concurrence:

Samuel A. Vega — Assessment Team Leader — 11/21/00 — Date

N/A — Responsible Assistant Manager — Date

Samuel A. Vega — Quality Assurance Manager — 11/21/00 — 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: _____ _____

19b. Trend Cause Code: _____

20. Closure: _____ _____

Quality Assurance Manager — Date

CAR CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: CAR 01-005	2. Activity No.: CBFO A-01-01	3. Page 2 of 3

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- 40 CFR 191 requires an assessment be made for a repository. Appendix C to 191 says this will be used to show compliance with 191.13 (containment).
- 40 CFR 194 describes how WIPP will show compliance with 191.
- 194.24 requires the radiological waste components (radionuclides in this case) be described. The description will include the quantity of the component and "may be derived from process knowledge, current non-destructive examination/assay, or other information and methods.
- 194.24 (c)(3) requires demonstration that use of process knowledge to quantify components in waste for disposal conforms with QA requirements found in 194.22.
- 194.24 (c)(4) requires ongoing controls to assure the limitations are not exceeded (need to track radionuclide mix to show the PA was correct).
- 194.22 (a)(2) requires a QA program be established for waste characterization and assumptions.
- 194.22 (a)(2) requires the CCA to discuss how QA will be used to assess the quality characteristics for data (QAOs).
- Chapter 4 of the CCA allows AK for waste characterization (4.1.1).
- Chapter 4, 4.1.3.3 describes how the CCA radionuclide inventory was estimated but will be determined quantitatively prior to shipment to confirm the estimate.
- Chapter 4, 4.3.4 specifies that the QA program as provided in the QAPP and methods manual (MM not relevant for radionuclides) will be used for characterization. It states that the QAOs for NDA are in the QAPP. This is how 194.22 will be met.
- Chapter 4, 4.4 restates that characterization will be performed in accordance with the QAPP and WAC.
- Chapter 4, 4.4.2 allows a combination of assay methods, including AK, can be used as long as the QAOs in the QAPP are met.
- Chapter 5 of the CCA (QA) states that the QAPP will be used to meet QA requirements.
- WAC and WCL of the CCA describe why some components are significant and must be tracked and why some can be dismissed. It explains why there are 10 significant radionuclides. These sections do not discuss making measurements.
- The requirements for NDA were in Chapter 9 of the QAPP. This material was moved to Appendix A of the WAC.
- Section 1.0 of the WAC states that the WAP will provide details for characterization programs. Attachment A, A.1 states that the isotopic ratios used to quantify all radionuclides present in the waste can be made using AK. It also states that AK will meet the WAP requirements.
- B4-1 and B4-3d of the WAP states that AK must be confirmed using sampling and analysis.

The ASTM methods that are the basis for assay describe how to quantify radionuclides in a container by using isotopic ratios for the radionuclides present in the waste. For use at WIPP, knowledge of these ratios can be provided by AK, but AK must be confirmed. Therefore, a site that uses isotopic ratios derived from AK must confirm that ratio by a measurement program.

CAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: CAR 01-005	2. Activity No.: CBFO A-01-01	3. Page 3 of 3

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CORRECTIVE ACTION REPORT

1. CAR No.: CAR 01-006	2. Activity Report No.: CBFO A-01-01	3. Page 1 of 2
4. Controlling Document: DOE-WIPP-069 "Waste Acceptance Criteria" and WSRC-RP-99-01095, R0 "SRS WIPP Disposal Program Waste Certification Plan"		5. CAO Assessment Team Leader: S. Vega
6. Responsible Organization: Savannah River Site		7. CAQ Was Discussed With: D. Ormond, J. D'Amelio and M. Mason

8. Requirement that was violated:

DOE/WIPP-069 WAC, Appendix A, Section A.7, Para 6 states:
"Sites must document how the individual elements contributing to TMU were determined and how they are combined to calculate the total TMU. The TMU must be correctly calculated and adequately documented. Compliance with these requirements will be evaluated in reviews of the TMU package for each assay system by an NDA technical specialist with assistance, as needed, from other CAO audit team members who have technical and practical proficiency in gamma and neutron assay techniques, statistics, TRU waste characteristics, and applicable regulatory requirements."

9. Condition Adverse to Quality:

The default isotopes values given for $Pu^{238, 239, 240, 241, 242}$ and Am^{241} in the SGS TMU document and in the SGS "MGA Results" printout are not the same. The values listed in these two documents are intended to be the default values from AK, which are those given in the TMU document.

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**

12. Types of Actions: Remedial: X **Investigative:** X **Root Cause:** X **Actions to Preclude Recurrence:** X

13. CAR Initiator: S. Davis Steve Davis **Date:** 11/21/00

14. Response Due Date: 12/22/00 **Corrective Action Plan Required:** YES

15. Concurrence:

Samuel A. Vega — Assessment Team Leader — 11/21/00 — Date

N/A — Responsible Assistant Manager — Date

Samuel A. Vega — Quality Assurance Manager — 11/21/00 — 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: _____ _____

19b. Trend Cause Code: _____

20. Closure: _____ _____
Quality Assurance Manager — Date

CAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: CAR 01-006	2. Activity No.: CBFO A-01-01	3. Page 2 of 2

Block #____