

United States Government

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Department of Energy

memorandumCarlsbad Area Office
Carlsbad, New Mexico 88221

DATE: October 7, 1997

REPLY TO
ATTN OF: CAO:NTP:RAS 97-1540 (UFC 2300.00)

SUBJECT: CAO Audit Report A-97-16

TO: Bruce Lebrun, Radioactive Waste Manager, LAAO

The Carlsbad Area Office (CAO) conducted an audit of Los Alamos National Laboratory's (LANL's) Quality Assurance (QA) Program for TRU waste characterization and certification activities in Los Alamos, New Mexico on September 10-11, 1997. The audit team determined that the implementation of the LANL QA Program was adequate and effectively implemented. As a result of the audit two (2) Observations were identified. The observations do not require a written response.

If you have any questions or comments concerning this report, please contact Robert A. Stroud at (505) 234-7483.

For Michael Rowan Brown

Don Watkins
Manager
National TRU Program

Attachment

cc: w/attachment
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CAO QA File



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U.S. DEPARTMENT OF ENERGY
CARLSBAD AREA OFFICE

AUDIT REPORT

OF THE

LOS ALAMOS NATIONAL LABORATORY
LOS ALAMOS, NEW MEXICO

AUDIT NUMBER A-97-16

SEPTEMBER 10 - 11, 1997

TRU WASTE CHARACTERIZATION
AND CERTIFICATION PROGRAM



Prepared By: R. Dennis Brown
R. Dennis Brown
Audit Team Leader

Date: 10/2/97

Approved By: M. Stalano
for R. Dennis Brown
CAO QA Manager

Date: 10/2/97

Approved By: Robert A. Stroud
Robert A. Stroud
CAO NTP Waste Certification Manager

Date: 10/7/97

1.0 EXECUTIVE SUMMARY

Carlsbad Area Office (CAO) Audit A-97-16 was conducted to evaluate the adequacy, implementation, and effectiveness of Los Alamos National Laboratory (LANL) transuranic (TRU) waste characterization and certification activities. In addition, the audit scope included verification of the completion and effective implementation of corrective actions for previously identified conditions adverse to quality from audits A-97-01 and A-97-07.

The audit was conducted at the LANL facilities in Los Alamos, New Mexico on September 10 through 11, 1997. The audit team concluded that the QA program is being satisfactorily implemented in accordance with LANL procedures corresponding to the scope of this audit. The team determined that the implementing procedures are adequate. The LANL technical program was also determined to be effective. The audit team verified implementation of corrective actions for six previous CAO Corrective Action Reports (CARs). The team concluded that the corrective actions for the six CARs (97-050, and 97-113 through 97-117) were implemented and effective.

The audit team did not identify any additional CARs that require corrective actions. One deficiency, isolated in nature and requiring only remedial corrective actions, was corrected during the audit (CDA). Two observations were identified and do not require a LANL response. The audit team noted three exemplary practices being performed by LANL personnel. The CDA, observations, and exemplary practices are described in Section 6.0 of this report.

2.0 SCOPE

The audit scope included evaluation of the adequacy, implementation, and effectiveness of the technical and quality assurance activities related to the LANL TRU waste characterization and certification programs. The audit emphasized evaluation of the technical and quality assurance activities that had not been fully implemented during the May 1997 (A-97-01) and the August 1997 (A-97-07) audits, and the effectiveness of corrective actions taken as a result of deficiencies identified during those audits.

The following CAO QAPD elements were evaluated:

- QA Program Implementation
- Documents and Records
- Work Processes
- Testing
- Data Documentation, Control, and Validation
- Software Requirements

The following CAO waste characterization elements from the Quality Assurance Program Plan (QAPP) were evaluated:

Acceptable Knowledge (AK)
Testing - Non-Destructive Assay (NDA)
Data Validation, Usability and Reporting

The following CAO Waste Acceptance Criteria (WAC) certification elements were evaluated:

Waste Stream Profile Data
WIPP Waste Information System Data

Corrective actions for the following corrective action reports (CARs) from CAO Audits A-97-01 and A-97-07 were evaluated:

CAR 97-050
CAR 97-113 through 97-117

The adequacy evaluations of LANL TRU Waste Characterization Program (TWCP) documents were based on current revisions of the following documents:

CAO Quality Assurance Program Document, CAO-94-1012

Transuranic Waste Characterization Quality Assurance Program Plan, CAO-94-1010

Waste Acceptance Criteria for the Waste Isolation Pilot Plant, DOE/WIPP-069

Programmatic and technical checklists were developed from current revisions of the following documents:

LANL Transuranic Waste Quality Assurance Project Plan, TWCP-PLAN-0.2.3

LANL Transuranic Waste Certification Plan, TWCP-PLAN-0.2.4

Related LANL technical and quality assurance implementing procedures (listed in Attachment 2)

CAO Corrective Action Reports (CARs) 97-050 and 97-113 through 97-117 from CAO Audits A-97-01 and A-97-07

3.0 AUDIT TEAM AND OBSERVERS

AUDITORS/TECHNICAL SPECIALISTS

R. Dennis Brown	Audit Team Leader/QA Manager/CAO
Robert A. Stroud	Technical Specialist/Waste Certification Manager/CAO
Mike Brown	Technical Specialist/CAO
Robert Paedon	Auditor/CTAC
Steve Calvert	Auditor/CTAC
Sid Ailes	Auditor/Technical Specialist/CTAC
Jim Bresson	Technical Specialist/CTAC
R. Vann Bynum	Technical Specialist/CTAC

EPA INSPECTION TEAM

Mike Eagle, EPA
Kyle Rogers, EPA
John Goode, A.T. Kearney
Patrick Kelley, S. Cohen & Associates
Ray Wood, A. T. Kearney
Angela Jones, A. T. Kearney

OBSERVERS

Ben Walker, EEG
Bill Weston, WID

4.0 AUDIT PARTICIPATION

Individuals involved in the audit are listed in Section 3.0 and Attachment 1. A preaudit meeting was held at LANL TA50, Building 37 on September 10, 1997. The audit concluded with a postaudit meeting at the same location on September 11, 1997.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The audit team concluded that the QA program is being satisfactorily implemented in accordance with LANL procedures. The team determined that implementing procedures are adequate. The LANL technical program was determined to be effective. The audit team also reviewed LANL corrective actions for six previous CAO CARs. The audit team concluded that the corrective actions for the CARs (97-050, and 97-113 through 97-117) were implemented and effective.

5.2 QA Program Audit Activities

A summary table of audit results is provided as Attachment 2. Details of audit activities, along with the specific objective evidence reviewed, are contained within the audit checklists. The checklists are maintained as QA Records.

5.3 Technical Activities

5.3.1 Acceptable Knowledge

The evaluation performed in the acceptable knowledge area involved the verification of corrective actions resulting from deficiencies identified during the previous audit (A-97-07). The audit team reviewed and evaluated actions taken as the result of CARs 97-114 and 97-117. CAR 97-114 identified a problem of assigning hazardous waste numbers consistent with the CAO QAPP requirements. CAR 97-117 identified a problem in the acceptable knowledge data packages, i.e., the checks to distinguish between TRU and low-level waste were not performed as required. The audit team evaluated the implementation and effectiveness of the corrective actions and concluded they were implemented and effective. Based on these evaluations, the audit team recommends closing both CARs.

5.3.2 Nondestructive Assay

The audit team evaluated the process for the assay of waste containers for the isotopic composition using the Fixed Energy Response Function Analysis with Multiple Efficiencies (FRAM) system. During the previous audit (A-97-07) the audit team had noted deficiencies (CAR 97-116) in the detailed technical procedure (DTP) and in the performance of the procedure by LANL personnel. During the first audit (A-97-01), the audit team had identified deficiencies (CAR 97-050) in determining the isotopic ratios of radionuclides based on acceptable knowledge. The audit team noted that there had been significant improvement in the DTP for Determining Isotopic Ratios in Waste Containers Using the RANT PC FRAM Assay System (DTP-1.2-029, R.2). The DTP had been extensively revised to accurately describe the operation of the FRAM and the evaluation of analysis results in response to CAR 97-116. In addition, the procedure had been expanded to provide detailed instruction on the screening of drums to determine the appropriate method of assay (i.e., Passive Active Neutron, High Efficiency Neutron Counter, or Tomographic Gamma Scanner) to characterize the drums. These changes and additions allow the use of FRAM to determine isotopic ratios rather than relying on acceptable knowledge.

Based on the review of the revised DTP and on the satisfactory observation of two complete drum assay cycles (demonstrated on TRU waste drums), the audit team recommends closing both of the previous CARs and determined that the FRAM process was implemented and effective in determining isotopic ratios (instead of by acceptable knowledge) and in screening drums for the appropriate assay method.

5.3.3 Software

The adequacy and effectiveness of the LANL software quality assurance program was evaluated for the control of software used for Nondestructive Assay (NDA) activities. The evaluation included the review and inspection of software classification, code development, baseline configuration control, and verification and validation activities for the MAESTRO, PC/FRAM, and PAN software. At the time of the evaluation, approved baselines were in place and verification and validation testing activities were complete.

Based on this evaluation, the audit team determined that controls for software classification, configuration management, installation and checkout, and software verification and validation testing were effective and fully implemented. The audit team also verified that corrective actions taken as a result of audit A-97-07 (CAR 97-113) were implemented and effective in providing sufficient documentation of validation testing to demonstrate acceptable performance of the software. The team recommends that the CAR be closed.

5.3.4 WIPP Waste Information System (WWIS)

A demonstration of the WWIS was performed to verify LANL's capability to implement the process in accordance with the quality procedure. The demonstration included data entry, forwarding of information to the WIPP Site, and acknowledgment of the transferred information. The data entry included inputting data for the characterization, certification, and shipment modules of the WWIS. The process was demonstrated by trained personnel as required by the procedure. In addition, a set of "false" data was transferred to demonstrate the ability of the system to verify the rejection of an invalid input. Electronic notification of rejection was satisfactorily received from the WIPP Site. Based on the demonstration, the audit team determined that LANL has appropriately implemented the WWIS and the process is effective.

6.0 CORRECTIVE ACTION REPORTS, DEFICIENCIES CORRECTED DURING THE AUDIT, OBSERVATIONS, AND RECOMMENDATIONS

6.1 Corrective Action Reports

NONE

6.2 Deficiencies Corrected During the Audit (CDA)

Deficiencies considered isolated in nature and requiring only remedial action may be corrected and verified during the audit. The following deficiency was corrected by LANL and verified by the audit team:

1. Earlier revisions of Section 14 and Attachment 11 of DTP-1.2-029 (for FRAM operation) required preparation of a Nonconformance Report (NCR) for every container of waste that either: (1) contained one or more "interfering" TRU radionuclides (e.g., Np-237 or U-235), or (2) indicated the presence of other interfering radionuclide (e.g., U-233, Th-227, et al). The NCR would indicate that there was no currently approved assay method. Revision 2 to the DTP eliminated the need for generation of NCRs under these conditions. It was noted by the audit team that Attachment 11, "FRAM Assay Operator/Analyst Checklist", still indicated that an NCR was required. An Interim Change Request (ICR) was prepared and approved to correct the oversight.

6.3 Observations

The following two Observations resulted from the audit:

1. During the closure of CAR 97-114, a memorandum, "Updated Radionuclide Matrix and UCNI Memo Secondary Radionuclides and Toxic Metals in TA-55 TRU Waste", was used to list the data by process codes. Traceability from the process codes to the process descriptions was not readily available. The traceability should be clarified and documented. In each case, LANL personnel could describe the traceability, but the traceability was not clearly described in the documentation.
2. A validation test case for the PC/FRAM software included an unqualified software package (SYNTH) to calculate the correction factor for shielding effects caused by a carbide source. An NCR was issued to document the nonconforming condition (LANL NCR 97-065). The NCR determined that the current operating limits for the FRAM DTP-1.2-029 were adequately qualified using the other four validation test cases. The audit team determined that the portion of the PC/FRAM software that includes the SYNTH package had not been implemented in the PC/FRAM procedure. However, LANL should ensure that the DTP for PC/FRAM is not revised to include heterogeneity effects (which employs the SYNTH software) until the validation test case is rerun using qualified software.

6.4 Recommendations

NONE

6.5 Exemplary Practices

1. The audit noted that there had been significant improvement in the Detailed Technical Procedure for determining Isotopic Ratios in Waste Containers Using the RANT PC FRAM Assay System (DTP-1.2-029, R.2) and in the performance of the procedure by LANL personnel. The DTP had been extensively revised to

accurately describe the operation of the FRAM and the evaluation of the analysis results. The procedure had been expanded to provide detailed instruction on the screening of drums to determine the appropriate method of assay to characterize the drums. In addition, LANL personnel did an exemplary job of performing this complex procedure in strict compliance with the written instructions.

2. The baseline evaluation for the PAN software included a table that provided a comprehensive matrix of software requirements, applicable test cases and test documentation. This matrix provided an excellent map for showing traceability between requirements and the demonstration of acceptable performance.
3. The baseline evaluation memorandums for PAN, PC/FRAM, and MAESTRO were exemplary and provided a comprehensive description of the software baseline reviews. The memos documented the intended use of commercial off-the-shelf software and described the adequacy of existing user and test documentation. The memos also provided a complete record of activities related to demonstrating acceptable performance of commercial-grade software for WIPP applications.

7.0 LIST OF ATTACHMENTS

- Attachment 1: Personnel Contacted During the Audit
- Attachment 2: Summary Table of Audit Results

NAME	ORGANIZATION	A	B	C
Fitzpatrick, John	LANL/CST-7		X	X
Foxx, Charles L.	LANL/NMT-7			X
Gavett, Marji	LANL/CST-7	X	X	X
Janecky, David	LANL/SQA SCM		X	X
LeBrun, Bruce	DOE/LAAO	X	X	X
Lucero, Fabiola	LANL/CST-25		X	
Montoya, Andrew J.	LANL/NMT-7			X
Offner, Steve	WID		X	
Padilla, Michelle	LANL/CST-7			X
Pothes, Harald	LANL/CST-7		X	
Rael, Charles	LANL/CST-7		X	
Rogers, Pamela	LANL/SPM		X	X
Sowers, Joe	LANL/CST-7	X	X	X
Taggart, Daniel P.	LANL/CST-7		X	X
Triay, Ines	LANL/Project Leader, TRU Waste Manager		X	X
Vigil, George	LANL/CST-1		X	X
Vigil, Jack	LANL/CST-7			X
Wachter, Joseph	Pajarito Science		X	X
Wander, Sandy	LANL/CST-7			X

A= Preaudit Briefing B= Contacted During Audit C= Postaudit Briefing

CAO AUDIT A-97-07 DETAIL SUMMARY									
REQUIREMENTS			DISPOSITION				EVALUATION		
PROGRAM ACTIVITIES	Procedures	Checklist Pages	CARs	CDAs	Obs	Rec	Adeq.	Impl.	Effect.
Organization, CAR 97-115	QAPjP	1					A	S	
WIPP Waste Information System	QP-1.1-034	3					A	S	
Software Control CAR 97-113	QP-1.1-006	4 1			2		A	S	

REQUIREMENTS			DISPOSITION				EVALUATION		
TECHNICAL ACTIVITIES	Procedures	Checklist Pages	CARs	CDAs	Obs	Rec	Adeq.	Impl.	Effect.
Acceptable Knowledge, Data Reconciliation and Reporting CARs 97-114 and 97-117	QP-1.1-021 QP-1.1-028	2			1				E
Non-destructive Assay CARs 97-050 and 97-116	DTP-1.2-029	10 2		1					E
WWIS	QP-1.1-034	2							
Software	QP-1.1-006	6							E

TOTALS/OVERALL EVALUATION	7	31	0	1	2	0	A	S	E
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CARs..... Corrective Action Requests
 Rec Recommendations
 Obs Observations
 Adeq Adequacy
 Impl..... Implementation
 Effect Effectiveness

CDAs..... Corrected During Audit
 S..... Satisfactory
 M..... Marginal
 E..... Effective
 I..... Indeterminate
 A..... Adequate