

United States Government

Department of Energy

memorandum

 Carlsbad Area Office
 Carlsbad, New Mexico 88220


DATE: September 19, 2000
 REPLY TO: CAO:QA:SAV:00-0886 UFC 2300.00
 SUBJECT: CAO Audit Report A-00-13
 TO: James Nunz, LAAO

The Carlsbad Area Office (CAO) conducted an annual recertification audit (in conjunction with an EPA inspection) of the Los Alamos National Laboratory (LANL) Transuranic Waste Characterization Program (TWCP) quality assurance, nondestructive assay, and transportation activities on August 28-31, 2000. The audit team concluded that assessed activities are adequate, effective, and satisfactorily implemented.

Two corrective action reports (CAO CARs 00-032 and 00-033) were identified and forwarded via separate correspondence. Two isolated deficiencies were identified and were corrected during the audit (CDA). Five observations and one recommendation are presented for management consideration.

The remainder of the LANL TWCP waste characterization and certification activities must be assessed for compliance with CAO requirements and WIPP Hazardous Waste permit prior to further TRU waste shipments from LANL. These are scheduled to be assessed during the week of September 25-29, 2000.

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

Lisa Chism
 for Samuel A. Vega
 Quality Assurance Manager

Attachment

cc w/attachment:

L. Chism, CAO
 P. Rogers, LANL
 M. Eagle, EPA
 S. Monroe, EPA
 D. Winters, DNFSB
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B. Walker, EEG
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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-00-13

AUGUST 28-31, 2000

TRU WASTE QUALITY ASSURANCE, NONDESTRUCTIVE ASSAY,
AND TRANSPORTATION PROGRAMS



Prepared By: *John W. Ptacek*
John W. Ptacek
Audit Team Leader

Date: 9/19/00

Approved By: *for Samuel A. Vega*
for Samuel A. Vega
CAO QA Manager

Date: 9/19/00

1.0 EXECUTIVE SUMMARY

Carlsbad Area Office (CAO) Audit A-00-13 was conducted to evaluate the adequacy, implementation, and effectiveness of Los Alamos National Laboratory (LANL) Transuranic Waste Characterization Program (TWCP) Quality Assurance, Nondestructive Assay, and Transportation activities. The U.S. Environmental Protection Agency (EPA) also conducted a concurrent inspection of the LANL Quality Assurance Program and an evaluation of the CAO Audit process. The remainder of the LANL Transuranic waste characterization activities and compliance with the WIPP Hazardous Waste Permit Waste Analysis Plan will be assessed as part of Audit A-00-16 during the week of September 25-29, 2000.

The audit was conducted at the LANL facility August 28-31, 2000. The audit team concluded that the LANL technical and quality assurance procedures continue to be adequate relative to the flow down of requirements from the CAO Quality Assurance Program Document (QAPD), Waste Acceptance Criteria (WAC), and TRUPACT-II Authorized Methods for Payload Control (TRAMPAC).

The audit team concluded that the defined LANL QA Program continues to be satisfactorily implemented in accordance with the LANL Quality Assurance Management Plan (QAMP), the LANL Quality Assurance Project Plan (QAPjP), and the LANL implementing procedures for the areas evaluated. The LANL technical areas of nondestructive assay and transportation were evaluated by the audit team and were determined to be implemented and effective.

The audit team identified two Corrective Action Reports (CARs) in the areas of procurement and measuring and test equipment. The team identified two isolated deficiencies requiring only remedial corrective actions that were Corrected During the Audit (CDA). Details relating to these isolated deficiencies are contained in the checklists. Five Observations were identified and one Recommendation was offered for management consideration. The two CARs have been previously issued under separate cover and are summarized in Section 6.0. The Observations and Recommendation are also discussed in Section 6.0.

2.0 SCOPE

The audit team evaluated the adequacy, implementation, and effectiveness of quality assurance and selected technical processes related to the LANL TRU Waste Characterization, Certification, and Transportation activities for debris wastes.

The following Quality Assurance (QA) elements were evaluated in accordance with the CAO QAPD:

Organization and Interfaces
Personnel Qualification and Training
QA Grading
Quality Improvement
Document Control
Records
Procurement
Measuring and Test Equipment
Control of Nonconforming Items
Corrective Actions
Audits and Assessments
Software Control

The following characterization technical elements were evaluated in accordance with the CAO WAC:

Nondestructive Assay (NDA) – Passive-Active Neutron Assay
Nondestructive Assay (NDA) – Tomographic Gamma Scan Assay
Nondestructive Assay (NDA) – High Efficiency Neutron Count Assay
Nondestructive Assay (NDA) – FRAM Isotopic Assay

The following transportation technical elements were evaluated in accordance with the CAO TRAMPAC:

Inspection of Packaging
TRUPACT-II Preparation and Loading
Shipping Preparation
Package Maintenance
Payload Certification
Documentation and Records

Evaluation of LANL TRU Waste Characterization Program (TWCP) documents was based on current revisions of the following documents:

LANL Transuranic Waste Quality Assurance Project Plan (QAPjP), TWCP-PLAN-0.2.3-001

LANL Transuranic Waste Certification Quality Program Plan, TWCP PLAN-0.2.4-001

Related LANL technical and quality assurance implementing procedures

3.0 AUDIT TEAM AND OBSERVERS

AUDITORS/TECHNICAL SPECIALISTS

Samuel Vega	Quality Assurance Manager, CAO
John Ptacek	Audit Team Leader, CTAC
Steven Calvert	Auditor, CTAC
Norm Frank	Auditor, CTAC
Wayne Ledford	Auditor, CTAC
Amy Arceo	Auditor, CTAC
Dee Scott	Auditor, CTAC
Jim Scheutz	Auditor (in training), CTAC
Jim Bresson	Technical Specialist, CTAC
Tom Ward	Technical Specialist, WID
Dorothy Gill	Technical Specialist (in training), CTAC
Randy Fitzgerald	Technical Specialist (in training), CTAC

INSPECTORS/OBSERVERS

Mike Eagle	EPA Inspector
Ben Walker	EEG Observer

4.0 AUDIT PARTICIPANTS

LANL individuals involved in the audit process are identified in Attachment 1. A preaudit meeting was held in Technical Area (TA) 48, Building RC-29, Conference Room 118 on August 28, 2000. A daily meeting was held with LANL management and staff to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held in the DOE-Los Alamos Area Office Building Conference Room at 528 35th Street, Los Alamos, on August 31, 2000.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The audit team concluded that the adequacy of the LANL QA Program is satisfactory in meeting the requirements of CAO's QAPD, Revision 3; WIPP WAC, Revision 7; and TRAMPAC, Revision 18. The audit team concluded that the QA program continues to be satisfactorily implemented. The LANL technical processes (NDA and transportation) evaluated by the audit team are determined to be implemented and effective.

5.2 QA Program Audit Activities

A summary table of audit results is provided as Attachment 2. Details of audit activities, including specific objective evidence reviewed, are contained within the audit checklists. Checklists are maintained as QA records.

LANL QA program activities were determined to be adequate, overall, and effectively implemented. Two deficiencies were identified in the areas of procurement and measuring and test equipment records. CAO CAR 00-032 addresses a lack of implementation of requirements for documenting procurement requisition reviews and approvals and the conduct of receipt inspections. CAO CAR 00-033 addresses a lack of some required data elements in the measuring and test equipment QA records.

Two Observations were identified in the area of audits and assessments. Observation 1 addresses proposed changes in one of the two methods that LANL uses for Management Assessment. Observation 2 proposes accelerating implementation of the new internal audit process. Neither of these Observations constituted a deficiency during the audit, however, they should be addressed to prevent potentially deficient conditions in the future.

5.2.1 Software Control

Quality assurance requirements for control of software used for processing, controlling, measuring, and statusing of hazardous and radioactive materials were evaluated. The evaluation included a review of the processes for the development and control of software baselines, software classification, and the review of completed software documentation. The software review included code documentation for the PC/FRAM (Maestro/PC FRAM), Tomographic Gamma Scanning system, Waste Management System, Headspace Gas Analysis System (HGAS), RTR Field Database, and spreadsheets for WWIS Certification Module entry. Verification of corrective actions for CAO CAR 99-080 (issued during previous Audit A-99-04) was attempted. Most committed corrective actions were verified as satisfactorily completed, except for reconciliation of LANL's baseline documentation with their software inventory list. This verification will be attempted during Audit A-00-16 on September 25-29, 2000. Evaluation of the revised LANL software quality assurance program resulted in the issuance of Recommendation 1 relating to documentation of annual software reviews. The written procedure is adequate and satisfactorily implemented. Associated technical activities relating to software quality assurance are effective.

5.3 Technical Activities

Evaluations of applicable LANL technical activities related to debris waste streams are summarized below. A list of procedures evaluated during the audit is provided as Attachment 3.

5.3.1 Nondestructive Assay (NDA)

The LANL non-destructive assay (NDA) program was evaluated and determined to consist of four parts: assay using the mobile passive-active neutron system (PAN); activities related to the determination of isotopic ratios using the Fixed Energy Response Function Analysis with Multiple Efficiency (FRAM) assay system; assay using multiple tomographic gamma scanner (TGS) systems; and assay that uses a high efficiency neutron counter (HENC) system.

All of these systems have been reviewed in previous audits so the initial basic calibration and QAO verification did not require review. There were no noted conditions that required recalibration for any of the subject systems, however, annual verifications of calibration, required by WIPP-WAC Attachment A, Section A-5, were reviewed. The LANL NDA program was compared to the requirements of the WIPP-WAC, Revision 7, Appendix A, during the period since the previous audit (June 1999).

The audit team determined that the procedures for the above LANL NDA processes were adequate and effectively implemented. Three Observations were prepared. Observation 3 concerns no project level data reviews being performed on assay data generated over the past several months. This area will be further evaluated during Audit A-00-16 on September 25-29, 2000. Observation 4 relates to redundant data reporting for TGS assay results. Observation 5 relates to TGS generation level QA review form signature blocks.

5.3.2 LANL Transportation

The audit team evaluated LANL TRUPACT-II inspection and maintenance, payload certification, packaging, loading, and transportation tracking and communications (TRANSCOM) processes. LANL satisfactorily performed a payload assembly and loading demonstration for the audit team to verify implementation of procedures. The audit team also reviewed a sampling of data packages from previous LANL TRU waste shipments to verify implementation of certification activities, transportation tracking, and communication processes. The audit team concluded that the processes and controls are acceptable for the assembly and leak check of the TRUPACT-II. The audit team determined that the written procedures are adequate and satisfactorily implemented and that technical activities are effective.

6.0 CORRECTIVE ACTION REPORTS, OBSERVATIONS, & RECOMMENDATIONS

6.1 Corrective Action Reports

The following corrective action reports (CARs) were identified during the audit:

6.1.1 CAR 00-032

This CAR documents several deficiencies that were identified in the implementation of the LANL procurement procedure (TWCP-QP-1.1-005, Revision 5). The deficiencies relate to lack of implementation of specified requirements for documenting technical reviews, buyer approvals, QA requirements, and receipt inspections.

6.1.2 CAR 00-033

This CAR documents deficiencies that were identified in the implementation of the LANL measuring and test equipment procedure (TWCP-QP-1.1-018, Revision 5). The deficiencies relate to lack of implementation of requirements for documenting the calibration schedule or interval and the calibration data and status results.

6.2 Observations

The following Observations were identified during the audit:

6.2.1 Observation 1

The last management assessment performed by the LANL Audits and Assessments (A&A) Division for the TWCP does not meet all requirements for management assessments. The process should be revised before A&A performs another assessment. Presently, management "walk-arounds" conducted and documented by LANL TWCP staff satisfy QAPD requirements for management assessment.

6.2.2 Observation 2

TWCP had not fully implemented their recently revised audit program. The previous annual audit was conducted in July-August of 1999 and the next audit was scheduled for May 2001. This would result in an interval between annual audits of approximately 21 months, which is considered excessive. Although some of the delays were quite understandable, the causes and the rationale for the delays were not well documented. Justification and extenuating circumstances for the delays were documented during the audit in a LANL memo to file, and the next internal audit is now scheduled for January 2001.

6.2.3 Observation 3

There was no project level data verification and validation (V&V) for the Nondestructive Assay (NDA) characterization activities for all four NDA systems (Refer to section 5.3.1 above for additional information). Project level V&V must be satisfactorily assessed prior to resumption of waste shipments. It is currently planned to include NDA project level V&V activities in the scope of Audit A-00-16 on September 25-29, 2000.

6.2.4 Observation 4

The LANL Tomographic Gamma Scanner NDA Batch Data Summary Sheet reports TRU activity in two ways (with and without 1.64 sigma) reflecting both the obsolete and the current reporting conventions, respectively. This presents the risk of reporting the wrong value into the WWIS. The report format should be revised to remove the obsolete value. During the audit, LANL issued an interim change notice (ICN) to revise the form to report only the "without" value.

6.2.5 Observation 5

The LANL Tomographic Gamma Scanner NDA generation level QA review form has two signature blocks for the QA reviewer. In data package LA-00-TGS-002, the second block was not signed, erroneously indicating an incomplete review. The form should be revised to one signature or the reviewers trained to sign twice. During the audit, the discrepant form was signed by the reviewer and an ICN was issued to delete the second signature.

6.2 Recommendations

The following recommendation is presented for LANL management consideration:

6.2.1 Recommendation

The LANL software requirements checklist form contains signature lines for the annual reviews. In practice, LANL uses an alternate method to document their annual software reviews. It is recommended that the form be revised to delete the unused signature lines.

7.0 LIST OF ATTACHMENTS

- Attachment 1: Personnel Contacted During the Audit
- Attachment 2: Summary Table of Audit Results
- Attachment 3: Table of Procedures Audited

PERSONNEL CONTACTED DURING THE AUDIT

PERSONNEL CONTACTED				
NAME	ORG/TITLE	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Allen, Garry	LANL/EET Project Manager			X
Anderson, David	LANL/NMT-3 Technical Staff Member		X	
Bailey, Jim	LANL/EET QA Staff		X	
Baker, Michael	LANL/EET NDA Specialist	X	X	X
Bayhurst, Greg	LANL/EET QA Staff		X	
Chavez, Mario	LANL/EET Software QA Engineer	X	X	X
Crabb, Richard	LANL/ESA-MT Metrologist		X	
Deaven, Helen S.	LANL/EET Software QA			X
Dell, Larry	NTWP/WID Senior QA Engineer	X	X	
DesGeorges, Louise	LANL/ESA-MT Programmer		X	
Drypolcher, Tony	LANL/NMT-7 Technical Staff Member	X	X	
Estil, Wesley	LANL/EET Waste Certification Support	X	X	X
Fabryka-Martin, June	LANL/EET TWCP Deputy SPM	X	X	X
Fernandez, Ruby Ann	LANL/EET Training Specialist	X	X	X
Garcia, Louise	LANL/EET TWCP Records Manager	X	X	
Garcia, Mary Ann	LANL/EET Training	X	X	X
Gauler, Allen	LANL/ESA-MT Team Leader		X	
Gavett, Marji	LANL/EET QA Officer	X	X	X

PERSONNEL CONTACTED				
NAME	ORG/TITLE	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Harper, Johnny	LANL/EET Deputy Group Leader	X	X	
Hawkinson, David R.	LANL/EET TWCP Support (Team-21)	X		
Herrera, Jennifer	LANL/EET RMDC Staff		X	X
Hubmer, Steve	LANL/EET TRUPACT Technician	X	X	X
Janecky, David	LANL/EET Software QA Specialist		X	
Kosiewicz, Stan	LANL/EET Technical Staff Member			X
Lacy, Keith	LANL/EET Transportation Official	X	X	X
Lin, Mavis	LANL/EET TWCP Assistant SPM	X		
Lucero, Fabiola	LANL/EET RMDC Staff		X	
Martinez, Flavio	LANL/EET TRUPACT Technician	X	X	X
Martinez, Manuel	LANL/EET RMDC Team Leader	X	X	X
Miko, David	LANL/EET NDA Specialist	X	X	X
Mojica, Lee	LANL/EET RCT	X	X	
Montoya, Andrew J.	LANL/NMT-3 Team Leader	X	X	
Montoya, Gene M.	LANL/EET TRUPACT Shipper	X	X	X
Mullen, Richard	LANL/EET TRUPACT Technician	X		
Nunz, James	DOE-LAAO WM Program Manager			X
Patton, Patricia	LANL/EET TWCP Staff	X		
Pickrell, Mark	LANL/EET Group Leader		X	

CAO Audit A-00-13 Detail Summary

Evaluation Area	Concern Classification				QA Evaluation		
	CARs	CDAs	Obs	Rec	Adequacy	Implementation	Effectiveness
Organization & Interface					A	S	E
Training					A	S	E
QA Grading					A	S	E
Document Control					A	S	E
Records					A	S	E
Procurement	00-032				A	U	U
M&TE	00-033	2			A	S	E
CARs/NCRs		1			A	S	E
Assessments			1, 2		A	S	E
Software QA				1	A	S	E
NDA - HENC			3		A	S	E
NDA - RANT			3		A	S	E
NDA - PAN			3		A	S	E
NDA - TGS			3, 4, 5		A	S	E
Transportation					A	S	E
TOTALS	2	2	5	1	A	S	E

Definitions

E = Effective

S = Satisfactory

U = Unsatisfactory

I = Indeterminate

A = Adequate

[x] = Redundant or secondary listing

CDA = Corrected During Audit

CAR = Corrective Action Report

Obs = Observation

Rec = Recommendation

LANL PROCEDURES AUDITED (A-00-13)			
ITEMS	PROCEDURE NUMBER	REVISION NUMBER	TITLE
1.	QP 1.1-001	6	Procedure Preparation, Review, Approval, Revision, and Interim Change
2.	QP 1.1-002	4	Document Control
3.	QP 1.1-003	7	TWCP Training
4.	QP 1.1-004	6	Records Management
5.	QP 1.1-005	5	Procurement
6.	QP 1.1-006	8	Software Management
7.	QP 1.1-007	7	Nonconformance Reporting and Tracking
8.	QP 1.1-008	6	Corrective Action Reporting and Tracking
9.	QP 1.1-009	5	Surveillances
10.	QP 1.1-018	5	Measuring and Test Equipment
11.	QP 1.1-020	6	Root Cause Analysis
12.	QP 1.1-026	4	Trend Analysis
13.	QP 1.1-027	4	Audits
14.	QP 1.1-029	4	Grading TWCP Activities
15.	QP 1.1-030	3	Work Suspension
16.	QP 1.1-032	3	Hazardous Material Transportation and Tracking
17.	QP 1.1-033	3	Management Assessments
18.	DTP 1.2-009	6	Waste Assay Using the Passive-Active Neutron (PAN) Assay System
19.	DTP 1.2-010	4	Calibrating the Mobile Passive-Active Neutron Assay System
20.	DTP 1.2-011	2	Waste Assay Using the Tomographic Gamma Scanner
21.	DTP 1.2-016	2	Calibrating the Tomographic Gamma Scanner Assay System
22.	DTP 1.2-029	6	Determining Isotopic Ratios in Waste Containers Using the RANT PC/ FRAM Assay System
23.	DTP 1.2-030	3	TRUPACT II Operations and Leak Testing
24.	DTP 1.2-031	4	Varian Porta-Test Leak Detector Procedure
25.	DTP 1.2-032	3	Adjustable Center of Gravity Lift Fixture
26.	DTP 1.2-034	3	Waste Transportation Certification Implementation
27.	DTP 1.2-035	3	Off-site Transportation of CH-TRU Waste
28.	DTP 1.2-059	0	Operating the High Efficiency Neutron Counter using INCC
29.	DTP 1.2-060	0	Calibrating the High Efficiency Neutron Counter Using the INCC