



Department of Energy
Carlsbad Field Office
P. O. Box 3090
Carlsbad, New Mexico 88221

February 4, 2002



Mr. Steve Zappe, Project Leader
Hazardous Waste Bureau
New Mexico Environment Department
2905 Rodeo Park Drive East, Bldg. 1
Santa Fe, New Mexico 87505-6303

Re: Transmittal of the Final Audit Report for the Los Alamos National Laboratory
Visual Examination Technique (A-01-11)

Dear Mr. Zappe:

This letter transmits the Final Audit Report for the Los Alamos National Laboratory Visual Examination Technique Audit of TA-55 and the Off-Site Source Recovery Program as required by Section II.C.2.c of the WIPP Hazardous Waste Facility Permit. The audit was conducted May 8, 9 and 14 - 16, 2001.

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.

Please contact the CBFO Quality Assurance Manager, Ava L. Holland, at (505) 234-7423 should you have any questions concerning this audit report.

Sincerely,

Dr. Ines R. Triay
Manager

Enclosure

cc w/enclosure:
M. Gerle, WTS
C. Walker, Techlaw
CBFO Mailroom



Mr. Zappe

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cc w/o enclosure:
T. Harms, DOE-HQ
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U.S. DEPARTMENT OF ENERGY
CARLSBAD FIELD OFFICE

FINAL AUDIT REPORT

OF THE

LOS ALAMOS NATIONAL LABORATORY

LOS ALAMOS, NEW MEXICO

AUDIT NUMBER A-01-11

MAY 8, 9 and 14-16, 2001

TRU WASTE CHARACTERIZATION USING THE VISUAL EXAMINATION
TECHNIQUE



Prepared By:

A. Earl Bradford

A. Earl Bradford
Audit Team Leader

Date:

February 4, 2002

Approved By:

Ava L. Holland

Ava L. Holland
Carlsbad Field Office QA Manager

Date:

02/04/02

1.0 EXECUTIVE SUMMARY

Carlsbad Field Office Audit A-01-11 was conducted to evaluate the adequacy, implementation, and effectiveness of the LANL TWCP activities for visual examination (VE) and packaging of newly generated debris wastes. The VE Technique and packaging activities for the newly generated wastes are conducted by separate LANL organizations not within the currently approved TWCP. The new TWCP participating organizations evaluated were the LANL Nuclear Materials Technology (NMT) Division in Technical Area 55 (TA-55), which examines and packages newly generated wastes and the Environmental Technology Division, Waste Management (E-WM) Organization, which is responsible for visual examination and packaging of the sealed sources for the Off-Site Source Recovery (OSR) Project. Both organizations have initiated interface agreements with the TWCP that address their respective VE process and packaging operations. Final characterization of the newly generated waste, e.g. nondestructive assay (NDA) and headspace gas (HSG) analysis is the responsibility of the previously approved TWCP.

The audit was conducted at the LANL facilities May 8th and 9th and May 14 through 16, 2001. The audit team concluded that the LANL technical procedures were adequate, with one exception, relative to the flow down of requirements from the Waste Analysis Plan (WAP) of the WIPP Hazardous Waste Permit. The process determined to be inadequate was the packaging operations and visual examination process being conducted in TA-55. This was documented in CBFO Corrective Action Report (CAR) 01-039. LANL implemented corrective actions to address the condition documented in this CAR. The CAR was closed by CBFO on January 8, 2002. A CAR was also issued documenting records deficiencies relative to the acceptable knowledge (AK) developed for the OSR program. This CAR (01-040) has also been closed. Based on the closure of these two CARs, the LANL program for performing the VE technique for TA-55 and the OSR program is determined to be adequate, satisfactorily implemented, and effective. Two Observations and one Recommendation were also identified during the audit. The CARs, Observations, and Recommendations are described in Section 6.0.

2.0 SCOPE

The audit team evaluated the adequacy, implementation, and effectiveness of technical and quality assurance processes related to the LANL TRU waste characterization and certification activities for newly generated debris waste being packaged and visually examined in TA-55 and by E-WM in the Chemistry, Materials, and Research (CMR) Facility for the OSR Program.

The following quality assurance (QA) elements in relation to the LANL support organizations were evaluated in accordance with the Carlsbad Field Office QAPD and the WAP:

Organization/QA Program
Personnel Qualification and Training

Documents and Records
Control of Nonconforming Items
Procurement
Software Quality Assurance

The following characterization technical elements were evaluated in accordance with the Waste Analysis Plan of the WIPP Hazardous Waste Permit:

Visual Examination Technique conducted in TA-55 and the OSR Program
Generation Level and Project Level Data Verification and Validation
Acceptable Knowledge Documentation associated with TA-55 and the OSR Program

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 (and TRAMPAC), TWCP PLAN-0.2.4-001

Related LANL technical and quality assurance implementing procedures

3.0 AUDIT TEAM AND OBSERVERS

AUDITORS/TECHNICAL SPECIALISTS

Jody Plum	Carlsbad Field Office Management Representative
Marlin Horseman	Audit & Assessment Manager, CTAC
Earl Bradford	Audit Team Leader, CTAC
Steven Calvert	Auditor, CTAC
Dee Scott	Auditor, CTAC
Pete Rodriguez	Auditor, CTAC
Wayne Ledford	Auditor/VE Technical Specialist, CTAC
Jim Schuetz	Auditor, CTAC
Charlie Riggs	Auditor, CTAC

OBSERVERS

Steve Zappe	NMED
Steve Holmes	NMED
Will Fetner	NMED
June Dreith	NMED/TechLaw
Steve Phillips	NMED/TechLaw
Ben Walker	EEG

4.0 AUDIT PARTICIPANTS

LANL individuals involved in the audit process are identified in Attachment 1. A pre-audit meeting was held in the Physics Auditorium, Technical Area 3, Building 215, on May 14, 2001. A daily meeting was held with LANL management and staff to discuss issues and potential deficiencies. The audit was concluded with a post-audit meeting held in Conference Room 15, Building 37, Technical Area 50, on May 16, 2001.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The audit team concluded that the overall LANL QA program was adequate, satisfactorily implemented and effective to control the activities of the support organizations packaging the newly generated debris wastes.

The audit team concluded that the adequacy of the LANL technical processes, with exception of the TA-55 VE process, were satisfactory in meeting the requirements of the current WIPP Hazardous Waste Permit - Waste Analysis Plan (WAP). The AK Summary reporting process being performed by the OSR Program was marginally implemented and marginally effective. Based on LANL's corrective actions taken to address the CARs issued during the audit (see section 6.1), these programs are now considered adequate, satisfactorily implemented, and effective.

Audit activities, including specific objective evidence reviewed, are described below and in the CBFO checklists. The CBFO checklists are maintained as QA records. A list of procedures evaluated during the audit is provided as attachment 3.

5.2 Technical Activities

Evaluations of applicable LANL technical activities related to the newly generated debris waste streams are summarized below.

5.2.1 Visual Examination Technique

The visual examination technique was observed in both areas packaging and examining the newly generated wastes at LANL. TA-55 VE activities were observed and batch data reports supporting the activity were evaluated. Several deficiencies were noted in the TA-55 implementing procedures and the method the TA-55 Operators were utilizing to document their VE activities. Procedure deficiencies included procedures referencing forms that were not identified, procedures requiring reports with no format provided, and procedures that did not identify records or define record classification requirements. Process deficiencies were identified with TA-55 WMS system in relation to the electronic approval signature for two individuals performing VE. The first signature was recorded by the WMS software and was applied in one designated location and the required second signature was noted in a comment field.

This method of providing objective evidence with the software does not provide functionality for individual application of an electronic approval signature. Consequently, the batch data generated by TA-55 did not provide sufficient objective evidence that two VE operators performed the WAP required functions. CAR 01-039 was issued to address the deficiencies (refer to section 6.1).

The audit team determined that the visual examination process being performed in TA-55 was inadequate. The written procedures were not adequate and not in compliance with requirements. Implementation and effectiveness of the TA-55 process was left open pending resolution of the procedural deficiencies. The CAR documenting the deficient conditions (CAR 01-039) has been closed and the CAR, with objective evidence supporting its closure, is in attachment 2. Based on the actions taken by LANL to resolve CAR 01-039, the VE technique used by TA-55 is now considered adequate, satisfactorily implemented, and effective. The audit team also identified a practice in performing the packaging operation in TA-55 that may lead to a deficient condition in the future. This item is presented as Observation 1 (refer to section 6.2).

The VE technique and packaging operations performed in the CMR Facility for the OSR Program and supporting data packages were determined to be in compliance with requirements. The OSR Program procedures and processes were determined to be adequate, satisfactorily implemented and effective. The audit team identified a practice in performing the data package review for the OSR VE process that may lead to a deficient condition in the future. This item is presented as Observation 2 (refer to section 6.2).

5.2.2 Acceptable Knowledge

Activities related to the Acceptable Knowledge process were reviewed. This review included the evaluation of AK summary documentation for the newly generated wastes being processed by the TA-55 operation and the sealed sources being packaged by the OSR Program. The AK Summary reports were evaluated to ensure that an independent technical review had been completed and for traceability of the roadmap and its supporting documentation. Reference documents were reviewed during the traceability portion of the evaluation. It was determined that traceability of the information utilized in the OSR summary report was unsatisfactory. The AK Summary report did not reference all the supplemental source documents used to establish the conclusions documented in the report. CAR 01-040 was issued to address the deficiency (refer to section 6.1). This CAR has been closed.

During evaluation of the AK process and the associated OSR Program AK documentation, a number of inaccuracies and inconsistencies in data content were identified and discussed. The inaccurate and inconsistent items identified were related to a PCB definition, the needed removal of an inappropriate material code (U213), failure to address a needed material code (D001), and the repeated use of the indecisive term "Usually" in the AK Summary documentation. This concern is identified in Recommendation 1 (refer to section 6.3). LANL chose to follow the audit team's

recommendation and processed revisions to the documents. The audit team verified that the recommendations had indeed been implemented prior to the exit meeting.

With the exception of the issue identified in CAR 01-040, the LANL AK written program was adequate and satisfactorily implemented and the technical activities related to the AK process are effective.

Because the LANL AK program for debris waste has been approved by NMED (ref. Audit A-00-16), a B6 checklist for AK is not included in this audit report. Verification of proper implementation of the AK reconciliation process for newly generated wastes will be reviewed during future audits.

5.2.3 Data Validation; Level 1 and 2, Generation Level and Project Level Data Review and Reporting

The data validation process was evaluated by review of batch data packages. The evaluation included examination of the data packages to assure that correct data reviews are occurring.

The audit team determined that the written program is adequate and satisfactorily implemented and that the technical validation activities are effective.

6.0 Corrective Action Reports (CARs), OBSERVATIONS, RECOMMENDATIONS

6.1 Corrective Action Reports (CARs)

During the audit, the audit team identified Conditions Adverse to Quality (CAQ) and documented those condition(s) on Corrective Action Reports (CARs).

Condition adverse to Quality (CAQ) – Term used in reference to failures, malfunctions, deficiencies, defective items, and nonconformances.

Significant Condition Adverse to Quality – A condition which, if uncorrected, could have a serious effect on safety, operability, waste confinement, TRU waste site certification, compliance demonstration, or the effective implementation of the Quality Assurance (QA) program.

The following two WAP related Corrective Action Reports were identified during the audit:

6.1.1 CAR 01-039

This CAR documented both procedural adequacy issues and process deficiencies that were identified while witnessing the TA-55 VE process and packaging operations. The concerns were as follows:

1. Electronic approval signature for Visual Examination (VE) personnel was applied in only one location with the second VE person noted only in a comment field. Software did not provide functionality for individual application of an electronic approval signature for both VE personnel.
2. The batch data reports reviewed for TA-55 and the associated WMS data did not provide objective evidence that two qualified VE operators perform the process described in NMT7-WI3-SOP-TA55-013 as waste items are packaged into drums. The WAP requires either electronic or written signatures.
3. Procedure NMT7-WI3-SOP-TA55-013 did not identify or reference how the "Raw Data Collection Form" is generated.
4. The LANL procedures for VE technique in TA-55 did not identify the format or content of a VE technique batch report.
5. The LANL procedures for VE technique in TA-55 did not identify the records generated by performing the procedure or specify their classification, i.e., Lifetime or Non-Permanent.

LANL revised their process to require the written signatures of two qualified VE operators, identify the format of batch data report, identify the records generated by the process, and define how the "Raw Data Collection Form" was generated.

6.1.2 CAR 01-040

This CAR documented a deficiency that was identified while reviewing the AK Summary Report and supporting source documentation for the OSR Program. The OSR AK Summary report did not reference all source documents in the Road Map.

LANL revised their road map and added needed source documentation to their AK record.

6.2 Observations

During the audit, the audit team identified conditions, which warrant input by the audit team to the audited organization regarding potential problems or suggestions for improvement. The audit team members, in conjunction with the Audit Team Leader (ATL), evaluated these conditions and classified them as Observations or Recommendations using the following definitions. Once a determination is made, the audit team member, in conjunction with the ATL, categorizes the conditions appropriately.

Observation – A condition that, if not controlled, could result in a CAQ

Recommendations – Suggestions that are directed toward identifying opportunities for improvement and enhancing methods of implementing requirements.

The following two Observations were identified by the audit team as areas of concern that were not yet actual deficient conditions, but which raise the probability of future deficiencies if not corrected.

6.2.1 Observation 1

When waste item numbers are obtained from WMS, the numbers were not immediately marked on the item. This practice relies upon the memory of the operators to correctly identify the items later to assure traceability of the item is maintained. Item numbers should be marked on the item as soon as possible.

6.2.2 Observation 2

On OSR batch report, LA-01-OSR-VE-004, the individual who performed the technical supervisor review also was a data generator (VE recorder on container LA00000058567), while this is not prohibited by the WAP, it is a practice that should be avoided.

6.3 Recommendations

The following WAP related recommendation was provided for management consideration.

6.3.1 Recommendation 1

During evaluation of the AK processes, several areas for improvement of the AK Summary documentation were discussed with cognizant LANL personnel. The audit team recommends that the AK Summary documentation be revised to incorporate the agreed upon enhancements and clarifications related too:

- PCB Definition
- Remove U213 Code
- Add D001 Code
- Remove the word "Usually" from text

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Corrective Action Supporting Documentation
Attachment 3: Objective Evidence
Attachment 4: Audited LANL Implementing Procedures

PERSONNEL CONTACTED DURING AUDIT A-01-11				
NAME	ORG/TITLE	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Abeyta, Cristy	EWM OSR, Environmental Scientist		X	
Anderson, David	NMT3, System Administrator		X	
Fabryka-Martin, June	LANL/EET TWCP Deputy SPM	X	X	X
Fernandez, Ruby Ann	LANL/EET Training Coordinator	X	X	X
Garcia, Frank	IM-S, Record Specialist		X	
Garcia, Louise	LANL/EET Document Control Coordinator		X	X
Garcia, Mary Ann	EET, Training Specialist		X	
Gavett, Marjorie	LANL/EET TWCP SPQAO	X	X	X
Gibson, Yvonne	NMT-7, Editor		X	
Goyal, Kapil	NMT-7, Staff Member	X	X	X
Hargis, Ken	EWM OSR, Program Manager			X
Harper, Johnny	EET Deputy Group Leader	X		
Hatchnell, Jeff	NMT-7, Operations Team Leader		X	
Huchton, Roger	NMT-7, Program Coordinator	X	X	
Johnson, Jerry	IM-S, Record Specialist		X	
Kosiewicz, Stan	EET, OSR Interface	X	X	X
Leonard, Lee	E-WM OSR Project Leader			X

PERSONNEL CONTACTED DURING AUDIT A-01-11				
NAME	ORG/TITLE	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Matzke, Jim	FWO-SWO		X	
Martinez, Amy	NMT-7, Document Control Custodian		X	
Martinez, Manuel	EET SQA	X	X	X
Montoya, Andrew	NMT-7 Team Leader	X	X	X
Musgrave, John	C-INC AK SMEd		X	
Navarjo, Carlene	CCN-2, Network Administrator		X	
Patton, Patricia	EET, Records Coordinator		X	X
Pearson, Mike	E-WM OSR Project Engineer	X	X	X
Pickrell, Mark	EET Group Leader	X	X	
Poteet, Doris	EET, SCMC		X	
Sanchez, Lonnie	NMT7, QA Specialist	X	X	X
Rogers, Pamela	EET TWCP SPM		X	X
Souza, Larry	EET TWCP QA	X	X	X
Taylor, Wayne	NMT-11, Staff Member		X	
Trujillo, Michael	NMT-7, Technician		X	
Weide, Ron	NMT7, Group Leader			X
Weir, Shannon	EET Records Manager	X	X	X
Wulff, Dennis	NMT7, Technical Lead		X	X

LIST OF WAP RELATED PROCEDURES AUDITED (A-01-11)

NUMBER	PROCEDURE NUMBER	REVISION	TITLE
1.	QP-1.1-010	R.11	Project Level Data Validation and Verification
2.	QP-1.1-021	R.5/IC3	Acceptable Knowledge Documentation
3.	DTP-1.2-064	R.3	Waste Characterization Data Reconciliation with Acceptable Knowledge
4.	OSR-MISC-002	R1	Off-Site Source Recovery Transuranic Waste Interface Document
5.	OSR-OP-120	R5	Visual Examination and Packaging of OSR Sealed Sources
6.	NMT7-AP-TA55-018	R3	TA-55 Transuranic Waste Interface Document
7.	NMT7-SOP-TA55-013	R1	Inspecting, Packaging, Rejecting, and Remediating Transuranic Waste for WIPP and for TA-54 Safe Storage
8.	NMT7-WI1-SOP-TA55-013	R1	Inspecting, Labeling, and Preparing TRU Waste Containers
9.	NMT7-WI2-SOP-TA55-013	R3	Performing Visual Examinations of TRU Waste
10.	NMT7-WI3-SOP-TA55-013	R1	Packing TRU Waste Containers
11.	NMT7-WI4-SOP-TA55-013	R1	Sealing TRU Waste Containers
12.	NMT7-WI5-SOP-TA55-013	R1	Nonconformances
13.	NMT7-WI6-SOP-TA55-013	R1	Data Review, Validation, and Verification for TRU Waste