

United States Government

  
Department of Energy

# memorandum

Carlsbad Area Office  
Carlsbad, New Mexico 88221

JAN 30 1997

DATE: JAN 30 1997  
REPLY TO: CAO:AT:MLC 97-0124  
ATTN OF:  
SUBJECT: Carlsbad Area Office Surveillance Report S-96-48

TO: Steve Zappe, NMED

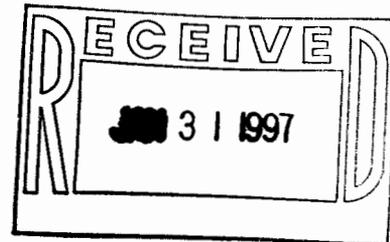
Please find attached a copy of the subject surveillance report of the Los Alamos National Laboratory (LANL) TRU Waste Characterization Program (TWCP). I hope this satisfies your needs.

If you need more information, please call Ms. Lea Chism at (505) 234-7442.

*for* *More Stations*  
R. Dennis Brown, Manager  
Quality Assurance

Attachment

cc w/o attachment:  
S. Vega, CAO



**memorandum**Carlsbad Area Office  
Carlsbad, New Mexico 88221

FYI

DATE: September 26, 1996

REPLY TO  
ATTN OF: CAO:ONTWO:TJR:96-2326

SUBJECT: Issuance of Carlsbad Area Office Surveillance Report S-96-48

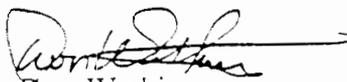
TO: J. Vozella, Assistant Area Manager Environment and Projects, LAAO

Attached is the Carlsbad Area Office (CAO) Surveillance Report S-96-48 of the Los Alamos National Laboratory (LANL) TRU Waste Characterization Program (TWCP). The surveillance was conducted on August 13-16, 1996, at the LANL facilities in Los Alamos, New Mexico. Please note that I have upgraded Corrective Action Report (CAR) 96-081 to a *Significant Condition Adverse to Quality* (Block 11 of the CAR) due to the numerous deficiencies noted in the CAR. LANL management should focus attention on successful implementation of their quality assurance program for CAO-sponsored technical work.

Please forward this report to Pamela Rogers, TWCP Project Manager, with the following actions:

1. Two Corrective Action Reports (CARs) were identified during the surveillance and are attached to the report. Please determine the proposed corrective actions, investigative actions, and actions to preclude recurrence as required by Block 12 of each CAR. Also identify the individual assigned responsibility for completing the proposed actions and provide a schedule for completing each action.
2. Please transmit the CAR responses to my office no later than the date indicated in Block 14, for review and concurrence. Included with the surveillance report are blank "CAR Continuation Sheets" and "Instructions for Completing Corrective Action Response."

If you have any questions or require additional information concerning these CARs, please contact me at (505) 234-7478.

  
Don Watkins  
Manager  
National TRU Program

Attachment

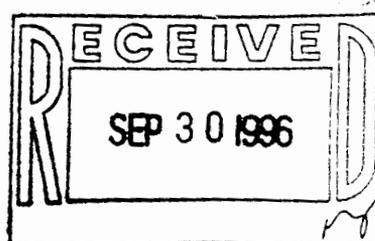


Joseph Vozella

- 2 -

September 26, 1996

cc w/attachment:  
K. Hunter, CAO  
M. McFadden, CAO  
T. J. Reese, CAO  
L. Chism, CAO  
P. Rogers, LANL  
M. Gavitt, LANL  
B. LeBrun, LAAO  
H. Plum, LAAO  
✓ F. Lentz, CTAC



U.S. DEPARTMENT OF ENERGY  
CARLSBAD AREA OFFICE

SURVEILLANCE REPORT

OF

LOS ALAMOS NATIONAL LABORATORY  
Los Alamos, New Mexico

SURVEILLANCE S-96-48

August 13-16, 1996

TRANSURANIC WASTE  
CHARACTERIZATION PROGRAM



Prepared by:

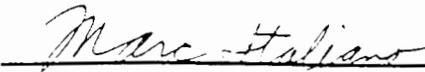


Kenneth O. Gilkerson, CTAC  
Surveillance Team Leader

Date:

9/17/96

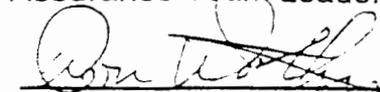
Concurred by:

  
for R. Dennis Brown, DOE-CAO  
Assurance Team Leader

Date:

9/25/96

Issued by:

  
D. Watkins, DOE-CAO  
Team Leader, National TRU Program

Date:

9/25/96

## 1.0 EXECUTIVE SUMMARY

Surveillance S-96-48 was conducted on August 13-16, 1996 at Los Alamos National Laboratories (LANL) in Los Alamos, New Mexico. The purpose of this surveillance was to evaluate the controls established for the LANL Transuranic Waste Characterization Program (TWCP) in accordance with the requirements contained in the LANL QAPjP, CSTDO-PLAN-002, R0, *Los Alamos National Laboratory Transuranic Waste Characterization Quality Assurance Project Plan*, dated November 10, 1995.

The Surveillance Team determined that the TWCP was not fully implemented at the time of this surveillance. The procedures for implementing the program were either not yet developed or were being revised to address the requirements of the CAO QAPD and the QAPP. Two CAO corrective action documents were thus issued. CAR 96-081 identifies deficiencies in flowdown of QAPD requirements to implementing procedures, and CAR 96-082 identifies an implementation issue relative to records processing. *The Survey Team* One observation regarding the maintenance of lab equipment was identified. ~~It should be~~ noted that no waste characterization/certification activities are currently ongoing. While deviations from the QA program were identified, no adverse impacts on the quality of the actual work activities were identified. In addition, five recommendations are offered for management consideration. Although the program is not fully implemented, it has greatly improved since the Program Review conducted December 1995, particularly in the area of organization and organizational interface. The draft procedures and Waste Certification Plans reviewed indicate that when implemented, program requirements for waste characterization and certification will be met.

## 2.0 SCOPE

Surveillance S-96-48 was conducted to evaluate LANL waste certification and characterization processes for newly generated and legacy transuranic waste. This surveillance included an evaluation of the adequacy and implementation of the LANL Quality Assurance Project Plan (QAPjP) and related procedures where applicable. In addition, the surveillance team evaluated the status and adequacy of the LANL Transuranic Waste Certification Plan. The areas reviewed in the surveillance included:

- Waste Characterization
- Waste Certification

- NDA/NDE
- CAO Quality Assurance and technical requirements flowdown
- Software Quality Assurance (relative to waste characterization/certification)
- Transuranic Waste Streams (Analysis and RCRA Codes)
- Acceptable Knowledge
- Status of implementation of Quality Assurance requirements as they relate to the waste characterization/certification process.

### 3.0 SURVEILLANCE TEAM AND OBSERVERS

#### SURVEILLANCE TEAM:

Kenneth Gilkerson, CTAC, Surveillance Team Leader  
 Richard Hicks, CTAC, Surveillance Team Member  
 John Ptacek, CTAC, Surveillance Team Member  
 Russ Bisping, CAO, Surveillance Team Member  
 Laurie Sparks, Westinghouse, Surveillance Team Technical Specialist  
 Dave Baran, New Brunswick Laboratory, Surveillance Team Technical Specialist

#### OBSERVERS:

Kyle Rogers, Office of Radiation and Indoor Air (ORIA),  
 Environmental Protection Agency (EPA)  
 Patrick Kelly, S. Cohen & Associates, EPA  
 Paula Hugo, AT Kearney, EPA  
 Steve Zappe, New Mexico Environmental Department (NMED)  
 Janice Archuleta, NMED  
 Craig Snider, CAO  
 Dennis Brown, CAO  
 Ben Walker, Environmental Evaluation Group (EEG)

### 4.0 SURVEILLANCE PARTICIPANTS

NAME	ORGANIZATION	A	B	C
Abercrombie, Loren	LANL, ESH 19/CST25	X		
Ansell, Gerald	LANL, CST-12	X		
Archuleta, Janice	NMED, Observer	X	X	
Bacigalupa, Gian	LANL, ESH-19	X	X	X

NAME	ORGANIZATION	A	B	C
Betts, Stephen	LANL, CST-7		X	
Christensen, David	LANL CST-14			X
D'Anna, Lee	LANL, AA-1	X		X
Enter, Janie	LANL, CST-7		X	
French, Sean	LANL, ESH-19, CST-5, CST-14		X	
Gautier, Peggy	LANL, CST-3	X		
Gavett, Marji	LANL, CST-7 QA	X	X	X
Gruetzmacher, Kathleen	LANL, NMT-7	X	X	
Hakonson, Kelly	LANL, CST-12		X	
Harris, Gordon	LANL, CST-5		X	
Harper, Johnny	LANL, CST-7	X	X	X
Helfinstine, Suzann	LANL, ESH-12	X		
Hugo, Paula	AT Kearney , EPA Observer	X	X	X
Janecky, David	LANL, CST-7		X	
Kelly, Patrick	S. Cohen & Associates, EPA Observer	X	X	X
Kosiewicz, Stan	LANL, CST-7			X
LeBrun, Bruce	LAAO, DOE			X
Lombardo, Anthony	LANL, CST-12		X	
Lucero, Fabiola	LANL, CST-25, RMDC	X	X	X
Maez, Marshall	LANL, NMT-7/ESH-14	X	X	
Mark, Jon	LAAO, DOE	X		X
Martinez, David	LANL, CST-3		X	
Oakley, Marta	LANL, AA-1	X		X
Plum, H. L.	LAAO, DOE	X		
Ramsey, Susan S.	LANL, NMT-7	X		X
Reed, Sheila	LAAO, DOE	X		X
Rogers, Kyle	EPA, Observer	X	X	X
Rogers, Pamela	LANL, CST-7 TWCP Project Manager	X	X	X
Schuman, Paul	LANL, ESH-19	X		X

NAME	ORGANIZATION	A	B	C
Smith, Kathryn K.	LANL, NMT-7		X	
Snider, Craig	CAO, DOE, Observer	X	X	
Sowers, Joe	LANL, CST-7	X	X	X
Stanhope, Cathy	LANL, CST-7	X	X	X
Taggart, Daniel P.	LANL, CST-7	X	X	X
Vigil, Jack	LANL, CST-7		X	
Walker, Ben	EEG, Observer	X	X	X
Wieneke, Ron	LANL, NMT-7			X
Yeamans, David	LANL, CST-			X
Zappe, Steve	NMED, Observer	X	X	X

A= Pre-Surveillance Briefing    B= Contacted During Surveillance    C= Post-Surveillance Briefing

## 5.0 SURVEILLANCE RESULTS

The conduct of the surveillance of the LANL Transuranic Waste Characterization Program included interviews of cognizant personnel; reviews of plans, procedures, and other documents; examinations of facilities; follow up of previously identified issues from the Program Review; and evaluations of the objective evidence and observations discerned during the surveillance. The following areas were examined:

### *Requirements Flowdown*

The LANL QAPjP incorporates both the technical and QA requirements of the CAO QAPP. The QAPjP requires the QA program to be conducted in accordance with DOE Order 5700.6C, the CAO QAPD, and the CAO QAPP. The Surveillance Team tracked the flowdown of the CAO QAPD requirements to the TWCP implementing procedures and determined that, although, the TWCP meets most of the basic requirements described in DOE Order 5700.6 C, it does not meet all of the CAO QAPD requirements particularly in the areas of Corrective Action and Software Quality Assurance. CAR 96-081 was written to address program adequacy issues. It should be noted that TWCP Management was aware of program adequacy issues and that most TWCP procedures were in draft or being revised at the time of the surveillance.

### *Status of Quality Assurance Implementation*

The status of implementation of Quality Assurance requirements as they relate to the waste characterization and certification processes can be summarized for the most part as "not yet implemented." Since a program that adequately

addresses all the QA requirements has not yet been established, there was little implementation to evaluate. It was found that the procedures for records management were not being implemented as written; CAR 96-082 was written to address this.

#### *Software Quality Assurance*

Software Quality Assurance is not being implemented for the TWCP. The procedure in place does not meet QAPD requirements, and the draft revision that was reviewed needs to include additional elements to meet all of the requirements. Specific areas requiring modification include classification, testing, inventory, configuration management, problem reporting, and corrective actions. The adequacy CAR 96-081 addresses these deficiencies.

#### *Waste Characterization*

Waste characterization activities have been suspended until TWCP can get its procedures revised, developed, and in place. Twenty drums of waste had been characterized previously using the procedures initially developed after the 1995 program review. It was during this activity that the TWCP realized that the procedures and processes in place were not adequate and that the data generated for these drums of waste did not meet program requirements. As a result, subsequent characterization activities were suspended.

#### *Waste Certification*

The waste certification program will be defined and documented in the LANL Transuranic Waste Certification Plan CSTDO-004. This plan is still an unapproved draft, although it has been reviewed by CAO and has a few outstanding issues. LANL's waste certification hinges on the approval and implementation of this plan.

#### *NDA/NDE*

The surveillance team evaluated the NDA/NDE transuranic waste assay program to determine the status of program compliance to the CAO QAPP and LANL QAPjP. Although no transuranic waste is currently being assayed, procedures and processes for use of the Passive/Active Neutron (PAN) assay device and the Tomographic Segmented Gamma Scanner (T/SGS) were examined based on existing procedures and past use. The LANL personnel have extensive experience in developing and using this technology. The procedures for using these systems (e.g., TWCP-DOP-CST7RANT-015,-014,-012) are being revised to fully address QAPP Chapter 9 requirements. Two radiography systems for NDE were also evaluated; they are also being revised to meet operation and maintenance requirements. While the Radioactive Assay and Nondestructive Testing (RANT) organization have the equipment, personnel, and expertise capable of providing accurate quality measurements, the procedures (e.g., calibration), documentation (statistical review of QC data), and training records

required by Chapter 9 of the QAPP are either incomplete (e.g., undergoing revision to address all QAPP requirements), or are not yet in place. See recommendation number one in Section 6.4.

#### *Acceptable Knowledge (AK)*

The area of "Acceptable Knowledge" was evaluated during the surveillance. This program is not being implemented, because requirements for AK are not yet documented in the CAO/DOE QAPP. However, the AK program at LANL/TWCP has been initiated using guidance from WIPP in the form of Appendix C9 of the WAP, Section 4.0 of the draft QAPP, Rev. 1, and discussions with the CAO's Waste Certification Manager. LANL personnel made presentations to the Surveillance Team about how they anticipate the AK program will be implemented.

The LANL TRU Waste Certification Plan (Rev. d final DRAFT-PLAN-CSTDO-004) defines the path that TWCP will take to get its waste ready and certified for shipment to the WIPP. This document, along with the relevant facility-specific TRU Waste Interface Documents will, in future revisions, define the TWCP's implementation of the AK requirements. Since these documents are not final yet, the lower-tier documents that deal specifically with AK have not yet been developed.

Most of the AK requirements that are currently available have not yet been compiled into an auditable record according to the requirements of the WAP Appendix C9 (and the soon-to-be-released interim changes to the QAPP). However, TWCP has written a draft Laboratory Standard for AK (AKLS) which addresses these requirements to some degree, but does not meet all of the requirements that will be imposed. An example of issues not addressed is how LANL will confirm "Acceptable Knowledge." It is recommended that the final revision of the AKLS be patterned after, and address, all final AK requirements of the WAP and QAPP. See recommendation number two in Section 6.4

Because of the lack of formal AK requirements, it was not possible to conduct a complete evaluation of TWCP's AK program. Consequently, this aspect of the surveillance was primarily used to record TWCP's progress in developing their AK program, resulting in program observations and recommendations. No CARs were issued.

#### *RCRA Code Assignments*

LANL's current QA requirements associated with the assignment of RCRA codes appear to be extensive. The initial assignment of RCRA codes is documented and undergoes an independent review and official (random) QA check. The Waste Management Coordinator also reviews the assignment. Additionally, there is a database that contains a document trail for all assigned RCRA codes.

A limited number of personnel have access to this database (i.e., can change the RCRA code assignments).

However, LANL does not have a defined program in place that outlines the governing procedures and personnel training requirements for the assignment of RCRA codes. Some formal training and documented guidance is available for personnel who assign RCRA codes, such as, general training courses for Treatment Storage Disposal (TSD) workers, RCRA, Waste Generation, etc. ("RCRA Personnel Training," for example). There is no training, however, that specifically addresses how to assign RCRA hazardous waste codes to the TRU mixed waste destined for the WIPP. Specific methodology for performing this activity is not documented. For example, LANL has no procedures for the assignment and reassignment of RCRA codes or for the removal of inappropriate RCRA codes.

The AK requirements referred to above include guidance on the assignment of RCRA codes. A recommendation was made that LANL review this guidance when it becomes final and develop and implement governing procedures and specific training requirements for the assignment of RCRA codes, possibly as a subset of the AK program. See recommendation number four in Section 6.4 of this report.

#### *Analytical Laboratories*

A data package for 20 drums from the *LANL Transuranic Waste Characterization Project Initiative 605 Deliverable* was reviewed. The processing of these drums and the resultant data package identified real-time problems and issues. TWCP activities were suspended until procedures could be evaluated and rewritten to address these problems as issued. This data package will not be used as acceptable quality data to support waste characterization; rather, it will be used to test the program and identify areas for improvement. The surveillance team evaluated this package to provide additional guidance.

These drums contained cement, which caused a variety of matrix interference effects in the analyses. These effects included out-of-spec spike/surrogate recoveries. All out-of-spec issues were addressed appropriately by LANL using non-conformance reports, and the out-of-spec data were appropriately flagged.

No chain of custody records were found in the data package except those that were attached to NCRs. This lack will need to be addressed in future waste characterization efforts.

The data package itself was difficult to review because of the way it was assembled. There was no table of contents or index. Because different sample numbers were assigned for each analysis, there were many sample numbers to keep track of. There were a few correlation tables to allow the reviewer to relate the many different sample numbers back to the original drum, but these were sometimes difficult to find. In short, this data package appeared to be complete, but was not in an auditable form. It is recommended that future data packages be detailed enough to allow any reviewer to find any piece of information quickly and easily. Specifically, the table of contents and/or index of the data package should be detailed enough to allow any reviewer to find any piece of information quickly and easily. See recommendation number five in Section 6.4 of this report.

*What?*  
During a visit to the CMR, a log book for a refrigerator that is used to store samples received by the CMR was reviewed. This refrigerator was out of spec (temperature was too high) at various times earlier this year. No notations were made in the log book as to what actions (if any) were taken to bring the refrigerator back into compliance. If TRU waste samples were being stored in this refrigerator, an NCR would be required if/when the refrigerator was out of compliance to assess impact on data. An observation was identified relative to this in Section 6.3 of this report.

## 6.0 CORRECTIVE ACTION REPORTS/DEFICIENCIES CORRECTED/ OBSERVATIONS/ RECOMMENDATIONS

### 6.1 Corrective Action Reports

Two Corrective Action Reports (CARs) were generated during the surveillance.

#### CAR 96-081

The LANL TWCP procedures do not adequately implement all of the requirements of the CAO 94-1012-QAPD R-0 and R-1. Examples include activities related to Software Quality Assurance, Quality Improvement (Conditions Adverse to Quality, Control and Disposition of Nonconforming Items, Improvement Analysis, e.g., Trending), Interface Control, Independent Assessments (e.g., Audits and Surveillances), Personnel Indoctrination and Training, and Records Management.

#### CAR 96-082

Incomplete records have been received by the TWCP Records Center and are being maintained in records storage as permanent records. Dual storage is not being maintained and the fire rating of the storage cabinet cannot be determined.

## 6.2 Corrected Deficiencies

None

## 6.3 Observations

An observation was identified relative to the sample receiving area of the CMR. The logbook for a refrigeration unit indicated that the refrigerator temperature was out of specification on several occasions (temperature  $> 4 \pm 2$  degrees Celsius). No notations were made as to what actions were taken to bring this unit back into compliance. A review of records disclosed that there was no transuranic waste stored in this unit at the time(s) it was out of specification, otherwise a deficiency document would have been required. LANL needs to investigate the actions the lab is required to take to assure that its equipment is properly maintained to specification requirements. This observation does not require a response.

## 6.4 Recommendations

1. The calibration and operation procedures of the NDA/NDE systems that are being revised should be verified for compliance with all requirements of the QAPP, especially in the areas of response to out-of-control situations; statistical review of QC data; development of more detailed control charts of all controlled parameters (with mean, 2 sigma, and 3 sigma limits); firm defensible estimates of the accuracy, precision, and total uncertainty of each method; final traceability documents for Plutonium (Pu) pin standards; and more complete training records.
2. The draft lab standard for "Acceptable Knowledge" was reviewed and found to be incomplete. An example of issues not addressed is how LANL will confirm "Acceptable Knowledge." It is recommended that LANL use the WIPP WAC Appendix C9 as guidance for the Acceptable Knowledge program until the new CAO QAPP Section 4.0 (Acceptable Knowledge) is issued.
3. The Waste Characterization Reduction Repackaging Facility has a new visual examination glove box (mobile unit) that is operational. Procedures have not been developed for visual exam, nor have personnel been assigned, trained, or qualified for its use. It is recommended that these activities be initiated soon.
4. Before the Waste Certification Program, is implemented, a written procedure needs to be developed addressing how RCRA Code assignments are processed, and identifying training requirements and organizational responsibilities and interfaces.

5. The data packages were difficult to review because of the way they are assembled. It is recommended that data packages be assembled such that the table of contents and/or index is detailed enough to allow any reviewer to find any piece of information quickly and easily.

## 7.0 ATTACHMENTS

CAR-96-081

CAR-96-082

# CORRECTIVE ACTION REPORT

1. CAR No.: 96-081	2. Activity Report No.: S-96-48	3. Page <u>1</u> of <u>3</u>
4. Controlling Document: CAO-94-1012 QAPD R-0, R-1		5. Affected CAO Team Leader: D. Watkins
6. Responsible Organization: Los Alamos National Laboratories Transuranic Waste Characterization Program		7. Discussed With: Pam Rogers, Site Project Manager Marji Gavett, Site QA Officer
8. Requirement: QAPD R-0, Section 1.1 requires participants to develop, implement, and maintain their quality assurance programs in accordance with DOE Order 5700.6C or 10 CFR Part 830, including guidance provided in this QAPD [R-0]. QAPD R-1 Para. 1.1.1.5A requires participant management to establish and implement policies, plans, and procedures that control the quality of work consistent with the provisions of this QAPD. Para. 1.1.2.1A requires each program participant to develop and follow procedures that implement the [QAPD] requirements described therein. Para. 1.1.2.1.D requires participants to develop QA implementing procedures that provide for top down implementation of the QAPD, QAPP, and QAPjPs, as applicable.		
9. Condition Adverse to Quality: The LANL TWCP procedures do not adequately address all of the requirements of the CAO 94-1012 QAPD R-0 and R-1. Examples include activities related to Software Quality Assurance, Quality Improvement (Conditions Adverse to Quality, Control and Disposition of Nonconforming Items, Improvement Analysis, e.g., Trending), Interface Control, Independent Assessments (e.g., Audits and Surveillances), Personnel Indoctrination and Training, and Records Management. (continued next page)		
10. Suggested Actions: 1. Develop a Matrix of QAPD R-1 requirements to TWCP implementing procedures and develop procedures and/or procedure changes as necessary. 2. Provide a schedule of completion of these procedures based on milestones relative to the start-up of Waste Characterization Certification activities. Provide date for implementation. (continued next page)		
11. Significant Condition Adverse to Quality (Yes or No)?: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
12. Applicable Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>K. O. Gilkerson</u>		Date: <u>8/21/96</u>
14. Response Due Date: <u>10/31/96</u>		
15. Concurrence:	<u>Don U. Smith</u> Responsible Team Leader	<u>9/25/96</u> Date
	<u>John Stalder</u> Assurance Team Leader	<u>9/25/96</u> Date
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet		
17. Acceptance of Proposed Corrective Actions:		
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader
_____	_____	_____
Date	Date	Date
18. Verification of Corrective Action:		
19. Verified By (Signature): _____		
_____	_____	_____
Verifier	Date	Date
20. Closure: _____		
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader
_____	_____	_____
Date	Date	Date

# CAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 96-081

2. Activity Report No.: S-96-48

3. Page 2 of 3

## Block # 9 cont'd

NOTE: LANL's effective date for implementing the QAPD R-1 is August 25, 1996; but, with few exceptions, examples of inadequate flowdown of QA requirements can be found in both revisions. LANL's current program is not expected to be revised before August 25, 1996. Regardless, corrective actions to this CAR must meet QAPD R-1 requirements.

## DISCUSSION:

### Software Quality Assurance (SQA)

- The TWCP Quality Procedure, TWCP-QP-1.0-020, *Procedure for Software Management* (Revision 0, effective 3/7/96), does not adequately convey the requirements contained in section 6.0 of both revisions of the CAO QAPD. Areas requiring modification or amplification include classification, testing, inventory, configuration management, and problem reporting/corrective actions.

### Trending

- Both QAPD revisions and LANL TWCP Corrective Action/NCR procedures require trending of Conditions Adverse to Quality to be performed. The TWCP does not have trending procedures, nor is trending being performed, even though 92 NCRs documenting Conditions Adverse to Quality have been issued to date.

### Corrective Action Process

- Both revisions of the QAPD require Conditions Adverse to Quality to be evaluated for significance and to address investigative actions (extent of condition), root cause, and actions to prevent recurrence as necessary. The QAPD R-1 describes/defines significance explicitly and requires the preceding actions for all "Significant Conditions Adverse to Quality." LANL's Nonconformance and Corrective Procedure, TWCP-QP-1.0-003 (R-0), defines deficiency documents such as Nonconforming Condition Reports, Corrective Action Reports, and Findings. This procedure does not specifically address "Significant Conditions Adverse to Quality," although it requires a CAR for flagrant violations of procedure and repetitive nonconforming conditions or if personnel safety is at risk. This is similar to the QAPD definition of significance (but not the same); i.e., "if not corrected could have a serious effect on safety, operability, waste isolation, compliance, or the reliability of the QA program." Furthermore, if the violation is determined "flagrant" (significant), the LANL procedure does not require a work stoppage in order to be evaluated. This procedure does not address the processing of findings which, by LANL definition, are also Conditions Adverse to Quality and are issued as a result of Assessments (Audits). A review of audit findings and finding responses resulting from LANL Audits/Assessments disclosed that they are not evaluated for significance in accordance with the QAPD. There is no documentation of extent of condition or root cause evaluation and, in many cases, no proposed dates of corrective action.

### Nonconforming Items/Conditions

- LANL NCRs are issued for both programmatic violations and nonconforming *items* without distinction. The TWCP procedures don't require the dispositions "use-as-is" and "repair" to have a technical justification as do both QAPD revisions. A review of actual "use-as-is" dispositions disclosed that technical justifications are not being documented. Additionally, it is not clear how programmatic issues requiring corrective action responses differ from nonconforming items requiring a rework, repair, use-as-is, etc.

### Assessments

- LANL's procedures for independent assessments and personnel qualifications for Lead Auditors in leading Assessments are consistent with the QAPD, R-0. The QAPD R-1 specifically addresses independent assessments as *Audits* and *Surveillances* and makes a distinction between them. Although LANL has a surveillance form and has scheduled Surveillances to be performed, it does not have a procedure for performing Surveillances.

### Interfaces

- While draft Transuranic Waste Characterization Interface Documents (TWIDs) are the key LANL interface documents, their description and usage are not presently defined, except in a draft document.

### Indoctrination and Training

- LANL procedure TWCP-QP-1.0-003 (R-0) addresses training, qualification, and certifications; it does not address employee indoctrination to general criteria such as the QAPD, and applicable codes, standards, and regulations as required.

### Records Management

- The LANL Records Management Procedure TWCP-QP-1.0-004 (R-0) does not adequately address the QAPD requirements for the storage, safekeeping, and disposition of QA Records. Specifically, it doesn't describe the LANL TWCP records storage facility, and the filing and indexing system, nor does it define records access control.

# CAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 96-081

2. Activity Report No.: S-96-48

3. Page 3 of 3

Block # 10 cont'd:

Software QA recommended actions:

The current draft Revision 1 to TWCP-QP-1.0-020 is a major step toward achieving compliance with the CAO QAPD requirements. The document should be refined to achieve complete adequacy, issued, and implemented.

All software used in waste characterization or supporting the TWCP should be inventoried, classified, and controlled in accordance with the above software QA requirements. The following items were identified during the surveillance as containing software modules to which the above requirements should apply.

- Passive/Active Neutron (PAN) System
- Segmented Gamma Scan (SGS) System
- Tomographic Gamma Scan (TGS) System
- Laboratory Information Management System (LIMS)
- Automated Waste Management System [TA-55]
- Any specialized instrument programming (GC/MS, ICP, or FTIR)
- Any database or spreadsheet applications containing detailed formulas or macros
- Any software associated with characterization technologies or processes under development

## CORRECTIVE ACTION REPORT

1. CAR No.: 96-082	2. Activity Report No.: S-96-48	3. Page <u>1</u> of <u>2</u>
4. Controlling Document: TWCP-QP-1.0-004, R.0	5. Affected CAO Team Leader: D. Watkins	
6. Responsible Organization: LANL TWCP	7. Discussed With: P. Rogers, Site Project Manager M. Gavett, Site QA Officer	
<p>8. Requirement: Paragraph 6.2.3 requires Records Center personnel to document receipt of an incomplete record by completing the bottom section of the TWCP Records Center Record Transmittal Form and sending a copy to the record source, along with the administrative incomplete record and a completed TWCP Record Center Record Return Form. (Continued on Page 2)</p>		
<p>9. Condition Adverse to Quality: Incomplete records have been received by the Records Center and are being maintained in records storage as permanent records. Although incomplete portions of the records, e.g., signatures, are flagged as an indicator for correction, no action is being taken to correct the incomplete record. (Continued on Page 2)</p>		
<p>10. Suggested Actions: Review TWCP-QP-1.0-004 to assure that higher-tier program requirements are addressed and are implemented according to the implementing procedure. Obtain documentation for the fire-rated cabinet being used and establish single or dual storage of records as appropriate.</p>		
11. Significant Condition Adverse to Quality (Yes or No?): YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
12. Applicable Types of Actions: Remedial: <input checked="" type="checkbox"/> Investigative: <input checked="" type="checkbox"/> Root Cause: <input type="checkbox"/> Actions to Preclude Recurrence: <input checked="" type="checkbox"/>		
13. CAR Initiator: <u>Rich Hicks</u>		Date: <u>8/21/96</u>
14. Response Due Date: <del>9/15/96</del> <sup>10/31/96</sup> <u>DW</u> <sub>9/15/96</sub>		
15. Concurrence: <u><i>Don Watkins</i></u>	<u>9/25/96</u>	<u><i>Mark Fleenor</i></u> <u>9/25/96</u>
Responsible Team Leader	Date	Assurance Team Leader Date
16. Corrective Actions Proposed by the Responsible Organization: See attached CAR continuation sheet		
17. Acceptance of Proposed Corrective Actions:		
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader Date
18. Verification of Corrective Action:		
19. Verified By (Signature): _____		
_____	_____	_____
Verifier	Date	
20. Closure: _____		
_____	_____	_____
Responsible Team Leader	Date	Assurance Team Leader Date

# GAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No.: 96-082

2. Activity Report No.: S-96-48

3. Page 2 of 2

Block # 8

2. Paragraph 6.6.2 requires dual storage of records, which is provided on a computer database or computer-generated storage disk. Computer-generated records are required to be maintained in a "fire-rated" safe at a separate designated location for dual storage purposes. Section 1.5.2.6F of the QAPD R-1 requires a two-hour fire-rated vault for a single storage records facility and Section 1.5.2.6H requires a one-hour fire-rated container for temporary storage of records.

Block # 9

2. Dual storage of records is not being accomplished as required by the procedure. Furthermore, the Record Storage Center cabinet presently being used to store permanent QA Records is not certified as a two-hour fire-rated vault meeting the National Fire Protection Association Standards and thus does not meet QAPD R-1 requirements for single storage of records. Nor is it clear whether the cabinet being used is a one-hour fire-rated container for temporary storage of records.

# CAO CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No:

2. Activity Report No.:

Page \_\_\_\_ of \_\_\_\_

Block # \_\_\_\_

# CAR CORRECTIVE ACTION REPORT

(continuation sheet)

1. CAR No: \_\_\_\_\_

2. Activity Report No.: \_\_\_\_\_

Page \_\_\_\_ of \_\_\_\_

Block # \_\_\_\_\_

## INSTRUCTIONS FOR COMPLETING CORRECTIVE ACTION RESPONSE

You are requested to provide a response to a Corrective Action Report (CAR) by the due date identified in Block 14 of the CAR. If this date cannot be met, provide a written request for extension to the appropriate CAO Team Leader. This request must include justification for the delay and must be provided prior to the due date.

The response shall address all applicable corrective action types indicated in Block 12. As appropriate, develop the response in accordance with the following sequence and format:

In order to develop the CAR response, perform investigative action (if indicated in Block 12 of the CAR) to determine the extent and impact of the deficiency and to identify the root cause. Next, determine the actions required to correct the adverse condition. A review of the suggested improvements and recommended actions (if any) provided in Block 10 of the CAR may assist you in the determination. The response must include the following information, as appropriate:

1. Corrective Action Response for CAR # \_\_\_\_\_
  - A. Remedial Action-Describe actions required or taken to correct the specific conditions noted.
  - B. Extent and Impact of the Deficiency-Describe the investigative actions performed to determine the extent and impact of the condition and the results.
  - C. Root Cause Determination-identify the root cause of the condition as determined through investigative action.
  - D. Corrective Action to Preclude Recurrence-Identify the actions required to address the root cause of the condition in order to preclude recurrence.
2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date. If it becomes apparent that any of the corrective action due dates cannot be met, a written request for extension must be provided to the CAO Team Leader.
3. The response must include the dated signature of the individual having the overall responsibility for timely completion of the corrective actions.