

U.S. DEPARTMENT OF ENERGY  
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

OF

LOS ALAMOS NATIONAL LABORATORY

LOS ALAMOS, NEW MEXICO

AUDIT YMP-94-08

AUGUST 15 THROUGH 19, 1994

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## 1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit YMP-94-08, the audit team determined that the Los Alamos National Laboratory (LANL) is satisfactorily implementing an effective QA program in accordance with the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 0, for the Civilian Radioactive Waste Management Program and LANL's implementing procedures for QA Program Elements 1.0, 2.0, 5.0, 6.0, 12.0, 16.0, 17.0, 18.0 and Supplements I, II, and III. The audit team determined that implementation of QA Program Elements 4.0 and 7.0 was unsatisfactory because of deficiencies identified in this report. Compliance with QA Program Element 15.0 could not be verified since no implementation has occurred. These determinations were made by verifying that selected QARD requirements were satisfactorily implemented through LANL procedures utilizing the Requirements Traceability Network (RTN) which is in the final approval process, and the audit process. In addition, the audit team determined that LANL is satisfactorily implementing all technical activities evaluated.

The audit team identified five deficiencies during the audit that resulted in issuance of five OCRWM Corrective Action Requests (CAR). CAR YM-94-078 documented deficiencies in completed QA record packages. CAR YM-94-079 documented the use of inappropriate buffers when calibrating pH meters. CAR YM-94-080 documented that the procurement procedure was not in compliance with QARD requirements. CAR YM-94-081 documented a procedure violation in scientific notebooks (SNs) whereas data recorded was not explained as to its acceptability or unacceptability. CAR YM-94-082 documented that the traceability of software requirements into the software design was not performed during the design phase as required.

The following strengths and/or improvements in the LANL QA Program were noted during the audit:

- The LANL personnel training and qualification program was extremely well implemented. Records of employee training and qualification were found to be detailed and well maintained.
- All personnel at LANL were very familiar with the QA program and interested in complying with all QA program requirements.
- The technical work being performed by LANL and contractor personnel is of high quality. Significant effort has gone into performance of scientific investigations and integration between ongoing studies.

## 2.0 SCOPE

The audit was conducted to evaluate the adequacy of, compliance to, and the effectiveness of the LANL QA Program as described in the QARD and LANL implementing quality documents.

The QA program elements/requirements evaluated during the audit, in accordance with the published audit plan, are as follows:

### QA PROGRAM ELEMENTS/REQUIREMENTS

- 1.0 Organization
  - 2.0 Quality Assurance Program
  - 4.0 Procurement Document Control
  - 5.0 Implementing Documents
  - 6.0 Document Control
  - 7.0 Control of Purchased Items and Services
  - 12.0 Control of Measuring and Test Equipment
  - 15.0 Nonconformances
  - 16.0 Corrective Action
  - 17.0 Quality Assurance Records
  - 18.0 Audits
- Supplement I, Software  
Supplement II, Sample Control  
Supplement III, Scientific Investigation

The following QA program elements were considered during the development of the audit plan and found to be not applicable, since the current LANL QA Program has no activity for which these elements apply:

- 3.0 Design Control
  - 8.0 Identification and Control of Items
  - 9.0 Control of Special Processes
  - 10.0 Inspection
  - 11.0 Test Control
  - 13.0 Handling, Storage, and Shipping
  - 14.0 Inspection, Test and Operating Status
- Supplement IV, Field Surveying  
Appendix A, High Level Radioactive Waste Form Production  
Appendix B, Transportation  
Appendix C, Mined Geological Disposal System

### TECHNICAL AREAS

The following technical areas were evaluated during the audit:

<u>Work Breakdown Structure (WBS) No.</u>	<u>Title</u>
1.2.3.4.1.2.1	Batch Sorption Studies
1.2.3.4.1.3.1	Dissolved Species Contamination Limits
1.2.3.4.1.4.1	Dynamic Transport Column Experiments

### 3.0 AUDIT TEAM

The following is a list of audit team members and their assigned areas of responsibility:

<u>Name/Title</u>	<u>QA Program Elements/ Requirements or Technical Areas</u>
Stephen R. Maslar, Audit Team Leader, Yucca Mountain Quality Assurance Division (YMQAD)	
Donald J. Harris, Auditor, YMQAD	2, 4, 7, and 15
Stephen D. Harris, Auditor, YMQAD	16 and Supplement I
Thomas J. Higgins, Auditor, YMQAD	Supplement III
Frank J. Kratzinger, Auditor, YMQAD	12 and Supplement II
Walter R. Coutier, Auditor, Headquarters Quality Assurance Division (HQAD)	5, 6, and 17
Dennis C. Threatt, Auditor, HQAD	1 and 18
Paul L. Cloke, Technical Specialist, Science Applications International Corporation (SAIC)/Technical and Management Support Services (T&MSS), Las Vegas, Nevada	WBS Nos. 1.2.3.4.1.2.1, 1.2.3.4.1.3.1 and 1.2.3.4.1.4.1

There were no observers on this audit.

### 4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The preaudit meeting was held at LANL offices in Los Alamos, New Mexico on August 15, 1994. A daily debriefing and coordination meeting was held with LANL management and staff, and daily audit team meetings were held to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held at LANL offices in Los Alamos, New Mexico on August 19, 1994. Personnel contacted during the audit are listed in Attachment 1. The list includes an indication of those who attended the preaudit and postaudit meetings.

### 5.0 SUMMARY OF AUDIT RESULTS

#### 5.1 Program Effectiveness

The audit team concluded that, in general, the LANL QA Program is adequate and is being satisfactorily implemented for the scope of this audit.

Individually, QA Program Elements 1.0, 2.0, 5.0, 6.0, 12.0, 16.0, 17.0, 18.0, and QARD Supplements I, II, and III are satisfactorily implemented. QA Program Elements 4.0 and 7.0 were found unsatisfactory. QA Program Element 15.0 was not evaluated since the element has not yet been implemented. In addition, technical activities were found to be satisfactorily implemented.

**5.2 Stop Work or Immediate Corrective Actions Taken**

There were no Stop Work Orders (SWOs), immediate corrective actions or related additional items resulting from this audit.

**5.3 QA Program Audit Activities**

Details of the QA program audit activities are provided in Attachment 2. A list of objective evidence reviewed during the audit is provided in Attachment 3 of this report.

**5.4 Technical Audit Activities**

Details of technical activities audited are included in Attachment 2. A list of objective evidence reviewed during the audit is provided in Attachment 3 of this report.

**5.5 Summary of Deficiencies**

The audit team identified five deficiencies during the audit for which five CARs have been issued. Seven additional deficiencies were identified and corrected prior to the postaudit meeting.

Synopses of deficiencies documented as CARs and those corrected during the audit are detailed below. Information copies of the CARs are included in Attachment 4.

**5.5.1 Corrective Action Requests**

As a result of the audit, the following CARs were issued:

**CAR YM-94-078**

Completed record packages did not contain all of the documentation required by the LANL-YMP-QP-06.1 procedure. Six record packages are identified on the CAR with open deficiencies. Three record packages were corrected during the audit.

**CAR YM-94-079**

The pH meters were being calibrated without using proper buffer solutions. The buffer solutions used are for calibration of pH values between 7 and 10. The pH measurements recorded are outside of this calibration range. The LANL-INC-DP-35 procedure requires the buffers used for calibration be within the range of the measurements taken. This condition is a procedure problem only and does not require issuance of a Nonconformance Report.

CAR YM-94-080

Procurement procedure LANL-YMP-QP-04.6 was not in compliance with all the QARD requirements. In some instances, the procedure only reiterated the QARD requirements with no methodology on how to satisfy the requirements and no provisions or mechanism to demonstrate the requirements were satisfied. This procedure has not yet been implemented.

CAR YM-94-081

LANL-YMP-QP-03.5 used for making entries into an SN requires that data recorded be evaluated and a statement entered into the SN explaining the acceptance or rejection of the data. Five SNs were found that did not show objective evidence that the data was evaluated.

CAR YM-94-082

Software procedure LANL-YMP-QP-03.26 requires that during the design phase, traceability of each software requirement into the software design be demonstrated. The source code for one software program did not identify the traceability of the requirements in the software design package.

**5.5.2 Deficiencies Corrected During the Audit**

Deficiencies which are considered isolated in nature and only requiring remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

1. Procedure LANL-YMP-QP-12.3, Revision 1, Paragraph 6.6.2.9, requires that a label, tag or other suitable marking be placed on the Measuring and Test Equipment (M&TE). Contrary to this requirement, RC-45-001, Weight Set, was found not to have a calibration tag identification. The weight set was properly tagged with a calibration sticker and the number was matched to the computer tracking number (RC-45-001) prior to the audit exit meeting.
2. Procedure LANL-YMP-QP-12.3, Revision 1, Paragraph 6.3.2, requires that the Principal Investigator (PI) or Custodian ensure that the calibration is performed. Paragraph 6.6.2.9 requires that a label, tag or other suitable marking be placed on the M&TE. Contrary to this requirement, Balance Part Number (PN) 817330 had no documentation or label showing a calibration since September 9, 1993. The calibration frequency for this balance is six months. The balance was calibrated and a label attached to

the balance prior to the audit exit meeting. LANL Corrective Action Report (CAR) No. 242 was issued during the audit covering the evaluation of any items associated with use of this balance after the calibration expired.

3. Procedure LANL-YMP-QP-08.1, Revision 4, Paragraph 6.1.1.1, requires that a Sample Collection Report (SCR) be submitted to the Sample Management Facility (SMF) in accordance with Yucca Mountain Administrative Procedure (YAP)-SII.4Q. Contrary to this requirement, documented evidence of an SCR for sample No. 00500656 was not available. An SCR was initiated for this sample and submitted to the SMF prior to the audit exit meeting.
4. The QARD, Revision 1, requires that the organization's policy statement direct mandatory compliance with the QA program, provide a system of positive control over external interfaces, and implementing documents include identification of lifetime and nonpermanent QA records. Contrary to these requirements, LANL-YMP-QP-01.4, Revision 1, did not adequately address these requirements. LANL-YMP-QP-01.4, Revision 2, was approved and issued during the audit to correct the deficiencies.
5. LANL-YMP-QP-18.1, Revision 6, Paragraph 6.1.3.4, requires that an annual evaluation of external organizations be documented on a Supplier Annual Performance Evaluation form. Contrary to this requirement, survey number LA-SR-SIMCO-94-005 for the annual evaluation of SIMCO Electronics was not documented. This was corrected by documenting the survey on the required form prior to the audit exit meeting.
6. QARD, Revision 0, Subsection 17.2.2B requires that individuals evaluating QA records ensure that QA records are legible, accurate and complete. Deficiencies in the following record packages were corrected during the audit as noted:
  - a. Record Package for LANL-YMP-QP-06.1, Revision 7 was corrected to note reviewer organization, correct page count, date and page numbering notation. Actions were properly annotated and verified during the audit.
  - b. Record source file for LANL-YMP-QP-06.1, Revision 7 was corrected to include a copy of the Review Criteria form. Corrections to record package were properly annotated and verified during the audit.

- c. Record source file for LANL-CST-DP-63, Revision 4 was corrected to include a copy of the Detailed Technical Procedure (DP) Review Criteria Form. Corrections to record package were properly annotated and verified during the audit.
7. Revision 2 (effective January 31, 1994), Section 6.4.4.1 and Revision 3, Section 6.1.5.1 (effective August 1, 1994) of procedure LANL-YMP-QP-03.5 require that for work performed per a DP, the SN shall contain identification numbers and revision of the applicable DP.

Contrary to this requirement, the sample preparations described in TWS-INC-01-93-12 do not list the applicable technical procedures for chemical pH, optical reflection, etc. measurements documented throughout the SN. These deficiencies were corrected in the SN and verified prior to the audit exit meeting.

### 5.5.3 Follow-up of Previously Identified CARS

1. CAR YM-93-049 was issued on June 6, 1993, and was closed on November 17, 1993. It addressed external interfaces that were not controlled and documented in accordance with Quality Procedure (QP)-01.1, Revision 2.

During the course of the audit, it was determined that no Interoffice Memorandum of Understandings (IMOU) were in existence. This was confirmed in discussions with LANL Quality Assurance Project Leader (QAPL). In addition, a review of the Master List of Controlled Documents, dated July 13, 1994, indicated that Quality Assurance Procedure QAP-01.1 was listed as being deleted and the Control Manual 086 did not contain the procedure. The corrective actions instituted to satisfy this CAR were determined to be effective.

2. CAR YM-93-050 was issued May 25, 1993, and addressed the need to provide traceability of attachment pages for Attachment 1 of procedure LANL-ESS-13-DP-609. The CAR response was accepted and the CAR closed on August 11, 1993. The corrective action was effective and is being implemented. However, procedure requirements for affecting revisions to DPs were not in full compliance for this minor procedure change, nor documented justification provided for deviating from procedure requirements. (See CAR YM-94-078, Item D, Attachment 4 of this report.) The corrective actions instituted to satisfy this CAR were determined to be effective.

3. CAR YM-93-051 was issued on June 8, 1993 and was closed on November 2, 1993. It addressed the condition that only selected individuals were trained to LANL-YMP-QP-17.4, Revision 0; however, Section 9.0 of the procedure required all LANL Yucca Mountain Project (YMP) employees to be trained.

During the course of the audit, it was determined that LANL-YMP-QP-17.4, Revision 0 was revised to delete the requirement that all employees be initially trained to the procedure and that formal training would be conducted within six months of employment or the effective date of the procedure for those employees who conduct work listed in Section 6.0 of the procedure. A listing of personnel was obtained from the Training Coordinator and a sample of LANL employees and augmented staff reviewed to determine compliance with the CAR corrective action. The corrective action instituted was determined to be effective.

## 6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by the LANL management.

1. LANL-YMP-QP-01.3, Revision 2, Conflict Resolution, does not contain adequate provisions for closure of documentation when conflicts are turned over to OCRWM for resolution. LANL-YMP-QP-01.3 should be revised to add a process for closing documentation within LANL when turned over to OCRWM.
2. Two codes, Colloid Transport Code - Nuclear (CTCN) and part of Lawrence Livermore National Laboratory ODEPACK (LSODPK) have been controlled under the requirements of the Quality Assurance Requirements Document QARD DOE/RW-0214. The two codes are inter-related in that the LSODPK software is a re-use application to CTCN (it appears one is needed to use the other). The records of the LSODPK code in the LANL records system contain information that does not meet the current software requirement procedures and are questionable whether they meet the requirements of the Software Quality Assurance Program (SQAP) Section 5.2.2.3 and the definition of Scientific and Engineering Software in effect at the time of performance of these activities.

Since activities using these packages has been halted and the PI is now working on non-quality affecting activities, it is recommended that these codes be removed from use in the YMP environment. Any future work should be performed using the current procedural process. In addition, a record should be added that explains the reasoning for removing these codes and a search should be made for any reports containing application of these codes on the YMP.

3. The notebook style adopted by the batch sorption and column transport tasks is very helpful in many respects; however, it is difficult to follow in other ways. It is recommended that near the beginning of each notebook, a short narrative be inserted to explain briefly but comprehensively the following:
  - a. What quantities are being measured.
  - b. How they are measured (i.e., what detailed procedure applies or what technique a vendor uses).
  - c. An explanation of all entries in tables of data, such as column headings or meanings of terms used in rows or lines.
4. The modules of the source code for TRACRN had many subroutines under the change and revision number of the module. This permits minimal control of large numbers of lines of code. LANL should improve the change/revision control capability of these subroutines by limiting the number of lines to a more easily handled size.
5. Procedure LANL-YMP-QP-17.6, Revision 1, Paragraph 6.10.5 contains typographic errors in referencing Subsections 6.10.5.1 and 6.10.5.2. LANL should revise the procedure to address current subsection references.
6. QP-3.26, Revision 1, Section 6.7 requires the Review/Audit Report and Recommendation (RRR) form to reference the Software Review Notice (SRN) form and the Resubmission deadline. The fields that have these numbers in the database appear to be correct; however, the numbers are not always being transferred to the record copy. The record copy indicates "none" in the SRN reference block and "N/A" in the Resubmission deadline block. One other isolated observation on the Software Variance form (SVA) 6: the Engineering Change Directive (ECD) reference was not correctly indicated. These minor inconsistencies in the records system should be resolved for these forms and possibly others.
7. The following QARD requirements contained in Supplement I of the QARD that were implemented into LANL procedures, do not address or contain quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished in the implementing procedures. The words of the QARD were only reiterated.
  - a. QP-03.21, Revision 2
    - Supplement I.2.5B.1. - Included in LANL-YMP-QP-3.21, Section 6.3.3.1, third paragraph, bullet 1.
    - Supplement I.2.5B.2. - Included in LANL-YMP-QP-3.21, Section 6.3.3.1, third paragraph, bullet 1.

- Supplement I.2.8B.4. - Included in LANL-YMP-QP-3.21, Section 6.2.3, second paragraph, second sentence.
- b. QP-03.5, Revision 3
- Supplement I.2.10A. - Included in LANL-YMP-QP-03.5, Attachment 2, E., second sentence.
  - Supplement I.2.10B. - Included in LANL-YMP-QP-03.5, Section 6.4.3, and Attachment 2, E., first and fourth sentences.
  - Supplement I.2.10C. - Included in LANL-YMP-QP-03.5, Attachment 2, E., fifth sentence.

These items are being resolved in conjunction with the RTN Matrix review currently in progress; therefore, it was determined that issuance of a CAR is inappropriate for this condition.

8. Technical reports should be produced that provide the reader sufficient detail to understand the methodology and results clearly, and to determine if the results and conclusions are well supported without having to make additional inquiries or examine other documents. This could be accomplished and reflected by a more comprehensive internal review by staff who understand the scientific principles, but are not directly involved in the work.

## 7.0 LIST OF ATTACHMENTS

- Attachment 1: Personnel Contacted During the Audit
- Attachment 2: Audit Details
- Attachment 3: Objective Evidence Reviewed During the Audit
- Attachment 4: Information Copies of CARs

ATTACHMENT 1

Personnel Contacted During the Audit

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted During Audit</u>	<u>Postaudit Meeting</u>
Bolivar, S.	LANL/QAPL	X		
Canepa, J.	LANL/TPO	X		
Carpenter, S.	LANL/Associate Investigator		X	
Caslos, B.	LANL/PI	X		
Chavez, P.	LATA/Training Coordinator	X		
Clark, D.	LANL/Associate Investigator		X	
Clevenger, M.	LANL/Deputy QAPL	X		
Cloke, P.	SAIC/T&MSS Tech Specialist	X		X
Cole, E.	LATA/Department Mgr.	X		
Cotter, C.	LANL/Lead Sorp Tech		X	X
Coutier, W.	HQAD/Auditor	X		X
Day, J.	LATA/Project Quality Liaison	X		
Gainer, G.	LATA/QA Eng.		X	
Gillespie, P.	LANL/Quality Eng.	X		
Gundlach, B.	LATA/QA Eng.	X		
Harris, D.	YMQAD/Auditor	X		X
Harris, S.	YMQAD/Auditor	X		X
Higgins, T.	YMQAD/Auditor	X		X
Hobart, D.	LANL/Co-PI		X	
Kratzinger, F.	YMQAD/Auditor	X		X
Kung, K.	LANL/Associate Investigator		X	
Levy, S.	LANL/PI	X		
Martinez, S.	LATA/Records Coordinator	X		
Maslar, S.	YMQAD/ATL	X		X
Martinez, C.	LATA/QA Eng.			X
Romero, B.	LATA/DCC	X		
Shay, R.	LATA/QA Lead	X	X	
Strieterheier, B.	LANL/Tech Specialist	X		
Tait, D.	LANL/Staff	X	X	
Threatt, D.	HQAD/Auditor	X		X
Triay, I.	LANL/PI		X	
Waltershied, J.	LATA/Tech Data Coordinator	X		
Weaver, S.	LANL/Tech Specialist	X	X	
Wichman, L.	LATA/QA Lead	X	X	

LEGEND:

DCC - Document Control Coordinator      Eng. - Engineer  
 LATA - Los Alamos Technical Associates      Sorp - Sorption  
 TPO - Technical Project Officer

## ATTACHMENT 2

### Audit Details

The following is a summary of LANL QA Program activities covered during the audit. The list of objective evidence reviewed and specific procedures audited is provided in Attachment 3.

#### 1.0 ORGANIZATION

The evaluation of QA Program Element 1.0 was based on interviews with LANL personnel and examination of objective evidence to determine the degree of compliance with selected requirements of LANL-YMP-QP-01.2, LANL-YMP-QP-01.3, and LANL-YMP-QP-01.4, implementing procedures which reflect QARD requirements. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

#### Requirements:

##### **OCRWM QARD, Section 1.0, Organization**

- All sections of the LANL QPs for Organization reflect the applicable requirements of the QARD.

##### **Stop Work Control (LANL-YMP-QP-01.2)**

- The QAPL investigates potential stop work conditions either identified by LANL employees or documented as significant conditions adverse to quality on CARs.
- The QAPL documents SWOs and forwards copies to supervisors responsible for resolution and the TPO.
- YMP supervisors complete required sections of the SWOs and return a copy to the QAPL who issues a LANL CAR if it involves a condition adverse to quality.
- The QAPL ensures that work on affected activities does not continue except as approved by conditional release.
- The responsible supervisor ensures that the requirements for lifting the SWO are completed.
- The QAPL assigns an employee to verify that the conditions to lift the SWO were met.

- Records associated with stop work control are maintained.

**Conflict Resolution (LANL-YMP-QP-01.3)**

No implementation.

**The LANL-YMP Organization and Quality Program Description (LANL-YMP-QP-01.4)**

- The policy statement is approved and signed by the TPO and defines employee responsibility to the QA program.
- The program overview summarizes the QARD criteria that governs the QA program and references the applicable documents that implement QARD criteria.
- YMP employees who conduct activities governed by the LANL YMP QA Program are required to train to LANL-YMP-QP-01.4.
- The duties and responsibilities of employees are described in position descriptions.
- Signature authority for actions required by implementing documents are documented and submitted as QA records.
- LANL YMP personnel are oriented to applicable concepts and requirements of the QA program.
- LANL implementing documents that meet applicable QARD requirements are identified in the RTN and the matrix is maintained by the Yucca Mountain Site Characterization Office (YMSCO).

**Results:**

SWOs, organization charts and letters of delegation of signature authority were reviewed to determine compliance with procedure requirements. Additionally, interviews were conducted with LANL YMP personnel to determine if work subject to QARD requirements was conducted in accordance with the approved procedures.

With the exception of the procedural deficiencies (Section 5.5.2, Item 4) corrected during the audit and one recommendation (Section 6.0, Item 1), the implementation of organizational requirements and stop work authority were satisfactory. The implementation of procedural requirements for conflict resolution were indeterminate due to lack of activity.

Based on the above review of objective evidence, the implementation of QA Program Element 1.0 was determined to be satisfactory.

## **2.0 QUALITY ASSURANCE PROGRAM**

The evaluation of QA Program Element 2.0 was based on interviews with LANL personnel and examination of objective evidence to determine the degree of compliance with selected requirements of LANL-YMP-QP-02.4, LANL-YMP-QP-02.5, LANL-YMP-QP-02.7, LANL-YMP-QP-02.11, LANL-YMP-QP-02.12, and LANL-YMP-QP-02.15, implementing procedures which reflect QARD requirements. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

### **OCRWM QARD, Section 2.0, Quality Assurance Program**

- All sections of the LANL QPs for the QA Program reflect the applicable requirements of the QARD.

### **Management Assessment (LANL-YMP-QP-02.4)**

- The TPO shall initiate an Annual Management Assessment by issuance of a memorandum.
- The Assessment Team Leader shall prepare an Assessment Plan which includes as a minimum:
  - adequacy of the LANL YMP organizational structure and staff;
  - adequacy and effectiveness of the QA program;
  - adequacy of the personnel qualification and training programs;
  - effectiveness of the corrective action reporting system;
  - adequacy of the QA program management administrative activities (e.g., tracking systems), evaluation, and reporting systems; and
  - the status of any corrective actions issued by the QAPL as a result of the previous management assessment.
- The Assessment Team members shall be independent of LANL YMP QA organization.
- The Assessment Team Leader shall prepare and signed the Assessment Report which included:
  - an executive summary or abstract
  - description of the assessment defined in checklist question 2-2.
  - list of persons contacted

- descriptions of results that address items in the assessment scope
- recommendations
- The QAPL shall evaluate the deficiencies identified in the report and issues CARs as appropriate.
- The TPO shall prepare a memorandum on the final disposition of any report recommendation and ensures the implementation commensurate with impact on affected activities.

#### **Selection of Personnel (LANL-YMP-QP-02.5)**

- The YMP Position Description shall contain one of the following titles:
  - Technical Project Officer
  - Deputy Technical Project Officer
  - Project Scientist
  - Project Leader
  - Deputy Project Leader
  - Functional Coordinator (e.g., Records Coordinator)
  - Functional Liaison (e.g., QA Liaison)
  - Functional Specialist (e.g., Technical Specialist)
  - Functional Advisor (e.g., Science Advisor)
  - Principal Investigator
  - Associate Investigator
  - Research Collaborator
  - Research Technician
  - QA Engineer
  - Resident File Custodian
  - Administrative Assistant
  - Limited Function Employee (employees who perform limited functions)
- The position description shall contain a description of the position duties and responsibilities and establishes the minimum education and experience requirements of the job position.
- The Training Coordinator shall ensure the minimum education and experience are verified for employees through the LANL personnel office or non-employees; the Training Coordinator ensures the verification is completed.

#### **Personnel Training (LANL-YMP-QP-02.7)**

- The supervisor shall identify each document to be read by the employee on the YMP Training Record by identifier and revision level.
- The employee shall complete Section III of the LANL-YMP Training Record.

- The instructor shall conduct formal training sessions and completes Section II of the LANL YMP Training Record.
- The employee completes Section III of the LANL YMP Training Record, Revision 3, for reading assignments.

**Personnel Orientation (LANL-YMP-QP-02.11)**

- The supervisor shall provide an overview of the LANL YMP using Attachment I as a guide and ensures the Orientation is documented on the Orientation form and completes Section III of the form.

**Exemption Control (LANL-YMP-QP-02.12)**

- The responsible PI or higher level management shall complete Section I of the Exception Justification form when the requirements are not commensurate with the following:
  - consequence of failure
  - importance of any data generated
  - complexity of implementation of the activity
  - reliability of the process
  - reproducibility of the results
  - necessity for special controls or processes
  - degree of standardization
  - history of service quality
- The TPO shall complete the Exception Justification, Section II and sign and date.
- The QAPL shall complete the Exception Justification, Section III and sign and date.

**Requirements Traceability (LANL-YMP-QP-02.15)**

- Prior to approval of the LANL YMP QPs, the RTN specialist shall verify the applicable QARD requirements were addressed.
- The RTN specialist shall update the RTN Matrix and ensure the RTN Matrix (hardcopy) and justifications for exceptions and requirements determined to be N/A, were sent to the DCC or for processing according to LANL-YMP-QP-06.1.

**Results:**

The evaluation of this QA program element was based on the examination of objective evidence identified in Attachment 3 of this report to determine compliance with

selected requirements taken from implementing procedures LANL-YMP-QP-02.4, LANL-YMP-QP-02.5, LANL-YMP-QP-02.7, LANL-YMP-QP-02.11, LANL-YMP-QP-02.12, and LANL-YMP-QP-02.15. Based on the interviews and the objective evidence, the implementation of QA Program Element 2.0 reflects the applicable requirements of the QARD and the methodology for the implementation of the requirements. It was noted; however, that there was limited implementation of the current revision of the above listed QPs. Based on the above implementation, QA Program Element 2.0 was determined to be satisfactory.

**4.0**     **PROCUREMENT DOCUMENT CONTROL**  
**7.0**     **CONTROL OF PURCHASED ITEMS AND SERVICES**

The evaluation of QA Program Elements 4.0 and 7.0 was based on selected requirements of the LANL implementing procedure reflecting QARD requirements. Compliance with the QARD and LANL procedure was based upon interviews with LANL personnel, a review of requirements and an examination of objective evidence for procedure LANL-YMP-QP-04.6. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

**Requirements:**

**OCRWM QARD, Sections 4.0 and 7.0, Procurement Document Control and Control of Purchased Items and Services**

- All sections of the LANL QP for Procurement Document Control and Control of Purchased Items and Services reflect the applicable requirements of the QARD.

**Procurement (LANL-YMP-QP-04.6)**

- The purchase requester shall complete a Purchase Request which includes the statement of technical and quality requirements.
- The technical reviewer shall ensure the technical requirements were adequately addressed and shall sign and date the Purchase Request.
- The requester shall identify a recommended supplier on the Purchase Request.
- The QA Liaison shall review the procurement documents to ensure the QA requirements were properly specified and determine the qualification status of the supplier, then sign and date the Purchase Request.
- When LANL purchasing organization changes the procurement documents as a result of bid evaluations or precontract negotiations, the requester and QA representative shall perform the following:

- Ensure that changes made to procurement documents during bid evaluation have been incorporated into the procurement documents.
  - Verify that the appropriate requirements of this procedure are included in the purchasing documents.
  - Evaluate exceptions, alternatives or changes specified by the supplier to determine the impact on the intent of the procurement documents or quality of the services to be furnished.
- Prior to authorizing the supplier to begin work, the requester and a LANL YMP QA Representative shall evaluate the Purchase Order (PO) to ensure that the Purchase Request requirements were correctly incorporated into the PO. This evaluation will consider the following subjects consistent with the importance, complexity, and quality of the services being procured:
    - Technical requirements
    - QA program requirements
    - Supplier personnel
    - Supplier past performance
    - Alternatives or exceptions to the requirements stated in the Statement of Technical and Quality Requirements
  - If the evaluation is satisfactory, the requester provides the supplier through Purchasing the written authorization to begin work.
  - For analytical services, the requester shall prepare an acceptance plan and documented the plan in a notebook or by other means. The acceptance plan should address the following information, as appropriate:
    - A description of the duplicates, blanks, and standards
    - Criteria that will be used to accept the results
    - Conditions for acceptance if all criteria are not met
  - The requester shall complete a Purchase Request and addresses the following requirements:
    - a. Provides a description of the work to be performed.
    - b. Identifies the documentation to be submitted to LANL for information, review, or acceptance.
    - c. Identifies a schedule for submittal of documents.

- d. Specifies disposition requirements for sample remnants.
  - e. Specifies, as applicable, any special sample requirements such as, handling, preparation, environmental considerations, etc.
  - f. Specifies the general parameters of the expected data.
  - g. Requires the supplier to provide LANL with the analytical results.
  - h. Requires the supplier to provide LANL with documentation stating the analytical services conform to procurement document requirements.
- The requester, upon completion of purchased services, receipt of analytical data or laboratory results, or delivery of M&TE calibration, shall verify that procurement requirements have been met by using one or more of the following methods:
    - Evaluation of the supplier certificate of conformance.
    - Review of objective evidence (such as personnel qualifications, calibration certificates, etc.) for conformance to the procurement document requirements.
    - Verification of the technical adequacy of the service.
    - For acceptance of analytical services, perform the following actions, as appropriate:
      - \* Compare the results of analysis of the standards or blinds, as applicable, to their known value to determine the accuracy of the analysis.
      - \* Compare results of duplicate analysis of the same sample material to determine the precision of the analysis.
      - \* Ensures that a copy of the acceptance plan is included in the record package or the notebook identification number and page number where the acceptance plan is documented, is referenced.
    - Performance of satisfactory surveys or audits of the work.

**Results:**

The evaluation of these QA program elements was based on the examination of objective evidence to determine compliance with selected requirements from implementing procedure LANL-YMP-QP-04.6. Based on the interviews and the objective evidence evaluated, the implementation of QA Program Elements 4.0 and 7.0 was determined to have no implementation of the current effective procedure. The procedure was determined to be inadequate in several areas, in that in some instances,

it only reiterates the QARD requirements with no methodology on how to satisfy the requirements and no provisions were incorporated into the procedure to demonstrate how the requirement was satisfied. CAR YM-94-080 was issued covering the above deficiencies. Based on the above review of objective evidence, the implementation of QA Program Elements 4.0 and 7.0 was determined to be unsatisfactory.

**5.0 IMPLEMENTING DOCUMENTS**  
**6.0 DOCUMENT CONTROL**

The evaluation of QA Program Elements 5.0 and 6.0 was based on interviews with LANL QA organization personnel and examination of objective evidence to determine the degree of compliance with selected requirements of LANL-YMP-QP-06.1, LANL-YMP-QP-06.2, and LANL-YMP-QP-06.3, implementing procedures which reflect QARD requirements. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

**Requirements:**

**OCRWM QARD, Sections 5.0 and 6.0, Implementing Documents and Document Control**

- All sections of the LANL QPs for Implementing Documents and Document Control reflect the applicable requirements of the QARD.

**Document Control (LANL-YMP-QP-06.1)**

- DCC distributes controlled documents and updates master file.
- Individuals are performing work to controlled implementing documents.
- Document recipients acknowledge receipt of controlled documents.
- Obsolete documents are removed from the control system and DCC update status.
- Records associated with the control of documents are maintained.

**Preparation, Review, and Approval of Quality Administrative Procedures (LANL-YMP-QP-06.2)**

- Action Request Forms are completed for new, revised, or deleted QPs.
- The responsible affected organizations are involved in the review process for procedures and their revisions, and are provided review criteria.
- Reviewing organizations complete QA Review Checklists and comments are resolved to the satisfaction of the reviewer.

- Procedures and revisions are authorized by responsible organizations, contain an effective date, and are distributed in accordance with the controlled process.
- A QA record package of procedures and revisions contain the documentation required.

**Preparation, Review and Approval of Detailed Technical Procedures (LANL-YMP-QP-06.3)**

- Action Request Forms are completed for new, revised, or deleted DPs.
- The responsible affected organizations are involved in the review process for procedures and their revisions, and are provided review criteria.
- Reviewing organizations complete QA Review Checklists and comments are resolved to the satisfaction of the reviewer.
- Procedures and revisions are authorized by responsible organizations, contain an effective date, and are distributed in accordance with the controlled process.

**Results:**

Distribution letters, procedure recipient lists, and memorandum requests for procedures were compared for compliance to procedure requirements. Controlled manuals were verified against recipient assigned and transmitted documents. Selected controlled manuals were sampled for content of revisions per master index and controlled distribution.

Additionally, QA record packages were reviewed for accuracy, content, and completeness:

With the exception of deficiencies in records package content as noted in CAR YM-94-078 (Section 5.5.1), and the deficiency corrected during the audit (Section 5.5.2, Item 6), the processing of procedures was performed in accordance with procedure commitments and satisfactorily implemented.

Based on the above review of objective evidence, the implementation of QA Program Elements 5.0 and 6.0 was determined to be satisfactory.

**12.0 CONTROL OF MEASURING AND TEST EQUIPMENT**

The evaluation of QA Program Element 12.0 was based on selected requirements of the LANL implementing procedure reflecting QARD requirements. Compliance with the QARD and LANL procedure was based upon interviews with LANL personnel, a review of requirements, and an examination of objective evidence for procedure LANL-YMP-QP-12.3. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

**Requirements:**

**OCRWM QARD, Section 12.0, Control of Measuring and Test Equipment**

- All sections of the LANL QPs for Control of Measuring and Test Equipment reflect the applicable requirements of the QARD.

**Control of Measuring and Test Equipment and Standards (LANL-YMP-QP-12.3)**

- Control of consumable standards is such that traceability through documentation exists. LANL is to complete Attachment 1 of this procedure and review completed forms for correctness.
- If traceability to recognized standards or a physical constant does not exist, then the basis for calibration is documented.
- For agencies that provide calibration services, LANL qualifies the provider in accordance with the LANL Program. Review these qualifications for applicability to the type of calibration performed.
- For M&TE equipment which could not be calibrated or was found to be out of tolerance, LANL initiates a CAR in accordance with LANL-YMP-QP-16.4.
- M&TE equipment Identification (ID), description, physical location, tolerance and required accuracy, interval of calibration and special handling or storage requirements are stipulated for each type of M&TE equipment.
- M&TE equipment and standards are properly tagged and identified and traceable to calibration documentation.
- For M&TE equipment calibrated at each use, the calibrator records the following information in a notebook:
  - M&TE ID
  - Reference standard ID
  - Calibration data, results and statement of acceptability

**Results:**

The evaluation of this QA program element was based on the examination of selected M&TE records for LANL calibrated equipment as well as for the calibration standards that are used for calibration. In addition, randomly selected pieces of M&TE were examined for verification of items such as calibration tags.

Although two conditions were found which required correction during the audit (see Section 5.5.2, Items 1 and 2), the M&TE records and instruments were found to be in compliance with procedural and programmatic requirements and the implementation of QA Program Element 12.0 was determined to be satisfactory.

#### **15.0 NONCONFORMANCES**

The evaluation of QA Program Element 15.0 was based on interviews with LANL personnel, and examination of objective evidence to determine the degree of compliance with selected requirements of YAP-15.1Q. Compliance could not be determined at this time, since no implementation has occurred.

#### **16.0 CORRECTIVE ACTION**

The evaluation of QA Program Element 16.0 was based on selected requirements of LANL implementing procedures reflecting QARD requirements. Compliance with the QARD and LANL procedures was based upon a review of requirements and an examination of objective evidence for procedures LANL-YMP-QP-16.2 and LANL-YMP-QP-16.4. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

##### **Requirements:**

##### **OCRWM QARD, 16.0, Corrective Action**

- All sections of the LANL YMP QPs for Corrective Action reflect the applicable requirements of the QARD.

##### **Corrective Action Reports (LANL-YMP-QP-16.4)**

- Initiation of a CAR when a QA requirement is not met.
- Actions of the CAR Coordinator.
- Action of the QAPL
- Completion of specified activities within the required working day limit.
- Verification of the CAR by a QA organization member not responsible for the resolution of the CAR.
- CAR extensions controlled correctly.
- Signatures by responsible personnel.

**Trending (LANL-YMP-QP-16.2)**

- Actions of the QAPL for evaluation of adverse trends.
- Preparation of a quarterly trend analysis.
- Record submittal of quarterly trend analyses.

**Results:**

Selected CARs and Deficiency Reports (DRs) used in the previous revision of the procedure, were evaluated for compliance to the procedural requirements. The results of the evaluation based on objective evidence reviewed and the interview with the CAR Coordinator, showed satisfactory compliance to procedural requirements.

Selected trend reports were evaluated for compliance to the requirements of the specified procedure. The results of the evaluation based on objective evidence reviewed and the interview with the QAPL indicated satisfactory compliance to procedural requirements.

Based on the above review, the implementation of QA Program Element 16.0 was determined to be satisfactory.

**17.0 QUALITY ASSURANCE RECORDS**

The evaluation of QA Program Element 17.0 was based on interviews with LANL QA organization personnel, and examination of objective evidence to determine the degree of compliance with selected requirements of procedure LANL-YMP-QP-17.6 which reflect QARD requirements. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

**Requirements:**

**OCRWM QARD, Section 17.0, Quality Assurance Records**

- All sections of the LANL QP for QA Records reflect the applicable requirements of the QARD.

**Records Management (LANL-YMP-QP-17.6)**

- The records source determines whether a record is to be included in the YMSCO records management system.
- Records are protected from damage or loss until turned over to the Records Custodian.

- Access to records is controlled by secured facilities and list of authorized personnel is maintained and posted.
- Privileged and one-of-a-kind records are uniquely identified and controlled.
- Records are identified with primary record identifiers.
- Records are forwarded to the Records Custodian within 20 days of acceptance by the records source.
- Corrections to records are re-authenticated by records source with signature and date.
- Transmittal of record packages to the Records Custodian are legible, accurate, and complete per procedure requirements.
- Duplicate copies of records submitted to the Records Custodian are maintained and protected until notified by the Records Custodian of acceptance.

**Results:**

The evaluation of compliance to this procedure was based on selected record source's files for records submitted to the records coordinator, record coordinator's files for records submitted to the Records Custodian, training files for "privileged" record packages, and individual records referenced on record transmittals to the Records Custodian. Record files were verified for required content, processing, and identification.

CAR YM-94-078 was issued to document errors in page count, dates, identification of reviewing organization, omission of action request forms, and review criteria forms in several record packages. Minor deficiencies were corrected during the audit. See Section 5.5.2., Item 6.

With the exception of the above discrepancy and based on the above review, the implementation of QA Program Element 17.0 was determined to be satisfactory.

**18.0 AUDITS**

The evaluation of QA Program Element 18.0 was based on interviews with LANL organization personnel and examination of objective evidence to determine the level of compliance with selected requirements of LANL-YMP-QP-018.1, LANL-YMP-QP-018.2, and LANL-YMP-QP-018.4, implementing procedures which reflect QARD requirements. The specific requirements selected for evaluation of compliance and effectiveness are listed below.

**Requirements:**

**OCRWM QARD, Section 18.0, Audits**

- All sections of the LANL YMP QPs for Audits reflect the applicable requirements of the QARD.

**Audits (LANL-YMP-QP-18.1)**

- The Verification Coordinator prepares an annual audit schedule that includes internal and external audits and identifies the audit number, audit dates, and the audited LANL groups and subcontractor organizations.
- Internal audits are scheduled to provide coverage, consistency, and coordination with ongoing work; at a frequency commensurate with the status and importance of the work; as early in the life of the work as practical and at intervals consistent with the schedule for accomplishing the work; and annually or at least once during the life of the work, whichever is shorter.
- External audits are scheduled based on the need, extent, and frequency determined after an organization has been selected to perform work for LANL YMP and the determination is based on the nature, complexity, relative importance, and quantity of the services to be performed and the supplier's quality performance.
- External audits for compliance are performed triennially, at a minimum; the need to schedule additional external audits is evaluated when a major change occurs in a supplier's contract scope or work methodology; and each organization is evaluated annually to determine the need to schedule additional audits.
- The audit schedule is revised, as necessary, to ensure that coverage is currently maintained to include any additional audits of supplier organizations.
- The audit team leader is a certified lead auditor in accordance with LANL-YMP-QP-18.4; the audit team members are qualified in accordance with LANL-YMP-QP-18.4; the audit team is independent of any direct responsibility for performing the audited work; and the audit team members have sufficient authority and organizational freedom.
- The audit team leader prepares an audit plan and the Verification Coordinator reviews the audit plan and then forwards it to the supervisor of the audited organization.
- The audit team leader briefs the audit team members on the details of the audit and provides each team member an audit assignment.

- The audit team members prepare checklists and list, as applicable, requirements from the QARD, steps from implementing procedures, or other elements to be verified.
- The audit team leader conducts a preaudit meeting with representatives from the audited organization to discuss the details of the audit and a postaudit meeting to review the audit's results.
- The audit team members examine objective evidence to evaluate effective implementation of the audited elements; perform technical evaluations of the applicable procedures, instructions, and work activities; document the results; and initiate a CAR for each identified deficiency that was not corrected during the audit.
- The audit team leader prepares an audit report, the Verification Coordinator reviews the report, and forwards a copy to the supervisor of the audited organization.
- Records associated with audit activities are maintained.

#### **Surveys (LANL-YMP-QP-18.2)**

- The Verification Coordinator ensures that surveys are performed to verify the quality of work in progress, identify deficiencies, ensure prompt corrective action is taken and timely implementation of corrective action.
- The Verification Coordinator assigns a survey number, a survey leader, and a survey team that has knowledge of the work to be surveyed and was not directly responsible for the work to be surveyed.
- The survey team leader determines the scope of the survey and, if applicable, briefs the survey team on the details of the survey and assigns each member a survey responsibility.
- The survey team performs the survey, documents the survey findings, and initiates a CAR for identified deficiencies that were not corrected during the survey.
- The survey leader prepares a report, the Verification Coordinator reviews the report, and forwards a copy to the supervisor of the surveyed organization.
- Records associated with survey activities are maintained.

#### **Auditor Qualification and Lead Auditor Certification (LANL-YMP-QP-18.4)**

- The Verification Coordinator ensures the competence of an auditor candidate to perform audits by training.

- The Verification Coordinator ensures that a technical specialist receives training as described in LANL-YMP-QP-18.4 and the level of experience or training has been evaluated to be commensurate with the scope, complexity, and special nature of the work being audited.
- The Verification Coordinator ensures that a lead auditor candidate has verifiable evidence that a minimum of 10 credits have been accumulated according to LANL-YMP-QP-18.4.
- The Verification Coordinator ensures that the lead auditor candidate has participated in a minimum of five QA audits or equivalent verifications within a period of time not to exceed three years, and that one audit was nuclear-related QA.
- The Verification Coordinator develops and administers an examination to evaluate the lead auditor candidate's comprehension and ability to apply the knowledge attained during the provided audit training.
- The Verification Coordinator documents lead auditor certifications.
- The lead auditor maintains proficiency in accordance with LANL-YMP-QP-18.4.
- The TPO, QAPL, or Verification Coordinator annually evaluates each lead auditor's proficiency.
- Lead auditors who fail to maintain proficiency for a period of two or more years are requalified.
- Records associated with auditor qualification and lead auditor certification are maintained.

**Results:**

Audit schedules, audit plans, audit reports, supplier annual performance evaluations survey reports, CARs, auditor qualification records, and lead auditor certification records were reviewed to evaluate compliance with procedural requirements. Also, interviews with LANL YMP QA personnel were conducted to determine if work subject to QARD requirements was conducted in accordance with procedural requirements.

With the exception of a deficiency corrected during the audit (see Section 5.5.2, Item 5 of this report) regarding completion of the required form for documenting the results of a survey, implementation of procedural requirements for audits and surveys was determined to be satisfactory.

Based on the above review of objective evidence, the implementation of QA Program Element 18.0 was determined to be satisfactory.

## **SUPPLEMENT I, SOFTWARE CONTROL**

The evaluation of QA program element Supplement I was based on selected requirements of the LANL implementing procedures reflecting QARD requirements. Compliance with the QARD and LANL procedures was based upon personnel interviews, review of the procedural requirements for procedures LANL-YMP-QP-03.20, LANL-YMP-QP-03.21, LANL-YMP-QP-03.26 and LANL-YMP-QP-03.27, and applicable documentation generated as a result of implementation of these procedures. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

### **Requirements:**

#### **OCRWM QARD, Supplement I, Software**

- All sections of the LANL YMP QPs for Software Control reflect the applicable requirements of the QARD.

#### **Software Configuration Management (LANL-YMP-QP-03.20)**

- Configuration ID requirements are met.
- ECD form release labeling is performed correctly.
- Baseline Certification is performed as required.
- Baseline Sanctioning is performed as required.
- Variances are documented and handled correctly.
- Adequate Status Accounting is performed.
- Change Tracking and Reports are generated as required.
- Adequate control is applied to the Computer Program Library.

#### **Software Life Cycle (LANL-YMP-QP-03.21)**

- SCRs and/or Software Incident Report forms are used as required.
- Use of ECDs and LifeCycle Specifications (LCS) forms are used for work assigned.
- The LifeCycle process defined on the LCS.

#### **Reviews of Software (LANL-YMP-QP-03.26)**

- Requirements, design, and implementation traceability.

- Verification and validation (V&V) by the developer.
- Preparation of the Baseline Submission Summary form by the developer.
- Software configuration management audit performance.
- Use of the SRN form with review packets.
- Reviewer activities: V&V, testing, baseline evaluation.
- Use of Review/Audit Item Disposition and RRR forms by the Change Control Board (CCB) during review activities.
- Change Control Authority Identification and resolution of review issues.

**Documentation of Software (LANL-YMP-QP-03.27)**

- Coding standards are developed for the language of the code.
- Creation of baselines as indicated in the LCS form.

**Results:**

The OCRWM QARD, Supplement I, Software requirements were evaluated for compliance to the LANL implementing documents. Several inconsistencies exist between the QARD requirements and the implementing procedures that are intended to comply with them. Since this audit was not considered a baseline audit, these inconsistencies were submitted to the LANL representative responsible for RTN input. These inconsistencies will be evaluated and changes accepted during the YMSCO RTN Matrix acceptance review process. See Recommendation 7 in Section 6.0 of the audit report.

Selected software packages were reviewed for compliance to the specified procedures for software.

OCRWM CAR YMP-94-082 was written to document a condition adverse to quality relative to traceability of software requirements into the software source-code documentation prologue.

A recommendation was made relative to specific information required by QP-03.26, Section 6.7 which requires the RRR form to reference the SRN form number and the resubmission deadline (see Recommendation 6 of Section 6.0 of the audit report).

A recommendation was made relative to configuration control of modules for the source code of TRACRN (see Recommendation 4 of Section 6.0 of the audit report).

A recommendation was made relative to removing two codes in the records system. CTCN and part of LSODPK have been controlled under the requirements of the QARD DOE/RW-0214 and the LANL SQAP written to meet these requirements. The two codes are inter-related in that the LSODPK software is a re-use application to CTCN (it appears one is needed to use the other). See Recommendation 2 in Section 6.0.

All other forms and records observed were controlled appropriately. In spite of the above recommendations and the one CAR, the implementation of QA Program Element Supplement I, Software, was considered satisfactory.

#### **SUPPLEMENT II, SAMPLE CONTROL**

The evaluation of this QA program supplement was based on selected requirements of the LANL implementing procedure reflecting QARD requirements. Compliance with the QARD and LANL procedure was based upon interviews with LANL personnel, a review of requirements, and an examination of objective evidence for procedure LANL-YMP-QP-08.1. The specific requirements selected for evaluation of compliance and effectiveness are listed below:

##### **Requirements:**

#### **OCRWM QARD, Supplement II, Sample Control**

- All sections of the LANL YMP QP for Sample Control reflect the applicable requirements of the QARD.

#### **Identification and Control of Samples (LANL-YMP-QP-08.1)**

- For samples collected in the field by the PI, verify the following:
  - Method of collection
  - Field location
  - Specifics on sample orientation relative to the location that was sampled.
- All samples are traceable to the YMSCO SMF through identification numbers supplied by the SMF or the number supplied by the PI. In either case, all numbers shall be traceable to a SMF number.
- An SCR is submitted to the YMSCO SMF in accordance with YAP-SII.4Q.
- Sample identification and control is adequately documented to permit derivatives from its origin, through all analytical or other processing, to its present location or final disposition.
- Samples are stored within appropriate environments, based upon physical conditions, intended purpose and expected storage life. Special storage and shipping requirements are required to be documented.

Results:

This evaluation was based on the review of selected samples that were collected in the field at the ESF starter tunnel and were being processed by LANL. The documentation associated with the samples was reviewed along with the visual examination of the samples in their assigned storage places.

Based upon the objective evidence reviewed, even with the one deficient condition corrected during the audit (see Section 5.5.2, Item 3), the LANL implementing procedure for sample control was determined to satisfactorily implement the requirements of QA Program Element Supplement II.

**SUPPLEMENT III, SCIENTIFIC INVESTIGATION**

The evaluation of QA Program Element Supplement III was based on interviews with LANL personnel and examination of objective evidence to determine the degree of compliance with selected requirements of LANL-YMP-QP-03.5, LANL-YMP-QP-03.23, LANL-YMP-QP-03.24, and LANL-YMP-QP-08.3, implementing procedure which reflect QARD requirements. Compliance with the QARD and implementing LANL procedures was determined by interviews, and a review of technical reports and open SNs. The selection of objective evidence was guided by the technical scope defined for this audit. The specific procedures and their requirements selected for evaluation of compliance and effectiveness are listed below:

Requirements:

**OCRWM QARD, Supplement III, Scientific Investigation**

- All sections of the LANL YMP QPs for Scientific Investigations reflect the applicable requirements of the QARD.

**Documenting Scientific Investigations (LANL-YMP-QP-03.5)**

- Notebook pages are numbered in sequence, with entries made daily.
- Notebooks contain a table of contents or index which list major sections and (data) attachments.
- The first numbered page lists the primary record identifier, employee(s) responsible, the number of the applicable Study Plan (SP), title of the activities recorded.
- The title and revision of the DP used, procedurally-required information, and unique identification of M&TE are recorded in the notebook.
- Date, description, methods/objectives, equipment, software, and M&TE are recorded for scientific work not governed by a formal controlled procedure.

- Each entry contains a description of work that permits a qualified individual to repeat the work and achieve comparable results without consultation.
- Each entry is signed and dated.
- Attachments are labelled with the notebook's primary record identifier and its own attachment number.
- Attachments are referenced in the notebook their attachment number.
- Data are evaluated and a statement entered explaining acceptance or rejection of the data.
- Compromised data are evaluated for acceptance or rejection by a qualified individual.
- Notebooks and their attachments/data are subjected to a technical review annually, when the activity ends, or the notebook is closed out.

**Preparation and Review of Technical Information Products and Study Plans (LANL-YMP-QP-03.23)**

Insufficient activity to perform an evaluation.

**Submittal of Design and Test-Related Information (LANL-YMP-QP-03.24)**

No implementation of this procedure.

**Transfer Of Data (LANL-YMP-QP-08.3)**

- Technical data that is submitted to the technical database is identified via a Data Tracking Number.
- For acquired data, the Technical Data Coordinator enters the information into the Automatic Technical Data Tracking System (ATDT).

**Results:**

The implementation of QA Program Element Supplement III was based on the quality and completeness of selected SNs and interviews of Principal and Associate Investigators and their staff. The review identified two conditions adverse to quality, the issuance of a CAR, and the lack of implementation of two procedures. None of these conditions were determined to be serious. The results for the individual procedures follow.

LANL-YMP-QP-03.5: The overall compliance with this procedure is considered adequate. The Principal and Associate Investigators as well as a number of

technicians of all three technical areas (WBS 1.2.3.4.1.2.1, 1.2.3.4.1.3.1, and 1.2.3.4.1.4.1) were interviewed, and 11 related SNs were reviewed in detail. Based on this examination, two conditions were identified as requiring corrective action:

- 1) Six SNs did not list the DP followed in the use of instruments to acquire data. This condition was corrected during the audit and objective evidence of this fact provided to the auditor. See Section 5.5.2, Item 7.
- 2) Five SNs lacked the required statement(s) to document evaluation of data to determine its acceptability or rejection. This condition did not lend itself to immediate correction and consequently CAR YM-94-081 was issued.

LANL-YMP-QP-08.3: Compliance with this procedure is adequate. Selected sets of acquired data were reviewed. The sets of data were assigned a Data Tracking Number and entered into the ATDT. Since the other requirements of this procedure are new requirements, there was no data to review to evaluate the other requirements.

Based on the above review of objective evidence, the implementation of QA Program Element Supplement III is satisfactory.

#### **TECHNICAL EVALUATIONS:**

The evaluation of Batch Sorption Studies, Dissolved Species Contamination Limits, and Dynamic Transport Column Experiments Programs was based on interviews with LANL personnel and examination of objective evidence. The items evaluated to verify the technical adequacy of implementation are listed below:

#### **WBS 1.2.3.4.1.2.1 - Batch Sorption Studies**

##### **SP 8.3.1.3.4.1/3:**

- The number of batch sorption tests as a function of rock composition that are planned to be run simultaneously.
- Procedures used during the operation of the following instruments:
  - Ion chromatograph
  - Alkalinity titrator
  - Surface analyzer
- Assurance that the computer codes RAYGUN, GAMANAL, SPECANAL, and commercial spread-sheet programs yield correct answers.
- Whether the three major ground water compositions listed in the SP will be expanded to use vadose water analysis.

- The number of batch sorption tests as a function of sorbing elements that are planned to be running simultaneously.
- Selection of representative batch sorption measurements as a function of ground water composition.
- Determination of ground water compositional parameters that have the greatest impact on the sorption behavior.
- Activity that will determine the "most active ground water composition."
- Number of the approximately 380 tests for sorption onto pure minerals that will be needed before the other activities can be started.
- Method of determining that the pure mineral experiments lead to a determination of representative rock compositions and of background water compositions.

**Effect of Natural Organics on Cd and Np Sorption, Paper By Kung and Triay:**

- SP under which the investigation of "Effect of Natural Organics on Cd and Np Sorption" was performed.
- Studies of Cd sorption.
- The rationale for studying sorption onto AlOOH.
- Determination of whether Cd and Np exist in solution as free ions or are bound in complexes.
- How interference from the scintillation spectrum of  $^{233}\text{Pa}$  with that of  $^{237}\text{Np}$  is resolved.
- What percentages of the Al and Fe oxides surfaces were covered by organic material based on the experimental results.
- The purpose of the Cd electrode.
- Valence of Np.

**Neptunium (V) Sorption on Hematite ( $\text{Fe}_2\text{O}_3$ ) in Aqueous Suspension: Effects of Carbonate and EDTA, Paper by Kohler, Honeyman, vanGeen and Leckie:**

- Choice of a surrogate for Np-complexing organic ligands.
- Any work planned or completed to demonstrate whether or not Np forms an inner sphere complex on hematite.

- Any independent check of the modeling results from FITEQL and HYDRAQL.
- Determination of whether any of the model results represent predictions, as opposed to data fits.
- Current qualification status of HYDRAQL and FITEQL.

**WBS 1.2.3.4.1.3.1, Dissolved Species Contamination Limits**

**SPs 8.3.1.3.5.1 and 2, 2.1.1:**

- Evaluation of whether the rationale that the solubility of a radionuclide provides an upper bound to dissolved concentration applies in the case that the major phase is glass or crystalline  $UO_2$ .

**LA-12562-MS:**

- Choice of procedures used for the radionuclide solubilities measured at Lawrence Berkeley Laboratory (LBL).
- Use of the procedures noted in the SP.
- Examination of a selection of the procedures, or copies of the laboratory notebooks (e.g., for preparation of actinide stock solutions, pH measurements).
- Determination of impact of potential degassing of  $CO_2$  between the time that well J-13 water was taken and the time it was filtered at LANL.
- Determination of impact of potential formation of precipitates between filtration of well J-13 water at LANL and use at LBL.
- Evaluation of the actual extent of contamination during sampling and handling.
- Examination of the records for temperature and pH during example experiments to confirm the statements on the standard deviation of pH and constancy of temperature.
- The effect on the water chemistry due to additions of  $HClO_4$  and  $NaOH$ . Examine records to confirm that the effect was not "substantial."
- Maintenance of atmosphere while pH electrodes were removed and inserted.
- Qualification of the statement "no significant evaporative loss" of solutions at elevated temperatures.
- Review of records to confirm that no contaminants above the detection limits were found for the Np and Pu stock solutions, and that valence purity was established.

- Examination of the possibility that the procedure may result in the formation of colloidal  $\text{CaCO}_3$  and adsorption of actinides onto the colloidal particles.
- The temperature before the pH was adjusted and the actinide added.
- Use of the gas compositions (presumably calculated as detailed in the SP) in Table V for actually producing the desired pHs.
- Potential changes in the spectra of samples taken at elevated temperatures before the spectra were measured.

**LA-12562-MS AND LA-12563-MS:**

- Utilization of data for precipitated Np solids whose characterization remains poor.
- How Np solids for undersaturation studies can be synthesized, in view of their uncertain character.
- Determination of the rationale behind the statement that crystalline material might have a higher solubility than the Pu (IV) polymer.
- Examination of why the formation of different polymorphs of  $\text{NdOHCO}_3$  should depend on pH.
- Theoretical rationale for the statement that complexation with perchlorate is weak for most cations.

**APRIL 1994 MONTHLY REPORT FROM LANL:**

- Examination of results of the following investigations:
  - 1) Spectrometric determinations
  - 2) Spectra and results
  - 3) Raman spectra and results
- Evaluation of whether the data for thermochemical data obtained from the experiments, or located in the literature, agree acceptably well with those in GEMBOCHS.
- Determination of the meaning of "background" in the statement made that two cells will be set up, one for the sample and one for "background."
- Quantification for the "significant difference" between the EXAFS and IR results.
- The pH dependence of Pu solubility.
- The current view of the Am/Nd solubility results.

**MIGRATION 1993:**

- Determination of whether studies of solubility, specific to other sites, provide insights to solubility at Yucca Mountain.
- Determination of what C and O isotopic studies show in respect to speciation.

**WBS 1.2.3.4.1.4.1 - Dynamic Transport Column Experiments**

**SP 8.3.1.3.6.1:**

- Determination of the mechanism for radionuclide transporting solid tuff columns.
- Parameters for the elution curve, e.g., skewness.
- Sorption kinetics in columns vis-a-vis those in batch experiments.
- Reversibility of sorption in column experiments.
- Effect of crushing on sorption.
- Independence of parameters from each other.
- Feasibility of long (four-year) centrifuge experiments.
- The meaning of "interchange" in Section 1.1, first paragraph.
- Choice of linear versus non-linear isotherms.
- Range of fracture apertures to be studied.
- Determination of free column volume by elution of tritiated water work.
- Use of autoradiography to show the flow path.
- Accuracy of the measurements.
- Process to be used if batch Kds can't be accepted.
- Satisfaction of the assumptions of Hiester and Vermeulen.
- Development of stratification preventive during settling of material in the column.
- Examination of some laboratory notebooks to assure that the procedures in Table 3 were followed.

- Justification of an accuracy of ten percent for utilization in projections out to 10,000 years.
- Determination of whether the evaluations and derivations in Section 3.1.4 have been independently verified.
- Accuracy of the determination of the retardation factor from Equation 11.
- Selection of the experiment durations in Tables 1, 4, 7, and 10.
- Review of retardation factors determined from fitting to Equation 11.
- Examination of laboratory notebooks to confirm compliance with detailed procedures in Tables 9 and 14.

Results:

The quality of work was found to be high with an abundance of data being produced. During the audit, many specific details were checked, based primarily on published reports and milestone reports sent to the YMSCO. One aspect that was not checked, but might be on a future audit, was the reproducibility of results from duplicate or multiplicative experiments. The technical specialist was pleased to note that one of his prior recommendations has been implemented; this dealt with the ability to backtrack from data in a published report to the laboratory notebook wherein the data were originally recorded. This was clearly evident for papers published by the CAR group, but was not checked for the sorption group. Cooperation from LANL staff was excellent, as was that from LBL staff who had performed much of the work audited.

It proved possible for the technical specialist to track and to understand data in laboratory notebooks unassisted, but in some cases with difficulty. This difficulty led to a recommendation that, at the beginning of the looseleaf notebooks maintained by the sorption group, a brief explanation of the procedures be incorporated and that all entries, such as column headings, be clearly explained. See audit report, Section 6.0, Item 3.

Examination of the laboratory notebooks at the CAR facility revealed that some staff there were not following the procedure for pH determination exactly. This necessitated the writing of OCRWM CAR YM-94-079. The practice followed had no impact on the scientific validity of the data. Nevertheless, the procedure should be changed to avert future violations.

The staff clearly understand what they are doing and matters related to their investigations, whether or not corresponding procedures have been written. This provides assurance that the scientific work will be conducted correctly. Evidence of this showed up from the fact that LANL had already identified most of the concerns raised by the technical specialist and was taking or planning suitable ways to address them.

During the course of the audit, numerous occasions arose in which it was apparent that results were satisfactory or satisfactory statements were included in various documents, but

documentation was incomplete. Some examples are: 1) In the report on the sorption of Cd and Np, the valence of Np was not mentioned, 2) In this same report, it seemed as though the authors thought that the Cd electrode measures total Cd in solution, rather than only free Cd ion, 3) Responses to questions about the adsorption of Cd and Np indicated that Np does not form complexes with organic compounds, but that Cd generally does. This should have been documented by reference citations. Similarly, the basis for assuming that DOPA forms bidentate complexes on oxide surfaces should have referred to the known literature for the similar structure for catechol and the relevant literature cited, 4) In the solubility work, the reports make statements about standard deviations or constancy of values, but no data are cited. Tables of data might be put into an appendix, or a statement made that data diskettes can be supplied upon request (a procedure which is done fairly often in the open scientific literature when the database is large), and 5) Details, e.g., schematics of experimental setups, were not always provided.

The recommendation is to produce reports that provide the reader enough detail to understand the methodology and results in considerable detail, i.e., to adjudge whether or not the results and conclusions are well supported without having to make additional inquiries or examining other documents. Perhaps this could be accomplished and reflected by a more comprehensive internal review by staff who understand the scientific principles, but otherwise have little specific knowledge of the project. See audit report, Section 6.0, Item 8.

Based on the above review of objective evidence, the implementation of technical work is satisfactory.

### ATTACHMENT 3

#### Objective Evidence Reviewed During the Audit

##### QA PROGRAM ELEMENT 1.0, "ORGANIZATION"

###### Procedures:

Compliance with the following procedures was reviewed:

OCRWM QARD, DOE/RW-0333P, Revision 1, Section 1.0  
LANL-YMP-QP-01.2, Revision 2, "Stop Work Control"  
LANL-YMP-QP-01.4, Revisions 1 and 2, "The Los Alamos YMP Organization and  
Quality Program Description"

###### Objective Evidence Examined:

LANL-YMP-QP-01.2 and LANL-YMP-QP-01.4:

RTN Matrix Report, dated 7/12/94 - not approved  
SWO-LA-03, Revision 1, dated 3/5/92  
SWO-LA-03, Revision 2, dated 2/11/93  
SWO-LA-08, dated 7/14/92  
LANL-YMP-QP-03.23, Revision 2  
LANL-YMP-QP-04.6, Revision 1  
LANL-YMP-QP-06.2, Revision 3  
LANL-YMP-QP-08.3, Revision 1  
LANL-YMP-QP-16.4, Revision 1  
LANL-YMP-QP-18.1, Revision 6  
Memo LA-EES-13-07-94-004, dated 7/27/94, "Delegation of Signature Authority"  
Memo LA-EES-13-05-94-109, dated 5/6/94, "Delegation of Signature Authority"

##### QA PROGRAM ELEMENT 2.0, "QUALITY ASSURANCE PROGRAM"

###### Procedures:

Compliance with the following procedures was reviewed:

OCRWM QARD, DOE/RW-0333P, Revision 0, Section 2.0  
LANL-YMP-QP-02.4, Revision 2, "Management Assessment"  
LANL-YMP-QP-02.5, Revision 3, "Selection of Personnel"  
LANL-YMP-QP-02.7, Revision 3, "Personnel Training"  
LANL-YMP-QP-02.11, Revision 3, "Personnel Orientation"  
LANL-YMP-QP-02.12, Revision 1, "Exemption Control"  
LANL-YMP-QP-02.15, Revision 1, "Requirements Traceability"

**Objective Evidence:**

**LANL-YMP-QP-02.4:**

**Letter, J. Canepa ESS-13 to D. Summers ICO-1 MS C307, dated 7/26/93, re: QA Management Assessment Yucca Mountain Site Characterization Plan (YMSCP)**

**Assessment Plan No. 93-07, prepared by L. Reese, dated 8/3/93**

**Assessment Plan Team:**

**L. Reese, Team Leader  
L. Quinliar  
J. Noble  
T. Rust**

**YMSCP QA Management Assessment No. 93-07, signed by Assessment Team Leader, L. Reese on 8/31/93**

**Letter, S. Bolivar to J. Canepa, dated 9/20/93, re: Review of Management Assessment Report No. 93-07**

**Letter, J. Canepa to S. Bolivar, dated 11/12/93, re: Evaluation of the Management Assessment Plan No. 93-07, LANL YMSCP**

**LANL-YMP-QP-02.5:**

**Position Descriptions were reviewed for the following personnel:**

**N. Elkins, Deputy TPO, 6/11/92  
E. Springer, PI, 3/23/93  
J. Ganor, Associate Investigator, 5/3/94  
R. Oliver, Test Planning and Design Project Leader, 6/21/94  
T. Ickes, QA Specialist, 1/3/94  
D. Hobart, Co-PI, 11/10/93 (LBL)  
G. Griego, Field Test Specialist, 4/23/93  
R. Wilkin, Associate Investigator, 5/3/94**

**Position Descriptions for the following personnel contained a description of assigned duties and responsibilities:**

<b>N. Elkins</b>	<b>T. Ickes</b>	<b>R. Oliver</b>	<b>R. Wilkin</b>
<b>G. Griego</b>	<b>J. Ganor</b>	<b>E. Springer</b>	<b>D. Hobart</b>

Personnel Qualification forms for education and experience were verified for the following personnel:

N. Elkins, Employment Representative 10/21/94  
D. Hobart (LBL), LANL Supervisor 3/9/90  
G. Giego, Employment Representative 5/31/94  
R. Oliver LANL, Supervisor 6/21/94  
E. Springer LANL, Supervisor 5/5/88  
T. Ickes (LATA), Training Coordinator 8/16/94  
R. Wilkin (Penn State), LANL Supervisor 5/3/94  
J. Ganor (Yale), LANL Supervisor 5/5/94

**LANL-YMP-QP-02.7:**

The training records forms documented each document and revision level to be read by the employee and the dates the employees indicated completion of the assignment.

N. Elkins (2/2/94, 3/14/94)  
R. Oliver (2/2/94, 2/16/94, 2/21/94, 3/10/94, 5/28/94, 6/22/94)  
G. Griego (1/3/94, 1/21/94, 2/11/94, 3/10/94, 7/14/94)  
E. Springer (2/7/94, 4/19/94, 6/24/94)  
J. Ganor (5/4/94)  
T. Ickes (12/6/93, 1/3/94, 1/26/94, 2/9/94, 3/10/94, 4/20/94, 7/26/94, 8/10/94)  
R. Wilkin (5/3/94, 5/4/94, 6/13/94)  
D. Hobart (1/28/94)

The training instructor completed Section II of the YMP training record for formal instructions provided to the employees.

Employee, Training Class, Instructor, Date:

N. Elkins, Orientation, J. Canepa, 5/15/92  
E. Springer, Orientation, J. Canepa, 2/7/92 and  
QP-17.6, Records, J. Day, 4/19/94  
J. Ganor, Orientation, D. Bish, 5/4/94  
R. Oliver, Orientation, N. Elkins, 6/21/94  
T. Ickes, Orientation, C. Martinez, 1/3/94,  
QP-18.1, J. Day, 2/9/94 and QP-17.6, J. Day, 3/10/94  
G. Griego, Orientation, R. Kovach, 1/21/94  
R. Wilken, Orientation, D. Bish, 5/4/94  
D. Hobart, Orientation, (re: YMP-Orientation - required prior to 11/10/94)

The employee completed Section III of the LANL YMP Training Record for Read Assignments.

T. Ickes, Training Forms, dated 7/26/94 and 8/10/94

**LANL-YMP-QP-02.11:**

N. Elkins, Orientation form LANL-YMP-QP-02.11, Revision 1, dated 5/15/92  
R. Oliver, Orientation form LANL-YMP-QP-02.11, Revision 2, dated 6/21/94  
G. Griego, Orientation form LANL-YMP-QP-02.11, Revision 1, dated 1/27/94  
E. Springer, Orientation form LANL-YMP-QP-02.11, Revision 1, dated 2/7/92  
T. Ickes, Orientation form LANL-YMP-QP-02.11, Revision 1, dated 1/3/94  
R. Wilkin, Orientation form LANL-YMP-QP-02.11, Revision 2, dated 5/4/94  
J. Ganor, Orientation form LANL-YMP-QP-02.11, Revision 2, dated 5/4/94  
D. Hobart, Orientation form LANL-YMP-QP-02.11, Revision 1, dated 3/15/91

**LANL-YMP-QP-02.12:**

Exemption Justification ES-01 form Revision 0, originator N. Elkins

WBS and Activity Title 1, 2, 3, 9, 7 (submittal of Design and Test Related Information record package for Test Planning Packages (TPPs) and Job Packages (JPs) to the Central Records Facility (CRF) only

Exclude the activity from QP-17.6, Revision 0, Section 6.8 requires records to be submitted to the CRF. Administrative Procedure (AP)-5.21Q and AP-5.32Q requires records to be submitted to Las Vegas LRC for TPPs and JPs. Exception approved by J. Canepa on 4/4/94 in Section II without conditional terms

**LANL-YMP-QP-02.15:**

LANL-YMP-QP-06.2, Revision 3, "Preparation, Review and Approval of Quality Administrative Procedures," Paragraph 6.3

LANL-YMP-QP-03.23, Revision 2. Cover letter from S. Bolivar, dated 5/25/94, designated P. Gillespie as the RTN Reviewer. The QP Review Sheet was signed 6/15/94 indicating no comments

LANL-YMP-QP-16.4, Revision 1. Cover letter from S. Bolivar dated 6/7/94 designated P. Gillespie as the RTN Reviewer. The QP Review Sheet was signed 6/29/94 indicating no RTN comments. Note: QP Revision 1, requires an RTN review; previously it was an administrative task

Corrective Action Effectiveness:

Verified by sample of LANL employees and augmented staff from listing of personnel obtained from the training coordinator

P. Chavez 4/19/94  
F. Perry 6/16/94  
B. Romero 6/14/94

A. Mitchell 3/10/94  
G. Griego 3/10/94  
P. Palmer 7/28/94

E. Kluk 1/27/94  
P. Rogers 1/27/94  
L. Hersman 4/19/94

LANL/YMSCP Master List of Controlled Documents, dated 7/13/94, QP Control  
Manual 086

**QA PROGRAM ELEMENT 4.0, "PROCUREMENT DOCUMENT CONTROL" AND  
QA PROGRAM ELEMENT 7.0, "CONTROL OF PURCHASED ITEMS AND SERVICES"**

Procedures:

Compliance with the following procedures was reviewed:

OCRWM QARD, DOE/RW-0333P, Revision 0, Sections 4.0 and 7.0  
LANL-YMP-QP-04.6, Revision 1, "Procurement"

Objective Evidence:

PR2801M (Penn State) Scope of Work, SP 8.3.1.3.3.2, Deliverables QP Req. LANL's  
Program specific QP and procedures, audit before commenced, Rights of Access,  
Deficiencies. No subcontract

PR2801M, Robert Raymond, Technical Review, Group Leader, 1/7/94

PR2801M Sole Source Justification, David Bish 1/6/94

PR2801M (Yale University) QA Reviewer, QAL Lyle Wichman, 1/10/94

PR2801M, Sole Source Justified

PR2802M, Yale University, Scope of Work, SP 8.3.1.3.3.2, Deliverables, Technical  
Procedure work to LANL QA Program (ID specific procedures) all work to LANL  
QP, Rights of Access Audits/Deficiencies, No subcontracts work authorization

PR2802M, Robert Raymond, Technical Review, Group Leader, 1/7/94

PR2802M (Yale University) Sole Source Justification, David Bish 1/6/94

PR2802M (Yale University) QA Reviewer, QAL Lyle Wichman, 1/10/94

PR2802M, Sole Source Justified

PR3387Q Sole Source Justification, C. Harrington, 7/12/94

PR3387O (Yale University) QA Reviewer, QAL Lyle Wichman, 7/21/94

PR3387 (University of Arizona) Sole Source Justified

PR3387Q, 7/12/94, Requester C. Harrington

10Be or 14C dating of rock samples

Analyses Results for acceptance by 10/1/94 scheduled

Dispose of remnants

Sample preparation whether mineral separates

Precision Results with normal parameters by 10/1/94

Results with statement of conformity to YMSCO

Statement of conformance to Procurement Documents

LA/YMP Audit Report LA-AR-EES-1/YU-94-01, 6/15/94

Subcontract 2802M0014-3A, effective 1/1/94

Quality Management Procedure QMP-04.6, Revision 1, Procurement, fails to describe the methodology on how to satisfy the requirements or provide any mechanism to demonstrate how the requirements were satisfied. See CAR YM-94-080.

**OA PROGRAM ELEMENT 5.0, "IMPLEMENTING DOCUMENTS"**  
**OA PROGRAM ELEMENT 6.0, "DOCUMENT CONTROL"**

**Procedures:**

Compliance with the following procedures was reviewed:

OCRWM QARD, DOE/RW-0333P, Revision 0, Sections 5.0 and 6.0  
LANL-YMP-QP-06.1, Revision 7, "Document Control"  
LANL-YMP-QP-06.2, Revision 3, "Preparation, Review, and Approval of  
Quality Administrative Procedures"  
LANL-YMP-QP-06.3, Revision 2, "Preparation, Review, and Approval of  
Detailed Technical Procedures"

**Objective Evidence:**

LANL-YMP-QP-06.1, LANL-YMP-QP-06.2 and LANL-YMP-QP-06.3:

Quality Procedure Recipient List, dated 8/11/94  
Quality Procedure Recipient List, dated 8/3/94  
Quality Procedure Recipient List, dated 5/5/94  
Individual Quality Procedure Recipient List, dated 8/11/94  
Controlled Procedure Manual Nos. 056, 008, 013, 073, 085, 014, and 045.  
Quality Procedure Distribution Letter, dated 7/13/94  
Quality Procedure Distribution Letter, dated 8/1/94  
Memo requesting Quality Procedures, dated 8/5/94  
Revision to LANL-YMP-QP-06.1, Revision 6  
Revision to LANL-YMP-QP-06.1, Revision 7  
Revision to LANL-YMP-QP-06.2, Revision 2  
Revision to LANL-YMP-QP-06.2, Revision 3  
Revision to LANL-YMP-QP-06.3, Revision 1  
Revision to LANL-YMP-QP-07.6, Revision 1

**OA PROGRAM ELEMENT 12.0, "CONTROL OF MEASURING AND TEST  
EQUIPMENT"**

**Procedures:**

Compliance with the following procedures was reviewed:

OCRWM QARD, DOE/RW-0333P, Revision 0, Section 12.0  
LANL-YM-QP-12.3, Revision 1, "Control of Measuring and Test Equipment  
and Standards"

Calibration Records for the following M&TE:

PN 348308	Balance
PN 400569	Balance
RC 45-001	Weight Set
PN 486954	Balance
PN 625067	Balance
SN 56203	Thermometer
SN 20322906	Weight
PN 405661	Balance
PN 645140	Balance
PN 823216	Atomic Force/Scanning Tunneling Microscope
YMP#4	Weight Set (Standard)

Tagging for the following M&TE:

PN 400569	Balance
PN 348308	Balance
PN 817330	Balance
PN 645140	Balance
PN 625067	Balance
PN 486954	Balance
RC-45-001	Weight Set
YMP#4	Weight Set (Standard)

Notebooks for the calibration of the following M&TE:

SN 001620	pH Meter
SN 817090	pH Meter
PN 652589	Spectrometer
PN 441222	Spectrometer

Performance Evaluations for the following M&TE Service Companies:

Mettler Instrument Corp., 7/11/94  
Simco Electronics, Inc., 1/28/94

Miscellaneous:

Computer print-out of Active M&TE, dated 8/15/94

**QA PROGRAM ELEMENT 16.0, "CORRECTIVE ACTION"**

**Procedures:**

Compliance with the following procedures was reviewed:

OCRWM QARD, DOE/RW-0333P, Revision 0, Section 16.0  
LANL-YMP-QP-16.4, Revision 1, "Corrective Action Reports"  
LANL-YMP-QP-16.2, Revision 3, "Trending"

**Objective Evidence:**

**LANL-YMP-QP-16.4:**

CAR 235 - open	CAR 233 - closed
DR 0230 - closed	DR 0229 - open
DR 0231 - open	

CAR Extensions: Extension form for DR 0229  
Extension form for DR 0231

**LANL-YMP-QP-16.2:**

Trend Report, LA-TREND-94-01  
Trend Report, July 1 - September 30, 1993  
Trend Report, April 1 - June 30, 1993

**QA PROGRAM ELEMENT 17.0, "QUALITY ASSURANCE RECORDS"**

**Procedure:**

Compliance with the following procedures was reviewed:

OCRWM QARD, DOE/RW-0333P, Revision 0, Section 17.0  
LANL-YMP-QP-17.6, Revision 1, "Records Management"

**Objective Evidence:**

QA Record Package LA-EES-13-04-94-279, dated 4/12/94  
QA Record Package LANL-YMP-QP-06.2, R3, dated 6/29/94  
QA Record Package LANL-YMP-QP-06.1, R7, dated 6/22/94  
QA Record Package LANL-YMP-QP-06.2, R2, dated 2/3/94  
QA Record Package LANL-YMP-QP-06.3, R1, dated 2/2/94  
QA Record Package LANL-YMP-QP-06.1, R6, dated 2/2/94  
QA Record Package LANL-YMP-QP-17.6., R1, dated 6/10/94

QA Record Package LA-MTE-PN-817352, dated 7/28/94  
QA Record Package LANL-YMP-QP-03.20, R1, dated 7/29/94  
QA Record Package LANL-EES13-DP-609, R1, dated 7/20/94  
QA Record Package LANL-LS2-DP-404, R0, dated 7/28/94

Training record, R. Kovach, dated 8/10/94  
Training record, S. Bolivar, dated 8/10/94

Records source document file LANL-YMP-QP-06.1, R7, dated 6/15/94  
Records source document file LANL-CST-DP-63, R4, dated 7/8/94  
Records source document file LANL-CST-DP-66, R2, dated 6/10/94

Record transmittal to CRF 94-A36, dated 8/9/94  
Record transmittal to CRF 94-26, dated 8/12/94  
Record transmittal to CRF 94-26, dated 8/11/94

### QA PROGRAM ELEMENT 18.0, "AUDITS"

#### Procedures:

Compliance with the following procedures was reviewed:

OCRWM QARD, DOE/RW-0333P, Revision 0, Section 18.0  
LANL-YMP-QP-18.1, Revision 6, "Audits"  
LANL-YMP-QP-18.2, Revision 4, "Surveys"  
LANL-YMP-QP-18.4, Revision 0, "Auditor Qualification and Lead Auditor  
Certification"

#### Objective Evidence:

##### LANL-YMP-QP-18.1:

1994 LANL YMP Audit Schedule, Revision 0, dated 1/31/94  
1994 LANL YMP Audit Schedule, Revision 2, dated 6/15/94  
1994 LANL YMP Audit Schedule, Revision 3, dated 8/16/94  
1993 LANL YMP Audit Schedule, Revision 4, dated 9/28/93  
LANL YMP Vendor External Survey and Audit Schedule 1994, dated 1/13/94  
Audit Plan LANL-AR-93-11, dated 11/2/93  
Audit Plan LANL-AR-93-12, dated 10/21/93  
Audit Plan LA-AR-EES-1/YU-94-01, dated 5/4/94  
Audit Plan LA-AR-EES-13/TCO-94-02, dated 5/12/94  
Audit Checklists for audit LA-AR-EES-1-94-04  
Audit Report LANL-AR-93-11, dated 1/17/94  
Audit Report LANL-AR-93-12, dated 12/23/93  
Audit Report LA-AR-EES-1/YU-94-01, dated 6/15/94  
Revised Audit Report LA-AR-EES-1/YU-94-01, dated 8/18/94

Audit Report LA-AR-EES-13/TCO-94-02, dated 6/28/94  
DR LANL-0231, dated 12/23/93  
DR LANL-0232, dated 12/23/93  
CAR-233, dated 3/29/94  
CAR-234, dated 4/28/94  
Memo TWS-EES-13-01-94-003, dated 1/17/94  
Memo LA-EES-13-06-94-210, dated 6/15/94  
LANL YMP Survey Schedule Calendar Year 1994, Revision 1, dated 6/20/94

**LANL-YMP-QP-18.2:**

Supplier Annual Performance Evaluation for Mettler Instrument Corporation,  
dated 7/11/94  
Survey Report LA-SR-SIMCO-94-005, dated 1/28/94  
Supplier Annual Performance Evaluation for SIMCO, dated 8/18/94  
Survey Report LA-SR-EES-13/LV-TCO-94-02, dated 5/6/94  
Survey Report LA-SR-EES-1-94-04, dated 5/17/94  
Survey Report LA-SR-CST-94-06, dated 5/10/94  
Survey Report LA-SR-EES-13-94-11, dated 6/17/94  
Memo LA-EES-13-06-94-208, dated 6/17/94  
Memo LA-EES-13-05-94-220, dated 5/13/94  
Memo LA-EES-13-04-94-312, dated 4/29/94  
Memo LA-EES-13-05-94-219, dated 5/10/94

**LANL-YMP-QP-18.3:**

Record of Auditor Qualification/Certification for A. Burningham, dated 3/27/92  
Record of Auditor Qualification for T. Ickes, dated 8/2/94  
Record of Lead Auditor Qualification/Certification for J. Young, dated 10/26/93  
Personnel Qualification Evaluation for J. Young, dated 7/19/93  
Record of Lead Auditor Qualification/Certification for C. Martinez, dated 4/28/93  
Record of Lead Auditor Annual Evaluation for C. Martinez, dated 4/28/94  
Personnel Qualification Evaluation for C. Martinez, dated 6/28/93  
Record of Lead Auditor Qualification/Certification for J. Day, dated 5/31/90  
Personnel Qualification Evaluation Form for J. Day, dated 3/19/90  
Record of Lead Auditor Annual Evaluation for J. Day, dated 6/30/94  
Record of Lead Auditor Qualification/Certification for P. Gillespie, dated 9/13/91  
Personnel Qualification Evaluation Form for P. Gillespie, dated 5/13/91  
Record of Lead Auditor Qualification/Certification for P. Gillespie, dated 9/10/93  
Lead Auditor Examination for J. Day, dated 5/24/90  
Lead Auditor Examination for C. Martinez, dated 4/28/93  
Lead Auditor Examination for J. Young, dated 10/5/93  
Lead Auditor Examination for P. Gillespie, dated 9/13/91

## **SUPPLEMENT I, 'SOFTWARE'**

### **Procedures:**

The following procedures had not been implemented at the time of the audit. The software packages evaluated had been controlled using procedures that preceded QARD DOE/RW-0333P. The previous procedures were the same as the current ones for the most part and were used to evaluate the identified software packages.

OCRWM QARD, DOE/RW-0333P, Revision 0, Supplement I  
LANL-YMP-QP-03.20, Revision 2, "Software Configuration Management"  
LANL-YMP-QP-03.21, Revision 2, "Software Life Cycle"  
LANL-YMP-QP-03.26, Revision 1, "Reviews of Software"  
LANL-YMP-QP-03.27, Revision 1, "Documentation of Software"

### **Objective Evidence:**

Reviewed Scientific and Engineering Software documentation packages for the following software titles and versions for compliance to LANL-YMP-QP-03.20 and LANL-YMP-QP-03.21:

TRACRN Version 01-00-00  
CTCN Version 01-00-00  
LSODPK Version 01-00-00

Due to the nature of inter-relationship of requirements the following objective evidence is for all above mentioned procedures:

The following baseline documents for TRACRN:

Verification and Validation Plan  
Software Requirements Specification  
Software Design Specification  
Models and Methods Summary  
Code list  
Version Description Document  
Verification and Validation Report  
Users Manual  
File list

The following baseline documents for CTCN:

Software Requirements Specification

The following baseline documents for LSODPK:

Verification and Validation Report

The following documents were evaluated in the Configuration Control system. All numbers are unique identifiers.

**Engineering Change Notices**

ECN117  
ECN124

**Engineering Change Directives**

ECD5          ECD43          ECD44          ECD117

**Baseline Certification Notices**

BCN6          BCN74          BCN106          BCN107          BCN101

**Baseline Submission Summary**

BSS1          BSS94          BSS113          BSS105  
BSS117          BSS121          BSS123

**Software Variances**

SVA6

**Software Change Requests**

SCR5          SCR47          SCR48

**Life Cycle Specifications**

LCS5          LCS43          LCS44

**Software Review Notices**

SRN1          SRN92          SRN103  
SRN113          SRN117          SRN119

**Review/Audit Item Disposition**

RID306          RID307          RID319  
RID320          RID321          RID234  
RID235          RID346          RID347  
RID348          RID349          RID350  
RID351          RID357          RID358  
RID359          RID360          RID361  
RID362          RID363

**Review/Audit Report and Recommendations**

RRR1	RRR9	RRR184
RRR193	RRR208	RRR212
RRR221	RRR229	RRR231
RRR232	RRR236	RRR244
RRR245	RRR246	RRR249

Configuration Control Board Minutes (forms CMM 37 through 41) for CTCN.

**QA PROGRAM SUPPLEMENT II, SAMPLE CONTROL**

**Procedure:**

Compliance with the following procedures was reviewed:

OCRWM QARD, DOE/RW-0333P, Revision 0, Supplement II  
LANL-YMP-QP-08.1, Revision 4, "Identification and Control of Samples"

**Samples Reviewed:**

<u>SMF Number</u>	<u>LANL ID</u>	<u>Date</u>
00500656	ESF F	11/03/93
00501033	ESF/0+66	08/13/93
00100302	FR#1	12/03/93
00503209	FR-F	12/03/93

SCRs for the above.

**QA PROGRAM SUPPLEMENT III, SCIENTIFIC INVESTIGATION**

**Procedures**

Compliance with the following procedures was reviewed:

OCRWM QARD, DOE/RW-0333P, Revision 0, Supplement III  
LANL-YMP-QP-03.5, Revisions 2 and 3, "Documenting Scientific Investigations"  
LANL-YMP-QP-08.3, Revision 2, "Transfer of Data"

**Objective Evidence**

LANL-YMP-QP-03.5:

Scientific Notebooks in use for WBS 1.2.3.4.1.2.1:

TWS-INC-12-92-07, issued to K. S. Kung

LA-CST-03-94-09, issued to S. C. Weaver  
LA-CST10-NBK-94-004, issued to S. C. Weaver

**Scientific Notebooks in use for WBS 1.2.3.4.1.3.1:**

TWS-INC-01-93-12, issued to P. A. Palmer  
TWS-CST-02-94-03, issued to D. L. Clark  
LA-CST-03-94-013, issued to S. A. Ekberg  
TWS-INC-06-93-09, issued to S. A. Ekberg and C. D. Tait  
TWS-INC-01-93-10, issued to C. D. Tait

**Scientific Notebooks in use for WBS 1.2.3.4.1.4.1:**

TWS-INC-02-93-01, issued to S. C. Weaver  
LA-CST10-NBK-94-001, issued to A. Furlano  
LA-CST-03-94, issued to S. C. Weaver

**LANL-YMP-QP-08.3:**

**Data Packages:**

<u>Submitted</u>	<u>WBS Number</u>	<u>Data Tracking Number</u>
3-20-92	1.2.3.2.1.1.1	LA000000000025.002
1-26-93	1.2.3.4.1.2.1R3	LA000000000032.001
3-01-92	1.2.3.4.1.3.1	LA000000000012.001
2-18-94	1.2.3.4.1.2.1	LA000000000092.001

**TECHNICAL**

**Objective Evidence:**

**WBS 1.2.3.4.1.2.1 - Batch Sorption Studies**

Study Plan for Batch Sorption Studies and Development of Sorption Models, YMP-LANL-SP 8.3.1.3.4.1, R0, 8.3.1.3.4.3, R0, approved by YMSCO, 7/28/94

Sorption and Desorption Ratio Determinations by a Batch Sample Technique for the Dynamic Transport Task, LANL-CST-DP-86, R1, effective date 8/8/94

Kung, K. S., and Triay, I. R. (1994). Draft 2 of "Effect of Natural Organics on Cd and Np Sorption," intended for publication in the Proceedings of MIGRATION '93.

pH Measurement, LANL-INC-DP-35, R2, effective date 12/10/91

Laboratory Notebook LA-CST-03-94-013, assigned to Scott A. Ekberg, started on 3/28/94

**WBS 1.2.3.4.1.3.1 - Dissolved Species Contamination Limits**

Nitsche, H., Roberts, K., Prussin, T., Keeney, D., Carpenter, S. A., Becraft, K., and Gatti, R. C. (1993). Milestone Report 3344, "Characterization and Comparison of Solids from Oversaturation Experiments of Neptunium, Plutonium, and Americium in UE-25p #1 and J-13 Well Water from the Yucca Mountain Region"

Nitsche, H., Roberts, K., Xi, R. H., Prussin, T., Becraft, K., Al Mahamid Al Rifai, I., Carpenter, S. A., Gatti, R. C., and Novak, C. F. (1993). Long-Term Solubility and Speciation of Plutonium in Simulants of Brines from the Waste Isolation Pilot Plant, Abstracts, Fourth International Conference on the Chemistry and Migration Behavior of Actinides and Fission Products in the Geosphere, MIGRATION '93, Charleston, SC, USA, 12/12-17/93, p. 8

Silber, H. B., Nitsche, H., Gatti, R., Gehmecker, H., Feige, G., Bucher, J., and Edelstein, N. (1993). The Effects of Radiolysis upon Speciation and Solubility of Neptunium in Brine Solutions, Abstracts, Fourth International Conference on the Chemistry and Migration Behavior of Actinides and Fission Products in the Geosphere, MIGRATION '93, Charleston, SC, USA, 12/12-17/93, p. 15

Morris, D. E., Conradson, S. D., Tait, C. D., Chisholm-Brause, C. J., Berg, J. M., Musgrave, J. A., and Donohoe, R. J. (1993). Uranium Speciation in a Shallow Subsurface Environment: Results from a DOE Facility, Abstracts, Fourth International Conference on the Chemistry and Migration Behavior of Actinides and Fission Products in the Geosphere, MIGRATION '93, Charleston, SC, USA, 12/12-17/93, p.35

Nitsche, H., Gatti, R. C., Standifer, E. M., Lee, S. C., Müller, A., Prussin, T., Deinhammer, R. S., Maurer, H., Becraft, K., Leung, S., and Carpenter, S. A. (1993). Measured Solubilities and Speciations of Neptunium, Plutonium, and Americium in a Typical Groundwater (J-13) from the Yucca Mountain Region, Milestone Report 3010-WBS 1.2.3.4.1.3.1, LA-12562-MS

Nitsche, H., Roberts, K., Prussin, T., Müller, A., Becraft, K., Keeney, D., Carpenter, S. A., and Gatti, R. C. (1994). Measured Solubilities and Speciations from Oversaturation Experiments of Neptunium, Plutonium, and Americium in UE-25p #1 Well Water from the Yucca Mountain Region, Milestone Report 3329-WBS 1.2.3.4.1.3.1, LA-12563-MS

Yucca Mountain Site Characterization Project, Monthly Activity Report, April, 1994

Clark, D. L., and Palmer, P. D. (1993). Oxygen-17 and Carbon-13 NMR Studies of Uranyl and Neptunyl Carbonate Complexes in Near-neutral Solution, Abstracts, Fourth

International Conference on the Chemistry and Migration Behavior of Actinides and Fission Products in the Geosphere, MIGRATION '93, Charleston, SC, USA, 12/12-17/93, p. 32

Laboratory Notebook TWS-INC-01-93-10, assigned to C. Drew Tait, started 1/13/93, open

Study Plan "Dissolved Species Concentration Limits and Colloid Behavior," YMP-LANL-SP-8.3.1.3.5.1, R0, 8.3.1.3.5.2, R0, effective date 11/22/93

#### **WBS 1.2.3.4.1.4.1 - Dynamic Transport Column Experiments**

Triay, I. R., Robinson, B. A., Lopez, R. M., Mitchell, A. J., and Overly, C. M. (1993). Neptunium Retardation with Tuffs and Groundwaters from Yucca Mountain, Proceedings of the Fourth Annual International High Level Radioactive Waste Management Conference, Las Vegas, NV, 4/26-30/93, pp. 1504-1508

Kohler, M., Honeyman, B. D., van Geen, A., and Leckie, J. O. (1994). Neptunium (V) Sorption on Hematite ( $\alpha\text{-Fe}_2\text{O}_3$ ) in Aqueous Suspension: Effects of Carbonate and EDTA, Milestone No. 3424, submitted for publication to *Geochemica et Cosmochimica Acta*

Stock Solution Binder II, TWS-CST-01-94-01, assigned to Ines Triay, started 1/4/94, open

Study Plan, "Dynamic Transport Column Experiments," DRAFT, YMP-LANL-SP-8.3.1.3.6.1, R0, submitted to YMSCO 3/10/93

Laboratory Notebook TWS-INC-01-93-12, assigned to Phillip D. Palmer, started 1/11/93, closed 7/27/94

#### **Documents examined before and during the audit:**

The Preparation of Solutions of Pure Oxidation States of Neptunium, Plutonium, and Americium, LANL-INC-DP-78, R1

The preparation of Solutions of Pure Oxidation States of Neptunium, Plutonium, and Americium, LANL-INC-DP-78, R1, effective date 4/10/91

Katz, J. I., Seaborg, G. T., and Morss, L. R. (1986). The chemistry of the Actinide Elements, 2nd ed., Vol. 1, Chapman and Hall, New York., Fig. 7.31

Spectra-Physics Manual for PDL-2 Pulsed Dye Laser Performance Reports, December 1985

Xerox copy of LBL laboratory notebook TWS-LBL-01-89-02, assigned to Raymond C. Gatti, pp. 93-101, entries all dated 5/1/89

Draft of "Concentration Determination of Soluble Radionuclides from Data Provided By a Low-energy Gamma-ray Counting System," LANL-LBL-DP-01, R0, dated 6/6/94

Gatti, R. C., Nitsche, H., Carpenter, S. A., Roberts, K. E., Becraft, K. A., and Prussin, T. G. (1994). "Determining Plutonium Concentration in Solution using a Germanium Crystal and a New L X-ray Spectrographic Method," Proceedings, 5th International Conference on High Level Radioactive Waste, Las Vegas, NV, 5/22-26/94. (Xerox provided that lacked the page numbers in the Proceedings)

Copy of title page of "Analysis of Strong Acid Anions by Ion Chromatography (Dionex Model 16)," TWS-INC-DP-45, R0, Effective date 5/28/85. Superseded and removed 6/5/89

Xerox copy of LBL laboratory notebook TWS-LBL-06-86-01, pp. 85, 4/22/ 87; 86, 4/24/87; 93, 5/21/87; and 94, 5-27-87

Xerox copy of LBL laboratory notebook TWS-LBL-01-92-02, assigned to Traudel G. Prussin, p. 125, dated 8/14/92; p. 126, dated 8/18/92; p. 128, dated 8/21/92; and p. 130, dated 8/24/92

Xerox copy of LBL laboratory notebook TWS-LBL-05-88-01, assigned to Traudel G. Prussin, p. 184, dated 5/23/89; p. 186, dated 5/26/89; and p. 188, dated 5/30/89

Xerox copy of LBL ring binder 2F-4 (TWS-LBL-08-91-03). Designation indicates link to laboratory notebook 2F (TWS-LBL-02-90-04, assigned to Traudel G. Prussin. Binder page nos. 000019-000026, dated 5/12-19/90

Xerox copy of LBL laboratory notebook TWS-LBL-02-90-03 (1L), p. 51, dated 4/23/90. Entries by Heidi Maurer

Clark, D. L., Hobart, D. E., and Neu, M. P. (1994). Actinide Carbonate Complexes and Implications for Actinide Environmental Chemistry, LA-UR-94-1718, Draft dated 8/15/94, intended for publication in Chemical Reviews

Laboratory Notebook TWS-CST-02-94-03, assigned to David L. Clark, started 2/3/94

Tait, C. D., and Clark, D. L., "Contributions to YMP Geochemistry Visit: Solubility Task," 8/9/94

Hobart, D. E., Palmer, P. D., and Newton, T. W. (1986). The Carbonate Complexation of Plutonium (IV), DRAFT, intended for submission as a Nevada Nuclear Waste Storage Investigations Interim Report, LA-UR-86-968. (This appears to have been published in 1987, under the same title and revised, as LA-UR-85-3775)

Laboratory notebook TWS-INC-02-93-01, assigned to Ines Triay, started 2/3/93, nearly done, but not closed

**ATTACHMENT 4**

**Information Copies**

**of**

**Corrective Action Requests**

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<b>OFFICE OF CIVILIAN          RADIOACTIVE WASTE MANAGEMENT          U.S. DEPARTMENT OF ENERGY          WASHINGTON, D.C.</b>		8 CAR NO.: <u>YM-94-078</u> PAGE: <u>1</u> OF <u>2</u> QA
<b>CORRECTIVE ACTION REQUEST</b>		
1 Controlling Document QARD DOE/RN-0333P, Revision 0		2 Related Report No. YMP-94-08
3 Responsible Organization LANL-YMP	4 Discussed With M. Clevenger/S. Martinez	
5 Requirement: QARD Subsection 17.2.2B requires that individuals creating QA records shall ensure that QA records are legible, accurate, and complete.		
6 Adverse Condition: Contrary to the above requirement, the following deficiency was noted: <ul style="list-style-type: none"> <li>A. The record package for LANL-YMP-QP-06.1, Revision 7 contains errors in page number count, dates, identification of reviewing organization, and copies of the complete procedure.</li> <li>B. The record package for LANL-CST-DP-66, Revision 2 was missing DP Action Request Form, the even pages of the final approved procedure, and the review criteria sheet.</li> <li>C. Record package for LANL-LS2-DP-404, Revision 0 was missing the DP Action Request Form. Record package has been microfilmed.</li> <li>D. The microfilmed record package for LANL-EES13-DP-609, Revision 1 did not contain DP review sheets or DP review criteria.</li> <li>E. The record source's copy file for LANL-YMP-QP-06.1, Revision 7 was missing the Review Criteria form.</li> <li>F. The record source's copy file for LANL-CST-DP-63, Revision 4 was missing DP Review Criteria form.</li> </ul>		
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	13 Response Due Date: 20 Working Days From Issuance
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
12 Recommended Actions: 1) The in-house copy of the record package was corrected on 8/15/94 for QP-06.1. 2) Obtain copy from records center and make appropriate corrections. (Continued on next page)		
7 Initiator Walter R. Coutier <i>W.R. Coutier</i> 8/18/94	14 Issuance Approved by: QADD <i>[Signature]</i> Date <u>8-24-94</u>	
15 Response Accepted QAR _____ Date _____	16 Response Accepted QADD _____ Date _____	
17 Amended Response Accepted QAR _____ Date _____	18 Amended Response Accepted QADD _____ Date _____	
19 Corrective Actions Verified QAR _____ Date _____	20 Closure Approved by: QADD _____ Date _____	

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PAGE: 2 OF 2  
QA

**CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)**

**13 Recommended Action(s) (continued)**

- 3) Provide remedial actions to correct the specific deficiencies noted and conduct evaluation to determine extent of deficiencies in other record packages and provide corrective action to preclude recurrence.

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<b>CORRECTIVE ACTION REQUEST</b>		
1 Controlling Document LANL-INC-DP-35, REVISION 2		2 Related Report No. YMP-94-08
3 Responsible Organization LANL-YMP	4 Discussed With C. Brew/C. Tait	
5 Requirement: INC-DP-35, Revision 2, Paragraph 6.22, third sentence requires at least two buffers that have Ph values surrounding the expected Ph of the solution to be measured, be selected for calibration of the Ph meter.		
6 Adverse Condition: Contrary to the above requirement, buffers of Ph 7 and Ph 10 were always selected regardless of the expected Ph. Five examples of this condition were noted in scientific notebook TWS-INC-01-93-12, Pages 10, 13, 14, 21, and 88, where the actual Ph value was notably outside of the 7 to 10 Ph range.		
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	13 Response Due Date: 20 Working Days From Issuance
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
12 Recommended Actions: 1) Change procedure to more clearly specify buffers to be used.		
7 Initiator Paul L. Cloke <i>Paul L. Cloke 5/23/94</i>	14 Issuance Approved by <i>[Signature]</i> for <i>[Signature]</i> Date <u>8.24.94</u>	
15 Response Accepted OAR _____ Date _____	16 Response Accepted OADD _____ Date _____	
17 Amended Response Accepted OAR _____ Date _____	18 Amended Response Accepted OADD _____ Date _____	
19 Corrective Actions Verified OAR _____ Date _____	20 Closure Approved by: OADD _____ Date _____	

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<b>CORRECTIVE ACTION REQUEST</b>		
1 Controlling Document QARD DOE/RW-0333P		2 Related Report No. YMP-94-08
3 Responsible Organization LANL YMP QA	4 Discussed With M. Clevenger/P. Gillespie	
5 Requirement: 1) Section 2.0, Quality Assurance Program Documents, Subsection 2.2.2, Step B . Affected organizations shall establish QA implementing documents applicable to their scope of work that translates QARD requirements into work processes. <p style="text-align: center;">(Continued on next page)</p>		
6 Adverse Condition: Contrary to the above requirements, LANL-YMP-OP-04.6, Revision 1, Procurement procedure, in some instances only reiterates the QARD requirements with no methodology on how to satisfy the requirements and no provisions or mechanism to demonstrate the requirements were satisfied, examples are: Paragraphs 6.1.6, 6.3, 6.4 and 6.5.  NOTE: LANL-YMP-OP-04.6, Revision 1, Procurement, has not been implemented as of August 19, 1994.		
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	13 Response Due Date: 20 Working Days From Issuance
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
12 Recommended Actions:		
7 Initiator Donald J. Harris     8/17/94 <i>clifitarius</i>	14 Issuance Approved by: QADD <i>[Signature]</i> for Date <u>8-24-94</u>	
15 Response Accepted QAR _____ Date _____	16 Response Accepted QADD _____ Date _____	
17 Amended Response Accepted QAR _____ Date _____	18 Amended Response Accepted QADD _____ Date _____	
19 Corrective Actions Verified QAR _____ Date _____	20 Closure Approved by: QADD _____ Date _____	

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6 CAR NO.: YH-94-080  
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QA

**CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)**

5 Requirements (continued)

- 2) Section 5.0, Implementing Documents, Subsection 5.2.2, Content of Implementing Documents, Step C requires in part, "...a sequential description of work to be performed."
- 3) Step D requires quantitative or qualitative acceptance criteria sufficient for determining the activities were satisfactorily accomplished.
- 4) Step G requires methods for demonstrating the work was performed as required, such as for provisions for recording inspection and test results, check off lists or sign off blocks.

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<b>CORRECTIVE ACTION REQUEST</b>		
<b>1 Controlling Document</b> LANL-YMP-QP-03.5, Revision 2		<b>2 Related Report No.</b> YMP-94-08
<b>3 Responsible Organization</b> LANL-YMP	<b>4 Discussed With</b> C. Tait/M. Clark	
<b>5 Requirement:</b> Paragraph 6.6.1 of QP-03.5, Revision 2 requires that data be evaluated and a statement is entered into the notebook explaining the acceptance or rejection of the data.		
<b>6 Adverse Condition:</b> Contrary to the above requirement, data recorded in the following scientific notebooks had no evidence of any such evaluation. <ul style="list-style-type: none"> <li>• TWS-INC-01-93-12</li> <li>• TWS-CST-02-94-03</li> <li>• LA-CST-03-94-013</li> <li>• TWS-INC-06-93-09</li> <li>• TWS-INC-01-93-10</li> </ul>		
<b>9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u></b> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	<b>10 Does a stop work condition exist? Yes ___ No <u>X</u></b> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	<b>13 Response Due Date:</b> 20 Working Days from Issuance
<b>11 Required Actions:</b> <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
<b>12 Recommended Actions:</b> • Comply with existing procedures.		
<b>7 Initiator</b> Thomas J. Higgins <i>[Signature]</i> 8-23-94	<b>14 Issuance Approved by:</b> QADD <i>[Signature]</i> for Date 8-24-94	
<b>15 Response Accepted</b> QAR _____ Date _____	<b>16 Response Accepted</b> QADD _____ Date _____	
<b>17 Amended Response Accepted</b> QAR _____ Date _____	<b>18 Amended Response Accepted</b> QADD _____ Date _____	
<b>19 Corrective Actions Verified</b> QAR _____ Date _____	<b>20 Closure Approved by:</b> QADD _____ Date _____	

OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

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QA

**CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)**

**5 Requirements (continued)**

satisfied by the module. Ensure that each requirement in the Software Requirements Specification is implemented within one or more modules of the software design (as embodied in the documentation prolog of each software module).

**ORIGINAL**  
 THIS IS A RED STAR

<b>OFFICE OF CIVILIAN          RADIOACTIVE WASTE MANAGEMENT          U.S. DEPARTMENT OF ENERGY          WASHINGTON, D.C.</b>		CAR NO.: <u>YM-94-082</u> PAGE: <u>1</u> OF <u>2</u> QA
<b>CORRECTIVE ACTION REQUEST</b>		
1 Controlling Document QP-03.26, Revision 1		2 Related Report No. YMP-94-08
3 Responsible Organization LANL-YMP	4 Discussed With B. Gundlach	
5 Requirement: The third paragraph of QP-03.26, Revision 1, Section 6.1.2.1b. requires that during the design phase, traceability of software requirements into the software design be demonstrated as follows:  Specify (in the requirements traceability section of each source-code documentation-prolog) the identifying number of each software requirement		
6 Adverse Condition: Contrary to the above requirement, the source code for TRACRM, requirements traceability section, indicates "None."		
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	13 Response Due Date: 20 Working Days From Issuance
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Extent of Deficiency <input type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination		
12 Recommended Actions:		
7 Initiator <i>S.D. Harris</i> Stephen D. Harris 8/16/94	14 Issuance Approved by: <i>[Signature]</i> QADD <i>[Signature]</i> Date <u>8-24-94</u>	
15 Response Accepted QAR _____ Date _____	16 Response Accepted QADD _____ Date _____	
17 Amended Response Accepted QAR _____ Date _____	18 Amended Response Accepted QADD _____ Date _____	
19 Corrective Actions Verified QAR _____ Date _____	20 Closure Approved by: QADD _____ Date _____	