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U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

FOR LIMITED SCOPE AUDIT OF

LOS ALAMOS NATIONAL LABORATORY

LOS ALAMOS, NEW MEXICO

AUDIT NO. YMP-92-12

MARCH 17 THROUGH 20, 1992

PRIMARY ELEMENTS EVALUATED:

3.0	Scientific Investigation Control and Software
5.0	Instructions, Procedures, Plans, and Drawings
6.0	Document Control
17.0	Records

ADDITIONAL ELEMENTS EVALUATED:

2.0	Quality Assurance Program
8.0	Identification and Control of Samples and Data
13.0	Handling, Shipping, and Storage
18.0	Audits

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EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit YMP-92-12, it was determined that Los Alamos National Laboratory (Los Alamos) is satisfactorily implementing an effective QA program in accordance with the Los Alamos Quality Assurance Program Plan, Revision 5, and implementing procedures for primary audit elements 3.0, "Scientific Investigation Control and Software Control," 5.0, "Instructions, Procedures, Plans, and Drawings," 6.0, "Document Control," and 17.0, "Records." The audit scope was expanded to include elements 2.0, "Quality Assurance Program," 8.0, "Identification and Control of Samples and Data," 13.0, "Handling, Shipping and Storage," and 18.0, "Audits." All activities evaluated for the additional elements were also satisfactory, except for Element 13.0, Los Alamos Quality Procedure (QP), TWS-QAS-QP-13.1, Revision 2, "Handling, Storage, and Shipping Equipment," for which there was no implementation.

Results of the technical activities evaluated during the audit are as follows:

1. WBS 1.2.3.4.1.2.1 and 1.2.3.4.1.2.3 (Batch Sorption Studies and Sorption Models) - Based on objective evidence examined during the audit, this technical activity is satisfactory (implementation was found to be in compliance with approved procedures).

2. WBS 1.2.3.4.1.2.2 (Biological Sorption and Transport) - Insufficient implementation has occurred in this area in order to determine compliance.

3. WBS 1.2.3.4.1.3 (Radionuclide Retardation by Precipitation Processes) - Insufficient implementation has occurred in this area in order to determine compliance.

4. WBS 1.2.3.4.1.4 (Radionuclide Retardation Dispersive, Diffusive and Advective Processes) - Based on objective evidence reviewed during the audit, this technical activity was satisfactory.

5. WBS 1.2.3.4.1.5.1 (Retardation Sensitivity Analysis) - Based on objective evidence reviewed during the audit, this technical activity was satisfactory.

The audit team identified five deficiencies during the course of the audit. Three deficiencies were resolved prior to the post-audit conference; one was considered to be an additional example of a deficiency already identified in open Corrective Action Request (CAR) YM-91-041 (issued in April 1991), and CAR YM-92-027 was issued against the Yucca Mountain Site Characterization Project Office (YMPO). CAR YM-92-027 documents a condition where the Los Alamos Study Plan for Biological Sorption and Transport does not reference the specific technical procedures used in the task, although, procedures with specific procedure numbers and titles have been approved. Also, several other study plans reviewed during the audit, contain references to procedures which have been superseded. This CAR was addressed to the YMPO to assure that if a similar condition exists with other participant organization study plans, review of the study plans will be performed to assess which, if any, may require revision to

update listing of technical procedures. For details of corrective action taken during the audit and details of the additional example to CAR YM-91-041, see Section 6.0 of the audit report.

An area within the Los Alamos QA Program that was a strength worthy of note was the excellent performance of the Software QA Program.

It was apparent to the audit team that a great deal of time and effort has been expended by the Los Alamos Yucca Mountain Site Characterization staff to achieve an effective QA program. The Los Alamos staff should be commended for the cooperation and effort necessary to bring their QA program to this level. The audit team also appreciated the cooperativeness and professional attitude of the Los Alamos staff during the conduct of this audit.

1.0 INTRODUCTION

This report contains the results of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Audit No. YMP-92-12 performed at Los Alamos National Laboratory (Los Alamos) by a team of auditors from the Yucca Mountain Quality Assurance Division (YMQAD) of the Office of Quality Assurance (OQA). The audit was conducted March 17 through 20, 1992, at the Los Alamos offices in Los Alamos, New Mexico, in accordance with the approved audit plan.

2.0 AUDIT SCOPE

This limited scope audit was conducted to evaluate portions of the Los Alamos QA Program, in accordance with the published audit schedule. The purpose of the audit was to determine whether the requirements and commitments imposed by OCRWM, as reflected in the Los Alamos Quality Assurance Program Plan (QAPP), Revision 5, and implementing procedures, were being met. This was done by verifying implementation and effectiveness of the system in place, as well as verifying compliance with requirements.

In addition, the audit team followed up on open Corrective Action Request (CAR) YM-92-03, and reviewed a representative sample of closed CARs identified during previous audits of Los Alamos to determine the effectiveness of Los Alamos corrective actions.

The applicable programmatic elements evaluated during the audit, in accordance with the published audit schedule, are identified below along with the auditor responsible for the evaluation:

Program Elements		Auditors
3.0	Scientific Investigation Control (including software control)	G. Heaney/N. Cox
5.0	Instructions, Procedures, Plans, and Drawings	S. Bates
6.0	Document Control	S. Bates
17.0	Records	J. Martin

Programmatic Element 3.0, "Design Control," was considered during development of the audit scope and determined to be not applicable since Los Alamos has no current activities for which this element applies.

Additional programmatic elements selected during conduct of the audit for evaluation are identified below:

Program Elements		Auditors
2.0	Quality Assurance Program	J. Martin
8.0	Identification and Control of Samples and Data	G. Heaney
13.0	Handling, Shipping, and Storage	S. Dana
18.0	Audits	G. Heaney

The audit scope included a review and evaluation of the following technical activities:

WBS Number	Title	Technical Specialist
1.2.3.4.1.2.1 & 1.2.3.4.1.2.3	Batch Sorption Studies and Sorption Models	P. Cloke
1.2.3.4.1.2.2	Biological Sorption and Transport	A. Simmons
1.2.3.4.1.3	Radionuclide Retardation by Precipitation Processes	A. Simmons
1.2.3.4.1.4	Radionuclide Retardation Dispersive, Diffusive and Advective Processes	A. Simmons
1.2.3.4.1.5.1	Retardation Sensitivity Analysis	P. Cloke

3.0 AUDIT TEAM AND OBSERVERS

Audit Team

Stephen R. Dana, Audit Team Leader
Sandra D. Bates, Auditor
Paul L. Cloke, Technical Specialist
Neil D. Cox, Auditor
Gerard Heaney, Auditor
John S. Martin, Auditor
Ardyth M. Simmons, Technical Specialist

Observers

Bill Belke, U.S. Nuclear Regulatory Commission (NRC)
Pauline Brooks, NRC
Neil Coleman, NRC
Bruce Mabrito, Southwest Research Institute (representing NRC)
Susan Zimmerman, State of Nevada

4.0 PERSONNEL CONTACTED

Los Alamos personnel contacted during the audit are listed in Enclosure 1.

5.0 AUDIT RESULTS

5.1 Program Effectiveness

Overall, Los Alamos is satisfactorily implementing an effective QA Program in accordance with the Los Alamos QAPP, Revision 5, and implementing procedures for primary audit elements 3.0, 5.0, 6.0, and 17.0. The audit scope was expanded to include QA Program Elements 2.0, 8.0, 13.0, and 18.0. All activities evaluated for the additional elements were also satisfactory, except for QA Program Element 13.0, Los Alamos Quality Procedure (QP) TWS-QAS-QP-13.1, Revision 2, for which there was no implementation. A statement for each primary QA Program Element is provided below:

1. 3.0, Scientific Investigation and Software Control

   Based on objective evidence examined during the audit, this audit element is satisfactory (i.e., implementation was found to be in compliance with approved procedures and/or instructions).

   The implementation of QP-03.5, Revision 0, in conjunction with the scientific studies, was satisfactory. For scientific notebooks evaluated during the audit, the Principal Investigators (PIs) were documenting the notebooks exceptionally well. There was no implementation for QP-03.7, Revision 0, Peer Reviews, so compliance could not be determined.

   The implementation of the Software Quality Assurance Plan (SQAP) and its applicable QPs was satisfactory. The Software QA program is performing exceptionally well.

2. 5.0, Instruction, Procedures, Plans, and Drawings, and 6.0, Document Control

   Based on objective evidence reviewed during the audit, these audit elements were satisfactory. One deficiency was identified and corrected during the audit and is discussed in detail in Section 6.2.

3. 17.0, Records

Based on objective evidence reviewed during the audit, this audit element was satisfactory. One deficiency was identified but was considered an additional example of a deficiency already identified in open CAR YM-91-041 (See Section 6.1 for details). Two deficiencies were identified and corrected during the audit and are discussed in detail in Section 6.2.

5.2 Programmatic and Technical Activities

Details of programmatic and technical activities can be found in Enclosures 2 and 3.

5.3 Summary of Deficiencies

No CARs were issued to Los Alamos as a result of this audit. However, CAR YM-92-027 was issued to the Yucca Mountain Site Characterization Project Office (YMPO) as a result of the audit (see Enclosure 2 for details). Additionally, a condition related to CAR-91-041 was identified and is explained in Section 6.1. Also, three deficiencies corrected during the audit are explained in Section 6.2.

6.0 SYNOPSIS OF DEFICIENCIES

6.1 Corrective Action Requests

Although no CARS were issued to Los Alamos as a result of this audit, an additional example of a deficiency associated with CAR YM-91-041 was identified. The additional example is: Los Alamos Quality Assurance Program Plan, Revision 5, Section 17, Paragraph 17.5, states in part, "LANL shall maintain a list that contains the signature and initials of persons authorized to authenticate records." Contrary to the requirement, Los Alamos does not have an authenticators list or a procedural prerequisite for a list.

Los Alamos is requested to take appropriate action to resolve the additional deficiency and be prepared to discuss the action(s) taken during YMQAD follow-up verification.

6.2 Deficiencies Corrected During the Audit

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

1. LANL-YMP-QP-06.1, Revision 3, Section 6.5, states in part, "...Withdrawn controlled documents are stamped "Obsolete;" superseded controlled documents are stamped "Superseded." After stamping the document, the QA Support Resident File Custodian sends copies to the Records Processing Center according to TWS-QAS-QP-17.3." A QP Action Request (AR) was initiated on February 18, 1991, requesting that this requirement be deleted; however, in the interim, obsolete and superseded documents were not being submitted as required, but were being submitted at a later date along with the record package. A revision to LANL-YMP-QP-06.1, Revision 3, was issued prior to the close of the audit to delete the requirement of Section 6.5 of the procedure in question. A follow-up action was requested to determine if other deficiencies exist as a result of issuing ARs (which require procedure revision) in lieu of interim change notices. A request was made for a status report on all outstanding ARs. A draft survey report was made available prior to the close of the audit. Subsequent to the audit, Survey Report No. LANL-SR-92-001, was initiated and remitted on March 25, 1992. The report states that Los Alamos personnel conducted a survey to determine whether or not other procedural requirements were being met pending completion of ARs. It was determined that all other procedural requirements are being met during the interim between request and issuance of ARs. A total of 21 ARs are in the pending file (3 dating from 1990, 16 dating from 1991, and 2 initiated in 1992).

2. LANL-YMP-QP-17.3, Revision 1, paragraphs 6.2 and 6.2.1, require that a log be maintained to indicate the status of records which have been assigned a Terminal Waste Storage (TWS) number. During review of the TWS Log for the LANL INC 7/11 group, it was noted that the status of three records was not being maintained as required. This deficiency was corrected during the course of the audit.

3. LANL-YMP-QP-17.3, Revision 1, Attachment 3, "Records Rejection Form," requires the resident file custodian to complete the form upon return of a corrected record. In review of Record Rejection Forms, nine records were found which had not been completed as required. This deficiency was corrected during the course of the audit.

7.0 RECOMMENDATIONS

During the audit several areas were identified within the Los Alamos QA Program where there are opportunities for improvement. The following recommendations are offered for Los Alamos management consideration:

1. Although a satisfactory accounting was made for all pending ARs, a problem could surface during future audits concerning the expediency of correcting deficiencies through corrective action that requires a revision instead of an interim change notice. Timeliness of needed procedure changes could also result in a deficiency. This system should be monitored through the use of an action tracking system, with time limits established to assure that needed actions are incorporated into procedures in a timely manner and that needed changes are not allowed to go unheeded.

2. It would be desirable, whenever the TRACRN software is run, for the output to record automatically what version of the software was used.

3. It would be desirable, whenever the TRACRN software is run, for the output to record automatically what input data were used, including any versions of data bases that may be read as part of the input.

4. To a considerable degree, it seems feasible to use the code output to accomplish the documentation needed for QA. This could be done by always including at or near the beginning of the output, sufficient statements as to the purpose of the current run, what was changed from the previous run(s) and why, references to preceding run(s), perhaps a summary of the preceding run(s), etc. In other words, all the information needed to track the progress of the investigation. Compared to what appears to be in the code presently, this would require adding an input field for these comments and statements to echo them on output.

8.0 ENCLOSURES

Enclosure 1: Personnel Contacted During The Audit
Enclosure 2: Audit Details
Enclosure 3: Objective Evidence Reviewed During The Audit

ENCLOSURE 1

PERSONNEL CONTACTED DURING THE AUDIT

Name	Organization	Title	Pre-Audit	Contacted During Audit	Post-Audit
Sandra D. Bates	SAIC/YMQAD	QA Auditor	X	X	X
William Belke	NRC	Audit Observer	X	X	X
Kay H. Birdsell	LANL	Principal Investigator	X		X
Stephen L. Bolivar	LANL	QA Project Leader	X	X	X
Pauline Brooks	NRC	Audit Observer	X	X	X
Julie A. Canepa	LANL	Technical Project Officer	X		X
Prestinia L. Chavez	LANL/LATA	Training Coordinator	X	X	X
Michael J. Clevenger	LANL	QA Leader	X	X	X
David L. Clark	LANL	Assc. Investigator		X	
Paul L. Cloke	SAIC	Technical Specialist	X	X	X
Neil Coleman	NRC	Audit Observer	X	X	X
Neil D. Cox	SAIC/YMQAD	QA Auditor	X	X	X
Stephen R. Dana	SAIC/YMQAD	Audit Team Leader	X	X	X
John L. Day	LANL/LATA	QA Verification Coordinator	X	X	X
Steve Donahue	LANL	Software Configuration Mgr.		X	
Mary Drake	LANL	RFC		X	
Gabriela M. Gainer	LANL/LATA	QA Engineer	X	X	
Paul F. Gillespie	LANL/LATA	QA Engineer	X	X	
Gerard Heaney	SAIC/YMQAD	QA Auditor	X	X	X
Larry Hersman	LANL	Principal Investigator	X	X	X
Carol LaDelfe	LANL	QA Leader	X	X	
Robert M. Lopez	LANL	Research Technician	X		X
Bruce Mabrito	NRC/SWRI	Audit Observer	X	X	X
John S. Martin	SAIC/YMQAD	QA Auditor	X	X	X
Sandra J. Martinez	LANL/LATA	Records Assistant	X	X	X
Lynn P. McDonald	LANL	QA Leader	X		
Alan J. Mitchell	LANL	Research Technician	X	X	X
Terry L. Morgan	LANL	QA Leader	X	X	X
David E. Morris	LANL	P.I. Solubility Task	X	X	X
Martin A. Ott	LANL	Research Technician	X	X	
Connie Overly	LANL	Research Technician		X	
Phillip D. Palmer	LANL	Chemical Technician		X	
Pamela Z. Rogers	LANL	PI/Sorpion	X	X	X
Betty M. Romero	LANL/LATA	Document Control Ctr.	X	X	X
Lynn A. Sanders	LANL/LATA	Records Coordinator	X	X	X
Richard S. Shay	LANL/LATA	Sr. Quality Engineer	X	X	X
Ardyth Simmons	DOE/YMP	Geologist, Tech. Specialist	X	X	X
Everett P. Springer	LANL	Principal Investigator	X	X	X
C. Drew Tait	LANL	Assc. Investigator		X	
Ines R. Triay	LANL	Technical Coordinator	X	X	X
Karen A. West	LANL	Admin.Ctrl.Proj.Ldr.	X	X	
Donna L. Williams	LANL/LATA	QA Leader	X	X	X
Susan Zimmerman	State/NV	Observer	X	X	X

ENCLOSURE 2

AUDIT DETAILS

The following is a summary of activities evaluated during the audit. A list of objective evidence reviewed for these activities is identified in Enclosure 3.

QUALITY ASSURANCE PROGRAM ELEMENTS

1. 2.0, Quality Assurance Program

During the course of the audit it was necessary to expand upon the basic audit elements listed within the audit plan. This was accomplished in order to ensure that personnel responsible for the submittal of records were trained to the requirements for records submittal as delineated within Quality Procedure (QP) 17.3. Training records for seven Los Alamos employees were carefully reviewed and evidence that appropriate training to QP 17.3, as procedurally required, was found to be acceptable.

One Principal Investigator's (PI) training file was examined to verify education and experience as related to the position description. This file was also found to be acceptable.

2. 3.0, Scientific Investigation Control and Software Control

1. Activities Audited by G. Heaney

Procedural compliance was reviewed for QPs 03.2, 03.3, 03.5, and 03.7. Five Technical Information Products (TIPs) were reviewed for compliance to QP-03.2 requirements. Most of the TIPs were in process; therefore, final review packages were not available for each document. In-process processing of the review packages was in compliance with requirements. Certifications for each technical reviewer were verified to be on file in accordance with procedural requirements.

The preparation of Site Characterization Plan (SCP) study plans (SPs) in accordance with QP-03.3 was not in compliance with procedural requirements. Los Alamos has an open Deficiency Report (DR) No. LANL-0172 documenting the deficiency. The tables within the five SPs reviewed during the audit containing the QA and Technical procedures were not up-to-date. Some technical procedures were not listed and several deleted QPs are listed. Since the SPs are now Yucca Mountain Site Characterization Project Office (YMPO) documents, Corrective Action Request (CAR) YM-92-027 has been issued to YMPO for appropriate corrective action.

No peer reviews have been initiated; therefore, compliance to QP-03.7 procedure requirements was not verified.

The audit was expanded to include sample control and traceability for the technical activities audited. Samples were selected and the traceability throughout the laboratory notebooks was excellent. Samples were identified and controlled to avoid commingling. Los Alamos Technical Associates (LATA) survey reports were reviewed to ensure a Biological Sorption task notebook was corrected to ensure sample traceability. This item was a follow-up to YMPO Surveillance No. SR-87-022.

2. Activities Audited by N. Cox

All activities were being conducted under approved Scientific Investigation Plans (SIPs) while new SPs were being prepared.

The programmatic audit details for Sorption and Retardation Sensitivity Analysis may be combined. Both activities were subject to QA Grading Reports and both activities were involved in preparation of SPs to replace the SIPs. Four scientific notebooks were examined and two of these had been closed and sent to the local records center. The closed notebooks were the subject of three interim, independent reviews and a final independent technical review. All notebook entries were signed and dated at the time of entry, and all notebooks were legible and understandable. Consequently, compliance with procedure QP-03.5, Revision 0 was satisfactory. Milestone Report 746, for which software was used, stated that the software was not validated as required by the Software Quality Assurance Plan (SQAP).

The Software Configuration Management System was operating in compliance with all requirements. At the end of February 1992, a total of 193 software items had been sanctioned for use by the Configuration Control Board (CCB). All software items were subject to CCB control, and all documentation was readily retrieved. The performance of this system is exemplary.

3. <u>5.0, Instructions, Procedures, Plans, & Drawings and 6.0, Document Control</u>

Documents were found to be in compliance with procedural requirements based on the following:

1. Upper tier requirements of the Los Alamos Quality Assurance Program Plan (QAPP), i.e., qualitative and quantitative criteria, checkpoints, means for identifying approved or rejected products or services, and other requirements audited are being incorporated into lower tier requirements documents, as applicable.

2. Document Control methods were traced from initiation through submittal to document holders and to the Record Processing Center and were in compliance with procedural requirements.

3. Los Alamos QPs and Detailed Procedures (DPs) are being prepared, reviewed, and approved in accordance with procedural requirements.

4. Record submittals for QPs and DPs are traceable, timely, and in compliance with procedural requirements with one exception. The deficiency was corrected during the audit.

4. 13.0, Handling, Shipping, and Storage

This element was evaluated as a follow-up to audit YMP-92-01, which determined that element 13.0 was indeterminate due to a lack of activity. The results of the evaluation are as follows. Implementation of procedure TWS-QAS-QP-13.1, Revision 2, was discussed with Steve Bolivar (Los Alamos) and John Day (LATA). Both stated that Los Alamos is not implementing this procedure and it may be deleted in the near future. The requirements for handling, storage, and shipping contained in the Los Alamos QAPP are being implemented in accordance with the DPs.

5. 17.0, Records

A total of eight records packages, which included two completed scientific notebooks, were thoroughly reviewed during the evaluation of quality assurance records to determine compliance of records sources to QP-17.3. This evaluation included entering required information, completeness, legibility, authentication, and transmittal. In addition, an evaluation of the records center activities was performed to determine compliance to QP-17.3. This evaluation consisted of a check of record retrievability, access control, records storage, verification/acceptance activities, and records processing. With the exception of one deficiency, added to existing CAR YM-91-041, and two minor deficiencies corrected during the audit, Los Alamos was found to be in compliance with QP-17.3

TECHNICAL ACTIVITIES

1. Technical Activities Evaluated by P. Cloke

1. WBS 1.2.3.4.1.2.1 and 1.2.3.4.1.2.3

All items that were investigated during the audit were found to be satisfactory, and work is in compliance with technical procedures. There was some initial confusion about the applicable grading report, but this was satisfactorily explained,

and the actual work was being performed in accordance with a proper report.

Although this portion of the audit did not specifically deal with software, some inquiry was made, and the results were found to be satisfactory. Some audit items dealt with the status of needed controlling documents. It was found that the most critically needed of these are actively under development. Priorities also appear to be correctly set in respect to technical work. Examinations of laboratory notebooks showed that entries are in compliance with requirements, and, moreover, are readily understood. Detailed technical items, such as how certain phenomena are being, or will be, investigated, all received well-informed and excellent attention.

2. WBS 1.2.3.4.1.5.1

All items that were investigated during the audit were found to be satisfactory and work is in compliance with technical procedures. Much of the audit dealt with confirming that the various requirements of the Los Alamos SQAP were being followed; this was confirmed. This examination probed the code TRACRN most carefully, as it is software being developed by Los Alamos. Several of the documents which control this development, as required by the SQAP, were examined. In addition, portions of the source code, which these control documents specified to be changed, were examined; and changes were found to be in compliance with the specifications. Priorities for future work appear to be properly set.

2. Technical Activities Evaluated by A. Simmons

1. WBS 1.2.3.4.1.2.2 and SP 8.3.1.3.4.2

SP 8.3.1.3.4.2 was revised in accordance with reviewers' comments and with Administrative Procedure AP-1.10Q. The SP has not been modified to indicate that ESF access will be via ramps as opposed to shafts. The PI will make this modification. Access by ramps rather than shafts will not compromise sampling methods. Samples will have to be collected aseptically under any circumstances and will be collected under the same procedures. Samples will be crushed to subsample sizes, divided into portions for various subcontract laboratories, and sealed in sterile, air-tight containers for shipping. Handling will be minimized. Subsamples will be further divided at the subcontract lab using a glovebox to prevent contamination. It will be necessary for laboratories to analyze samples within 72 hours of receipt or their methods will be suspect. The source of samples to date has been from surfaces near G-4 and UZ25e-1. The samples contain normal soil organisms and have been used primarily for development of procedures with some to support the Pu sorption work. The samples have not been qualified.

The standard microbiological techniques will not be brought into compliance with QA until samples have been obtained from the Exploratory Studies Facility (ESF). The process will work in the following way. Yucca Mountain Site Characterization Project (YMP) will provide samples to various laboratories for analysis. The subcontracted labs will use various methods, some of which will be complementary. The labs will work to the requirements of Los Alamos QA Program and submit detailed procedures. Los Alamos will check the results of the various methods against one another and those methods/procedures which provide the best reproducability will become Los Alamos DPs.

The only DP currently being worked to is the procedure for chelation, TWS-LS2-DP-401. TWS-LS2-DP-403, Purification of Siderophore, is presently being developed and is described in laboratory notebook TWS-LS2-05-90-04. Essentially, the notebook provides a record of development of DPs. Once a DP is written, it serves as a record of the optimal method of performing the work.

No separate grading report is in effect for chelation work or sorption work described in SP 8.3.1.3.4.2. The grading report that will be used is No. 11, which covers the whole geochemistry program. All work in this study will become quality-affecting after a DP is written for the work and the experiment is repeated using samples obtained from the ESF. Procedure TWS-LS2-DP-402 was used to study sorption of actinide elements by microorganisms for SP 8.3.1.3.5.1 and has been scoping work to date. The procedure to assess sorption of actinides by microorganisms has been developed to the point of understanding sorption of 239Pu4+ by a siderophore (TWS-LS2-DP-402). It is not understood how chelated organisms, (i.e., organisms that have taken up metals), will sorb actinides. Experiments are currently being conducted using crushed tuff columns that approximate vadose zone conditions to assess this. A procedure to describe sorption by chelated organisms is being developed. Early work has shown that the presence of microorganisms strongly influences the agglomeration rates of colloids. However, the procedure to assess this has not yet been fully developed.

Milestones 3176, 3177, 3080, and 3092 have been delayed because the nature of purification of the siderophore compound is time-consuming and requires resolution of numerous spectroscopic peaks into one before the PI can state unequivocally that the siderophore is pure. The milestone, "Production and Purification of Siderophore," will be a quality-affecting activity as will milestone 3176, "Determination of Formation Constants." Once they are completed, the procedures will be in place and will be repeated using ESF samples.

In summary, insufficient implementation has occurred in this area in order to determine compliance. The status of the study is such that experimental procedures are being developed to test the extent of sorption by microrganisms. Once the procedures are determined to be effective in producing the desired

results, they will be verified and termed quality-affecting. In addition, four milestone reports due at the close of FY 92 will be quality-affecting. All of the work planned for the ESF will be quality-affecting.

2. WBS 1.2.3.4.1.3 and SP 8.3.1.3.5.1/2

The speciation studies will focus on fastest pathways (as opposed to all pathways) in the following manner. Rather than focusing on differences in physical pathways, the study will use preferential chemical conditions as a starting point. The groundwater chemistry task will determine the chemistry of the most active water at the site. Speciation of radionuclides in this water under varying conditions of pH, Eh, and temperature will be examined.

Radionuclide speciation will be determined under a range of representative conditions and with experimental results on radionuclide solubility and limit-determining solids, radionuclide solubility will be calculated under a specific set of conditions. Experimental and calculational results will be compared. Additional experiments will be performed if necessary. If there is good agreement between experimental and calculational results, the database will be exercised over all anticipated conditions to see if regulatory release limits are met. This information will be provided to radionuclide sorption and transport studies.

The rationale for characterization of colloid studies is as follows. The size of colloids is such that they are too small to be analyzed by light-scattering techniques but too large to be analyzed by membrane osmometry. Nevertheless the limitations of these known techniques will be assessed first. Of the two, light scattering techniques, perhaps combined with small-angle X-ray scattering, appears to be the most promising.

Little progress has been made in determining the best method of assessing the bulk charge of colloids. The PI reasoned that weight and size of colloids should be determined first, followed by density, and then the size to charge ratio, before determining bulk charge. All (except perhaps density) are interrelated. Electrophoretic techniques will again be preferred in characterizing bulk charge. In the area of chemical reactivity, little progress has been made recently. The study has determined that colloids will react with sulfuric acid and some work has correlated reactivity with colloid size. Although physical characterization and chemical reactivity may be to some extent unrelated, advances in PAS work to characterize colloids should produce results that will speed up reactivity studies. In addition, Los Alamos has learned that use of pure stock solutions which it has prepared with 242Pu will produce better experimental results than using reactor-grade plutonium which oxidizes rapidly due to radiolysis effects.

All ongoing work by Los Alamos using Nuclear Magnetic Resonance (NMR) and PAS methods is considered scoping. Work done by Lawrence Berkeley Laboratory (LBL) for this study is quality-affecting, but this was not audited by YMP. It was audited internally by Los Alamos. Examination of the LBL audit report was performed and there were no deficiencies. The NMR methods are too new to have tested procedures; these are being developed at the present time. The PAS work will become quality-affecting as soon as software QA has been approved. This should occur by the end of FY92 since the process is well underway.

All data generated by the study, "Radionuclide Retardation by Precipitation Processes," will be provided to the thermodynamic database GEMBOCHS. This includes raw data, pH, temperature, solubilities, IR spectra, and PAS spectra. No data has been submitted yet.

In summary, insufficient implementation has occurred in this area in order to determine compliance. Currently, none of the work conducted in this study is quality-affecting because of delay in software QA. However, it is anticipated that most of the software in use will be approved by the end of FY 92, with the exception of that used for NMR. Almost all data collected by this study will be quality-affecting; the only exception would be if new techniques become potentially useful toward the end of the pre-licensing period. In this case, data would be collected in an R&D mode. Note that some of this work is done at LBL and is internally audited.

3. WBS 1.2.3.4.1.4 and SPs 8.3.1.3.6.1 and 8.3.1.3.6.2

WBS 1.2.3.4.1.4 had very thorough and commendable documentation in notebooks, including sample logbook, binder explaining pedigree of samples, and laboratory notebooks. The investigators appeared to be implementing their work very effectively from both a technical standpoint and from the standpoint of implementation of the QA program.

The grading report with the title "Dynamic Transport Column Experiments" (#35) is not actually being used by this study but was written for work done in the international program. SP 8.3.1.3.6.1 will use Grading Report No. 11, which applies to all of WBS 1.2.3.4.

Rock coring methods used to prepare a tuff beaker are done with a diamond drill bit and are cooled by a stream of de-ionized water, which also washes loose material and contaminants away from the tuff. The literature has demonstrated that actinides will sorb to geologic materials in preference to non-geologic materials when both are present. Preparation is done under LANL-INC-DP-67. For the diffusion tests, scaling factors will first be assessed in the laboratory, going from crushed tuff to solid tuff columns, and then will be addressed by

diffusion studies in the ESF (these are described under WBS 1.2.3.3.1.2.5). Scaling factors will be explained in more detail in Revision 1 of SP 8.3.1.3.6.2, which will be sent to YMPO very soon. The same progression from crushed tuff to column experiments will be used for scaling in the dynamic transport experiments, but field-scale validation will be done in the C-well complex and in the ESF under the field validation experiments (SP 8.3.1.3.7.2).

The absence in SP 8.3.1.3.6.1 of accuracy and precision levels considered normal for analytical chemical experiments was noted by study plan reviewers also. The PI had to do an error analysis for each measurement (counting, weighing, etc.). The derived precision and accuracy will be provided in tables in Revision 1 of SP 8.3.1.3.6.1. It will be done in each section of the SP for each parameter.

Instabilities of Np and Pu in solution have now been corrected. Np solutions are now stable after 25 days. The problem was corrected by using a neutral pH solution which prevents precipitation of a Np-carbonate complex. Solution of the problem is documented in notebook TWS-INC11-06-91-04. The Pu problem is being solved by filtering the solution.

Heterogeneities in porosity are addressed through the integrated testing work done by Lawrence Livermore National Laboratory. This information will be provided to I. Triay. Triay has also addressed the problem in the (draft) publication "Radionuclide Migration Laboratory Studies for Validation of Batch Sorption Data."

Based on objective evidence reviewed during the audit, this technical activity was satisfactory.

ENCLOSURE 3

OBJECTIVE EVIDENCE REVIEWED DURING THE AUDIT

PROCEDURES

LANL-EES-DP-105, R2	Thermal Calibration Procedure
LANL-EES-DP-107, R2	Thermogravimetric and Differential Scanning Calorimetry Analyses
LANL-EES-DP-110, R2	Zeolite Purification/Separation Procedure
LANL-EES-DP-124, R1	Use of Binocular Microscope in Fracture Mineralogy Studies
LANL-EES-DP-326, R0	Ion-Chromatographic Determination of Constituent Concentrations in Solution
LANL-INC-DP-35, R2	pH Measurement
LANL-INC-DP-78, R1	The Preparation of Solutions of Pure Oxidation States of Neptunium, Plutonium, and Americium
LANL-INC-DP-83, R1	Storage and Handling of Solid Samples
LANL-INC-DP-87, R1	Identification, Storage, and Handling of Samples at Hydro Geo Chem
LANL-INC-DP-88, R0	Collection of Soil Samples for Analysis of Moisture Content, Bulk Density, Halides and Chlorine Isotopes
LANL-INC-DP-89, R0	Procedure for Sieving Soil and Rock Samples
LANL-INC-DP-90, R0	Measurement of Moisture Content of Soil Samples
LANL-INC-DP-92, R0	Sample Leaching to Extract Soluble Chloride and Bromide
LANL-INC-DP-95, R0	Preparation of Samples for Chlorine-36 Analysis
LANL-INC-DP-97, R0	Preparation of Carrier Solution for Chlorine-36 Samples
LANL-YMP-QP-01.2, R1	Stop Work Control
LANL-YMP-QP-01.3, R1	Conflict Resolution
LANL-YMP-QP-02.5, R1	Selection of Personnel
LANL-YMP-QP-03.23, R0	Preparation and Review of Technical Information Products and Study Plans
LANL-YMP-QP-04.4, R1	Procurement of Commercial-Grade Items and Services
LANL-YMP-QP-04.5, R2	Procurement of Noncommercial-Grade Items and Services
LANL-YMP-QP-06.1, R3	Document Control
LANL-YMP-QP-06.2, R1	Preparation, Review, and Approval of Quality Administrative Procedures
LANL-YMP-QP-06.3, R0	Preparation, Review, and Approval of Detailed Technical Procedures
LANL-YMP-QP-06.3, R1	Preparation, Review, and Approval of Detailed Technical Procedures
LANL-YMP-QP-08.1, R2	Identification and Control of Samples
LANL-YMP-QP-16.2, R1	Trending
LANL-YMP-QP-16.3, R0	Deficiency Reports

LANL-YMP-QP-17.3, R1	Records Management (Superseded by LANL-YMP-QP-17.4)
LANL-YMP-QP-17.4, R0	Records Preparation
LANL-YMP-QP-17.5, R0	Records Processing
TWS-EES-13-DP-601, R0	Balance Calibration by a Service Organization
TWS-EES-13-DP-607, R0	Procedure for Volcanism Sample Storage and Control
TWS-INC-DP-05, R2	Sorption, Desorption Ratio Determination of Geologic Materials by a Batch Method
TWS-INC-DP-62, R2	Bulk NTS Well Water Samples
TWS-INC-DP-84, R0	Cuttings Collection Procedure
TWS-HSE12-DP-303, R0	Zero Point of Charge (Potentiometric Method)
TWS-HSE12-DP-306, R0	Kinetic Batch Sorption
TWS-HSE12-DP-310, R1	Calibration and Use of the Phototachometer
TWS-HSE12-DP-316, R1	Preparation of Standard and Reagent Solutions
TWS-HSE12-DP-320, R0	Measurement of Dissolved Oxygen
TWS-QAS-QP-02.4, R0	Procedure for Management Assessment
TWS-QAS-QP-03.2, R0	Procedure for Preparation and Technical and Policy Review of Technical Information Products (Superseded by LANL-YMP-QP-03.23)
TWS-QAS-QP-03,3, R0	Procedure for Preparation and Review of an SCP Study Plan (Superseded by LANL-YMP-QP-03.23)
TWS-QAS-QP-03.5, R0	Procedure for Documenting Scientific Investigations
TWS-QAS-QP-03.7, R0	Procedure for Peer Review
TWS-QAS-QP-08.2, R0	Procedure for Control of Data
TWS-QAS-QP-02.8, R0	Indoctrination and Training Development and Review
TWS-QAS-QP-04.1, R2	Procedure for Procurement (Superseded by LANL-YMP-QP-04.4)
TWS-QAS-QP-04.2, R2	Procedure for Accepting the Performance of Procured Services (Superseded by LANL-YMP-QP-04.4)
TWS-QAS-QP-04.3, R1	Qualification of Suppliers of Engineered Items and Services (Superseded by LANL-YMP-QP-04.4)
TWS-QAS-QP-05.1, R3	Preparation of Quality Administrative Procedures (Superseded by LANL-YMP-QP-06.2)
TWS-QAS-QP-05.2, R2	Preparation of a Detailed Technical Procedure (Superseded by LANL-YMP-QP-06.3)
TWS-YMP-QP-02.9, R0	Personnel Proficiency Evaluations

STUDY PLANS

SCP 8.3.1.3.4.1/.3	Sorption (WBS 1.2.3.4.1.5.A)
SCP 8.3.1.3.4.2	Microbiology (WBS 2.3.4.1.5)
SCP 8.3.1.3.5.1/.2	Solubility Determination (WBS 1.2.3.4.1.4.A)
SCP 8.3.1.3.7.1.1,.2,.3	Retardation Sensitivity Analysis (WBS 2.3.4.1.7.A)
SCP 8.3.1.2.2.2, Rev. 1,	Water Movement Tests
SCP 8.3.1.2.3.1.7, Rev. 2,	Saturated Zone Groundwater Flow System Characterization Site
SCP 8.3.1.3.4.2, Rev. 0,	Biological Sorption and Transport
SCP 8.3.1.3.6.2, Rev. 0,	Diffusion
SCP 8.3.1.3.6.1, Rev. 0,	Dynamic Transport Column Experiments
SCP 8.3.1.3.5.1, Rev. 0 and 8.3.1.3.5.2, Rev. 0	Dissolved Species Concentration Limits and Colloid Behavoir

TECHNICAL INFORMATION PRODUCTS

1. "Carbon-13 Characterization of Actinyl (VI) Carbonate Complexes in Aqueous Solution" TWS-INC-11-08-91-01.

2. "Technical Information Product Formation, Characterization, and Stability of Pu (IV) Colloid: A Progress Report" TWS-INC-7-10-90-01.

3. "Size Determination of Pu Colloids Using Autocorrelation Photo Spectroscopy" TWS-INC-11-12-91-03.

4. "Radionuclide Migration As a Function of Mineralogy" TWS-INC-11-07-91-12.

5. "Radionuclide Migration Laboratory Studies for Validation of Batch Sorption" TWS-INC-11-11-91-07.

SCIENTIFIC NOTEBOOKS

TWS-INC-7-05-90-08
TWS-EES-5-7-91-03
TWS-LS2-DP-4017
TWS-LS2-05-90-04
TWS-LS2-08-89-01
TWS-INC-11-11/88-10
TWS-INC-11-7/86
TWS-INC-11-06-91-04
TWS-INC11-10-91-04
TWS-INC-07-91-17
TWS-INC-11-5188-16
TWS-EES-5-6-89-10
TWS-LS2-11-90-004
TWS-LS2-02-89-01
TWS-LS2-02-90-01
TWS-INC-11-5-89-28
TWS-INC-11-9/88-6
TWS-INC-11-9/82-54
TWS-INC11-9/82/49

MILESTONE REPORT

K. H. Birdsell, et al, Interim Report: Sensitivity Analysis of Integrated Radionuclide Transport Based on a Three Dimensional Geochemical/Geophysical Model, TWS-EES-5-4-91-02, Milestone R746,
LA-UR 91-1321

PUBLICATIONS

1. Triay, I.R., Hobart, D.E., Mitchell, A.J., Newton, T.W., Ott, M.A., Palmer, P.D., Rundberg, R.S., and Thompson, J.L., (1991), Size Determinations of Plutonium Colloids Using Autocorrelation Photon Spectroscopy, Radiochimica Acta 52/53, p. 127-131.

2. Nitsche, H., Gatti, R.C., Standifer, E.M., Lee, S.C., Muller, A., Prussin, T., Deinhammer, R.S., Maurer, H., Becraft, K., Leung, S., and Carpenter, S.A., (draft dated 7/1991), Measured Solubilities and Speciations of Neptunium, Plutonium, and Americium in a Typical Groundwater (J-13) from the Yucca Mountain Region, YMP Milestone Report 3010.

3. Reprint of published work done partly under subcontract by Stanford University: Combes, J-M., Chisholm-Brause, C. J., Brown, Jr., G. E., Parks, G. A., Conradson, S. D., Eller, P. G., Triay, I. R., Hobart, D. E., and Meijer, A. (1992). EXAFS Spectroscopic Study of Neptunium (V) Sorption at the α-FeOOH/Water Interface, Environmental Science & Technology, v. 26, pp. 376-382.

SOFTWARE DOCUMENTATION

1. Software Management Status Reports, dated March 11, 1992, by Steve Donahue, TWS-EES-13-03-92-037, showing 133 Software Change Requests, 8 Software Incident Reports, 135 Engineering Change Directives, 67 Engineering Change Notices, and 193 Software/Data Dissemination Releases (sanctioned users)

2. Software Requirements Specification for the TRACRN Application, ECD-0005

3. Verification & Validation Plan and Procedures for the TRACRN Application (in preparation), ECD-xxxx

4. Configuration Status Accounting Records, Vol. 6

5. Configuration Status Accounting Records, Vol. 15

6. Computerized Configuration Status Accounting (CSA) data base containing the following:

Model validation report for the software INTERFACE_TABLES.
Technical and Peer Review reports in minutes of the Configuration Control Board meetings.
Life cycle Specification and documentation for the software SIEMGETPUT.
Life cycle Specification for the software TRACRN.
Software Requirements Specifications for INTERFACE_TABLES and TRACRN.
Software Design Description for the software INTERFACE_TABLES.
Source code listings for SORBEQ, TRACRN, and ADA CONDITION NOTIFICATION.
Verification Plan/Report for SIEMGETPUT.

RECORDS/RECORD PACKAGES

TWS-EES-1-2-91-5
TWS-EES-1-3-91-5
TWS-EES-1-8-91-1
TWS-EES-5-11-91-5
TWS-EES-1-3-91-3
TWS-EES-1-3-91-7
TWS-EES-5-7-91-5
TWS-EES-13-LV-02-91-11

RECORD/RECORD PACKAGES REVIEWED FOR DUAL STORAGE

TWS-EES-1-7-91-5
TWS-ESS-13-11-91-42
TWS-EES-13-4-91-96
TWS-EES-1-8-91-7
TWS-EES-13-9-91-13
TWS-EES-13-12-91-23

TRAINING RECORDS

S. Bolivar
J. Canepa
D. Clark
M. Clevinger
S. Donahue
G. Gainer
L. Lopez
D. Morris
A. Odegard
B. Romero
L. Schempp
C. Tait
D. Updegraff

LOGS

TWS-EES-5
TWS-INC-7/11
TWS-EES-13
Records Rejection Log
TWS-EES-15

SAMPLES

1. 11C for the Biological Sorption task
2. E-50-C for the Colloid task
3. USWG-4, UE2SA1, and USWGU3 for the Dynamic Transport task

SURVEY REPORTS

SR-87-0034 SR-87-0050 SR-92-001

DEFICIENCY REPORTS

LANL-0159 LANL-0172

OTHER

1. TWS-EES-13-10-91-008, Dated October 21, 1991

2. TWS-EES-13-02-92-010, QP Distribution for December 23, 1991 - Record Package Traveler

3. Quality Administrative Procedure Action Request for QP-06.1, R2, Document Control

4. Los Alamos National Laboratory Quality Assurance Manual for the Yucca Mountain Site Characterization Project - Table of Contents - Distribution List

5. QA Grading Report Nos. 11, 35, and 47

6. Looked on-line on a computer terminal at an unmodified portion of the TRACRN source code and 77a modification of the same portion after memory management was incorporated.