

PROJECT OFFICE QUALITY ASSURANCE AUDIT REPORT FOR
THE YUCCA MOUNTAIN PROJECT OFFICE AUDIT OF
LAWRENCE LIVERMORE NATIONAL LABORATORY

AUDIT NUMBER 88-05

CONDUCTED: OCTOBER 24 - 28, 1988

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EXECUTIVE SUMMARY

PROJECT OFFICE AUDIT REPORT NO. 88-05

LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL)

LIVERMORE, CALIFORNIA

OCTOBER 24 THROUGH 28, 1988

In the opinion of the Project Office Audit Team, the Quality Assurance (QA) Program at LLNL is ineffective. The program is neither complete nor effectively implemented. The status of scientific investigations was indeterminate because of a lack of objective evidence to demonstrate technical adequacy. The audit was performed to NNWSI QAP NVO-196-17, Revision 4, effective 1/31/86. This program has been superseded and subsequent revisions approved by the Project Office. LLNL has not issued or implemented a QAPP which implements the approved Project QA Plan. The fact that LLNL has not effectively implemented this outdated program indicates that it may be difficult to implement the more stringent requirements of NNWSI/88-9, Revision 2, within the time frame committed to by the U.S. Department of Energy (DOE) for accomplishing a fully qualified QA Program.

Currently, the majority of the work performed by LLNL for the Yucca Mountain Project involves QA Level III activities; however, as a result of the audit, 23 deficiencies were identified, several of major significance (i.e. Corrective Action, Control of Measuring and Test Equipment (M&TE), QA Records, Control of Procured Services, and Training). Additionally, 21 observations and 9 recommendations were generated, one of these being of major importance (i.e. QA Level II or III to QA Level I upgrades). Many of the observations would have been documented as deficiencies if QA Level I work had been involved.

A major area of recurring concern identified during this and previous audits is the lack of verification of subcontractors' work by LLNL. Two subcontractors, Pacific Northwest Laboratories (PNL) and Argonne National Laboratory (ANL), perform the majority of QA Level I work that is now in progress. Audits of these two laboratories should be conducted, as soon as practicable. Other areas of concern is the lack of timely and effective corrective action on previously identified deficiencies. The development of an M&TE program at LLNL and the QA Records program were found to be ineffective. These deficiencies were originally identified in 1986 and 1987 respectively.

A major recommendation addresses concerns over the planned upgrade of existing computer codes EQ3NR and EQ6, developed in part under no formal QA Program, to QA Level II and then to QA Level I by way of peer reviews. Similarly, thermodynamic data being developed at QA Level III may, after review, be incorporated into a data base for use at QA Level I. These processes would be in conflict with the NNWSI/88-9, Section II, para. 2.2.3.

Executive Summary (continued)

With the QA Program currently ineffective, and the indeterminate nature of the scientific investigation, the status of both current and past work must be evaluated to determine the impact of the ineffective QA Program. It is realized that the majority of current work is QA Level III; however, the current QA Program at LLNL would not support QA Level I activities. Therefore, significant strides must be taken to complete and implement a QA Program that meets current Project Office QA Program requirements.

1.0 INTRODUCTION

This report contains the results of a QA Audit of LLNL Yucca Mountain Project activities. The audit was conducted at the LLNL facilities in Livermore, CA, October 24 through October 28, 1988. The audit was conducted in accordance with the requirements of QMP-18-01, Revision 3, "Audit System For The Waste Management Project Office." The QA Program Requirements to be verified were taken from NNWSI QA Plan, NVO-196-17, Revision 4.

2.0 AUDIT SCOPE

The purpose of this audit was to evaluate the effectiveness of the LLNL Quality Assurance Program through verification of the implementation of the LLNL QAPP, Revision 22 (5/4/88) and its implementing procedures and to assess the technical activities and results.

3.0 AUDIT TEAM PERSONNEL

The audit team consisted of the following:

Stephen Hans	Audit Team Leader	SAIC, Las Vegas, NV
John Friend	Lead Auditor	SAIC, Las Vegas, NV
James Clark	Auditor	SAIC, Las Vegas, NV
Mae Cotter	Auditor	SAIC, Las Vegas, NV
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Catherine Thompson	Auditor	SAIC, Las Vegas, NV
Norman Frank	Auditor	DOE/HQ (CER)
Karl Sommer	Auditor	DOE/HQ, Washington, DC
Florencio Ramirez	Auditor	DOE/SAN, Oakland, CA
Paul Cloke	Lead Technical Specialist	SAIC, Las Vegas, NV
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Keith Schwartztrauber	Technical Specialist	SAIC, Las Vegas, NV
Martha Mitchell	Technical Specialist	SAIC, Las Vegas, NV
Joseph Holonich	Observer	NRC, Washington, DC
Linda Riddle	Observer	NRC, Washington, DC
Kien Chang	Observer	NRC, Washington, DC
Tin Mo	Observer	NRC, Washington, DC
Robert Englehardt	Observer	NRC, Washington, DC
Susan Zimmerman	Observer	State of Nevada
Thomas Devine	Observer	State of Nevada
Don Shettel	Observer	State of Nevada
Hal Cleary	Observer	DOE/HQ (W)
Chris Pflum	Observer	SAIC, Las Vegas, NV
Nancy Voltura	Observer	YMP, Las Vegas, NV
Catherine Hampton	Observer	YMP, Las Vegas, NV
Mike Valentine	Observer	YMP, Las Vegas, NV

4.0 SUMMARY OF AUDIT RESULTS

4.1 Statement of Program Effectiveness

In the opinion of the Project Office Audit Team, the Quality Assurance Program at LLNL is ineffective; the program is neither complete nor effectively implemented. The status of scientific investigations is indeterminate because of a lack of objective evidence to demonstrate technical adequacy. The audit was performed to NNWSI QAP NV0-196-17, Revision 4, effective 1/31/86. However, this program has been superseded and the subsequent revision approved 6/1/88, by the Project Office has not been issued or implemented by LLNL.

The evaluation of the LLNL QA Program indicates a noticeable lack of awareness of quality assurance requirements throughout the organization, as observed during interviews of LLNL personnel by the entire audit team. This lack of awareness of requirements is a contributing factor to the ineffective implementation of the program.

The following QA Program elements had significant deficiencies identified relevant to QA Level I activities:

- o QA Program
- o Control of Purchased Services
- o Control of Measuring and Test Equipment
- o Corrective Action
- o QA Records

In addition, a major recommendation in the area of QA Level upgrades has been generated.

In summary, with the Quality Assurance Program currently ineffective, and indeterminate nature of scientific investigation, the status of both current and past work must be evaluated to determine the impact of the ineffective program on scientific investigations. It is realized that the majority of current work is QA Level III; however, the current QA Program cannot support QA Level I activities. Therefore, significant strides must be taken to complete and implement a Quality Assurance Program that meets current Project Office Quality Assurance Program requirements.

4.0 SUMMARY OF AUDIT RESULTS (CONTINUED)

4.2 Summary Of Technical Evaluation

The technical audit team found that the scientific staff at LLNL were very responsive to questioning during the audit. Their answers and discussion demonstrated that they had devoted a great deal of thought to the issues and knew how to proceed to meet project goals. They demonstrated scientific and technical insight into the nature of the various problems and how to solve them. It appeared that they were properly following the technical aspects of the procedures specified for the various activities. Verification of objective evidence was extremely difficult, since LLNL could not retrieve records from the Records Center and the majority of work is currently QA Level III. This is explained elsewhere in the report (see SDRs). In the few instances where records and laboratory notebooks were available (e.g., on some computer code developments), the evidence showed that careful and complete documentation was made. If these practices continue, it appears that when the QAPP is fully implemented, the scientific and technical work may be performed and documented in an acceptable manner.

4.3 Summary

A total of 23 Standard Deficiency Reports (SDRs) (Enclosure 3) and 21 observations (Enclosure 4) were identified as a result of this audit. In addition, the audit team generated nine (9) recommendations for consideration of both LLNL and the Project Office. A synopsis of each SDR and observation and the complete recommendations are contained in Section 6.0 of this report.

Deficiencies identified by the Project Office are qualified by Severity Level, which is related to the significance of the deficiency. A discussion of Severity Levels is provided in Enclosure 1.

At the time of the audit, seven SDRs remained open from previous Project Office surveillances and audits. Four of the SDRs, Nos. 020, 021, 024 (Audit 87-3) and 036 (Surveillance No. 87-1), remain open pending approval of a request for extension. During the audit, the audit team attempted to verify that corrective action had been completed on the remaining three SDRs, Nos. 035 and 038 (Surveillance No. 87-1) and 090 (Surveillance No. 88-002). In all three cases, the corrective action completion dates had passed and corrective action had not been effected. These three SDRs remain open.

The following program elements were deemed to be in compliance with the requirements of LLNL QAPP, Revision 22, and its implementing procedures:

- 1.0 - Organization
- 8.0 - Identification and Control of Materials, Parts, and Components
- 9.0 - Control of Processes (No Level I Work)
- 11.0 - Test Control (No Level I Work)
- 13.0 - Handling, Storage and Shipping

4.0 SUMMARY OF AUDIT RESULTS

4.3 Summary (Continued)

Program elements in which the audit team identified deficiencies were:

- 2.0 - Assurance
- 3A.0 - Scientific Investigation and Design Control
- 4.0 - Procurement Document Control
- 5.0 - Instructions, Procedures, and Drawings
- 6.0 - Document Control
- 7.0 - Control of Purchased Materials, Equipment, and Service
- 12.0 - Control of Measuring and Test Equipment
- 15.0 - Nonconformances
- 16.0 - Corrective Action
- 17.0 - Quality Assurance Records
- 18.0 - Audits

The following program elements were reviewed during the audit; however, no activities had taken place that would have required these elements to be controlled:

- 10.0 - Inspection
- 14.0 - Inspection, Test, and Operating Status

The following technical activities were reviewed as part of this audit:

<u>SIP</u>	<u>ACTIVITY</u>
1.2.2.2.L	Waste Package Environment
1.2.2.3.1	Waste Form Testing
1.2.2.3.2	Metal Barrier Testing
1.2.2.3.4	Integrated Testing
1.2.2.4	Design, Fabrication, and Prototype
1.2.2.5	Performance Assessment
1.2.3.8	Geochemical Modeling Code
1.2.6.9	Engineered Barrier Design Testing

5.0 AUDIT MEETINGS

5.1 Preaudit Conference

A preaudit conference was held with the LLNL Technical Project Officer (TPO) and his staff at 10:00 a.m. on October 24, 1988. The purpose, scope, and proposed agenda for the audit were presented and the audit team was introduced. The TPO then gave a description of the organization and the Yucca Mountain Project program at LLNL. A list of attendees for this meeting is provided in Enclosure 2.

5.0 AUDIT MEETINGS (CONTINUED)

5.2 Audit Status Meetings

Audit status meetings were held with the LLNL TPO and LLNL Deputy for Quality Assurance at 8:30 a.m. on October 25, 26, 27, and 28, 1988. A status of how the audit was progressing and identification of discrepancies were discussed daily.

5.3 Postaudit Conference

The postaudit conference was held at 2:00 p.m. on October 28, 1988. A synopsis of the preliminary SDRs and Observation identified during the course of the audit was presented to the TPO and his staff. A list of attendees for this meeting is provided in Enclosure 2.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.1 Standard Deficiency Reports (SDRs)

1. Nine of ten Personnel Qualification Records (PQRs) reviewed during the audit did not include a qualification summary and two did not contain position descriptions. Severity Level 2, SDR No. 224.
2. The requirements of the training program have not been met and the training provided has not been effective in achieving QA program implementation. Severity Level 1, SDR No. 225.
3. Procedure numbers are not traceable to the QA Level Assignment Review Meeting. Additionally, copies of procedure packages are not distributed as required. Severity Level 3, SDR No. 226.
4. Transmittals of five draft procedures did not contain explanations of comment resolution. Severity Level 2, SDR No. 227.
5. LLNL has not developed procedures to control interfaces between itself and its suppliers or other participants. Severity Level 2, SDR No. 228.
6. The Project Office has not established procedures for coordinating interfaces among participants. Severity Level 2, SDR No. 229, (issued to Project Office).
7. LLNL did not conduct a peer review of SIP 1.2.2.3.2, Activity E-20-15, using a Project Office internal procedure. Severity Level 2, SDR No. 230.
8. The Project Office did not provide LLNL with a procedure to conduct a peer review of SIP 1.2.2.3.2, Activity E-20-15. Severity Level 2, SDR No. 231, (issued to Project Office).

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.1 Standard Deficiency Reports (continued)

9. There was no objective evidence presented to indicate that purchase award documents had been reviewed for technical and quality requirements. Severity Level 2, SDR No. 232.
10. LLNL has not implemented a Quality Program to meet the requirements of NVO-197-17, Rev. 5. Work performed since 6/1/88 has not been performed to the latest approved LLNL QA program. Severity Level 1, SDR No. 233.
11. The use of Interim Change Notices and Instructional Memorandums to change controlled documents is not defined in the QAPP. Severity Level 3, SDR No. 234.
12. Computer files that contain document version numbers have not been updated since 1/29/88.. Severity Level 2, SDR No. 235.
13. LLNL 033 NWMP-P 6.1, Rev. 1, requires several activities to be performed by "Key Reviewers." "Key Reviewer" has not been defined or identified, and the activities assigned have not been performed. Severity Level 2, SDR No. 237.
14. No documentation of the bid evaluation or the selection of procurement source results was available during the audit. Evidence of exception to the requirement was also not provided. Severity Level 2, SDR No. 238.
15. LLNL procedures do not address repair and use-as-is dispositions to NCRs, thereby making it difficult to determine which NCRs require Project Office approval. Severity Level 3, SDR No. 239.
16. LLNL procedures do not provide a method for revising nonconformances. Severity Level 3, SDR No. 240.
17. An effective Corrective Action System has not been implemented at LLNL. Conditions adverse to quality have not been corrected in an effective or timely manner. Severity Level 1, SDR No. 241.
18. Software QA records generated by EQ3/6 activities could not be located during the audit. Severity Level 1, SDR No. 242.
19. LLNL has not conducted audits of PNL and ANL. Severity Level 1, SDR No. 243.
20. LLNL QA procedures do not define requirements for the use of technical specialists during audits. Severity Level 3, SDR No. 244.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.1 Standard Deficiency Reports (continued)

21. LLNL audit reports reviewed during the audit did not contain a statement concerning effectiveness. Severity Level 3, SDR No. 245.
22. The records management system documented in the LLNL QAPPs is not effective. Severity Level 1, SDR No. 246.
23. LLNL QAPP Series 19.X procedures do not contain documentation requirements consistent with NUREG-0856. Severity Level 2, SDR No. 247.

6.2 Observations

Programmatic

1. LLNL QAPPs 033-NWMP-P 5.1 and P 13.1 do not adequately define all criteria required for satisfactory performance of technical activities. Observation No. 88-05-01.
2. There is no matrix or data base used to track individual training requirements. There is no way to identify who needs specific training, who is delinquent or who has received training. Observation No. 88-05-02.
3. QA Level I procurement documents are not being forwarded to the Project Office QA Manager when the procurement is initiated. There is an interpretation problem as to when the documents should be forwarded. Observation No. 88-05-03.
4. Objective evidence of technical procedure reviews is not included as QA records. Observation No. 88-05-04.
5. LLNL procedures do not define procedure effective dates, nor the way they are used in the Document Control Process. Observation No. 88-05-05.
6. LLNL procedures do not adequately define methods for proper corrections to QA records. Observation No. 88-05-06.
7. LLNL procedures do not address requirements for the control and review of supplier certificates of conformance. Observation No. 88-05-07.
8. Trending of deficiencies has not included audit results from LLNL audits or outside organizations. Observation No. 88-05-08.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.2 Observations

Programmatic (continued)

9. No method has been defined for escalating disputes between QA and LLNL management to the Project Office PQM. Observation No. 88-05-09.
10. LLNL procedures do not define a method to track or followup on the status of nonconformance reports. Observation No. 88-05-10.
11. The following observations were identified during the audit concerning NWMP-P 15.01, Rev. 0, "Nonconformances":
 1. A new form not covered by current procedural instructions is already in use.
 2. The forms do not include the date of identification of the nonconformance.
 3. The copy of the files turned over as a records package contained superfluous documents, and the packages were not organized logically or indexed for ease of understanding.Observation No. 88-05-11.
12. Current QA staffing levels will not be adequate to implement and maintain the QA program once it is fully implemented. Observation No. 88-05-12.
13. The following conditions were noted for documents not yet designated as records that were associated with the collection, storage, and distribution of J-13 water.
 1. Improper corrections to logbook entries.
 2. Logbook entries for the past 18 months did not show evidence of review.
 3. Improper storage of documents.Observation No. 88-05-13.
14. Existing technical procedure numbers were being changed to be used as Technical Implementing Procedures without procedural guidance of QA or Project Office concurrence. Observation No. 88-05-14.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.2 Observations

Technical

1. A peer review should be initiated in accordance with Yucca Mountain Project Requirements to judge the sufficiency of the selection process used to date and in the future regarding the adequacy of the data base for minerals, man-made materials, and solution species needed for thermodynamic studies. Observation 88-05-15.
2. QAPP procedure 033-NWMP-P 2.2, Section 2.2.1, specified that "Peer reviews are employed at points of strategic consequence." The selection of barrier material is such a point; therefore, the alternate material program must consider a broad spectrum of materials that could adequately perform under the range of repository conditions. The broad spectrum of materials shall be reduced to a manageable number through the use of outside technical experts and concurred with by the Project Office for each category of material. The final alternate (or alternates) selected from this reduced list of candidates requires a peer review process in accordance with Yucca Mountain Project Requirements. Observation 88-05-16.
3. The disposition of matters related to chemical kinetics are "points of consequence" in the sense of LLNL 033-NWMP-P 2.2, Rev. 1, "Peer Review," and must be peer reviewed in accordance with Yucca Mountain Project Requirements. Prior to the peer review, this area must be given careful consideration as to what kinetic data are needed for licensing and to ensure these data are included in a sensitivity analysis. Observation No. 88-05-17.
4. There is no evidence that QA is involved in the review, planning, and implementation of the software procedures used to control LLNL work. Additional procedures are needed to assure QA controls for activities other than EQ3/6. Observation No. 88-05-18.
5. Based on the QA Level assignments made at LLNL for software, it will be difficult for future users of software documentation to determine which documents were developed per the LLNL QA program. LLNL should mark all documents, publications and records related to software to ensure that the data and information contained can be traced to its originating SIP, QA Level and WBS element. Furthermore, records that were not developed or verified and validated per the LLNL QA program should contain a disclaimer stating the work cannot be used to support the Yucca Mountain Project license application. Observation No. 88-05-19.
6. LLNL software QA procedures do not contain quantitative or qualitative criteria stating how existing software will be qualified for use to support the Yucca Mountain Project scientific investigation and/or the license application. Observation No. 88-05-20.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.2 Observations

Technical (continued)

7. For the geochemical modeling code EQ3/6, it was observed that some revisions to code versions are issued without performing verification test runs to check that modifications have not impacted previous work. Test runs should be conducted following significant numbers of changes, or for any single change that substantially revises previous versions. These runs should exercise those portions of the code that have been modified or may be impacted by such revisions. Observation No. 88-05-21.

6.3 Recommendations

Recommendation No. 1

Regualification of Work to QA Level I

Background

A frequent question during the course of the audit was the relationship between QA Level III or QA Level II work and subsequent planned QA Level I related work. This was especially evident in those activities dealing with the EQ3NR and EQ6 computer code developments and the determination of thermodynamic data for use with these codes.

It appears from an examination of the planned sequence of activities, specifically, those described in LLNL QAPP 033-NWMP-P 19.4, "Development of Computer Codes," that some portion of coding accomplished in prior years—in part not under any QA program—and some portion of ongoing coding at QA Level II will eventually be incorporated into the QA Level I release of EQ3NR and EQ6. At that time it must be possible to demonstrate satisfactorily to all concerned parties, and in particular to the NRC, that these codes are acceptable for use in QA Level I applications. As stated in SOP-02-02, Rev. 1, Subsection 5.3.1.3, Rev. 1, "data, documents, and computer codes...used in the licensing process...shall be QA Level I."

Thermodynamic data are being acquired under SIP 1.2.3.8.L, Activity J-20-8, at QA Level III. It is intended that these data be subjected to review by LLNL, using the NBS CATCH code and "International Peer Review Group Methods." If acceptable, these data will then be entered into a data base for use in conducting QA Level I activities. Presumably an outside peer review would be conducted, in accordance with QAPP 033-NWMP-P 2.2, although this was not explicitly stated. As noted above and stated in SOP-02-02, Rev. 1, data used in the licensing process must be QA Level I. A draft copy of the position paper proposed by LLNL (draft and accompanying correspondence) is provided in Enclosure 5. See especially pages 25 through 29.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.3 Recommendations

Recommendation No. 1
Regualification of Work to QA LEVEL I

Background (continued)

The process through which QA Level I is to be achieved for computer codes and associated data must be clearly understood. This process should be clearly stated and presented to the NRC for concurrence well in advance of license application.

During the audit, the technical specialist was told by members of the audit team from SAIC's QA Department that merely because work is conducted at QA Level I, it does not follow that the resulting data is automatically "QA Level I." The lead of the NRC observer team concurred with this statement. However, the technical specialists have to date failed to find any place in the regulations or NRC positions that states this. In fact, there were no references in approved plans, procedures, or regulations, except in SOP-02-02, Rev. 1, to "QA Level I data" or "QA Level I computer codes," only to QA Level I activities.

It is clear from the position paper referred to above that LLNL believes that if data are obtained from a QA Level I activity, then these data are QA Level I data. On the other hand the NNWSI QA Plan, 88-9, Section II, Subsection 1.4, Rev. 1, does refer to "primary data" for licensing purposes, in this instance applied to existing data that have been qualified in accordance with Administrative Procedure-5.9Q. Subsection 2.2.3.1 of this QA Plan, Section II, states (in part) that "QA Level I activities which are on the Q-list will provide the primary data input ..." (underlining added). The Q List, defined in Subsection 1.5.1 of this section, will presumably include the activities for which the thermodynamic data to be obtained by LLNL will be used. One may reasonably conclude that primary data may be derived either by qualification of existing data or as output from QA Level I activities, and that this is equivalent to LLNL's use of "QA Level I data" in place of "primary data." Therefore, a QA Level I activity must be adequate to ensure that any data produced for license application must "attain the required quality" (NNWSI QA Plan, 88-9, Section II, Subsection 1.7, Rev. 1). This makes it incumbent upon LLNL (and other participants, for whom similar problems exist) to include sufficient work within their activities, as, for example, described in their SIPs, procedures, or study plans, to guarantee that the output of these activities is suitable as "primary data for licensing purposes."

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.3 Recommendations

Recommendation No. 1
Regualification of Work to QA Level I

Background (continued)

A similar situation exists with respect to computer codes. The NNWSI QA Plan, 88-9, Section III, Subsection 3.1.7, Rev. 1, states that "Software that has not been developed in accordance with this QA Plan may be qualified for use provided the software is verified and validated," Presumably this means in respect to EQ3/6 that at some time these codes, which were partly developed outside a formal QA plan, must be "verified and validated, a software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this section" (Subsection 3.1.7). Subsequent redundant code developments must be done in accordance with Appendix H of the NNWSI QA Plan. (The revision number is deliberately omitted in view of ongoing activities, to arrive at requirements consistent with the development of a large and very complex scientific code.) The final revision of Appendix H will, presumably, continue to include requirements for verification, validation, review, etc. Thus, the activities that produce new code versions will automatically require that the codes "attain the required quality" (NNWSI QA Plan, Section II, Subsection 1.7, Rev. 1).

The code itself, apparently, is never designated as having any QA Level (except as implied by SOP-02-02); rather it is validated to "assure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system" (NNWSI QA Plan, 88-9, Section III, Subsection 3.1.6 Rev. 1). This is entirely consistent with LLNL's stated position (verbally at least) that the codes must be validated for each application by the user. However, it also means that the development activities, i.e., those somewhat analogous to some combination of Appendix H, Rev. 0, Subsections 4.1.2.2, "Design Phase," and 4.1.2.3, "Implementation Phase," may be performed at QA Level I without implying that the result is a "QA Level I code" or that it is suitable for any specific application.

Even though the QAPP being used by LLNL, Section 033-NWMP-P 20.0, Subsection 20.0.3, Rev. 0, states that QA Level I is defined as "Activities conducted and items used with the intent to provide direct support...", the NNWSI Project QA Plan, Appendix H, Rev. 1, (see also the NNWSI Project QA Plan, 88-9, Section II, Subsection 2.2.3.1, Rev. 1), defines QA Level I as "those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with" The latter is consistent with 10 CFR Part 60, and does not restrict activities and items to those that provide direct support.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.3 Recommendations

Recommendation No. 1
Regualification of Work to QA Level I

Background (continued)

Also significant in this respect is the NNWSI Project QA Plan, 88-9, Section II, Subsection 2.2.3.1, Rev. 1, which states in part: "QA Level I must be applied for near-term safety as well as long term isolation as per the following:...Where items and activities will provide primary data which will be relied on for performance assessment of the repository system. This data are (sic) the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research which have a significant impact to site-characterization or are an essential part of the data base that directly support the final design of the repository and waste package performance." (Underlining and bolding added.) This appears to be consistent with LLNL's QAPP, Subsection 20.0.3.

Discussion

Consideration of the objective evidence cited above indicates that clear direction and definition of how to proceed has not yet been attained. Inconsistencies have been found within the NNWSI QA Plan, and between SOP-02-02 and other documents. Of particular importance are the statements in the NNWSI Project QA Plan, 88-9, Section II, Subsection 2.2.3.3, Rev. 1: "Design phases which are purely preliminary and are conducted to define the range of alternatives/methods/equipment which are felt to be worthy of more detailed study shall be assigned a QA level of III prior to execution. Those activities controlled in accordance with a QA Level III program cannot subsequently be used to directly support QA Level I activities." This together with the definitions of QA Levels I and II, leads to the opinion that the determination of thermodynamic data be conducted at QA Level I. Inasmuch as, the development of EQ3NR and EQ6 no longer appears to be "purely preliminary" and does involve radiological health and safety in respect to its applications to design and performance assessment, this activity must also be conducted at QA Level I. It is also worthy of note that the lead NRC observer at the audit was not fully convinced that the ongoing work at G-Tunnel should not also be done at QA Level I.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.3 Recommendations

Recommendation No. 1

Regualification of Work to QA Level I

Discussion (continued)

The audit team concurs with LLNL that a laboratory determination of some thermodynamic property under a QA Level I activity does not immediately qualify it as "primary data". A full peer review process or its equivalent is necessary before the laboratory result becomes so qualified (i.e., before it can be used in any subsequent QA Level I activity.) From a management point of view it is impractical to specify within each activity that such a peer review be conducted for each piece of data. Rather, concurrence must be reached that the totality of activities on thermodynamic data includes this review and that, until such a review is done, data produced by QA Level I activities that only make the measurements are not "primary data." Therefore, the NNWSI Project QA Plan, 88-9, Section II, Subsection 2.2.3.1, Rev. 1, should be modified to state that data produced by a QA Level I activity must be properly reviewed before they are qualified as primary data.

Recommendation

LLNL should do the following:

1. Review the SIPs and activities described therein to assure that, in view of the majority of the objective evidence cited above, the QA level assignments for all activities presently at QA Levels II and III are correct. Inasmuch as 10 CFR Part 60 does not specify "directly," the proper criterion should be whether any results of activities will be used directly or indirectly in the licensing process.
2. Where this review indicates that it is necessary, initiate upgrading the QA level assignments.
3. If, following this review, LLNL still believes that any results and/or records of QA Level II or III activities will be used, directly or indirectly, in the licensing process, specify explicitly how they will be upgraded for use at QA Level I. A clear demonstration of the suitability for use at QA Level I is essential. This might involve the preparation and submission of position papers, such as the data base position paper "Data Sources and Quality Assurance for the Compilation of a Chemical Thermodynamic Data Base for Use in Licensing of a High Level Nuclear Waste Repository; Position Paper" submitted to the Project Office on December 23, 1987.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.3 Recommendations

Recommendation No. 1

Regualification of Work to QA Level I (continued)

4. If it is not intended to repeat all existing computer programming that will undergo further development and for which part of the programming was not done at QA Level I, the specific procedure by which it will be shown that the code is acceptable for QA Level I applications needs to be described in detail. (See also related Item 6 below.)
5. Participate in the presentation of any proposed certification processes to DOE/HQ, after review and approval by the Project Office, and to the NRC.
6. Specify any new starts, restarts (from the beginning), or complete rebuilding of models or of computer codes of which did not entirely result from a QA Level I activity. Presumably it would be acceptable to the NRC if it were possible to demonstrate that EQ3NR and EQ6 were completely rebuilt using only those aspects of existing codes which are "purely preliminary" in the sense of the NNWSI Project QA Plan, 88-9, Section II, Subsection 2.2.3.3, Rev. 1.

The Project Office should do the following:

1. Address and aggressively pursue this matter until final resolution is obtained, including if possible concurrence by the NRC with a set of procedures to achieve project goals in a realistic manner, taking into account the actual way in which complex scientific codes must be developed and data determined and qualified.
2. Make changes in the NNWSI QA Plan to achieve consistency in this matter, specifically, for example, the NNWSI Project QA Plan, Appendix H, Rev. 1, by being silent in respect to the question of direct versus indirect support to license application, is inconsistent with NNWSI Project QA Plan, 88-9, Section II, Subsection 2.2.3.1, Rev. 1.
3. Change SOP-02-02 to make it consistent with the NNWSI QA Plan by eliminating the designation of data, documents, and computer codes as QA Level I. In the NNWSI QAP, only activities are assigned QA Levels.
4. Change the NNWSI Project QA Plan, 88-9, Section II, Subsection 2.2.3.1, Rev. 1, to state that data produced by a QA Level I activity must be properly reviewed before they are qualified as primary data.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.3 Recommendations

Recommendation No. 1
Requalification of Work to QA Level I

5. Change the NNWSI Project QA Plan, 88-9, Section III, Subsection 1.5, Rev. 1, to state that development of a computer code through an activity at QA Level I does not validate this code for subsequent use in QA Level I activities involving applications supporting, directly or indirectly, license application. This subsection should state that validation for use in a specific application of any model that incorporates the code must precede use of the code in that application.
6. Change the NNWSI Project QA Plan, 88-9, Appendix H, Subsection 1.0, Rev. 0, to state explicitly that part of the control process may consist of verification and validation of an existing (prior to full implementation of this QA Plan) code in accordance with NNWSI Project QA Plan, 88-9, Section III, Subsection 3.1.7, Rev. 1, prior to further development under this QA Plan. Otherwise this subsection could be interpreted to mean that such codes as EQ3NR, EQ6 and, to the best of the audit team's knowledge, TOUGH and other codes cannot be used in the Project—contrary to the approval and conduct of ongoing and planned activities.

Recommendation No. 2
Use of Salt Repository Project Office (SRPO) Work for the Yucca Mountain Project

In response to audit checklist item T-2, LLNL replied that programming for concentrated solutions (specifically the Helgeson-Kirkham-Flowers equations) has been added under the auspices of the SRPO. It was the clear understanding at LLNL and at SRPO that this effort, at that time under the oversight of P. Cloke (who is now at SAIC) and who was asked question T-2, was directed for both use in the salt project and in modeling the behavior of concentrated J-13 water in the NNWSI Project. However, the Project Office apparently has declined to accept this effort for use or to consider supporting the small amount of work still required work to debug this coding. It is recommended that (1) LLNL provide justification of the need for this coding in order to model the behavior of concentrated J-13 water, and (2) that the Project Office carefully weigh the advantages of using this existing work as compared to the new effort that would otherwise be required to accomplish milestone L032. Other former SRPO work potentially useful to the NNWSI Project should also be considered.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.3 Recommendations (continued)

Recommendation No. 3

Use Of Existing Reviewed Data Bases (Audit Item No. T-15)

It is recommended that LLNL not state or imply in various documents that all CODATA and NEA values will be accepted without review. Rather, these should be included in peer reviews of thermodynamic data. Not all experts accept all CODATA values as accurate, owing to inappropriate choice of reviewers.

Recommendation No. 4

Sensitivity Analyses (Audit Item No. T-18)

It is recommended that LLNL reconsider the decision not to perform perturbation analyses, and instead to rely solely upon the GRESS code. This appears to be a decision that needs concurrence by peers outside of LLNL.

Recommendation No. 5

LLNL's control of raw data is reasonable but not strict enough for licensing (Activities B-20-1, B-20-2). Their data management plans are under development. Specifically, the following is recommended:

1. An overall raw data control procedure should be developed. This would give broad guidelines for all LLNL activities.
2. Personal logbooks should be copied frequently, with the copies stored in a safe and separated place.
3. Back-up copies of other raw data should be made frequently.
4. A microfilm system should be set up near the ESF so that investigators can periodically film personal lab books or other hard data.

Recommendation No. 6

LLNL Procedure 033-NWMP-P 3A.0 for Scientific Investigation Control requires a Scientific Investigation Plan (SIP) to include:

3.A.1.1.3.6

"Any pertinent interfaces between this work and any other work, including all data, information and item inputs from other work to this work, and all data, information and item outputs from this work to other work."

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.3 Recommendations

Recommendation No. 6 (continued)

LLNLs SIP for WBS 1.2.2.5L includes activities whose inputs and outputs closely relate to activities conducted by other Yucca Mountain Project participants. They are:

1. The waste package performance assessment activity, which in part supports Sandia National Laboratories' (SNL's) total system performance assessment by providing a realistic time dependent source term.
2. Near field hydrothermal and transport studies, including radionuclide attenuation in the near field, which requires data and information on sorption and retardation from Los Alamos National Laboratory (Los Alamos).

In both cases, there has been some degree of communications at the working level between the organizations involved, but no formal mechanism exists to clearly establish the interfaces. The most common practice has been simply to rely on reports generated from the other organization for technical inputs. Some degree of close interface action took place during the SCP completion process through Working Group 6. It was, however, still an informal mechanism and was not specifically done to develop the necessary interface for this WBS task.

If the lack of coordination and lack of definition of interface persist, unnecessary overlap of activities may result. Even worse, some gaps may exist and the project may be left with an incomplete set of information for license application. In fact, at present the interface between the near field/source term and the SNL total system is completely undefined and LLNL's task will be proceeding with an undefined scope of work.

An additional problem that this lack of interface definition brings is that it will be very difficult for the project to control the budget and schedule without knowing which organization is responsible for the interface work.

Defining the interface between participant organizations is the responsibility of both the Project Office and the participant organizations. At the participant level, however, some actions can be taken either through the Project Office or directly between the concerned participants, although the former would be a more desirable approach. Therefore, it is very strongly recommended that LLNL, through the Project Office, establish as soon as possible a formal mechanism to define the interfaces with SNL, LANL and the USGS and have regular information exchange meetings with them.

6.0 SYNOPSIS OF SDRS, OBSERVATIONS AND COMPLETE RECOMMENDATIONS

6.3 Recommendations

Recommendation No. 7

LLNL is conducting many code development tasks other than EQ3/6; however, all the activities audited are being conducted at QA Level III assignments. The Project Office and LLNL should evaluate the impact of this work and its ultimate acceptability for use in QA Level I or II activities. If the work is to be used to support future QA Level I or II activities, the task should be reinitiated at QA Level I or II to avoid future questions with use of this work for license application stages.

Recommendation No. 8

LLNL is performing geochemical modeling work for several organizations other than the Yucca Mountain Project. This work may be used to support verification or validation activities for the Yucca Mountain Project. However, reports for this work are not being reviewed or entered into the Project Office QA records. If this work is intended to be used to support the Yucca Mountain Project license application or code verification/validation efforts, the reports should be reviewed, approved or accepted for use by the Project Office.

Recommendation No. 9

As a result of the LLNL audit, it was learned that the LLNL task leader for waste form activities was not aware of the methods used for storage and protection of records accumulated at PNL and ANL on Project QA Level I work.

Therefore, it is recommended that this be determined by the task leader at a convenient time, but no later than at the next audit of these subcontractors.

7.0 REQUIRED ACTION

A written response is required for each Standard Deficiency Report (SDR) delineated in section 6.0 above. Responses to each sdr are due 20 working days from the date of the SDR transmittal letter. Upon response, acceptance, and satisfactory verification of all remedial and corrective actions, the SDRs will be closed and llnl will be notified by letter of the closure.

A written response is required for the 21 observations contained in Enclosure 4 of this report. Responses are due 20 working days after the transmittal letter of this audit report.

7.0 REQUIRED ACTION (CONTINUED)

Written responses are not required for the recommendations contained in this audit report. The recommendations were generated by the audit team for the LLNL staff to consider during implementation of its QA Program.

ENCLOSURE 1

Severity Levels

Severity Level 1

Significant deficiencies considered of major importance. These deficiencies require remedial, investigative, and corrective actions to prevent recurrence.

Severity Level 2

A deficiency which is not of major importance, but may also require remedial, investigative, and/or corrective action to prevent recurrence.

Severity Level 3

A minor deficiency in that only remedial action is required. These deficiencies are generally isolated in nature or have a very limited scope. In addition, the integrity of the end result of the activity is not affected nor does the deficiency affect the ability to achieve those results.

AUDIT REPORT 88-05
ENCLOSURE 2

<u>NAME</u>	<u>ORGANIZATION</u>	<u>TITLE</u>	<u>PREAUDIT CONFERENCE</u>	<u>DURING AUDIT</u>	<u>POSTAUDIT CONFERENCE</u>
Aines, Roger	LLNL	Tech. Area Lead	X	X	X
Alegre, Barbara	LLNL	QA Staff	X	X	X
Ballou, Lyn	LLNL	Ast. NWM Proj. Lead	X		
Barany, Ronald	LLNL	SQA Specialist	X		X
Bell, Walt	LLNL	Metallurgist	X		
Bourcier, Bill	LLNL	Geochemist	X	X	
Braley, Roy	LLNL	Group Leader	X		
Brink, Marilyn	LLNL	Chemist	X		
Bruton, Coral	LLNL	Geochemist	X		
Bryan, Barbara	LLNL	Assoc. Adm. NWMP	X		
Bullen, Daniel	LLNL	Sr. Scientist	X	X	
Buscheck, Thomas	LLNL	Hydrologist	X		
Caldwell, Henry H.	SAIC	Manager, Audit Branch			X
Chang, Kien	US/NRC	MAT'L Engr.	X		
Chubb, Cris	LLNL	QA Tech			
Clark, James E.	SAIC	QA Engineer	X		X
Clark, JoAnn	LLNL	QA Staff	X	X	
Cleary, Hal	DOE/WESTON	MAT'L Engr.	X		
Cloke, Paul	SAIC	Lead Tech. Specialist	X		X
Cotter, Mae	SAIC	RMD Div. Manager	X		X
Commings, Nancy E.	LLNL	QA Staff	X		
Davis, Larry	TEKTRONIX	Site Manager	X		
David, Bill	LLNL	Engineer	X		
Day, R.	LLNL	Scientist		X	
Dobson, Charles	LLNL	PRIN, Admin.	X		X
Dronkers, John	LLNL	Manager, QA	X	X	X

AUDIT REPORT 88-05
ENCLOSURE 2

<u>NAME</u>	<u>ORGANIZATION</u>	<u>TITLE</u>	<u>PREAUDIT CONFERENCE</u>	<u>DURING AUDIT</u>	<u>POSTAUDIT CONFERENCE</u>
Emerson, Don	LLNL	Task Leader			X
Englehardt, Robert	US/NRC	QA Engineer	X		
Frank, Norman	DOE/CER	Quality Specialist	X		X
Friend, John C.	SAIC	QA Engineer/Lead Auditor	X		X
Gdowski, Greg	LLNL	Scientist	X		X
Glassley, Bill	LLNL	Tech. Area Leader	X	X	X
Halsey, Bill	LLNL	Engineer Staff		X	X
Hans, Stephen	SAIC	QA Engineer/Team Lead	X		X
Hansen, Linda	LLNL	Resource Manager	X	X	
Hampton, Catherine	YMP	QA Speicalist	X		X
Holonich, Joeseph	US/NRC	Observer, Team Leader	X		X
Jackson, Ken	LLNL	Geochemist	X		X
Johnson, C. S.	LLNL	Supervisor		X	
Kass, Jeff	LLNL	Tech. Area Leader	X	X	
Kersch, Keith	SAIC	Tech. Specialist	X		
Knauss, Kevin	LLNL	PI		X	
Kugler, August	LLNL	Project Specialist	X	X	
Lappa, David	LLNL	Task Leader	X	X	
Lewis, Lynne	LLNL	NWMP Schedule Manager	X		X
Lin, Wuren	LLNL	Geophysicist	X		
Lee, Kein	LLNL	Hydrologist	X		
Lucena, Robert	LLNL	QA & Metrology Manager	X		
Lummas, Lane	LLNL	QAE/QCE	X	X	X
Madson, Allen	LLNL	QA Specialist	X	X	
Manis, William	LLNL	Records Management	X	X	X
McCright, Dan	LLNL	Task Leader		X	

AUDIT REPORT 88-05
ENCLOSURE 2

<u>NAME</u>	<u>ORGANIZATION</u>	<u>TITLE</u>	<u>PREAUDIT CONFERENCE</u>	<u>DURING AUDIT</u>	<u>POSTAUDIT CONFERENCE</u>
McDaniel, Jerry	LLNL	QA Staff	X	X	X
McKeegan, Kevin	LLNL	Physicist	X		X
Mitchell, Jack	LLNL	Metallurgist	X		
Mitchell, Martha	SAIC	QA Engineer	X		X
Morissette, Richard	SAIC	Manager, WPI			X
Mo, Tin	US/NRC	Geochemist	X		
Nelson, Thomas	LLNL	Engineer	X	X	
Nitao, John	LLNL	Hydrologist	X		
Oberle, Ronald	LLNL	QA Engineer	X	X	X
O'connell, Bill	LLNL	TAL	X	X	X
Olness, Dolores	LLNL	Scientist	X		X
Palmer, John	LLNL	QA Manager	X		X
Park, U-Sun	SAIC	Tech. Specialist	X		
Peifer, Dennis	LLNL	Tech.		X	
Pflum, Chris	SAIC	Licensed Engineer	X		X
Phinney, Douglas	LLNL	Physicist	X		X
Ramerez, Abelardo	LLNL	Geologist	X		
Rameriz, Florencio	DOE/SAN	QA Engineer	X		X
Ramspott, Larry	LLNL	TPO	X	X	X
Revelli, Michael	LLNL	Systems Engineer	X		
Riddle, Linda	US/NRC	QA Specialist	X		
Ross, Claire	LLNL	QA Interface Specialist	X	X	X
Russel, Alan	LLNL	Prin. Engineer	X	X	X
Russel, Edward	LLNL	Engineer	X	X	
Ryerson, R.	LLNL	Task Leader		X	
Schock, Robert	LLNL	Program Leader	X		X
Schwartz, Larry	LLNL	Earth Scientist	X		X

AUDIT REPORT 88-05
ENCLOSURE 2

<u>NAME</u>	<u>ORGANIZATION</u>	<u>TITLE</u>	<u>PREAUDIT CONFERENCE</u>	<u>DURING AUDIT</u>	<u>POSTAUDIT CONFERENCE</u>
Schwartz, Ronald	LLNL	Mgmt. Analyst	X	X	X
Schwartztrauber, K.	SAIC	QA Engineer	X		
Sedlacek, James	LLNL	Supervisor	X		
SHAW, HENRY	LLNL	Tech. Area Leader	X	X	X
Shettel, Don	State Of NV	Tech. Observer	X		
Short, David	LLNL	Asst. TPO		X	
Silva, Robert	LLNL	Task Leader			X
Sommer, Karl	DOE/OCRWM	QA Engineer	X		X
Shout, Ray	LLNL	Physicist	X	X	X
Smith, David	LLNL	Science Assoc.	X		
Taylor, Allan	LLNL	Science Programer	X		
Tewes, Howard	LLNL	QA Staff	X		
Thatcher, Richard	LLNL	Systems Engineer	X		X
Thompson, Andrea	LLNL	Hydrologist	X	X	
Thompson, Catherine	SAIC	QA Engineer	X		X
Towse, Donald	LLNL	Geologist	X	X	
Uene, Lzeu-Shin	LLNL	Geo. Tech. Engineer	X		X
Ulseth, James	SAIC	QA Engineer	X		X
Valentine, Michael	DOE/YMP	Nat'l. Engineer			X
VanKonynebury, R.	LLNL	Engineer	X	X	X
Voltura, Nancy	DOE/YMP	QA Specialist	X		X
Walden, Pat	LLNL	QA Staff	X	X	X
Watwood, Don	LLNL	Engineer Assoc.	X		
Wilder, Dale	LLNL	Task Leader	X	X	X
Yunker, Leland	LLNL	Geologist	X		X
Zimmerman, Susan	State Of NV	QA Manager	X		X

ENCLOSURE 3

SDRs



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

WBS 1.2.9.3
"QA"

NOV 23 1988

NNI-881123-0099

Carl P. Gertz, Project Manager, YMP, NV

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) STANDARD DEFICIENCY REPORTS (SDRs) RESULTING FROM AUDIT 88-05 OF LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL) SUPPORT OF THE YUCCA MOUNTAIN PROJECT (NNI-1989-0499)

Enclosed are two SDRs, Nos. 229 and 231, which were generated during the course of Project Office QA Audit 88-05 of the LLNL Yucca Mountain Project QA Program Plan and technical activities. Please note that you are required to provide responses to each SDR by completing blocks 14 through 18, as appropriate, on the first page of each SDR. Be advised that the audit checklist references provided on each SDR are for Project Office internal use and should have no bearing on your ability to respond to the cited deficiencies.

A copy of your responses is due back to this office 20 working days from the date of this letter. You are asked to concurrently send the original of each SDR response to Nita J. Brogan of Science Applications International Corporation (SAIC), Las Vegas, Nevada.

If you have any questions, please contact Wendell B. Mansel of my staff at 794-7945 or John C. Friend of SAIC at 794-7164.

James Blaylock

James Blaylock
Project Quality Manager
Yucca Mountain Project Office

YMP:WBM-721

Enclosures:
SDRs 229 and 231

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By M. Mitchell		3b Branch Chief Concurrence Date	
	5 Organization YMP (Project Office)		6 Person(s) Contacted J. Kass/W. Halsey		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item T-108 - T-112) NVO 196-17 Rev. 4., Section 3.0, "Scientific Investigation Control and Design Control" part A., para. 3A.1.5. states in part, "A peer review of the plan					
Completed by Organization in Block 5	9 Deficiency Contrary to the above requirement, SIP 1.2.2.3.2 activity E-20-15 which includes a peer review, was approved by the WMPO on 3 Nov 1987. The WMPO internal procedures for peer review were not provided to LLNL as the					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Determine if other peer reviews have been completed or are in process with out appropriate procedural controls.					
	11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blumford 11/15/88	
	14 Remedial/Investigative Action(s) 15 Effective Date _____					
Completed by Org. QA Org.	16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date _____					
	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
Comp. by Orig. QA Org.	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verifi- cation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks					
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		
				PQM/Date		



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

SDR No. 229

Rev. 0

Page 2 of 2

8 Requirement (continued)

any other project activity including design activities, shall be coordinated among participants in accordance with procedures established by WMPO."

10 Recommended Actions (continued)

2. Determine the interface controls required for Project coordination of scientific investigations
3. Develop and implement procedures to effect the required coordination and control.
4. Provide training for Project Management and Participants management on the procedures developed.



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

WBS 1.2.9.3
"QA"

NOV 23 1988

NN1-881123-0083

Lawrence D. Ramspott
Technical Project Officer for Yucca Mountain Project
Mail Stop L-204
Lawrence Livermore National Laboratory
University of California
P.O. Box 808
Livermore, CA 94550

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) STANDARD DEFICIENCY REPORTS (SDRs) RESULTING FROM AUDIT 88-05 OF LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL) SUPPORT FOR THE YUCCA MOUNTAIN PROJECT (NN1-1989-0503)

Enclosed are 21 SDRs, Nos. 224-247, which were generated during the course of Project Office Audit 88-05 of the LLNL Yucca Mountain Project QA Program Plan and technical activities. SDRs 229, 231 and 236 are not part of this package and will require no actions on your part. Please note that you are required to provide responses to each SDR by completing blocks 14 through 18, as appropriate, on the first page of each SDR. Be advised that the audit checklist references provided on each SDR are for Project Office internal use and should have no bearing on your ability to respond to the cited deficiencies.

A copy of your responses is due back to this office 20 working days from the date of this letter. You are asked to concurrently send the original of each SDR response to Nita J. Brogan of Science Applications International Corporation (SAIC), Las Vegas, Nevada.

If you have any questions, please contact Wendell B. Mansel of my staff at FTS 544-7945 or John C. Friend of SAIC at FTS 544-7164.

James Blaylock
James Blaylock
Project Quality Manager
Yucca Mountain Project Office

YMP:WEM-723

Enclosures:
SDRs 224-247

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During AUDIT 88-05		3a Identified By K. Sommer/N. Frank		3b Branch Chief Concurrence Date	
	4 SDR No. 224		Rev. 0			
	5 Organization LLNL		6 Person(s) Contacted L.C. Lummus		7 Response Due Date is 20 Working Days from Date of Transmittal	
Completed by Originating QA Organization	8 Requirement (Audit Checklist Reference, if Applicable) (Audit Checklist item 2-8, 2-14, 2-15, and 2-16) 033-NWMP-R-21B.0 Rev 0, "Qualification of Personnel" para. 21B.0.4 states in part "PQR's contain They include a position description and a					
	9 Deficiency Contrary to the above requirement, 9 of the 10 PQR's reviewed during the audit did not contain a qualification summary. Also no position descriptions were found for B. Zucca and Murray Day. Additionally, the position descriptions					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Determine if this condition has had an adverse impact on the quality of the work done at LLNL to date.					
	11 QAE/Lead Auditor Date J.C. [Signature] 11/14/88		12 Branch Manager Date H.H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blaylock 11/14/88	
Completed by Organization in Block 5	14 Remedial/Investigative Action(s)					
	15 Effective Date _____					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date _____					
Completed by Org. QA Org.	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Veri- fication <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
Comp. by Orig. QA Org.	22 Remarks					
	23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date	
				PQM/Date		

ENCLOSURE



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

SDR No. 224

Rev. 0

Page 2 of 2

8 Requirement (continued)

qualification summary,"

9 Deficiency (continued)

(PDs) in the Personnel Qualifications Records (PQR's) are not consistent in format or content. Three of the 11 checked did not contain either education or experience minimums. Two of the 11 checked did not have any PD's. One did not have minimum experience or minimum education. The record files for training did not contain the PQR's and evaluations prior to approximately 1/88. When located, during the audit, these records were not contiguous in time from when a person started work on the project. These records need to be placed in the file and notations made to explain the missing records.

10 Recommended Actions (continued)

2. Implement the requirements of NNWSI 88-9, Rev. 1, for PQR's.

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 4
	3 Discovered During Audit 88-05	3a Identified By K. Summer/N. Frank	3b Branch Chief Concurrence Date		4 SDR No. 225 Rev. 0
	5 Organization LLNL	6 Person(s) Contacted L.C. Lummus/G. Kugler		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist Item 2-2,2-3,2-4,2-5,2-6,2-7and 18-12) 033-NWMP-R 21A.0, Rev 0, Training SEE PAGE 2.				
Completed by Organization in Block 5	9 Deficiency Contrary to the requirements of A and B above the requirements of the training program have not been met and the training provided has not been effective in achieving QA program implementation. Specific violations of requirements are				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Develop methods to assure compliance with LLNL YMP QA Program training requirements.				
Completed by Organization in Block 5	11 QAE/Lead Auditor Date J. C. Friend 11/14/88	12 Branch Manager Date H.R. Caldwell NOV 14 1988	13 Project Quality Mgr. Date James Blaylock 11/19/88		
	14 Remedial/Investigative Action(s) 15 Effective Date _____				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date _____				
Comp. by Orig. QA Org.	18 Signature/Date				
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject	QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject	QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verifi- cation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory	QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks				
23 QA CLOSURE		QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date	



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8 Requirement (continued)

A. Para. 21A.0.4.2., "Types of Training" states in part,
"The overall Quality Assurance training program includes the following training activities.

- A brief and general course on the content and implementation of the LLNL-NWMP-Quality Assurance Program Plan (short title: General Course). Participation in this course is mandatory. The need for repetition of this course is evaluated annually.
- Orientation training in quality assurance (short title: Orientation) for new NWMP personnel within 60 days of starting work for the NWMP. This is to be followed up by the General Course within six (6) months after completion of the Orientation training.
- Training specifically tailored to the needs of individuals who manage or perform the work."

B. 21A.0.4.3 "Identification of Training Opportunities" states in part;

The General Course is scheduled and conducted with due regard to other schedule constraints. It may be conducted several times in order to allow attendance by all NWMP personnel. The continued relevance of the course is reviewed annually. The course is changed whenever there are significant revisions to the requirement and procedures and whenever there are significant and consistent QA program problem areas. Each time the course is significantly changed, it is again scheduled and conducted. The Orientation is also reviewed annually and changed when appropriate.

The specifically tailored training activities are identified on a case by case basis. The initial identification is made when an activity is subjected to the requirements of Procedure 033-NWMP-P 20.0, "Assigning Levels of Quality Assurance". It is then that the need is identified for application of specific QA requirements and procedures. The subsequent submissions for review of the implementing procedures may also serve as an indicator for training in a specific area.

The NWMP Project Leaders, any of the Technical Area Leaders or Task Leaders, or any individual who support the NWMP may at any time request specific training activities from the Deputy for QA.

9 Deficiency (continued)



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9 Deficiency (continued)

listed below.

A. The Orientation and the General Course have been combined into one course. There is no retrievable record of when individuals started work on the project. Of those individuals checked during the audit, only one individual had been trained within the 60 day time period. No indication of follow-up training was noted. Significant revisions to the QA program were noted, with no additional training.

There is no method developed to tailor training to the needs of the individuals. Training done by the Task Leaders (TL) is not documented nor is the completion of reading assignments documented. One TL stated that documentation of training was not a high priority.

There was no documentation to show that the Lead Auditors from Kaiser had attended the General Course or had received any specific training in the LLNL audit procedure.

B. There is no set schedule to conduct the General Course, it is held on an as needed basis. There is no documentation of an annual review. There have been three (3) revisions of the course: 1. 5/12/87; 2. 6/30/87; and 3. 9/23/87 with Program personnel not receiving training on the new versions of the course when training was received on the original or earlier version.

There is no positive method of tailoring, predetermining, and designating the training needs of an individual at any time during the project. Training given by the task leaders has not been documented.

Two of four auditors/technical specialists checked did not have records showing their qualifications or training.

There was no record that R. Dann or K. Baumgarten of H. J. Kaiser Engineers had received orientation to the LLNL QA program or specific training in the LLNL audit methods prior to being certified as Lead Auditors. The audit team recognizes that both have participated in and led LLNL internal audits in FY 1988.

10 Recommended Actions (continued)

2. Implement the methods developed.

3. Provide training for all current and future personnel doing work on the NWMP project. Document the training provided.



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10 Recommended Actions (continued)

4. Verify the training provided has been effective.

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3		Page 1 of 2
	3 Discovered During Audit 88-05		3a Identified By C. Thompson	3b Branch Chief Concurrence Date	4 SDR No. 226 Rev. 0
	5 Organization LLNL		6 Person(s) Contacted A. Madson		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist Item 20-5,7 and 11) 033-WMP-P 20.0, Rev 0, "Assigning Levels of Quality Assurance" para. 20.0.5.2.2. states in part: "All procedures written as a result of the meeting				
Completed by Organization in Block 5	9 Deficiency Contrary to the requirements above, procedure numbers are not traceable to the QA Level Assignment Review meeting. No schedule of procedure and procurement documentation was available, to allow the Deputy for QA to perform the				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input type="checkbox"/> Corrective These requirements are not YMP imposed, therefore the corrective actions are left to the discriptions of LLNL.				
	11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. E. Caldwell NMV 14 1988		13 Project Quality Mgr. Date James Blaylock 11/14/88
	14 Remedial/Investigative Action(s) 15 Effective Date _____				
Comp. by Orig. QA Org.	16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date _____				
	18 Signature/Date				
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date
Comp. by Orig. QA Org.	21 Verifi- cation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date
	22 Remarks				
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date	PQM/Date



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8 Requirement (continued)

have numbers assigned to them that are traceable to the meeting". Additionally, it states "The Deputy for QA obtains a schedule from the Task Leader within five (5) working days...The Deputy for QA is responsible for monitoring the progress of the procedure writing and procurement documentation preparation.

Paragraph 20.5.4 states in part "A controlled copy of the entire package is submitted to the appropriate sponsor,..."

9 Deficiency (continued)

required monitoring. Additionally, there was no objective evidence available to verify that a "Controlled Copy" of the entire package was submitted to the YMP Project Office, (Package reviewed include B-20-1 and B-20-2).

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By K. Sommer		3b Branch Chief Concurrence Date	
	5 Organization LLNL		6 Person(s) Contacted A. Madson		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 2-27) 033-NWMP-P2.1, Rev. 0 "Review and Approval of QA Administrative Requirements and Procedure" Para. 2.1.5. states in part "...the second draft is sent out"					
	9 Deficiency Contrary to the above, the transmittal memo covering the review of five (5) procedures, on the second draft, #'s 033-NWMP-P 5.0; 5.1; 5.2; 6.0; and 6.1 did not explain the resolution of the comments from the first draft.					
Completed by Organization in Block 5	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Investigate to determine if other procedures have the same or similar problems.					
	11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blaylock 11/14/88	
	14 Remedial/Investigative Action(s)					
	15 Effective Date _____					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
Comp. by Orig. QA Org.	17 Effective Date _____					
	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verification <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
22 Remarks						
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		
				PQM/Date		



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8 Requirement (continued)

accompanied by a copy of the first draft and a cover letter written by the draft's originator explaining the changes. The cover letter also explains why some comments are not incorporated, if such a situation exists."

9 Deficiency (continued)

10 Recommended Actions (continued)

2. Determine the impact of this procedural violation upon the quality of the scientific investigation activities.
3. Provide remedial action to correct the problems identified.

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Completed by Originating QA Organization
Completed by Organization in Block 5
Comp. by Orig. QA Org.

1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
3 Discovered During Audit 88-05		3a Identified By J.E. Clark		3b Branch Chief Concurrence Date	
4 SDR No. 228		Rev. 0			
5 Organization LLNL		6 Person(s) Contacted W. Glassley, H. Shaw, T. Nelson		7 Response Due Date is 20 Working Days from Date of Transmittal	
8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 3-9) SOP 02-01, Rev 1, (ICN 5/9/86), issued as LLNL interim procedure 033-NWMP-P 3A.0, Section 3A.6.1 states in part, "Interfaces between Participating					
9 Deficiency Contrary to the above requirements, LLNL has not developed procedures to control interfaces between itself and other Participants and itself and its suppliers. Procurement procedures establish practices for assigning and					
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Determine the extent of interface controls required for LLNL subcontracted activities. Modify contractual documents as necessary to provide interface					
11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell 15 Nov 88		13 Project Quality Mgr. Date James Blaylock 11/15/88	
14 Remedial/Investigative Action(s)					
15 Effective Date					
16 Cause of the Condition & Corrective Action to Prevent Recurrence					
17 Effective Date					
18 Signature/Date					
19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
21 Verifi- cation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
22 Remarks					
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date	
				PQM/Date	

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8 Requirement (continued)

Organization and their suppliers shall be controlled in accordance with procedures established by the Participating Organization."

9 Deficiency (continued)

monitoring suppliers work, but they do not specify transmittal controls for data and information.

10 Recommended Actions (continued)

controls.

2. Determine the impact of this procedural violation upon the scientific investigations completed to date, and those in process.

3. Develop and implement interface procedures which satisfy the YMP QA Program requirements.

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By M. Mitchell		3b Branch Chief Concurrence Date	
	4 SDR No. 230		Rev. 0			
	5 Organization LLNL		6 Person(s) Contacted J. Kass		7 Response Due Date is 20 Working Days from Date of Transmittal	
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item add to checklist during audit) NVO 196-17 Rev.4, Section 3.0 part A. "Scientific Investigation Control and Design Control", para 3A.1.5 states in part, "A peer review of the Plan shall					
	9 Deficiency Contrary to the above requirement, SIP 1.2.2.3.2 activity E-20-15 included a peer review to be done in accordance with LLNL procedure P.2.2. This procedure is not a WMPO internal procedure. This peer review was in progress					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Determine if the lack of WMPO procedural control has had an adverse impact on the quality of the peer review process to date.					
	11 QAE/Lead Auditor Date J. C. Friend (P. Friend) 11/14/88		12 Branch Manager Date H. H. Caldwell 15 Nov 98		13 Project Quality Mgr. Date James Blumfeld 11/15/88	
Comp. by Orig. QA Org.	14 Remedial/Investigative Action(s)					
	15 Effective Date _____					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date _____					
18 Signature/Date						
19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject						
20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject						
21 Verification <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory						
22 Remarks						
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		PQM/Date



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8 Requirement (continued)

be
conducted when WMPO deems it necessary. This review is conducted in accordance
with internal WMPO procedures."

9 Deficiency (continued)

as of Oct. 26, 1988.

10 Recommended Actions (continued)

2. Correct any deficiencies in the peer review process that have resulted from the lack of control.
3. Implement peer reviews activities to current QA program requirements.

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By J. A. Olseth		3b Branch Chief Concurrence Date	
	5 Organization LLNL		6 Person(s) Contacted Linda Hanson		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 4-4) 033-NWMP-P 4.0, Rev.0, para. 4.0.5.2, states in part "The procurement documents are stamped with a message that requests the LLNL Procurement					
Completed by Organization in Block 5	9 Deficiency Contrary to the above requirement, objective evidence, of a review of the purchase award documents to assure technical and quality requirements incorporation, was not provided during the audit.					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Investigate to determine if other procurements have occurred without the QA review.					
	11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blaylock 11/14/88	
	14 Remedial/Investigative Action(s) 15 Effective Date _____					
Comp. by Orig. QA Org.	16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date _____					
	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
Comp. by Orig. QA Org.	21 Verification <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks					
Comp. by Orig. QA Org.	23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date	
					PQM/Date	



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8 Requirement (continued)

Department to return to the NWMP QA Records copies of the contract award document that went to the Supplier. This request is to assure that the procurement when awarded, reflects the technical and quality assurance requirements originally defined by the NWMP....The Deputy for QA follows up with the LLNL Procurement Department every 30 days until the requested copies of the purchase award documents are obtained. When the copies are received, they are compared with the original request.

9 Deficiency (continued)

10 Recommended Actions (continued)

2. Implement the requirement for QA review for all past procurements and for all future procurements. Revise purchase documents as necessary.
3. Determine if there has been any adverse impact on the quality of the scientific investigation or design work done under the LLNL purview as a result of this procedural violation.
4. Retrain appropriate LLNL personnel as necessary in accordance with QA requirements. Document this retraining in accordance with the LLNL QAPP.

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By J.E. Clark		3b Branch Chief Concurrence Date	
	4 SDR No. 233		Rev. 0			
	5 Organization LLNL		6 Person(s) Contacted Alan Russell/Ron Oberle		7 Response Due Date is 20 Working Days from Date of Transmittal	
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 5-1) NNWSI QAP NVO 196-17, Rev 4, Section V,1.0 states in part, "All activities affecting quality on the NNWSI Project will be performed utilizing approved					
	9 Deficiency On June 1, 1988, WMPO approved LLNL's QA procedures that comprise the LLNL QAPP. These procedures met the requirements of the NNWSI Project QA Plan, NVO-196-17, Rev 5. As of Oct 25, 1988 the latest approved procedures have					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Initiate control over on going activities in accordance with provisions of the latest approved QAPP.					
	11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blaylock 11/14/88	
Completed by Orig. QA Org.	14 Remedial/Investigative Action(s)					
	15 Effective Date					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date					
Completed by Orig. QA Org.	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verification <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks					
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		PQM/Date



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8 Requirement (continued)

instructions, procedures drawings or other documents."

9 Deficiency (continued)

not been released for use nor implemented. Therefore the work activities performed since June 1, 1988 have not been performed to the latest approved LLNL QA program.

10 Recommended Actions (continued)

2. Determine if adverse impacts have occurred by using the obsolete QAPP on inprocess and completed work under the purview of LLNL.
3. Execute remedial actions as necessary to rectify adverse impacts identified.
4. Perform corrective actions to preclude recurrence of this program violation.

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1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3		Page 1 of 2
3 Discovered During Audit 88-05		3a Identified By M. Cotter	3b Branch Chief Concurrence Date	4 SDR No. 234 Rev. 0
5 Organization LLNL		6 Person(s) Contacted P. Walden/B. Manis		7 Response Due Date is 20 Working Days from Date of Transmittal
8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 6-10 and 6-3) NNWSI-SOP-0201. Rev 1, section 6.0 "Document Control", para. 6.1.1 states in part "...measures shall be established to control the preparation and issuance				
9 Deficiency Contrary to the above requirement, LLNL uses two documents, an Interim Change Notice (ICN) and an Instructional Memorandum to make changes to the QAPP. The use of these documents is not defined in the QAPP. Additionally, when				
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input type="checkbox"/> Corrective 1. Develop and implement controls for the use of the ICN and Instructional memorandum.				

Aprvl.

11 QAE/Lead Auditor Date J. C. Friend 11/14/88	12 Branch Manager Date H. B. Caldwell NOV 14 1988	13 Project Quality Mgr. Date James Blaylock 11/14/88
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Completed by Organization in Block 5

14 Remedial/Investigative Action(s)		15 Effective Date
16 Cause of the Condition & Corrective Action to Prevent Recurrence		17 Effective Date
18 Signature/Date		

Comp. by Orig. QA Org.

19 Response	<input type="checkbox"/> Accept <input type="checkbox"/> Reject	<input type="checkbox"/> Amended <input type="checkbox"/> Response	QAE/Lead Auditor/Date	Branch Manager/Date
20 Amended Response	<input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	<input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date	Branch Manager/Date
22 Remarks				
23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date	



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8 Requirement (continued)

of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality."

9 Deficiency (continued)

these documents are issued neither the QAPP Table of Contents nor the Document Control Master Index reflects the addition of these documents.

10 Recommended Actions (continued)

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By M. Cotter		3b Branch Chief Concurrence Date	
	4 SDR No. 235		Rev. 0			
	5 Organization LLNL		6 Person(s) Contacted B. Manis/P. Walden/B. Alegre		7 Response Due Date is 20 Working Days from Date of Transmittal	
Completed by Originating QA Organization	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 6-8) 033NWMP-P-6.1, Rev 1, "Issue of Controlled Documents" para. 6.1.5.1, states in part, "Computer files are established that list all documents by version"					
	9 Deficiency Contrary to the above requirements, computer files used for document control have not been up dated since Jan 29, 1988.					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Determine if this procedural violation has had any adverse impact on the past or current scientific investigation and design activities.					
Completed by Organization in Block 5	11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blyford 11/14/88	
	14 Remedial/Investigative Action(s)					
	15 Effective Date					
Completed by Organization in Block 5	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date					
	18 Signature/Date					
Comp. by Orig. QA Org.	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Veri- fication <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks					
	23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date	
PQM/Date						

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8 Requirement (continued)

numbers and which individuals received a copy.

10 Recommended Actions (continued)

2. Provide remedial actions to correct the specific problems noted during the investigation to determine adverse impact.
3. Develop corrective actions to prevent recurrence of this problem
4. Provide training to LLNL personnel as needed, in accordance with the LLNL QAPP requirements.

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By M. Cotter		3b Branch Chief Concurrence Date	
	4 SDR No. 237		Rev. 0			
	5 Organization LLNL		6 Person(s) Contacted B. Manis/P. Walden/B. Alegre		7 Response Due Date is 20 Working Days from Date of Transmittal	
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 6-12) 033NWP-P-6.1 Rev. 1, "ISSUE OF CONTROLLED DOCUMENTS" para. 6.1.5.2. states in part "Anyone receiving a controlled document may request to be removed from					
	9 Deficiency Contrary to the above requirements, there was no evidence provided during the audit to document the definition of who the Key Reviewers were. The document control staff did not know who the Key Reviewers were. There was no evidence					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Determine if these procedural violations have had an adverse impact on the scientific investigation and design work done to date.					
	11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blaylock 11/14/88	
Completed by Orig. QA Org.	14 Remedial/Investigative Action(s)					
	15 Effective Date					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date					
Comp. by Orig. QA Org.	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verification <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks					
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		PQM/Date



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8 Requirement (continued)

distribution with the Key Reviewers approval. Paragraph 6.1.5.2 states in part, "A Request for Collection of Documentation form (Figure 6.1.3) is sent to the individual removed from distribution, requesting return of the document and any quality assurance records that have been created by the use of the controlled document. A copy of the form is kept in the documents file and the distribution log is updated." Paragraph 6.1.5.4 states in part, "Once a Major Change has been reviewed and approved ... the Deputy for QA sends a "Request for Collection of Documentation " Form to all the current holders of the document. Copies of the Forms sent are kept in the documents folder and the distribuiton log is updated.

9 Deficiency (continued)

of the Key Reviewer approving the request for removal of copy holders from distribution. There is no documented evidence of the "Request for Collection of Documentation" Form being sent to individuals removed from distribution. There is no documented evidence of the Deputy for QA sending a "Request for Collection of Documentation" Form to copy holders of superseded documents.

10 Recommended Actions (continued)

2. Correct the specific problems identified during the LLNL investigation to determine impact.
3. Develop and implement method of document control which are compliant with YMP QAP requirements.
4. Provide training to LLNL personnel as necessary. Document the training in accordance with the LLNL QA program.

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Completed by Originating QA Organization
Completed by Organization in Block 5
Comp. by Orig. QA Org.

1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
3 Discovered During Audit 88-05		3a Identified By J.A. Cliseth		3b Branch Chief Concurrence Date	
5 Organization LLNL		6 Person(s) Contacted John Dronkers		4 SDR No. 238 Rev. 0	
7 Response Due Date is 20 Working Days from Date of Transmittal					
8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 7-2) NNWSI-SOP-02-01, Rev 1, section 7.2.2., states in part "that measures for evaluation and selection of procurement sources and the results thereof,					
9 Deficiency Contrary to the above requirement, no documentation of the bid evaluations and selection of procurement source results were available during the audit. Evidence of exception to this requirement was not provided during the audit.					
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Determine if this violation of requirement has had an adverse impact on the scientific investigation and design work done under the purview of LLNL.					
11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blaylock 11/19/88	
14 Remedial/Investigative Action(s)					
15 Effective Date					
16 Cause of the Condition & Corrective Action to Prevent Recurrence					
17 Effective Date					
18 Signature/Date					
19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
21 Verification <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
22 Remarks					
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date	
PQM/Date					



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8 Requirement (continued)

are documented.

9 Deficiency (continued)

10 Recommended Actions (continued)

2. Develop and implement a method of complying with YMP QA Program requirement for procurement activities.
3. Perform remedial action for the affected contracts or purchase award documents.

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By C. M. Thompson		3b Branch Chief Concurrence Date	
	5 Organization LLNL		6 Person(s) Contacted R. Oberle		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (Audit check-list item 15-7) NNWSI SOP-02-01, Rev 1, para. 15.2.3.4. states in part, "...final disposition of non-conformances such as use-as-is, reject, repair and rework to be					
Completed by Organization in Block 5	9 Deficiency Contrary to the above requirement, LLNL procedure 033-NWMP-P 15.01, Rev. 0, "Non-conformances", does not require the distinct use of the specific repair and use-as-is terminology, thereby making the need for WMPO approval subject					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input type="checkbox"/> Corrective 1. Determine if this procedural violation has had an adverse impact on the scientific investigation and design work done.					
	11 QAE/Lead Auditor Date J.C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell 11/14/88		13 Project Quality Mgr. Date James Blaylock 11/14/88	
	14 Remedial/Investigative Action(s) 15 Effective Date _____					
Completed by Organization in Block 5	16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date _____					
	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject					
Comp. by Orig. QA Org.	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verification <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks					
	23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date	
				PQM/Date		



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8 Requirement (continued)

documented". Paragraph 15.3 further states "Nonconformances for QA level I and II activities ... shall have WMPO approval before disposition is implemented when the disposition involves repair or use-as-is".

9 Deficiency (continued)

to interpretation.

10 Recommended Actions (continued)

2. Perform remedial actions to assure the YMP Project Office has approved all non-conformance reports as required.

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By C.M. Thompson		3b Branch Chief Concurrence Date	
	5 Organization LLNL		6 Person(s) Contacted R. Oberle		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 15-14) NVO 196-17, Rev. 4, states in part, "Each of the participating organizations..."					
Completed by Organization in Block 5	9 Deficiency Contrary to the above requirement, LLNL procedure 033-NWMP-15.0, Rev. 0, does not provide a method for revising non-conformance reports. In one case, NCR 11, the original disposition was revised but not approved in the same					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input type="checkbox"/> Corrective 1. Determine if this program violation has had an adverse impact on the quality of the scientific investigations and design work done.					
	11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. E. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blaylock 11/19/88	
	14 Remedial/Investigative Action(s) 15 Effective Date _____					
Completed by Orig. QA Org.	16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date _____					
	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject QAE/Lead Auditor/Date Branch Manager/Date					
Comp. by Orig. QA Org.	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject QAE/Lead Auditor/Date Branch Manager/Date					
	21 Verifi- cation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory QAE/Lead Auditor/Date Branch Manager/Date					
	22 Remarks					
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		PQM/Date



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8 Requirement (continued)

shall have written procedures for activities affecting quality" and that changes are reviewed and approved by the same organization that performed the original review and approval.

9 Deficiency (continued)

manner as the original disposition.

10 Recommended Actions (continued)

2. Provide remedial action to correct the specific problem noted.

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By C.M. Thompson		3b Branch Chief Concurrence Date	
	4 SDR No. 241		Rev. 0			
	5 Organization LLNL		6 Person(s) Contacted R. Oberle/R. Schwartz		7 Response Due Date is 20 Working Days from Date of Transmittal	
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist Section 16 all items) 033-NWMP-P 16.0 Rev. 0, Para. 16.0.1 states in part, "This procedure describes the controls necessary for the documentation, reporting, and implementation of					
	9 Deficiency Contrary to the above requirement, an effective Corrective Action System has not been implemented at LLNL. Conditions adverse to quality have not been corrected in an effective or timely manner. Examples of ineffective					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Determine the impact of this programmatic failure on the scientific investigation and design work performed under the purview of LLNL.					
	11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell 11/15/88		13 Project Quality Mgr. Date James Blanford 11/15/88	
Completed by Organization in Block 5	14 Remedial/Investigative Action(s)					
	15 Effective Date _____					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
Comp. by Orig. QA Org.	17 Effective Date _____					
	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verification <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
Comp. by Orig. QA Org.	22 Remarks					
	23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date PQM/Date	



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8 Requirement (continued)

corrective action for conditions adverse to quality."

9 Deficiency (continued)

corrective action noted during the audit include:

1. Observation No.4 from Project Office Audit 87-3 identified the need to increase efforts in the training area. Training was also reported by LLNL Management Assessment in 1987 as not being implemented. As of the date of this audit training is not implemented or if implemented is in-effective.
2. SDR's 38 and 90 from WMPO surveillance numbers 87-1 and 88-002 respectively identified the lack of an effective Calibration program established at LLNL. As of the date of this audit, LLNL still has not implemented a Calibration program.
3. As noted in SDR 245, of this audit, the LLNL internal audit program failed to follow up on conditions adverse to quality on at least two (2) occasions. This lack of follow-up is indicative of an ineffective corrective action program.

10 Recommended Actions (continued)

2. Implement a corrective action program which will identify, document and correct conditions adverse to quality in accordance with the YMP QA Program requirements.
3. Perform training for LLNL personnel as necessary, in accordance with the LLNL QAPP.

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Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By K. Schwartztrauber		3b Branch Chief Concurrence Date	
	4 SDR No. 242		Rev. 0			
	5 Organization LLNL		6 Person(s) Contacted B. Manis/R. Aines/N. Cummins		7 Response Due Date is 20 Working Days from Date of Transmittal	
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item T-227) LLNL requirement 033-NWMP-R-19.0, "SOFTWARE QUALITY ASSURANCE", Rev. 0, Section 19.05 defines the software quality assurance records to be generated,					
	9 Deficiency Contrary to the above requirements, software QA records generated by the Geochemical modeling (EQ3/6) activities could not be retrieved from the LLNL Records Managemnet System. The documents which were requested, i.e., file					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective See Audit 88-05 SDR 246 on the LLNL Records Management System for the appropriate corrective actions.					
	11 QAE/Lead Auditor Date J. C. Freind 11/14/88		12 Branch Manager Date H. H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James B. Baylock 11/15/88	
Comp. by Orig. QA Org.	14 Remedial/Investigative Action(s)					
	15 Effective Date					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date					
Comp. by Orig. QA Org.	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verifi- cation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks					
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		PQM/Date



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8 Requirement (continued)

collected, stored and maintained in accordance with LLNL procedure
033-NWMP-P-17.0.

9 Deficiency (continued)

folders, NCR's, publications and procurement documents.

10 Recommended Actions (continued)

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Completed by Originating QA Organization in Block 5 Aprvl. 5
Completed by Organization in Block 5
Comp. by Orig. QA Org.

1 Date Nov 7, 1988		2 Severity Level <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
3 Discovered During Audit 88-05		3a Identified By K. Sommer/N. Frank	3b Branch Chief Concurrence Date	4 SDR No. 243 Rev. 0
5 Organization LLNL		6 Person(s) Contacted R. Overle		7 Response Due Date is 20 Working Days from Date of Transmittal
8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 18-2 and 18-3) NVO-196-17, Rev 4, para. 18.3.1, states in part, "Each Participating Organization and				
9 Deficiency Contrary to the above requirement, LLNL does not conduct independent audits of PNL and ANL. LLNL had a representative which acted as a Sub-team Lead on a DOE/RL audit of PNL and as an Observer on an ANL internal audit. This				
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Develop and implement a method to perform independents audits of the QA programs at PNL and ANL. These audits must assure the implementation of YMP				
11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blaylock 11/15/88
14 Remedial/Investigative Action(s)				15 Effective Date
16 Cause of the Condition & Corrective Action to Prevent Recurrence				17 Effective Date
18 Signature/Date				
19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended <input type="checkbox"/> Reject Response		QAE/Lead Auditor/Date		Branch Manager/Date
20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date
21 Verifi- cation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date
22 Remarks				
23 QA CLOSURE	QAE/Lead Auditor/Date		Branch Manager/Date	PQM/Date



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8 Requirement (continued)

NTS Support Contractor shall conduct ... external (direct subcontractor) audits of activities under its direct control."

9 Deficiency (continued)

participation does not fulfill the stated YMP requirement for external audits.

10 Recommended Actions (continued)

QA Plan requirements which have been passed on to ANL and PNL by LLNL.

2. Determine if this programmatic violation has had an adverse impact on the scientific investigation and design work done to date.

3. Perform training as needed. Document the training in accordance with the LLNL QAPP.

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Completed by Orig. QA Org.	1 Date November 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3		Page 1 of 2		
	3 Discovered During Audit 88-05-01		3a Identified By K. Sommer/N. Frank		3b Branch Chief Concurrence Date		
	4 SDR No. 244		Rev. 0				
	5 Organization LLNL		6 Person(s) Contacted R. Oberle		7 Response Due Date is 20 Working Days from Date of Transmittal		
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) (Audit Checklist Question 18-14) NNWSI-SOP-02-01, Rev. 1, Appendix D, Section 2.1, states in part: "The responsible auditing organization shall establish ... the requirements						
	9 Deficiency LLNL procedure 033-NWMP-P 18.0, does not mention the use of technical specialists. At least two people were used in a technical capacity on audits 88-9 and 88-16.						
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1.) Document and implement the requirements for use of technical specialist on audits.						
	11 QAE/Lead Auditor Date <i>11/14/88</i>		12 Branch Manager Date <i>11/14/88</i>		13 Project Quality Mgr. Date <i>11/19/88</i>		
Completed by Orig. QA Org.	14 Remedial/Investigative Action(s)						
	15 Effective Date _____						
	16 Cause of the Condition & Corrective Action to Prevent Recurrence						
	17 Effective Date _____						
Comp. by Orig. QA Org.	18 Signature/Date						
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date		
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date		
	21 Verification <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date		
	22 Remarks						
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		PQM/Date	



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8 Requirement (continued)

for the use of technical specialist

10 Recommended Actions (continued)

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Completed by Orig. QA Org.	1 Date November 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05-01		3a Identified By K. Sommer/N. Frank		3b Branch Chief Concurrence Date	
	5 Organization LLNL		6 Person(s) Contacted R. Oberle		4 SDR No. 245 Rev. 0	
	7 Response Due Date is 20 Working Days from Date of Transmittal					
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) (Audit Checklist Questions 18-7 and 18-20), 033-NWMP-P-18.0, Rev. 2. Sections listed below: (1) 18.0.4.7 - Which states in part: "The results of an audit are included					
	9 Deficiency (1) Three of three audit reports by LLNL that were reviewed do not contain a statement concerning effectiveness.					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1.) Implement program requirements and include in all future audits.					
	11 QAE/Lead Auditor Date <i>J. Aron</i> 11/14/88		12 Branch Manager Date <i>R. Oberle</i> NOV 14 1988		13 Project Quality Mgr. Date <i>James Blaylock</i> 11/14/88	
Comp. by Orig. QA Org.	14 Remedial/Investigative Action(s)					
	15 Effective Date _____					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date _____					
18 Signature/Date						
19 Response		<input type="checkbox"/> Accept <input type="checkbox"/> Reject	<input type="checkbox"/> Amended Response	QAE/Lead Auditor/Date		Branch Manager/Date
20 Amended Response		<input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date
21 Verifi- cation		<input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date
22 Remarks						
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		PQM/Date



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8 Requirement (continued)

in the audit report, which contains the following information;
...a statement concerning the effectiveness of the
implementation of the QA elements that were audited...."

- (2) 18.0.4.9 - States: "Follow up actions to verify the effectiveness of the corrective actions is included in the scope of the subsequent audit of the task or subtask."

9 Deficiency (continued)

- (2) Neither audit 88-9 nor 88-12 contained checklist items to verify the effectiveness of the corrective actions to the FY87 audit of Geochemical Modeling EQ3/6. Fourty (40) findings resulted from the 87 audit and many of these were still open at the time of the follow up audit in 88.

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Completed by Originating QA Organization	1 Date November 7, 1988		2 Severity Level <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 8	
	3 Discovered During Audit 88-05-01		3a Identified By M. Cotter		3b Branch Chief Concurrence Date	
	4 SDR No. 246		Rev. 0			
	5 Organization LLNL		6 Person(s) Contacted B. Manis/P. Walden		7 Response Due Date is 20 Working Days from Date of Transmittal	
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Items No. 17-3, 17-4, 17-5, 17-6, 17-9, 17-10, 17-12, 17-14, 17-15, 17-18, 17-19) NNWSI-QAP-NVO-196-17, Rev. 4, Para. 17.6 states in part, "Participating					
	9 Deficiency Contrary to the above requirement, the Records Management System documented in the LLNL QAPP 033-NWMP-P 17.0, 17.1, 17.2, 17.3, 17.4, 17.5, 17.6, 17.7, 17.9, are not effective. The following examples indicate the specific problem:					
	10 Recommended Action(s): <input type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input type="checkbox"/> Corrective 1.) Investigate to determine the extent of Records Management System deficiencies.					
	11 QAE/Lead Auditor Date <i>[Signature]</i> 11/14/88		12 Branch Manager Date <i>[Signature]</i> NOV 14 1988		13 Project Quality Mgr. Date <i>[Signature]</i> 11/15/88	
Comp. by Orig. QA Org.	14 Remedial/Investigative Action(s)					
	15 Effective Date _____					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date _____					
Comp. by Orig. QA Org.	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verifi- cation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks					
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		
				PQM/Date		



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

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8 Requirement (continued)

Organizations and NTS Support Contractors will define their individual Records Management System in their QAPPs. Records control requirements will include a method for record identification, content, verification for completeness, and necessary approval. A method for the interim storage of the records, during the period prior to the transfer to permanent storage, and a description of the equipment and facilities to be used will be included in the QAPP or an appropriate implementing procedure.

9 Deficiency (continued)

1. Procedures used - 033-NNWSI-P 17.0,
033-NWMP-P 17.1

Condition

Procedures do not adequately define a method to determine if records are legible, identifiable, accurate, complete, reproducible, and microfilmable. Records management staff state that there is no way for them to determine or review for requirements such as identity, accuracy or completeness. The system for insuring the legibility of documents is not defined by procedure and the staff is not completing the activity effectively, (see listed objective evidence). The Task Leaders do not ensure this nor do they have procedures that requires them to ensure this activity. Due to procedure and system inadequacy, there is also no order to records submitted to the Records Center. Several copies of each record may be submitted and processed within a package, (see LL 104395).

Records Reviewed

LL 105182
LL 105142
LL 105183
LL 1004711
LL 100472
LL 103367
LL 103371
LL 104593
LL 104395

2. Procedure Used - 033-NWMP-P 17.1

Condition



WMPO STANDARD DEFICIENCY REPORT CONTINUATION SHEET

N-QA-038
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9 Deficiency (continued)

Procedure defines the use of a "Best Available Copy" form to be used for records identified as not legible or adequate for the production of a clean microfilm copy. However, the form is not being used for records identified as not legible or adequate. There is no documented evidence of LLNL attempting to get a more acceptable copy or of following their record rejection procedure. The log to track rejected records has no entries. See objective evidence of sampling for such copies. Holmes and Narver (H&N) (the microfilming contractor) stamped the records "Best Available Copy" during their processing of the record.

Records Reviewed

LL 10472
LL 103367
LL 103371
LL 104593
LL 105128
LL 105142
LL 105183
LL 104673
LL 104605

3. Procedures Used - 033-NNWSI-P 17.0,
033-NWMP-P 17.3,

Condition

- A. Procedures identify that the originals of records are filed in T 1478, Room 164. Other procedures conflict with this statement and requires record originals to be filed in Room 172. However, during the audit it was discovered that there were no records in the records center which is in T-1478 Room 172 due to the fact that all records reviewed had been transmitted for microfilming on 10/18/88. Further investigation showed that procedure NNWSI-SOP-17-01, Para. 5.4.4, requires QA records to be collected as soon as possible after records completion, not to exceed 30 days. It is also evident that numerous completed records exist in task leaders files that have not been submitted to the records center, (see Objective Evidence).

Records Reviewed - A

PO B050359
PO B049220
SANL 610-008
SANL 622-010



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

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9 Deficiency (continued)

SANL 622-028

SANL 516-004

3. Procedures Used - 033-NNWSI-P 17.0,
033-NWMP-17.3,

Condition

- B. Procedure identifies that dual copies are stored in Bldg. 417 but recently the copies were moved to trailer 1453. The copies are not stored in 1 hour fire rated cabinets. Access to the files are not controlled. There is no access list, the cabinet is left unlocked during the day and is located in an open area. The filing cabinet storing the dual records is shared by other personnel for storing their records (such as training records). When retrieving the copies from the dual storage, it was discovered that records LL 105036 through LL 105089 were missing and could not be retrieved.

Records Reviewed - B

LL 105036 through LL 105089

10 Recommended Actions (continued)

- 2.) Determine if this programmatic violation has had an adverse impact on project work done to date under the purview of LLNL.
- 3.) Provide corrective actions to assure Yucca Mountain Project requirements are satisfied
- 4.) Train personnel in accordance with the YMP QAPP requirements.
- 5.) Implement a Records Management System which meets the requirements of the YMP QA Plan, NNWAI 88-9.



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
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9 Deficiency (continued)

3. Procedures Used - 033-NNWSI-P 17.0,
033-NWMP-P 17.3,

- C. Procedure identifies P. Walden and B. Zucca as the only people having keys to the record files for the record center and dual storage. During investigation, it was learned that B. Zucca is no longer working in the records management area and has not been removed from the procedure. It was also identified that B. Morris, J. Dronkers, J. Clark, and B. Alegre, had keys to the filing cabinets and are not identified in the procedure.



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

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Rev. 0

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9 Deficiency (continued)

4. Procedures Used - 033-NNWSI-P 17.5,

Condition

Procedure for film verification is not adequate. Procedure does not state how verification is accomplished or given a method to verify film effectively. Procedure does state all records are verified but staff (P. Walden) stated that only 5% was required. 5% is not defined as a requirement in any of the procedures.

5. Procedures Used - 033-NWMP-P 17.3,
033-NNWSI-P 17.0,

Condition

Procedure requires that one-of-a-kind records be identified and indexed. The records management staff stated that when one-of-a-kind records are received they send them back to the Task Leader. They have no means of accepting or maintaining these type of records. B. Manis stated that these records are stored in an excluded area (Bldg. 241, Room 1855). Records Management Procedure continually references 033-NWMP-P 17.8, storage of one-of-a-kind items, however, the procedure has never been written.

6. Procedures Used - NNWSI-SOP-17-01, Rev. 0

Condition

Procedure requires protection of QA records during processing cycle to prevent damage to records from hazards such as fire. The record center or dual storage area is not protected from fire by a fire alarm or sprinkler system or fire rated cabinets/safe. Additionally, the two facilities are separated by two buildings and are not located sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard as required by NQA-1 requirements for dual storage.



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
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9 Deficiency (continued)

Procedures Used - NNWSI-SOP-17-01, Rev. 0

Objective Evidence

Interview With - B. Manis

7. Procedures Used - NNWSI-SOP-17-01, Rev. 0

Condition

Procedure requires the development and maintenance of a QA document type list. This list can be used to identify records to be generated and retained. However, there is no procedure to develop or maintain this activity. Records staff stated that this was SAICs responsibility. Although SAIC maintains a master list for all participants, the responsibility to identify records generated remains with the participant.

Objective Evidence

Viewed master type list - LLNL had not completed a "type" list.



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

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Rev. 0

Page 8 of 8

9 Deficiency (continued)

8. Procedures Used - 033-NWMP-P 17.6,

Condition

A sampling of 12 records were chosen to verify retrievability of records in the records management system. The records listed under objective evidence were not retrievable. The ability to review records was extremely slow or not possible which limited the process of viewing records and taking a larger sampling.

Records Reviewed

NCR No. 16, NCR No. 14

LL 105039

LL 105043

Document Control, Transmittal and Review Records for 033-NWMP-P 6.0, Rev 1.

033-NWMP-R 21A.0

033-NWMP-R 19.0

033-NWMP-R 9.0

033-NWMP-P 5.0

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By K. Schwartztrauber		3b Branch Chief Concurrence Date	
	4 SDR No. 247		Rev. 0			
	5 Organization LLNL		6 Person(s) Contacted R. Aines/K. Jackson/K. Chubb		7 Response Due Date is 20 Working Days from Date of Transmittal	
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item T-236) 033-NWMP-R-19.1 Rev 0, Section 8.5, requires that a procedure or procedures be written to assure that the EQ3/6 code be documented in accordance with NUREG					
	9 Deficiency Contrary to the above requirement, LLNL procedure 033-NWMP-P19.5, P19.6 and the other 19.X series procedures do not contain documentation requirements consistent with NUREG-0856. The specific documentation requirements omitted					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Modify LLNL procedures to include the documentation requirements of NUREG 0856.					
	11 QAE/Lead Auditor - Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell NOV 14 1988		13 Project Quality Mgr. Date James Blaylock 11/15/88	
Completed by Orig. QA Org.	14 Remedial/Investigative Action(s)					
	15 Effective Date					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date					
Completed by Orig. QA Org.	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verifi- cation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks					
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		PQM/Date



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

SDR No. 247

Rev. 0

Page 2 of 2

8 Requirement (continued)

0856 and NNWSI-SOP-03-02.

9 Deficiency (continued)

from LLNL procedures include;

1. Software summary forms completion and submittal.
2. Descriptions of mathematical models and numerical methods.
3. Detailed information required in user manual documentation.
4. Descriptions of all work related to model review, code verification, validation, maintenance and listings of current and new versions as they are released.

10 Recommended Actions (continued)

2. Determine whether the existing documentation of EQ3/6 codes (e.g. UCRL-53414 and UCRL-53841) and changes to EQ3/6 are in accordance with NUREG-0856.
3. Update current documentation, as appropriate, to reflect documentation consistent with NUREG-0856.
4. Determine if this programmatic violation has had an adverse impact on the quality of the completed scientific investigation activities.

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization	1 Date Nov 7, 1988		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
	3 Discovered During Audit 88-05		3a Identified By J. E. Clark		3b Branch Chief Concurrence Date	
	4 SDR No. 229		Rev. 0			
	5 Organization YMP (Project Office)		6 Person(s) Contacted W. Glassley, H. Shaw, N. Voltura		7 Response Due Date is 20 Working Days from Date of Transmittal	
Completed by Organization in Block 5	8 Requirement (Audit Checklist Reference, if Applicable) (Audit checklist item 3-9) SOP-02-01 Rev 1, ICN 5/9/86 Section 3A.6.1 states in part "Interfaces between scientific investigations, or between a scientific investigation and					
	9 Deficiency Contrary to the above requirement, the YMP (Project Office) has not established procedures for coordinating interfaces among participants, except for design of the ESF.					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Determine the impact of this procedural violation upon the scientific investigations completed and those in-process for the Yucca Mountain Project.					
	11 QAE/Lead Auditor Date J. C. Friend 11/14/88		12 Branch Manager Date H. H. Caldwell 11/14/88		13 Project Quality Mgr. Date James Blaylock 11/14/88	
Completed by Org. QA Org.	14 Remedial/Investigative Action(s)					
	15 Effective Date					
	16 Cause of the Condition & Corrective Action to Prevent Recurrence					
	17 Effective Date					
Comp. by Orig. QA Org.	18 Signature/Date					
	19 Response <input type="checkbox"/> Accept <input type="checkbox"/> Amended Response <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	20 Amended Response <input type="checkbox"/> Accept <input type="checkbox"/> Reject		QAE/Lead Auditor/Date		Branch Manager/Date	
	21 Verifi- cation <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unsatisfactory		QAE/Lead Auditor/Date		Branch Manager/Date	
	22 Remarks					
23 QA CLOSURE		QAE/Lead Auditor/Date		Branch Manager/Date		
				PQM/Date		



WMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
10/86

SDR No. 231

Rev. 0

Page 2 of 2

8 Requirement (continued)

shall

be conducted when the WMPO deems it necessary. This review is conducted in accordance with internal WMPO procedures."

9 Deficiency (continued)

control for the peer review process. Approval of the referenced SIP did not constitute a WMPO internal procedure. As of the date of the audit the peer review was in process at LLNL and no WMPO procedural controls are in place.

10 Recommended Actions (continued)

2. If others exist determine if the lack of YMP procedural controls has had an adverse impact on the quality of the peer reviews performed to date on the project.
3. Implement peer review activities to current QA program requirements.

ENCLOSURE 4
OBSERVATIONS

WMPO OBSERVATION NO. 88-05-01

N-QA-012
8/88

Noted During:

QA Audit 88-05

Identified By:

J. E. Clark

Date:

10/26/88

Organization:

Lawrence Livermore
National Laboratory

Person(s) Contacted:

A. Russell, R. Oberle

Response Due Date is
20 Days from Date of
Transmittal

Discussion:

LLNL QAPP Procedure 033-NWMP-P 5.1, Section 5.1.5.1 states in part: "Technical procedures prescribing activities that affect quality include the necessary criteria or provisions to allow an independent determination that the activities have been satisfactorily accomplished." This requirement is not reflected in Section 5.1.5.2 of the same procedure where minimum contents of a Technical Procedure are specified. Procedure 033-NWMP-P 13.1 which governs a Level I activity, addresses the requirement but the accept/reject criteria are not specific enough to determine satisfactory performance of the sample collection activity.

QAE/Lead Auditor

Date

11/16/88

Branch Manager

Date

NOV 16 1988

Response:

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

WMPO OBSERVATION NO. 88-05-02

N-QA-012
8/88

Completed By Originating QA Organization

Noted During: QA Audit 88-05	Identified By: K. Sommer/N. Frank	Date: 10/28/88
Organization: Lawrence Livermore National Laboratory	Person(s) Contacted: L. C. Lummus	Response Due Date is 20 Days from Date of Transmittal

Discussion:

There is no table or data base to, 1) identify who needs what type of training, including technical/specific training, 2) who has received the required training, or 3) who is delinquent in required training. Use of such a data base tracking method would help with both assuring the required training is performed and in providing records of the training. (Audit Checklist Question 2-10)

QAE/Lead Auditor <i>[Signature]</i>	Date 12/7/88	Branch Manager <i>[Signature]</i>	Date Dec 98
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Completed By Responses

Response:

Signature:	Date:
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Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date
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Completed By QA Org.

Remarks:

WMPO OBSERVATION NO. 88-05-03

N-QA-012
8/88

Noted During:

QA Audit 88-05

Identified By:

J. A. Ulseth

Date:

10/27/88

Organization:

Lawrence Livermore
National LaboratoryPerson(s) Contacted: J. Drönkers/
R. Schwartz/J. ClarkResponse Due Date is
20 Days from Date of
Transmittal

Discussion:

Audit Checklist Question 4-8
MNWSI-196-17, Rev. 4, Section 4.4 states, "Participating organizations and NTS support contractors shall forward a copy of all procurement documents, as issued, to the WMPO when the purchase involves Quality Assurance Level I items."

QAE/Lead Auditor

Date

12/7/88

Branch Manager

Date

Response:

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

Observation No. 3 (cont'd)

LLNL Procedure 033-NWMP-P-4.0, Rev. 0 Section 4.0.5.2, last Para. states, "Copies of all procurement documents that support a Quality Assurance Level I activity are sent by the Deputy for QA to the WMPO for review, after the procurement document control process is complete." The Yucca Mountain Project Office (Project Office) considers that the term "as issued" in the requirement as meaning that the procurement documents are to be sent to the Project Office prior to the initiation of the procured activity. LLNL's interpretation of the requirement is to send the procurement document package after the procured activity is complete. This must be done also, but the Project Office needs to review the purchase award documents prior to the initiation of the procured activity.

WMPO OBSERVATION NO. 88-05-04

N-QA-012
8/88

Completed By Originating QA Organization

Noted During:

QA Audit 88-05

Identified By:

J. E. Clark

Date:

10/27/88

Organization:

Lawrence Livermore
National Laboratory

Person(s) Contacted:

W. Manis/
P. Walden/B. Allegie

Response Due Date is

20 Days from Date of
Transmittal

Discussion:

Objective evidence of technical procedure reviews are not included as QA records. Although marked-up copies reflecting comment resolutions are available, the original comments/concerns are not. The perspective of the reviewer cannot be evaluated, nor is the reviewer identity traceable. The review process should emphasize retaining the comments and the resulting resolutions as QA records, in addition to tracing the identity and acceptance of the reviewer. The review process should also include a QA review with appropriate criteria established for that review.

QAE/Lead Auditor

Date

12/7/88

Branch Manager

Date

7 Dec 88

Completed By Responses

Response:

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Completed By QA Org.

Remarks:

WMPO OBSERVATION NO. 88-05-05

H-QA-012

6/88

Noted During:
QA AUDIT 88-05Identified By:
M. CotterDate:
10/28/88Organization:
Lawrence Livermore
National LaboratoryPerson(s) Contacted:
B. Manis/P. WaldenResponse Due Date is
20 Days from Date of
Transmittal

Discussion:

WMPO Audit Report 87-3, Observation 5, states, "There is no way to determine the effective date of the procedures in the LLNL QAPP. Neither the procedures themselves nor the Table of Contents contain the effective date. The preparation date is used in the Table of Contents. This date may be significantly earlier than the actual effective date. It is therefore not clear when implementation should have occurred. An "effective date" should be clearly evident on the LLNL procedures. This will also prevent the inadvertent use of procedures prior to final approval." LLNL implemented the following method of issuing effective dates on controlled documents.

QAE/Lead Auditor

Date

11/16/88

Branch Manager

Date

NOV 16 1988

Response:

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

Observation No.5 (cont'd)

1. An effective date is stamped on each procedure when a person requests that procedure.
2. The effective date reflects the date the procedure was transmitted to the requester.

Procedures have not been revised to incorporate the method of issuing the effective date. Additionally, training of applicable personnel should be completed prior to the effective date of the procedure.

WMPO OBSERVATION NO. 88-05-06
**NQA-012
8/88**

Completed by Originating QA Organization

Noted During:
QA Audit 88-05

Identified By:
M. Cotter

Date:
10/26/88

Organization:
Lawrence Livermore
National Laboratory

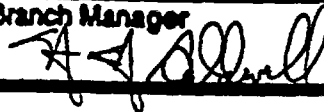
Person(s) Contacted:
B. Manis/P. Walden

**Response Due Date is
20 Days from Date of
Transmittal**
Discussion:

During the review of records processed by the records center, it was observed that unacceptable methods of record correction such as white-out and lining through information several times were being used. Initials of individuals making corrections and dates were not identified. Further evaluations determined that responsibilities or methods for the proper corrections of records have not been defined by procedure. (See Checklist Item No. 17-17.)

QAE/Lead Auditor
Date
Branch Manager
Date


12/7/88



7 Dec 88

Completed By Responsee

Response:
Signature:
Date:
Response Receipt Verified/Closed

QAE/Lead Auditor
Date
Branch Manager
Date

Completed By QA Org.

Remarks:

WMPO OBSERVATION NO. 88-05-07

N-QA-012
8/88

Completed By Originating QA Organization

Noted During:

QA Audit 88-05

Identified By:

J. A. Ulseth

Date:

10/27/88

Organization:

Lawrence Livermore
National Laboratory

Person(s) Contacted:

R. Schwartz

Response Due Date is
20 Days from Date of
Transmittal

Discussion:

Audit Checklist Question 7-10

NNQAI-SOP-02-01, Rev. 1, Section 7.2.7.2.1 states in part, "Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system..."

Discussion with the contact revealed that LLNL has not addressed the above requirement in the QA program to date but plan to include control of supplier certificates of conformance in the next revision of the QA program. The contact also stated that to date, there were no supplier certificates of conformance on file.

QAE/Lead Auditor

Date

12/7/88

Branch Manager

Date

[Signature] 7/28/88

Response:

Completed By Responses

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

Completed By QA Org.

WMPO OBSERVATION NO. 88-05-08

N-QA-012
8/88Noted During:
QA Audit 88-05Identified By:
C. M. ThompsonDate:
10/26/88Organization:
Lawrence Livermore
National LaboratoryPerson(s) Contacted:
R. OberleResponse Due Date is
20 Days from Date of
Transmittal

Discussion:

Trending of all types of deficiencies is not performed at LLNL. The last trend analysis report was dated 8/5/87 and contained only 19 NCRs. 30 internal audits have been performed as well as audits by outside organizations however, these were not included.

QAE/Lead Auditor

Date

11/16/88

Branch Manager

Date

NOV 16 1988

Response:

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

WMPo OBSERVATION NO. 88-05-09

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:
QA Audit 88-05

Identified By:
C. M. Thompson

Date:
10/26/88

Organization:
Lawrence Livermore
National Laboratory

Person(s) Contacted:
R. Oberle

Response Due Date is
20 Days from Date of
Transmittal

Discussion:

LLNL Procedure 033-NWMP-P 15.0 requires that disputes that cannot be resolved at the Project Leader level be escalated to the NWMP Leader. No method for escalating disputes to the Yucca Mountain Project Office (Project Office) PQM exists as required by NWWSI QAP 88-9, Rev. 1.

QAE/Lead Auditor

Date
11/16/88

Branch Manager

Date
NOV 16 1988

Response:

Completed by Respondee

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

Completed by QA Org.

WMPO OBSERVATION NO. 88-05-10N-QA-012
8/88Noted During:
QA Audit 88-05Identified By:
C. M. ThompsonDate:
10/26/88Organization:
Lawrence Livermore
National LaboratoryPerson(s) Contacted:
R. OberleResponse Due Date is
30 Days from Date of
Transmittal

Discussion:

It was reported in WMPO QA Audit No. 87-3 that NCRs were allowed to remain open an inordinate length of time and that there were no processing time limitations in the procedure for processing NCRs. Although there has been great improvement in this area, to date, the procedure has not been revised and no formalized method exists for following up on NCRs. One response, (NCR No. 17) due on 9/9/88, had not been received as of the date of the audit. No steps had been taken to obtain the response.

QAE/Lead Auditor

Date

Branch Manager

Date



11/16/88



NOV 16 1988

Response:

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

WMPO OBSERVATION NO. 88-05-11N-QA-012
8/88Noted During:
QA Audit 88-05Identified By:
C. M. ThompsonDate:
10/26/88Organization:
Lawrence Livermore
National LaboratoryPerson(s) Contacted:
R. OberleResponse Due Date is
20 Days from Date of
Transmittal

Discussion:

The following observations were identified during the audit concerning
NWMP-P 15.01, Rev. 0, "Nonconformances:"

1. A new form, not covered by current procedural instructions is already in use.
2. The forms do not include the date of identification of the finding.
3. The copy of the files turned over as a records package contained superfluous documents and the packages were not organized logically or indexed for ease of understanding.

QAE/Lead Auditor

Date

Branch Manager

Date

[Signature]

11/16/88

[Signature]

NOV 16 1988

Response:

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

WMPO OBSERVATION NO. 88-05-12

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:
QA Audit 88-05

Identified By:
F. Ramirez

Date:
10/27/88

Organization:
Lawrence Livermore
National Laboratory

Person(s) Contacted:
R. Lucero/J. Dronkers

Response Due Date is
30 Days from Date of
Transmittal

Discussion:

Review of the 1987 and 1988 Management Assessments done of NWMP indicate that although assistance of support contractor personnel are the principal resources in the development of the NWMP QA Program, it was observed that current staffing levels will not be adequate to implement and maintain the QA Program once it is fully implemented.

QAE/Lead Auditor:

Date

11/16/88

Branch Manager

Date

NOV 16 1988

Response:

Completed By Respondee

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

Completed By QA Org.

WMPO OBSERVATION NO. 88-05-13

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:
QA Audit 88-05

Identified By:
J. A. Ulseth

Date:
10/28/88

Organization:
Lawrence Livermore
National Laboratory

Person(s) Contacted:
K. Knauss/D. Peifer

Response Due Date is
20 Days from Date of
Transmittal

Discussion:

Audit Checklist Question 13-2

Task: Collection, Storage and Distribution of J-13 Water

The following conditions were noted for documents not yet designated as records, for the above task during discussion with the contacts and review of the log book J-13 Water Collection and Distribution, 1987 and 1988:

QAE/Lead Auditor

Date
12/7/88

Branch Manager

[Signature] 7/28/88

Date

Response:

Completed By Respondee

Signature:

Date:

Response Receipt Verified/Closed



QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

Completed By QA Org.

Observation No. 13 (cont'd)

1. Improper corrections to logbook entries, (i.e., lineouts and obliterations without signature and date, use of blue ink which will not produce a suitable microfilm.)
2. Logbook entries for past eighteen months did not show evidence of review to substantiate the on going work nor have the logbook book pages been sent to the records storage in timely intervals.
3. Improper storage of documents: The logbook is placed in a file cabinet in a locked trailer during off shift hours, however, the file cabinet is not fire proof, thus eighteen months of data collection is subject to loss.

WMPO OBSERVATION NO. 88-05-14

N-QA-012-
8/88

Completed By Originating QA Organization

Noted During:
QA Audit 88-05

Identified By:
J. Clark

Date:
10/28/88

Organization:
Lawrence Livermore
National Laboratory

Person(s) Contacted:
P. Walden/J. Dronkers

Response Due Date is
30 Days from Date of
Transmittal

Discussion:

Document Control personnel indicated that a new procedure system was being considered which would extract technical procedures from the LLNL QAPP. Per the proposed change, technical procedures would become Technical Implementing Procedures (TIPs), and would be housed in a dedicated manual separate and distinct from the QAPP. Adoption of this proposed system is encouraged, since the level of detail in the present operating/technical procedures is inappropriate for a "requirements" document.

QAE/Lead Auditor

Date

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Completed By Respondee

Signature:

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QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

Completed By QA Org.

Observation No. 14 (cont'd)

However, it was observed that existing technical procedure numbers were simply being changed (covered with "white-out") and the procedures readied for distribution as TIPS, without an approved procedure for the preparation, review, approval and issuance of such procedures. While there is an understandable desire for expediency in the transition, it is recommended that the changeover be accomplished in an orderly, documented process in accordance with standard QA program requirements. In addition to developing and implementing necessary procedures.

WMPO OBSERVATION NO. 88-05-15N-QA-012
8/88Noted During:
QA Audit 88-05Identified By:
P. ClokeDate:
10/25/88Organization:
Lawrence Livermore
National LaboratoryPerson(s) Contacted: R. Aines/
K. Jackson/J. Delany/D. OlnessResponse Due Date is
20 Days from Date of
Transmittal

Discussion: Several Audit Checklist Items, dealt with the selection of substances (minerals, aqueous solution species, etc...) for which thermodynamic data will be needed but are presently inadequate. Decisions about what elements, solids, etc... need further study constitute "points of consequence" as identified in 033-NWMP-P 2.2, Rev. 1. Therefore, peer review will be required. It is recommended that a peer review team be impaneled in the near future to judge the sufficiency of the selection process used to date and to provide guidance for the future, especially regarding the adequacy of the data base for minerals, man-made materials (metals, corrosion products, cementitious materials, etc...), and solution species.

QAE/Lead Auditor

Date

Branch Manager

Date

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Signature:

Date:

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QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

WMP0 OBSERVATION NO. 88-05-16

N-QA-012-
8/88

Completed by Originating QA Organization

Noted During:
QA Audit 88-05

Identified By:
D. Stahl/P. Cloke

Date:
10/28/88

Organization:
Lawrence Livermore
National Laboratory

Person(s) Contacted:
J. Kass

Response Due Date is
20 Days from Date of
Transmittal

Discussion:

QAPP procedure 033-NWMP-P 2.2, Section 2.2.1, specifies that, "Peer reviews are employed at points of strategic consequence." The selection of barrier material is such a point, therefore, the alternate material program must consider a broad spectrum of materials which could adequately perform under the range of repository conditions. The broad spectrum of materials shall be reduced to a manageable number through the use of outside technical experts, concurred with by the Yucca Mountain Project Office, for each category of material. The final alternate (or alternates) selected from this reduced list of candidates requires a peer review process.

QAE/Lead Auditor

Date

Branch Manager

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Response:

Completed by Responsee

Signature:

Date:

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QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

Completed by QA Org.

WMPO OBSERVATION NO. 88-05-17

NQA-012
8/88Noted During:
QA Audit 88-05Identified By:
P. ClokeDate:
10/25/88Organization:
Lawrence Livermore
National LaboratoryPerson(s) Contacted: R. Atnes/
K. Jackson/J. DelanyResponse Due Date is
20 Days from Date of
Transmittal

Discussion:

During questioning on modeling and development of kinetics, LLNL staff replied that the only plans in respect to kinetics are for code optimization of kinetic rate laws already incorporated into EQ 3/6. In spite of their statement that there exists a need for incorporating a model for nucleation rates, no satisfactory theory exists nor are there any plans to develop one. The kinetic data will not be put into the data base supplied to users, who must enter their own kinetic data for each computer run of EQ6. Consequently, kinetic data will not be examined during the planned sensitivity study. It is acknowledged that EQ6 is a quasi-equilibrium code. A LLNL representative keeps insisting that it is an "equilibrium" code, however, this is only

QAE/Lead Auditor

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Branch Manager

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Branch Manager

Date

Remarks:

Observation No. 17 (cont'd)

partially true. The aqueous solution is, with minimal exceptions sometimes specified at run time, kept, computationally, at equilibrium. However, this solution is not initially at equilibrium with at least one other phase, such as a mineral. EQ6 tracks the approach to a stable or metastable equilibrium state in accordance with some reaction model. If two or more phases are initially out of equilibrium with the aqueous solution, some treatment or model of the kinetics, either "relative" or "absolute" must be specified. Therefore, some adequate information on kinetics is essential. Moreover, there is no known way to accomplish "coupling" of geochemistry to hydrological transport, which is a subject of widespread interest and concern, except through the relative or absolute rates of chemical reaction and fluid phase movement. Therefore, the disposition of matters related to chemical kinetics are "points of consequence" in the sense of 033-NWMP-P 2.2.1, and must be peer reviewed. It is recommended that, before the peer review, this area be given careful consideration as to what kinetic data are needed for licensing and that these data be included in a sensitivity analysis.

WMPO OBSERVATION NO. 88-05-18

N-QA-012
8/88

Noted During:

QA Audit 88-05

Identified By:

K. Schwartztrauber

Date:

10/24/88

Organization:

Lawrence Livermore
National LaboratoryPerson(s) Contacted: K. Jackson/
N. Cummins/R. BaranyResponse Due Date is
20 Days from Date of
Transmittal

Discussion:

The software QA program at LLNL cannot be effective unless the QA organization is involved in the review, planning and implementation of software procedures used to control LLNL work. No evidence was provided that QA is seeing, reviewing, accepting, and involved in software development documentation. Furthermore, LLNL only has software QA procedures for EQ3/6 work. If new or additional procedures are not written, the software tasks at LLNL other than EQ 3/6 will not be subject to QA controls, when QA Level I and II activities are initiated.

QAE/Lead Auditor

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Branch Manager

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Date:

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QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

WMPO OBSERVATION NO. 88-05-19

N-QA-012
8/88Noted During:
QA Audit 88-05Identified By:
K. SchwartztrauberDate:
10/25/88Organization:
Lawrence Livermore
National LaboratoryPerson(s) Contacted:
K. Jackson/R. AinesResponse Due Date is
20 Days from Date of
Transmittal

Discussion:

Based on the QA Level assignments made at LLNL for software, it will be difficult for future users of software documentation to determine which documents were developed per the LLNL QA program. LLNL should mark all documents, publications and records related to software to ensure that the data and information contained can be traced to its originating SIP, QA Level and WBS element. Furthermore, records which were not developed or verified and validated per the LLNL QA program should contain a disclaimer stating the work cannot be used to support the Yucca Mountain Project license application.

QAE/Lead Auditor

Date

Branch Manager

Date

Response:

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QAE/Lead Auditor

Date

Branch Manager

Date

Remarks:

WMPO OBSERVATION NO. 88-05-20

N-QA-012
8/88Noted During:
QA Audit 88-05Identified By:
K. SchwartztrauberDate:
10/24/88Organization:
Lawrence Livermore
National LaboratoryPerson(s) Contacted:
N. Cummins/R. BaranyResponse Due Date is
20 Days from Date of
Transmittal

Discussion:

LLNL software QA procedures do not contain quantitative or qualitative criteria for how existing software will be qualified for use to support the Yucca Mountain Project scientific investigation and/or the license application.

QAE/Lead Auditor

Date

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Branch Manager

Date

Remarks:

WMPO OBSERVATION NO. 88-05-21

NQA-012
8/88

Completed by Originating QA Organization

Noted During:
QA Audit 88-05

Identified By:
K. Schwartztrauben

Date:
10/27/88

Organization:
Lawrence Livermore
National Laboratory

Person(s) Contacted:
R. Aines/ K Chubb

Response Due Date is
20 Days from Date of
Transmittal

Discussion:

For the Geochemical Modeling code EQ 3/6, it was observed that some revisions to code versions are issued without performing verification test runs to check that modifications have not impacted previous work. Test runs should be conducted following significant numbers of changes or for any single change which substantially revises previous versions. These runs should exercise those portions of the code which have been modified or may be impacted by such revisions.

QAE/Lead Auditor

Date

Branch Manager

Date

[Signature] Paul J. Cope

11/16/88

[Signature]

7 Dec 88

Response:

Completed by Respondee

Signature:

Date:

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QAE/Lead Auditor

Date

Branch Manager

Date

Completed By QA Org.

Remarks: