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

WBS #1.2.9.3
"QA"

JUN 05 1989

Leslie J. Jardine
Technical Project Officer for Yucca Mountain Project Office
Lawrence Livermore National Laboratory
Mail Stop L-204
P. O. Box 808
Livermore, CA 94550

CLOSURE OF STANDARD DEFICIENCY REPORTS (SDRs) 224, 225, 226, 227, 228, 230, 232, 233, 234, 235, 237, 238, 239, 240, 241, 243, 244, AND 245, REVISION 0, RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE AUDIT 88-05 OF LAWRENCE LIVERMORE NATIONAL LABORATORY

SDRs 224, 225, 226, 227, 228, 230, 232, 233, 234, 235, 237, 238, 239, 240, 241, 243, 244, and 245, Revision 0, have been closed based on satisfactory verification of completed corrective actions. A copy of the SDRs are enclosed for your files.

If you have any questions, please contact Wendell B. Mansel of my staff at (702) 794-7945 or FTS 544-7945, or Gerard Heaney of Science Applications International Corporation at (702) 794-7739 or FTS 544-7739.

Edwin L. Wilmot, Acting Director
Quality Assurance Division
Yucca Mountain Project Office

YMP:WBM-4217

Enclosures:
SDRs 224 thru 228, 230,
232 thru 235, 237 thru 241,
and 243 thru 245

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PDR WASTE
WM-11 PDC

FULL TEXT ASCII SCAN

Wm-11
102.7
NH03

JUN 05 1989

cc w/encls:
Ralph Stein, HQ (RW-30) FORS
Dwight Shelor, HQ (RW-3) FORS
R. E. Schwartz, LLNL, Livermore, CA
Gerard Heaney, SAIC, Las Vegas, NV
N. J. Brogan, SAIC, Las Vegas, NV
L. G. Scherr, SAIC, Las Vegas, NV
S. W. Zimmerman, NWPO, Carson City, NV
J. E. Kennedy, NRC, Washington, DC

cc w/o encls:
D. W. Short, LLNL, Livermore, CA
H. H. Caldwell, SAIC, Las Vegas, NV
P. J. Karnoski, SAIC, Las Vegas, NV
J. W. Gilray, NRC, Las Vegas, NV
F. L. Ramirez, SAN

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988 | 2 Severity Level ☐ 1 ☒ 2 ☐ 3 | Page 1 of 2

3 Discovered During	3a Identified By	3b Branch Chief Concurrence Date	4 SDR No.
AUDIT 88-05	K. Sommer/N. Frank		224 Rev. 0

5 Organization	6 Person(s) Contacted	7 Response Due Date is 20 Working Days from Date of Transmittal
LLNL	L.C. Lummus	

8 Requirement (Audit Checklist Reference, if Applicable)
(Audit Chicklist 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 decriptions were found for B. Zucca and Murray Day. Attitionally, the position descriptions

10 Recommended Action(s): ☒ Remedial ☒ Investigative ☒ Corrective

1. Determine if this condition has had an adverse impact on the quality of the work done at LLNL to date.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J.C. Friend 11/14/88	H.H. Caldwell NOV 14 1988	James B. Laylock 11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

(See Attached)

18 Signature/Date
L. Spellan 12/23/88 Ronald E. Schmitz 12/23/88

Comp. by Orig. QA Org.

		QAE/Lead Auditor/Date	Branch Manager/Date
19 Response	☒ Accept ☐ Reject ☐ Amended Response	[signature] 2-1-89	[signature] 2 Feb 89
20 Amended Response	☐ Accept ☐ Reject		
21 Verification	☒ Satisfactory ☐ Unsatisfactory	G. Heaney 5-24-89	[signature] 25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	[signature] 5/25/89	[signature] 25 May 89	for Wendell B. Mansel 5/30/89

ENCLOSURE

8 Requirement (continued)

qualification summary,"

9 Deficiency (continued)

(PDs) in the Personnel Qualifgications 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.

SDR #224

Remedial/Investigative Action(s)

Personnel Qualification Records will be completed for all QA personnel and personnel who have performed work on QA Level I and II SIP activities.

Effective Date: 5/01/89

Cause of the Condition & Corrective Action To Prevent Recurrence

Procedural controls did not provide mechanisms for precluding the assignment of personnel to QA Level I and II activities for whom qualifications were not yet documented in accordance with 033-NWMP-R-21B.0.

In bringing the QA Program into conformance with NNWSI 88-9 Rev. 2, procedures are being revised to require management action to complete qualification records concurrent with assignment of personnel to positions or functions affecting the quality of Level I or II activities. QA surveillances, QA holdpoints, and management readiness reviews will provide additional assurance of compliance prior to start of Level I or II activities.

Personnel will be trained to revised procedures.

Effective Date: 5/01/89

SDR NO. 224, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. Procedure 033-YMP-QP 2.10 "Qualification of Personnel", Rev. 0, para. 2.10.4 has been revised to require that a Personnel Qualification Record package be issued for all personnel prior to them performing quality affecting work.

2. Personnel training records were verified to be completed for procedure 033-YMP-QP 2.10 Rev. 0.

3. Personnel Qualification Records were contained within each LLNL personnel file reviewed during Project Office surveillance YMP-SR-89-096.

4. LLNL Audit Plan 89-08/89-09 listed procedures 033-YMP-QP 2.9 "Indoctrination and Training" Rev. 0 and 033-YMP-QP 2.10 "Qualification of Personnel" Rev.0 to be included in the scope of the audit to assure compliance with the procedural requirements for indoctrination, training, and qualification of personnel. The audit was conducted May 2-4, 1989.

ATTACHMENT TO
SDR NO. 224 REV.0

AUDIT PLAN

AUDIT No.: 89-08/89-09 **DATES OF AUDIT:** May 2-4, 1989

SUBJECT: Combined Audit: Training and Personnel Qualification, and Nonconformances, Corrective Action and Review of Technical Publications.

AUDIT SCOPE: This audit will examine and evaluate the implementation of Quality Procedures (QPs) that control:

1. Training and Qualification of Personnel;
2. Implementation of Systems for the control of Nonconformances and Corrective Actions;
3. Review of Technical Publications.

For those activities for which there has been no implementation of the QPs, an assessment of the readiness to implement such procedures will be made.

AUDIT TEAM: Robert Dann, Lead Auditor
Ken Baumgarten, Auditor
Gary DeLeon, Auditor in Training

EXTERNAL ORGANIZATIONS:
None

LIST OF REQUIREMENTS:
1. 033-YMP-QP 2.9, Rev. 0, Indoctrination and Training
2. 033-YMP-QP 2.10, Rev. 0, Qualification of Personnel
3. 033-YMP-QP 3.3, Rev. 0, Review of Technical Publications
4. 033-YMP-QP15.0, Rev. 0, Nonconformances....
5. 033-YMP-QP 16.0, Rev. 0, Corrective Action
6. 033-YMP-QP 16.1, Rev. 0, Processing of Externally Originated Corrective Action Documents
7. 033-YMP-QP 16.2, Rev. 0. T[illegible]nd Analysis
8. 033-YMP-QP 18.2. [illegible]ation of Quality Assurance Audit

"BEST AVAILABLE COPY"

NNWSI

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988	2 Severity Level ☒ 1 ☐ 2 ☐ 3	Page 1 of 4

3 Discovered During	3a Identified By	3b Branch Chief Concurrence Date	4 SDR No.
Audit 88-05	K. Summer/N. Frank		225 Rev. 0

5 Organization	6 Person(s) Contacted	7 Response Due Date is 20 Working Days from Date of Transmittal
LLNL	L.C. Lummus/G. Kugler	

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.

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): ☒ Remedial ☒ Investigative ☒ Corrective

1. Develop methods to assure compliance with LLNL YMP QA Program training requirements.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend [signature] 11/14/88	H.H. Caldwell [signature] NOV 14 1988	James Blaylock [signature] 11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date ______

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date ______

(See Attached)

18 Signature/Date [signature] 12/23/88 [signature] 12/23/88

Comp. by Orig. QA Org.

			QAE/Lead Auditor/Date	Branch Manager/Date
19 Response	☒ Accept ☐ Reject	☐ Amended Response	[signature] 2-1-89	[signature] 1 Feb 89
20 Amended Response	☐ Accept ☐ Reject			
21 Verification	☒ Satisfactory ☐ Unsatisfactory		D. Heaney 5-24-89	[signature] 25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	[signature] 5/25/89	[signature] 25 May 89	for Wendell B. Mansel 5/30/89

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 sigificant 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 Progect 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)

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 recieving training on the new versions of the course when training was received on the orginal 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.

10 Recommended Actions (continued)

4. Verify the training provided has been effective.

Remedial/Investigative Action(s)

QA program training will be completed for all personnel currently assigned as part of the in-process Program upgrade, including QA auditors. The QA Manager will be responsible for this training.

Qualification of personnel who have performed QA Level I and II SIP activities at LLNL will be documented by the responsible leaders or managers, based upon performance where training records are indeterminate. Task Leaders and Technical Area Leaders will be responsible for this action.

QA auditor knowledge of QA Program procedures is evidenced by the audit checklists prepared. The QA Manager will document and enter into personnel qualifications records qualification assessment based upon checklist adequacy and auditor performance. The QA Manager will be responsible for this action.

Training effectiveness is assessed by means of QA deficiency trending. Where future trend analysis indicates training deficiencies, corrective action required will include training. The QA organization will be responsible for this action.

Effective Date: 4/01/89

Cause of the Condition

1. Mechanisms for implementation were not provided by procedures.

2. Training was not resource loaded with dedicated staff and funded for effective implementation.

3. Training was assigned to the QA organization, precluding an adequate, independent QA overview of the training function.

4. No procedural mechanism triggered training when required.

Corrective Actions

1. The inadequacy of the training program was identified and documented by LLNL in FY88 internal QA audits and performance assessments. Procedures are being upgraded concurrent with the in-process, YMP QA Program revisions. The Project Administrator is responsible for this action.

2. A dedicated training specialist will be assigned full time to administration and coordination of training and training records. The Project Administrator is responsible for this action.

Corrective Action (Cont'd)

3. Training program responsibility will be assigned to Project Management and QA personnel will perform periodic surveillance of training. The Project Leader and QA organization are responsible for these respective actions.

4. QP21A, Training, is being revised to require the responsible leader or manager to initiate and complete an orientation and training record prior to assignment of individuals to Project work. The Project Administrator will be responsible for this action.

5. Personnel will be trained to revised procedures.

Effective Date: 4/01/89

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. QA program training has been initiated and is almost complete for all LLNL-YMP personnel. The Training Coordinator has issued a letter identifying those personnel who have not yet completed this training. Make-up training sessions for the training remaining to be completed will be scheduled for those specific individuals.

2. The qualification of personnel for those personnel files reviewed during Project Office surveillance YMP-SR-89-096 was complete and acceptable.

3. The QA Manager has completed a documented qualification assessment of all QA auditors. (Refer to attached letter, Oberle to QA Files, dated April 12, 1989)

4. LLNL has developed procedure 033-YMP-QP 16.2 "Trend Analysis", Rev.0 which will be utilized in the future to assess training effectiveness by the trending of QA deficiencies.

5. Training and qualification procedures 033-YMP-QP 2.9 "Indoctrination and Training" Rev. 0 and 033-YMP-QP 2.10 "Qualification of Personnel" Rev. 0, have been revised. The Project Office Surveillance Task Force has reviewed these procedures for compliance with the training and qualification requirements contained in the LLNL QAPP Rev. 0.

6. LLNL has assigned a dedicated training specialist to administrate and coordinate training activities.

7. Training program responsibility has been assigned to the Project Administrator. QA has recently audited training activities (refer to audit 89-08/89-09 performed May 2-4, 1989).

8. Procedure QP21A has been superceded by procedure 033-YMP-QP 2.9 "Indoctrination and Training" Rev. 0. Paragraph 2.9.3.2 of QP 2.9 states that the Technical Area Leaders are responsible for assuring that required indoctrination and training is accomplished. Paragraph 2.9.4 of QP 2.9 states that personnel assigned to the YMP receive indoctrination prior to performing activities that affect quality. Paragraph 2.9.5 of QP 2.9 states that personnel assigned to the YMP receive training on specific QA procedures prior to performing activities that affect quality. Paragraph 2.9.6 of QP 2.9 states that if needed to gain required proficiency, personnel receive technical training prior to performing activities that affect quality.

9. Personnel training records were verified to be completed for procedure 033-YMP-QP 2.9 Rev. 0.

Interdepartmental letterhead

Mail Station L 217

Ext: 32804

ATTACHMENT TO
SDR NO. 225 REV.0

April 12, 1989
QA:89/922

TO: QA Files

FROM: R. Oberle

SUBJECT: List of QA Auditors on LLNL YMP

Based upon a review of QA audits conducted on the LLNL YMP in the past, a list of auditors and their certification requirements is attached.

cc: R. Schwartz
B. Bryan
W. Stockdale

University of California
Lawrence Livermore
National Laboratory

ATTACHMENT TO
SOR NO. 225 REV.0

LLNL-YMP QA AUDITORS

AUDITORS	REMARKS	REQUIRES RE-CERTIFICATION
Baumgarten, Ken KE, QA	- Currently certified as a Lead Auditor - Performed some audits in early FY88 prior to YMP Cert.	Y
Dann, Robert KE, QA	- Same as Baumgarten	Y
Demicco, Michael LLNL, QA	- No certification on file - Participated in Audit 88-17	Y
Dronkers, John LLNL, QA	- Certified Lead Auditor since Oct.86	N
Master, Amar KE	- Participated in Audit 89-02 as an Auditor in Training - No Cert. required	N
McDaniel, Jerry KE	- Participated in Audits as either a Technical Specialist or as an Auditor in Training - No cert. required	N
Oberle, Ronald	- Certified as an Auditor per YMP	N
~~Ausmus, Beverly~~	~~- Technical Specialist~~ ~~- No Cert. required~~	~~N~~

Deleted RJO 11APR89

LLNL-YMP QA AUDITORS

AUDITORS	REMARKS	REQUIRES RE-CERTIFICATION
Fesnel, Frank	- Technical Specialist - No Cert. required	N
Becker, Dennly LLNL, QA	- Certified Lead Auditor in 1985 - No audit participation record - No audits in FY88 or 89 - Currently inactive	N
Lummus, Lane KE, QA	- No LLNL-YMP Cert. - Participated in audit 88-4 as auditor/Tech.Spec.	Y
Gill, Robin B&W, QA	- No YMP Cert. - Participated in 87-8 as Lead	Y
Moore, Wayland B&W, QA	- No YMP Cert. - Participated in ?	Y
Palmer, John	- No YMP Cert. - No evidence he ever participated in YMP Audits	N
Roberts, George B&W, QA	- Certified YMP Lead Auditor 10/27/87 - Lead Auditor 87-7	Y

Attachment 4 Page 3

LLNL-YMP QA AUDITORS

AUDITORS	REMARKS	REQUIRES RE-CERTIFICATION
Schwartz, Ronald LLNL, YMP QA	- No YMP Auditor Cert. - Participated in YMP Audits as an auditor Last: 3/9/88, 88-03	Y
Savage, Leroy KE, QA	- Participated in YMP audits as Auditor-in-training	N
Zucca, Bonnie	- No auditor Cert. - Participated in Audits in FY87 as auditor	Y
Daughtrey, H.T. B&W	- No Cert. required - 87-8, Tech. Adv.	N
Bruce, P. H. B&W	- Tech. Adv., 87-7	N

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988

2 Severity Level ☐ 1 ☐ 2 ☒ 3 Page 1 of 2

3 Discovered During	3a Identified By	3b Branch Chief Concurrence Date	4 SDR No.
Audit 88-05	C. Thompson		226 Rev. 0

5 Organization	6 Person(s) Contacted	7 Response Due Date is 20 Working Days from Date of Transmittal
LLNL	A. Madson	

8 Requirement (Audit Checklist Reference, if Applicable)
(Audit checklist Item 20-5,7 and 11)
033-NWMP-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

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): ☒ Remedial ☐ Investigative ☐ Corrective

These requirements are not YMP imposed, therefore the corrective actions are left to the discressions of LLNL.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend 11/14/88	H. H. Caldwell NOV 14 1988	James Blaylock 11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

(See Attached)

18 Signature/Date 12/23/88 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Reject ☐ Amended Response	QAE/Lead Auditor/Date 2-1-89	Branch Manager/Date 1 Feb 89
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date G. Heaney 5-25-89	Branch Manager/Date 25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	5/25/89	25 May 89	for 5/30/89

8 Requirement (continued)

have numbers assigned to then 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. Additionaly, there was no objective evidence available to verfy 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).

SDR #226

Remedial/Investigative Action(s)

Procedure 033-NWMP-P-20.0 will be replaced by a new procedure and unnecessary requirements will be deleted.

QA should not be required to monitor progress of procedures and procurement documents. QA has right of review and approval of quality related procedures, procurement documents, and changes which precludes release prior to performance of independent QA reviews.

It is not necessary to conduct a meeting to determine the need for a procedure.

Submittal of packages B-20-1 and B-20-2 to the Yucca Mountain Project Office is demonstrated by Yucca Mountain Project office approvals of the documents on file. No further action is planned on these specific packages. However, separate action to upgrade records management will improve performance on retention of transmittal records.

Effective Date: 5/01/89

Cause of Condition & Corrective Action to Preventive Recurrence

Unnecessary or unworkable elements were included in original procedures but were not identified and revised. The revision process was cumbersome and not all administrative direction in procedures was considered to be quality related.

Emphasis is being placed on workability of procedures at LLNL; procedures will be revised where not workable. A change notice process has been incorporated to provide a timely method for procedure revision.

Records Management has been reassigned from QA to Project Management and dedicated staff will be assigned to the records function.

Personnel will be trained to revised procedures.

Effective Date: 5/01/89

SDR NO. 226, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. Procedure 033-NWMP-P-20.0 has been replaced by procedure 033-YMP-QP 2.8 "Assigning Levels of Quality Assurance" Rev. 0.

2. Personnel training records were verified to be completed for procedure QP 2.8 Rev. 0.

3. Records management has been reassigned from QA to the LLNL YMP Administrator (refer to attached letter, Short to Program Participants dated November 3, 1989).

4. Records management personnel have been trained to procedure 033-YMP-QP 17.0 "Quality Assurance Records" Rev. 0 (refer to attached documentation of training completion).

5. A change notice process is now in place per procedure 033-YMP-QP 2.1 "Preparation, Approval & Revision of Quality Procedures and Requirements" Rev. 0, para. 2.1.5.4.

6. QA is now required to review quality related procedures per procedure 033-YMP- QP 2.1 Rev. 0. QA is also required to review procurement document packages per procedure 033-YMP-QP 4.0 "Procurement Control and Documentation" Rev. 0 para. 4.0.5.5.

PERSONNEL QUALIFICATION RECORD

ATTACHMENT TO SDR NO. 226 REV.0

M E M O R A N D U M - November 3, 1988

TO: Waste Management Program Participants

FROM: David Short David Short

SUBJECT: Appointment of Barbara Bryan as YMP Administrator

I am pleased to announce the appointment of Barbara Bryan as the Yucca Mountain Project Administrator effective immediately. Barbara will be reporting to me in this new capacity.

Barbara's functional responsibilities will include records management, document control, training coordination, technical procedure writing coordination, administrative procedure manual preparation, YMP office operations including coordination of the project's secretarial and clerical staff, control and transmission of the project's reports and publications, and action item tracking.

The successful accomplishment of our goals in each of these critical areas is essential to the success of the YMP. To this end, Barbara will be assembling a staff to fulfill the requirements we have established for ourselves and those imposed by the sponsor in the administrative areas.

Please provide Barbara with your full assistance as she takes on this challenging assignment.

cc: Robert Schock
Larry Schwartz

ATTACHMENT TO
SDR NO. 226 REV.0

Interdepartmental letterhead

Mail Station L 206

Ext. 3-3378

April 21, 1989

M E M O R A N D U M

TO: Records/Training File

FROM: William Manis/Barbara Bryan

SUBJECT: Training of Document/Records Management Personnel: Barbara Alegre and Kelly Kemsley

---

Hands-on training for Barbara Alegre and Kelly Kemsley on Procedures 6.0 Document Control and 17.0 QA Records has been on-going from April 4 through April 20 (and will continue). The training was presented by Bill Manis, Records Manager. Barbara Bryan observed and sometimes assisted. This is a record of a few specific times of training.

April 4, 1989:

Procedures QP 6.0, Document Control
AP 6.0, 6.1
QP 17.0, Quality Assurance Records
AP 17.0, 17.1, and 17.2

B. Alegre and K. Kemsley were given these procedures with the request to read them and prepare any questions they might have on the information.

April 6, 1989

As training for Procedure QP 17 and AP 17.0 and QP 6.0, hands-on computer instructions were given on: (1) how to inspect and log in documents, and (2) enter information on controlled distribution list.

April 7, 1989

As training for Procedure AP 6.0, Section 6.0.6.4, hands-on instructions were given on the Macintosh computer to: (1) revise forms and (2) print out forms.

As training for Procedure QP 6.0, Section 6.0.5.3, instructions were given on: (1) how to stamp controlled copies, and (2) how to make distribution of controlled copies.

ATTACHMENT TO
SDR NO. 226 REV.0

Weeks of April 10-14 and April 17-21, 1989:

Daily training through the actual performance of all functions in Document Control and Records continued. Hands-on computer training continued. Training included how documents were controlled, follow-up on QA receipts, how to input documents on the computer, how to set up and use files for all records.

Training was also given on the computer to input to the LLNL Action Item Log.

April 14, 1989

As a follow-up to the reading assignment on the procedures, Barbara Alegre, Kelly Kemsley, Barbara Bryan, and Bill Manis spent a training session devoted entirely to discussion of the written Document Control procedures QP 6.0 and AP 6.0, 6.1. Any questions on these procedures were discussed and answered. Any additional training that was needed was noted and done in the following days.

April 20, 1989

In the final session on the reading assignment, Barbara Alegre, Kelly Kemsley, Barbara Bryan, and Bill Manis devoted the entire time to discussion of the written Quality Assurance Records procedures QP 17.0 and AP 17.0, 17.1 and 17.2. Any questions on these procedures were discussed and answered.

This memo documents any "formal" one-on-one training given to Document Control and Records personnel. All training will be on-going.

W R Manis
William Manis, Document/Records Manager

Barbara Bryan
Barbara Bryan, Project Administrator

xc: Records File
Training Records for:
B. Alegre
K. Kemsley

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7,1988	2 Severity Level ☐ 1 ☒ 2 ☐ 3	Page 1 of 2	
3 Discovered During Audit 88-05	3a Identified By K. Sommer	3b Branch Chief Concurrence Date	4 SDR No. 227 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 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.

10 Recommended Action(s): ☒ Remedial ☒ Investigative ☒ Corrective

1. Investigate to determine if other procedures have the same or simular problems.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend [signature] 11/14/88	H. H. Caldwell [signature] NOV 14 1988	[signature] 11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date ______

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date ______

(See Attached)

18 Signature/Date [signature] 12/23/88 [signature] 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Reject ☐ Amended Response	QAE/Lead Auditor/Date [signature] 2-1-89	Branch Manager/Date [signature] 1 Feb 89
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date G. Heaney 5-24-89	Branch Manager/Date [signature] 25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date [signature] 5/25/89	Branch Manager/Date [signature] 25 May 89	PQM/Date For [signature] 5/30/89

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.

Remedial/Investigative Action(s)

Five LLNL Managers representing every element of the Project Organization reviewed and approved the final procedures issued, including the QA Manager. Their approval documents their review and acceptance.

There is no programmatic requirement for this provision in the procedure. There is no impact upon previously approved procedures. This procedural element will be deleted in the next revision.

Effective Date: N/A

Cause of the Condition & Corrective Action to Prevent Recurrence

Procedures occasionally include elements that are not required, are cumbersome to implement and consequently are not implemented.

Training will include emphasis upon either implementing procedures, or requesting change when warranted. In addition, a change notice process is being incorporated to enable timely implementation of procedure changes.

Personnel will be trained to revised procedures.

Effective Date: 5/01/89

SDR NO. 227, REV. 0

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. The requirement cited in the SDR has been deleted in current procedure 033-YMP-QP 2.1 "Preparation, Approval & Revision of Quality Procedures and Requirements" Rev. 0. This LLNL self imposed requirement was not a requirement of the Project QA Plan NNWSI/88-9.

2. Procedure 033-YMP-QP 2.1 Rev. 0, paragraph 2.1.5.4 now contains a change notice process to enable timely implementation of procedure changes.

3. Personnel training records were verified to be completed for procedure 033-YMP-QP 2.1 Rev. 0.

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7,1988 | 2 Severity Level ☐ 1 ☒ 2 ☐ 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): ☒ Remedial ☒ Investigative ☒ Corrective

1. Determine the extent of interface controls required for LLNL subcontracted activities. Modify contractual documents as necessary to provide interface

Aprvl.

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 B. Blaylock 11/15/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s) — 15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence — 17 Effective Date _____

(See Attached)

18 Signature/Date: [signature] 12/23/88 | R. E. Schwartz 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Reject ☐ Amended Response	QAE/Lead Auditor/Date: 2-1-89	Branch Manager/Date: 1 Feb 89
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date: B. Heaney 5-26-89	Branch Manager/Date: 30 May 89

22 Remarks: See Attached Block 22 Remarks for Verification JCB 5/30/89

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	5/30/89	30 May 89	for 5/30/89

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 satisify the YMP QA Program requirements.

SDR #228

Remedial/Investigative Actions

Quality Level I & II procurement documents will be reviewed to assure the adequacy of technical interface requirements. Where interface requirements are deficient, impact will be assessed and contract instructions provided to the contractor(s).

Adequate interface control includes:

- Specification of the LLNL-YMP technical requirements imposed
- Specification of the contractor technical submittals required for technical review or approval by LLNL-YMP
- Specification of the technical interface person or position at LLNL
- Specification of controls for changing technical documents transmitted

Effective Date: 3/01/89

Cause of the Condition & Corrective Action to Prevent Recurrence

Procedures governing purchase requisitions did not contain adequate technical interface requirements.

LLNL YMP procurement documents must include specification of the LLNL technical requirements and specification of the contractor submittals required for LLNL review and/or approval, with direction on the processing of changes thereto. These interface specifications are required for adequate control of the technical interface with the contractor.

Procurement control procedure 033-YMP-QP 4.0, Procurement Control and Documentation, when issued will include technical interface specifications and instructions in procurement documents.

Personnel will be trained to revised procedures.

Effective Date: 5/01/89

0497J/12/20/88

SDR #228 (continued)

Technical interface control between Participating Project Organizations must be addressed at the YMPO level, and is being addressed in the System Engineering Management Plan.

Effective Date: YMPO action

SDR NO. 228, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. LLNL completed a review to assure the adequacy of technical interface requirements for subcontracts (refer to the attached tables A & B for those subcontracts reviewed).

2. LLNL subcontract no. 9172105 to Babcock and Wilcox was reviewed and verified to include the following:
   A) Technical requirements are imposed as required by procedure 033-YMP-QP 4.0 "Procurement Control and Documentation" Rev. 0 paragraph 4.0.5.2.
   B) Subcontractor technical submittals are required to be reviewed and approved by the LLNL Task Leader.
   C) A LLNL Task Leader is identified as the technical interface.
   D) Changes are to be controlled in accordance with procedures 033-YMP-QP 4.0 Rev. 0, paragraph 4.0.5.6 and 033-YMP-QP 4.1 "Quality Assurance Requirements Specifications" Rev. 0 paragraph 4.1.5.4.

3. Interfaces are addressed in LLNL Yucca Mountain Project Quality Assurance Requirements Specifications (QARS) which are required to be included as part of procurement documentation packages. LLNL has issued QARS-001A, 001B, and 001C for Babcock and Wilcox, Argonne National Laboratory and Pacific Northwest Laboratory.

4. Training to procedures 033-YMP-QP 4.0 Rev. 0 and 033-YMP-QP 4.1 Rev. 0 was verified to be completed.

SubContract No	Acct No	Activity	GL	Cost ($K)	LLNL Contact (Interface)	Deliverables (Transmittals)	Contractor	Status
SANL 810-006	6071-31	D-20-42	I	446	SHAW	WSTEP	ANL	Active
SANL 810-007	6065-01(QA)	-	-	46	SHAW	✓	ANL	Active
	6065-28	D-20-28	I	150		✓		
	6065-29	D-20-27	III	40		✓		
	6065-03	D-20-30	III	70		✓		
	6065-31	D-20-31	III	235		✓		
	6072-01(QA)	-	-	9		I		
	6072-27	D-20-27	I	100		✓		
SANL-810-008	6073-18	E-20-18	III	125	KASS	✓	ANL	Active
SANL 810-005	6068-72	G-20-2	III	70	SHAW	✓	PNL	Active
	6071-13	D-20-49	III	143		~		
	6071-31	D-20-49	III	371		r		
	6071-40	D-20-44	I	225		✓		
	6071-41	D-20-45	I	225		✓		
	6071-50	D-20-46	I	336		✓		
	6071-52	D-20-48	I	119.2		✓		
SANL 823-003	6084-40	D-20-8	I	100	AINES	N.R.	NIST (NBS)	
917-2105	6081-25	H-20-4,-5	I	700++	RUSSELL	✓	B&W	
	6088-06	H-20-5	I		↓	✓		
PSA 8056005	6082-01		III	18	GLASSLEY	✓	Prof. COHEN (AT LLNL)	
B053018	6069-03	B-20-5	III	141K	GLASSLEY	✓	NORTHWESTERN U.	

(TABLE A)

ATTACHMENT TO SDR NO. 226 REV. 0

TABLE A

SHEET 1 OF 2

SOB Cont. No	Acct No	Activity	GL	Cost (K)	LLNL Cont.	Issue	Contractor	Status
2232603	6071-60	D-20-50	III	50++	Shaw	✓	B. Chin	Active
							Arizona U.	
B034268	6069-04	J-20-8	III	110K	Alves	✓	John Delaney	Active
	6079-76		III					
	~~6084~~-40		III					
	6080-06		III					
	6084-01		III					
B055747	~~6082~~-60	B-20-1	III	130K	Glassley	✓	SEA	Active
	6089-02	S-20-1						
Requisition 356224	6073-16	E-20-16	III	100	Kortenkamp	?	SEA	?
1414503	6080-06	J-20-8	III	205	Silva	✓	FL. State U.	Active
1684403	6080-07	J-20-8	III	160	Silva	✓	U.C.S.D.	Active
	6065-32	D-20-37	III	"	"	✓	"	"
2141603	6073-16	E-20-16	III	207	McCright	✓	O.S.U.	
2033103	6069-03	B-20-5	III	215+	Glassley	✓	Yale	

(TABLE A CONT'D)

ATTACHMENT TO SDR NO. 228, REV. 0

TABLE A

SUBCONT. NO.	ACCT NO.	ACTIVITY	QL	COST (K)	LLNL CONTACT (INTERFACE)	DSL. (TRANSMITTALS)	CONTRACTOR	STATUS
8371005	6069-25 6079-25 6084-25	B-20-8 J-20-8	III	150	AINES	✓	JOHN DILLON	CLOSED
1764003	6071-25 6073-09	E-20-13	III	222	FARMER	✓	SEA	CLOSED
SAWL 710-006	6071-31	D-20-49	IIII	402	SHAW J-13 304L SS	✓	ANL	CLOSED
SAWL 710-011	6073-18	E-20-18	III	200	KASS	✓	ANL	CLOSED
SAWL 710-010	6073-18	E-20-18	III	100	MCCRIGHT	✓	ANL	CLOSED
SAWL 710-007	6065-31 6072-31	D-20-27 -29 -30 -31	IIII	650	OVERBY	?	ANL	✓
SAWL-710-009	6065-76	D-20-31	III	49	SHAW	—	ANL	
SAWL 710-004	(SEE SAWL 610-004)			35	AINES	✓	ANL	
SAWL 710-013		D-20-31	III	~~43~~79	RYERSON	—	ANL	
8039914	6073	~~E-20-19~~/ E-20-15	I	89	HALSEY	✓	SEA	
SAWL 722-052	6073-13	—	III (IV?)	8.4	MCCRIGHT	✓	WESTINGHOUSE HANFORD (YAKIMA)	

(TABLE B)

TABLE B

ATTACHMENT TO SDR NO. 228, REV. 0

PAGE 1 OF 2

SUBCONTRACT NO	ACCT NO	ACTIVITY	QA	COST (K)	LLNL CONTACT	DEL
SAIC 722-053	6071-03 6073-13	D-20-42,44,45 G-20-13	I & III	70	SHAW	✓
SAIC 716-010	7885-25	D-20-46	I	20	SHAW	—
BO34339	6067-07	—	EXEMPT	60	BALLOU	✓
				~~105~~		
1496603	6092-25	5-20-1	III	105	WILDER	✓

TABLE A (CONT'D)

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988 | 2 Severity Level ☐ 1 ☒ 2 ☐ 3 | Page 1 of 2

3 Discovered During	3a Identified By	3b Branch Chief Concurrence Date	4 SDR No.
Audit 88-05	M. Mitchell		230 Rev. 0

5 Organization	6 Person(s) Contacted	7 Response Due Date is 20 Working Days from Date of Transmittal
LLNL	J. Kass	

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): ☒ Remedial ☒ Investigative ☒ 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.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend 11/14/88	H. H. Caldwell 15 Nov 88	11/15/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

(See Attached)

18 Signature/Date 12/23/88 12/23/88

Comp. by Orig. QA Org.

19 Response	☒Accept ☐Amended ☐Reject Response	QAE/Lead Auditor/Date 2-1-89	Branch Manager/Date 1 Feb 89
20 Amended Response	☐Accept ☐Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒Satisfactory ☐Unsatisfactory	QAE/Lead Auditor/Date G. Heaney 5-24-89	Branch Manager/Date 25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	5/25/89	25 May 89	for 5/30/89

8 Requirement (continued)

be
conducted when WMPO deems it necessary. This review is conducted in accordance with internl 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.

SDR #230

Remedial/Investigative Action(s)

The subject Peer Review was conducted in accordance with the LLNL NWMP procedure 033-NWMP-P2.2, Peer Review. This procedure implements the guidance of NUREG 1297. As required by procedure P2.2, a Quality Assurance representative served as a full-time participant in the Peer Review. Further, the Peer Review received the highest level of attention from the LLNL-YMP Management.

The Peer Review conducted implemented NUREG 1297 requirements. No deficiencies in the peer review conducted were identified by either the LLNL-YMP QA participant or by the DOE 88-05 auditor.

Because no deficiency has been identified, no remedial action will be implemented on the peer review conducted and no other QA Level I or II peer reviews have been performed at LLNL.

There is no evidence that the lack of a YMPO procedure has had an adverse impact on the Peer Review conducted at LLNL.

Effective Date: NA

Cause of the Condition & Corrective Action to Prevent Recurrence

Cause: lack of YMPO procedural guidance on peer review.

Future Peer Reviews will be conducted in accordance with the forthcoming procedure QP 2.2, Peer Review. This procedure implements the guidance contained in NNWSI/88-9.

The revised procedure, which implements the requirements of NNWSI 88-9, Rev. 2, will be issued and training will be completed consistent with the LLNL QA Program upgrade qualification schedule.

This condition resulted from lack of procedural guidance to participating organizations. However, the lack of such guidance did not have an adverse impact on the quality of LLNL's Peer Review process. YMPO action to prevent repetition was to include programmatic guidance in NNWSI 88/9 Revision 2.

Subsequent revisions of the QAPP allow participants to determine the need and to perform peer reviews.

Effective Date: 5/01/89

0497J/12/20/88

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. Procedure 033-YMP-QP 2.2 "Peer Review" Rev. 0 has been issued. The procedure has been reviewed by the Project Office Surveillance Task Force to ensure it was in compliance with the QA requirements for peer review contained in the Project QA Plan NNWSI/88-9, Rev. 2.

2. Personnel training records were verified to be completed for procedure 033-YMP-QP 2.2 Rev. 0.

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988

2 Severity Level ☐ 1 ☒ 2 ☐ 3 Page 1 of 2

3 Discovered During: Audit 88-05

3a Identified By: J. A. Ulseth

3b Branch Chief Concurrence Date

4 SDR No. 232 Rev. 0

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

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): ☒ Remedial ☒ Investigative ☒ Corrective

1. Investigate to determine if other procurements have occured without the QA review.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend/ [signature] 11/14/88	H. H. Caldwell [signature] NOV 14 1988	[signature] 11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date ________

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date ________

(See Attached)

18 Signature/Date [signature] 12/23/88 [signature] 12/23/88

Comp. by Orig. QA Org.

			QAE/Lead Auditor/Date	Branch Manager/Date
19 Response	☒ Accept ☐ Reject	☐ Amended Response	[signature] 2-1-89	[signature] 1 Feb 89
20 Amended Response	☐ Accept ☐ Reject			
21 Verification	☒ Satisfactory ☐ Unsatisfactory		[signature] 5-29-89	[signature] 30 May 89

22 Remarks
See Attached Block 22 Remarks for Verification [initials] 5/30/89

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	[signature] 5/30/89	[signature] 30 May 89	for [signature] 5/30/89

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 orginal 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.

SDR #232

Remedial/Investigative Action(s)

QA Level I and II procurements will be reviewed to verify that the procurement document contained the requirements of the requisition submitted to LLNL Procurement. This review will be documented in a QA surveillance report and any exceptions will be dispositioned in accordance with surveillance procedure requirements.

Effective Date: 4/01/89

Cause of the Condition & Corrective Action to Prevent Recurrence

Cause: The QA Manager was unable to obtain a submittal of the procurement documnents for review prior to issuance, and did not either require action or stop the process.

Interface between the LLNL-YMP and LLNL Procurement Department has not been resolved to obtain a resubmittal of procurement documents by the Procurement Department to the LLNL-YMP for approval prior to placement.

YMP procedures will be revised to implement QA review prior to contract award. This requirement will be raised to the highest laboratory management level necessary to effect compliance. Written agreements will be required.

QA will review procurement documents for QA Level I and II procurements prior to issuance, including changes, or the QA Manager will initiate work stoppage.

Project participants will be trained to new procedures.

Effective Date: 5/01/89

SDR NO. 232, REV. 0

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. LLNL performed surveillance no. S89-09 "Review of QA Level I and II Procurement Documents" to ensure procurement documents contained appropriate quality requirements. There were no deficiencies identified as a result of the surveillance.

2. Procedure 033-YMP-QP 4.0 "Procurement Control and Documentation" Rev. 0 requires a QA review of procurement documentation prior to contract award (refer to paragraphs 4.0.5.5 and 4.0.5.7.c). A copy of the memorandum of understanding for the QA review of procurement packages prior to release is attached to the SDR.

3. The QA Manager has the authority to initiate stop work orders per procedure 033-YMP-QP 2.7 "Stop Work Order" Rev. 0, paragraph 2.7.2.

4. Training to procedure 033-YMP-QP 4.0 Rev. 0 was verified to be complete.

ATTACHMENT TO
SDR NO. 232, REV. 0

SURVEILLANCE REPORT

SURVEILLANCE NO: S89-09 - Review of QA Level I and II Procurement Documents.

DATE PERFORMED: May 12, 1989

CONDUCTED BY: K. R. Baumgarten - Quality Assurance (ICF KE)

ACTIVITY AND CHARACTERISTICS OBSERVED:

- o Procurement Requisitions
- o Purchase Orders
- o Memorandum Requests to the Special Projects Office
- o SANL's
- o Subcontracts

PERSONNEL CONTACTED:

Al Madsen, Quality Assurance
Suzanne Bradley, Program Resource Manager
George Kline, Contracts Administrator

REFERENCE DOCUMENTS:

033-YMP-QP4.0 Rev. 0/1 Procurement Control and Documentation

SUMMARY OF RESULTS:

The review of procurements for the inclusion of quality requirements was judged to be satisfactory. Requisitions reviewed included or referenced appropriate quality requirements or specifications. These requirements were incorporated in SANL's, purchase orders, changes, or subcontract amendments. All documents reviewed were considered satisfactory. However, there is one comment relative to SANL 816-005 dtd. 3/7/89 issued to PNC; the SANL did not identify the LLNL QA requirements document by title and revision, eg; LLNL Yucca Mountain Project, QA Requirements for Pacific Northwest Laboratory, QARS-001C, Revision 0, February 13, 1989.

Prepared By: K R Baumgarten Date: May 17, 1989
Lead Auditor

Accepted by: R L E. [illegible] Date: 5/17/89
(signature, title)
LLNL-YMP QA Manager
5/17/89

ATTACHMENT TO SDR NO. 232, REV. 0

Reference: Surveillance Checklist - Items 2 & 3

PROCUREMENT TYPE/NO.	VENDOR	QA REQUIREMENT
SANL 810-006 810-007	ANL ANL	Ref SANL dtd 3/7/89 incorporated QA Requirement Specification QARS-001B, dtd. 2/10/89 per memorandum request.
SANL 816-005	PNL	Ref: Letter to Special Materials office from L. Ballou, dtd. 2/14/89, identifies QA specification NNWSI89-2, Rev. 2 that is mandatory for PNL to comply with. SANL dtd. 3/7/89 incorporated the QA specification referenced.
SANL 722-053	WHC	QA Level specified as QA Level I
REQUISITION 917268 P.O. 9172105	B&W	Requisition dtd. 4/27/89 to provide incremental funding to comply with NNWSI-89-9 Rev 2, and incorporate QARs-001A, Rev 0 QA Requirements specification. Amendment #6 to subcontract was transmitted to B&W incorporating these requirements in the subcontract.
REQUISITION 686879 P.O. 9172105	B&W	Quality requirements were included in the IFB and incorporated in the subcontract/purchase order.
REQUISITION 746021 P.O. 039914	SEA	Purchase order issued 5/2/88 references the QA Plan in tasks 2, 3 & 4, QA Level I. Procurement now closed.

ATTACHMENT TO
SDR NO. 232, REV. 0

Interdepartmental letterhead

*Mail Station L-*209

Ext: 26189

May 10, 1989
QA:89/971

TO: L. F. Young, Manager, Procurement Department

FROM: R. N. Schock, Energy Program Leader

SUBJECT: Memorandum of Understanding

The purpose of this memo is to record an understanding between the LLNL Procurement Department and the LLNL Yucca Mountain Project (YMP) regarding YMP Quality Level I and II procurement actions.

The YMP QA Level I and II procurements are few in number and consist primarily of service contracts. The U.S. Department of Energy (DOE) requires that the YMP QA Manager review the final documents for QA Level I and II procurement actions prior to release to assure that the documents incorporate the appropriate quality assurance requirements.

Discussions between the YMP QA Manager and Procurement Department personnel have resulted in an understanding that the YMP QA Manager (or designee) will review the purchase order in the procurement office prior to release of QA Level I or II purchase orders. This action will be initiated by a yellow notification form (attached) accompanying the purchase requisition. Procurement Department personnel will notify the QA Manager via phone that the document is ready for review. After the review the purchase order may be promptly released. The notification form will be completed by YMP staff and retained in the files of the YMP Resource Manager.

The agreed upon approach is intended to minimize disruption in the Laboratory's procurement operation. Review of purchase orders prior to release is not required for those procurements classified as Exempt, Commercial Grade, or QA Level III. These categories constitute greater than 95 percent of the YMP purchase orders.

The Energy Program and YMP sincerely appreciate the cooperation of the Procurement Department regarding this matter. Please initial your concurrence with this understanding and return a copy to me (L-209) and to Ron Schwartz, YMP QA Manager (L-204).

Attachment

RNS:RES:AAM/pw

cc: S. Bradley, L-204
L. Jardine, L-204
E. Moffet, L-650
R. Schwartz, L-204
D. Short, L-204
J. Weiner, L-650

University of California
Lawrence Livermore
National Laboratory

Madson

ATTACHMENT TO
SOR NO. 232, REV. 0

QUALITY ASSURANCE OFFICE
YUCCA MOUNTAIN PROJECT
EARTH SCIENCES DEPARTMENT

MAIL STATION L-204
EXT: 35032

MAY 12, 1989
QA:89/977

TO: M. Manausa, Special Materials Manager mm: 5/12/89

FROM: Les Jardine, LLNL-YMP Technical Project Officer

SUBJECT: Memorandum of Understanding

The purpose of this memo is to record an understanding between the LLNL Special Materials Office and the LLNL Yucca Mountain Project (YMP) regarding YMP Quality Level I and II SANL actions.

The YMP QA Level I and II SANL actions consist primarily of service contracts. The U.S. Department of Energy (DOE) requires that the YMP QA Manager review the final memorandum requests for QA Level I and II SANL actions prior to release to assure that the memorandum requests incorporate the appropriate quality assurance requirements.

Discussions between the YMP QA Manager and the Special Materials Office personnel have resulted in an understanding that the YMP QA Manager (or designee) will review the SANL Memorandum Request in the Special Materials Office prior to release of QA Level I or II SANL's. This action will be initiated by a yellow notification form (attached) accompanying the interdepartmental memorandum requesting the SANL. The Special Materials Office will notify the QA Manager via phone that the document is ready for review. After the review the SANL Memorandum Request may be promptly released. The notification form will be completed by YMP staff and retained in the files of the YMP Resource Manager.

The agreed upon approach is intended to minimize disruption in the Special Materials Office operation. Review of SANL Memorandum Requests prior to release is not required for those actions classified as Exempt or QA Level III.

The Energy Program and YMP sincerely appreciate the cooperation of the Special Materials Office regarding this matter. Please initial your concurrence with this understanding and return a copy to Ron Schwartz, YMP QA Manager (L-204).

Attachment
RES
LJ:RS:AM/jc

L. J. Jardine

cc: S. Bradley, L-204
L. Jardine, L-204
D. M. La Pre, L-128
R. Schwartz, L-204
D. Short, L-204

ATTACHMENT TO
SDR NO. 232, REV.0

University of California
Lawrence Livermore
National Laboratory

Req. No. _____

YUCCA MOUNTAIN PROJECT P.O. No. _____

NOTICE

THIS IS A QUALITY ASSURANCE LEVEL I OR II
PROCUREMENT ACTION

THE U.S. DEPARTMENT OF ENERGY (DOE) REQUIRES THE YMP QA MANAGER TO REVIEW THE FINAL PROCUREMENT DOCUMENTS AGAINST THE PROCUREMENT REQUEST PRIOR TO RELEASE TO THE SUPPLIER. THIS FORM DOCUMENTS THIS REVIEW.

PROCUREMENT DEPARTMENT / SPECIAL MATERIALS OFFICE

Please notify the QA Manager when the final purchase document/memorandum has been completed. A QA representative will review the final document/memorandum in your office. Completion of this form will authorize release to supplier.

REQUISITIONER (If the award document incorporates changes to the procurement request.)

I have reviewed the final procurement documents and concur that the revised provisions are consistent with the stated procurement objective.

_____ _____
Requisitioner Date

QA MANAGER

The final procurement documents have been reviewed and they are consistent with the procurement request and satisfy the appropriate QA requirements.

_____ _____
QA Manager Date

(The original form is on yellow paper)

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988	2 Severity Level ☒ 1 ☐ 2 ☐ 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

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): ☒ Remedial ☒ Investigative ☒ Corrective

1. Initiate control over on going activities in accordance with provisions of the latest approved QAPP.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend 11/14/88	H. H. Caldwell NOV 14 1988	James B Langford 11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

(See Attached)

18 Signature/Date L S Salmon 12/23/88 R. E. Johnson 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Amended ☐ Reject Response	QAE/Lead Auditor/Date 8-1-89	Branch Manager/Date 17 Feb 89
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date G. Heaney 5-25-89	Branch Manager/Date 25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION RESULTS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	5/25/89	25 May 89	for 5/30/89

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 occured 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.

SDR #233

Remedial/Investigative Action(s)

Scientific/technical activities performed subsequent to June 1, 1988, will be reviewed against SIP Quality Levels to identify any Level I or II activities performed at LLNL. Applicability of changes invoked by Rev. 5 will be assessed. Any impacts identified will be documented and dispositioned.

Disposition of QA Level I activities subcontracted to ANL and PNL is addressed in response to SDR 243.

Effective Date: 5/01/89

Cause of the Condition & Corrective Action to Prevent Recurrence

See LLNL letter QA: 88/658(0546R) from John Dronkers to James Blaylock dated 18 October 1988 (attached).

Concurrent with holding the issuance of Revision 5 of the QAPP, the LLNL-YMP QA Manager should have placed all QA Level I and II activities in work stoppage pending resolution of pending QA Program changes from the YMPO.

Responsiveness to continual revisions to Program documents is greatly impeded by failure to quantify the funding, schedule, and resources prior to proceeding (in accordance with DOE configuration management principles). Budget authorizations will be requested to allow implementation of future changes in Program requirements.

If the need to suspend issuance of a revised QA Program is necessary, QA Level I and II activities will be placed on hold pending resolution of requirements documents.

Effective Date: 1/01/89

0497J/12/20/88

SDR NO. 233, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. LLNL has performed a review of Quality Level I and II activities performed between June 1, 1988 and January, 1989. Results of this review have assessed that changes between NVO-196-17 Rev. 4 and Rev. 5 did not materially impact the conduct of LLNL activities (refer to attached investigation results).

2. LLNL has not had to suspend issuance of a revised QA program since initiation of the SDR. The revised LLNL QAPP Rev.0 was approved by the Project Office and was effective on February 10, 1989. The QAPP meets all the applicable quality assurance requirements of the Project QA Plan NNWSI/88-9 Rev. 2.

ATTACHMENT TO
SDR NO. 233 REV.0

REMEDIAL/INVESTIGATIVE ACTIONS FOR SDR #233

The period of concern for SDR #233 impacts is June, 1988 (the approval date of the LLNL-YMP QAPP Rev 2, which was written to implement NVO-196-17 Rev. 5) and January, 1989 when the Acting LLNL-YMP Technical Project Officer suspended QA Level I and II activities.

The following QA Level I and II activities were in progress during that period:

J-20-7	(EQ 3/6 Model Development)
J-20-9	(EQ 3/6 Documentation and Code Release)
J-20-10	(EQ 3/6 Code Maintenance)
D-20-42	(Saturated, Semi-Static Dissolution Tests)
D-20-44	(Oxidation Tests of Spent Fuel)
D-20-45	(Oven Oxidation Tests)
D-20-46	(Corrosion/Degradation/Release Tests)
D-20-27	(Unsaturated Testing of WVDP and DWPF Glass)
H-20-2	(Development of Waste Package Requirements)

Each of these activities was being conducted under technical implementing procedures drafted and approved prior to June 1, 1988. Activities at ANL and PNL were long-term tests conducted to the procedures in effect when initiated.

These procedures are governed by the QA requirements in place at the time of test initiation. Accordingly, there was no material impact on QA Level I and II technical activities in progress at LLNL and its subcontractors during the period from June, 1988 to January, 1989.

ATTACHMENT TO
SDR NO. 233 REV.0

The only QA Level I or II activity started during the time period of concern was E-20-15 (Establishment of Criteria for Metal Barrier Selection). This activity involved the conduct of a peer review. The subject peer review was conducted in accordance with the requirements specified in NVO-196-17 Rev. 5, which authorized peer reviews by participants. Accordingly, we have concluded that there was no material impact to this activity as a result of deferring issuance of the LLNL-YMP QAPP Rev. 2. In addition, activities (whether conducted at QA Level I, II, or III) performed prior to implementation of a an NRC approved QA program are subject to further project review to determine recovery and use consistent with the requirements of NNWSI 88/9 Rev 2 Appendix G, "Requirements for Qualification of Existing Data Not Generated Under A QA Program Meeting the Requirements of 10 CFR 60, Subpart G."

Based on the above stated assessment the changes between NVO-196-17 Rev. 4 and 5 would not have materially impacted the conduct of LLNL technical activities in progress or initiated between June, 1988 and January, 1989.

Lawrence Livermore National Laboratory

18 October 1988
QA:88/658(0546R)

ATTACHMENT TO
SDR NO. 233 REV.0

James Blaylock
Waste Management Project Office
U.S. Department of Energy
P.O. Box 98518
Las Vegas, NV 89193-8518

Dear Jim:

I have been asked to explain why I did not issue our procedures you approved to implement Rev. 5 of NNWSI's QAPP. The explanation is simple really: stability. Let me elaborate.

Our Rev. 5 procedures (our procedures corresponding to Rev. 5 of NNWSI's QAP) were approved by you on June 1, 1988. In fact, the approval letter was handed to me during the June 1 Project Quality Assurance Managers meeting. At that time we already knew that there was going to be a Rev. 6 to be called NNWSI-88/9 Rev. 0. Although I had not seen Rev. 0 when I came to the meeting, it had been approved by HQ on 19 May 1988 and controlled copies had been mailed to the participants on 25 May 1988 (participants had received uncontrolled copies which differed from the controlled copies prior to that). The June 1 meeting discussed Rev. 0 and also the time table for implementing Rev. 0. Our QAPP responsive to your Rev. 0 by June 30: our administrative QA procedures along with the Requirements Matrix by July 18: your review would take one week: everybody humming by the middle of September. Do you remember those heady days of June?

Of course, that June 1 meeting contained the seed of the eventual demise of all our plans and schedules. It was the statement that the NRC still had some concerns in four areas which had to be resolved before they would approve the Rev. 0.

The point of all this is that when you approved our Rev. 5 procedures, they were already totally and irrevocable obsolete, and we all were working on Rev. 0. We also knew that Rev. 0 would soon become Rev. 1, but no one knew the enormous resistance Rev. 1 would engender. Just as we now know that Rev. 2 is a given and Rev. 3 not far behind. I decided not to issue obsolete procedures, knowing that within 60 days I would have to issue revisions. My attempt here is to provide as much stability to the requirements as I can possibly gain. It makes them easier to implement.

Mes devoirs,

John Dronkers
Quality Assurance Specialist

cc: J. Estella, SAIC
J. Friend, SAIC
S. Hans, SAIC
S. Nolan, SAIC
L. Ramspott, LLNL
D. Short, LLNL
QA Staff
CF, OF, RF

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988	2 Severity Level ☐ 1 ☐ 2 ☒ 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 Intermim 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): ☒ Remedial ☐ Investigative ☐ Corrective

1. Develop and implement controls for the use of the ICN and Instrtuctional memorandum.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend 11/14/88	H. R. Caldwell NOV 14 1988	11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

(See Attached)

18 Signature/Date P. Walden 12/23/88 R. E. Adams 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Amended ☐ Reject Response	QAE/Lead Auditor/Date 2-1-89	Branch Manager/Date 1 FEB 89
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date G. Heaney 5-25-89	Branch Manager/Date 5-26-89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION RESULTS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	5/26/89	5/26/89	for 5/30/89

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)

SDR #234

Remedial/Investigative Action(s)

There are currently no interim change notices or instructional memoranda being processed. QAPP table of contents and the Document Control Master Index are being updated to reflect change notices and are being distributed to control copy holders.

Effective Date: 2/01/89

Cause of the Condition & Corrective Action to Prevent Recurrence

Instructional memoranda were issued for changes to procedures. Procedures did not define the use of change notices and instructional memoranda. These documents were used to make necessary, timely changes to procedures due to the lengthy process of submitting procedure revisions to YMPO for approval prior to implementation.

Records personnel were not properly supervised and trained to procedure 033-NWMP-P-6.1, Rev. 1, and as a result the QAPP Table of Contents and the Document Control Master Index were not updated and reissued at the time change notices were issued.

Restart of QA Level I and II activities at LLNL YMP will be based upon readiness for implementation of the NNWSI/88-9, Revision 2, QAPP procedures; therefore, control of previously issued change notices and instructional memoranda has no current significance.

New procedures are in preparation which cover the issue of change notices and the updating of tables of contents and the Document Control Master Index. Records personnel will be trained and supervised to the new procedures.

Effective 5/01/89

SDR NO. 234, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. The table of contents for the QAPP and Document Control Master Index have been updated to reflect the latest revisions of procedures. These tables have been distributed to controlled copy holders.

2. Personnel training records have been verified to be complete for procedures 033-YMP-QP 6.0 "Document Control" Rev. 0 and 033-YMP-QP 17.0 "Quality Assurance Records" Rev. 0.

3. QA Level I and II work activities have not been restarted at LLNL as of May 17, 1989.

4. Procedure 033-YMP-QP 2.1 "Preparation, Approval & Revision of Quality Procedures and Requirements" Rev. 0 has been revised to include the procedure for the generation and issuance of change notices.

5. Procedure 033-YMP-QP 6.0 Rev. 0, paragraph 6.0.5.8 has been revised to include the updating of the Document Control Master Index.

6. Procedure 033-YMP-QP 6.0 Rev. 0, has been revised to include the distribution of a revised table of contents when change notices are issued.

Interdepartmental letterhead

Mail Station L- 206

Ext. 3-3378

April 21, 1989

ATTACHMENT TO SDR NO. 234 REV. 0

M E M O R A N D U M

TO: Records/Training File

FROM: William Manis/Barbara Bryan

SUBJECT: Training of Document/Records Management Personnel: Barbara Alegre and Kelly Kemsley

---

Hands-on training for Barbara Alegre and Kelly Kemsley on Procedures 6.0 Document Control and 17.0 QA Records has been on-going from April 4 through April 20 (and will continue). The training was presented by Bill Manis, Records Manager. Barbara Bryan observed and sometimes assisted. This is a record of a few specific times of training.

April 4, 1989:

Procedures QP 6.0, Document Control
AP 6.0, 6.1
QP 17.0, Quality Assurance Records
AP 17.0, 17.1, and 17.2

B. Alegre and K. Kemsley were given these procedures with the request to read them and prepare any questions they might have on the information.

April 6, 1989

As training for Procedure QP 17 and AP 17.0 and QP 6.0, hands-on computer instructions were given on: (1) how to inspect and log in documents, and (2) enter information on controlled distribution list.

April 7, 1989

As training for Procedure AP 6.0, Section 6.0.6.4, hands-on instructions were given on the Macintosh computer to: (1) revise forms and (2) print out forms.

As training for Procedure QP 6.0, Section 6.0.5.3, instructions were given on: (1) how to stamp controlled copies, and (2) how to make distribution of controlled copies.

ATTACHMENT TO
SDR NO. 234 REV.0

Weeks of April 10-14 and April 17-21, 1989:

Daily training through the actual performance of all functions in Document Control and Records continued. Hands-on computer training continued. Training included how documents were controlled, follow-up on QA receipts, how to input documents on the computer, how to set up and use files for all records.

Training was also given on the computer to input to the LLNL Action Item Log.

April 14, 1989

As a follow-up to the reading assignment on the procedures, Barbara Alegre, Kelly Kemsley, Barbara Bryan, and Bill Manis spent a training session devoted entirely to discussion of the written Document Control procedures QP 6.0 and AP 6.0, 6.1. Any questions on these procedures were discussed and answered. Any additional training that was needed was noted and done in the following days.

April 20, 1989

In the final session on the reading assignment, Barbara Alegre, Kelly Kemsley, Barbara Bryan, and Bill Manis devoted the entire time to discussion of the written Quality Assurance Records procedures QP 17.0 and AP 17.0, 17.1 and 17.2. Any questions on these procedures were discussed and answered.

This memo documents any "formal" one-on-one training given to Document Control and Records personnel. All training will be on-going.

W R Manis
William Manis, Document/Records Manager

Barbara Bryan
Barbara Bryan, Project Administrator

xc: Records File
Training Records for:
B. Alegre
K. Kemsley

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7,1988 | 2 Severity Level ☐ 1 ☒ 2 ☐ 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

8 Requirement (Audit Checklist Reference, if Applicable)
(Audit checklist item 6-8)
033NWMP-P-6.1,Rev 1, "Issue of Controled 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): ☒ Remedial ☒ Investigative ☒ Corrective

1. Determine if this procedural violation has had any adverse impact on the past or current scientific investigation and design activities.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend 11/14/88	H. H. Caldwell NOV 14 1988	11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

(See Attached)

18 Signature/Date 12/23/88 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Reject ☐ Amended Response	QAE/Lead Auditor/Date 2-20-89	Branch Manager/Date 3 Feb 89
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date D. Heaney 5-25-89	Branch Manager/Date 5/26/89

22 Remarks SEE ATTACHED BLOCK 22 / CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	5/26/89	5/26/89	for 5/30/89

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 recurence of this problem
4. Provide training to LLNL personnel as needed, in accordance with the LLNL QAPP requirements.

Remedial/Investigative Action(s)

None required because manual logs were maintained to control distribution.

Effective Date: N/A

Cause of the Condition & Corrective Action to Prevent Recurrence

Procedure 033-NWMP-P 6.1, Rev. 1, describes a "computer file" which lists individuals and all controlled documents issued to them. This listing was started, found to be cumbersome to maintain and was discontinued. The procedure was not revised.

Although the "computer file" was not maintained, controlled distributions to appropriate personnel continued with the use of separate manual distribution lists. Document control procedures are being revised and the reference to the "computer file" will be deleted. Personnel will be trained to the new procedures.

Effective Date: 5/01/89

SDR NO. 235, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. Procedure 033-YMP-QP 6.0 "Document Control" Rev. 0 has been revised to delete the reference to the computer file.

2. Personnel training records were verified to be completed for procedure 033-YMP-QP 6.0 Rev. 0.

3. Controlled distribution of documents is being maintained in accordance with procedural requirements.

WMPO STANDARD DEFICIENCY REPORT

N-QA 038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988 | 2 Severity Level ☐ 1 ☒ 2 ☐ 3 | Page 1 of 2

3 Discovered During	3a Identified By	3b Branch Chief Concurrence Date	4 SDR No.
Audit 88-05	M. Cotter		237 Rev. 0

5 Organization	6 Person(s) Contacted	7 Response Due Date is 20 Working Days from Date of Transmittal
LLNL	B. Manis/P. Walden/B. Alegre	

8 Requirement (Audit Checklist Reference, if Applicable)
(Audit checklist item 6-12)
033NWMP-P-6.1 Rev. 1, "ISSUE OF CONTROLED DOCUMENMTS" 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): ☒ Remedial ☒ Investigative ☒ Corrective

1. Determine if these procedural violations have had an adverse impact on the scientific investigation and design work done to date.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend [signature] 11/14/88	H. H. Caldwell [signature] NOV 14 1988	James Blaylock [signature] 11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

(See Attached)

18 Signature/Date [signature] 12/23/88 [signature] 12/23/88

Comp. by Orig. QA Org.

		QAE/Lead Auditor/Date	Branch Manager/Date
19 Response	☒ Accept ☐ Reject ☐ Amended Response	[signature] 2-1-89	[signature] 1 Feb 89
20 Amended Response	☐ Accept ☐ Reject		
21 Verification	☒ Satisfactory ☐ Unsatisfactory	G. Heaney 5-25-89	[signature] for 5/26/89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	[signature] 5/26/89	[signature] for 5/26/89	for 5/30/89 Wendell B. Mansel

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 complient with YMP QAP requirements.
4. Provide training to LLNL personnel as necessary. Document the training in accordance with the LLNL QA program.

SDR #237

Remedial/Investigative Action(s)

Contrary to the statement in the SDR, there is evidence on file of the "Request for Collection of Documentation" form being sent to individuals removed from distribution. A check is being made to see if the form was sent to all individuals removed from distribution. Records personnel have been directed to read procedure 033-NWMP-P5.1, Rev. 0, section 5.1.5.3 for the definition of "Key Reviewer" (Pending Procedure Revision).

Several individuals were reassigned from the YMP and their documents were collected.

Effective Date: 4/01/89

Cause of the Condition & Corrective Action to Prevent Recurrence

Reference in procedure 033-NWMP-P6.1, Rev. 1, to A "Key Reviewer" (of a controlled document) notifying document control when an individual was to be removed from distribution was not workable. The procedure was not revised to reflect a workable method of notification.

Key Reviewers were procedurally identified as the immediate supervisors or managers of the document originators, however, deletions from distribution were authorized by delegation of the QA Manager.

Document control procedures are being upgraded and will include clarification of project personnel who can authorize or direct removal of an individual from controlled distribution. Document control forms are being revised to emphasize disposition of superseded documents. Personnel will be trained to the new procedures.

Effective Date: 5/01/89

SDR NO. 237, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. Procedure 033-YMP-QP 6.0 "Document Control" Rev. 0, paragraph 6.0.5.5 has been revised to include a section on the "Removal of Individuals From Controlled Distribution." The procedure specifies that an individual"s supervisor or management must authorize the request to remove an individual from the controlled distribution list.

2. "Controlled Document Transmittal Record" forms have been revised to emphasize disposition of superceded documents.

3. Personnel training records were verified to be completed for procedure 033-YMP-QP 6.0 Rev. 0.

4. Records personnel have read the section in procedure 033-NWMP-P5.1 "Preparation of Technical Procedures" Rev. 0 which identifies who a "Key Reviewer" is for technical procedures (refer to attached documentation).
   Note: This procedure has since been superceded by procedure 033-YMP-QP 6.0 Rev. 0.

ATTACHMENT TO
SDR NO. 237 REV.0

INDIVIDUAL COMMITMENT ACTION & FOLLOW-UP DESCRIPTION

Source Identifier: SDR # 237

Responsible Lead: Manis

Action Committed: CHECK & DOCUMENT INDIVIDUALS REMOVED FROM CONTROLLED DISTRIBUTION WERE SENT A REQUEST FOR COLLECTION OF DOCUMENTATION FORM. CHECK DISPOSITION OF THOSE DOCUMENTS.
DOCUMENT RECORDS PERSONNEL READING OF PROCEDURE 033-NWMP-P5.1, REV.0, SECTION 5.1.5.3 REGARDING "KEY REVIEWER".

Description of actions/results/status:
I HAVE READ PROCEDURE 033-NWMP-P5.1, SECTION 5.1.5.3 (COPY ATTACHED) REGARDING THE DEFINITION OF THE TECHNICAL PROCEDURE "KEY REVIEWER". THIS ACTIVITY HAS BEEN DELETED FROM THE CURRENT PROCEDURE.

W.R. Manis — 3/27/89
W.R. MANIS — DATE

Barbara Alegre — 3-27-89
B. J. ALEGRE — DATE

INDIVIDUALS RECENTLY REMOVED FROM CONTROLLED DISTRIBUTION WERE SENT A REQUEST FOR COLLECTION OF DOCUMENTATION FORM EXCEPT FOR THOSE WHO TERMINATED AND LEFT THE AREA. IN THE LATTER CASE, CONTROLLED DOCUMENTS WERE COLLECTED BY RECORDS PERSONNEL. IN BOTH CASES THE CONTROLLED DISTRIBUTION LIST HAS BEEN MARKED TO DECONTROL THE INDIVIDUAL.

Date action completed: 4/16/89 Responsible Lead: W. R Manis

LLNL YMP Close out date:
4/28/89

Follow-up/close out by:
RK Dacy

References & Attachments:

WMPO STANDARD DEFICIENCY REPORT

N-QA-028
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988	2 Severity Level ☐ 1 ☒ 2 ☐ 3		Page 1 of 2
3 Discovered During Audit 88-05	3a Identified By J.A. Ulseth	3b Branch Chief Concurrence Date	4 SDR No. 238 Rev. 0
5 Organization LLNL	6 Person(s) Contacted John Dronkers		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 there of,

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): ☒ Remedial ☒ Investigative ☒ Corrective

1. Determine if this violation of requirement has had an adverse impact on the sceintific investigation and design work done under the purview of LLNL.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend 11/14/88	H. H. Caldwell NOV 14 1988	James Blaylock 11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

(See Attached)

18 Signature/Date 12/23/88 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Reject ☐ Amended Response	QAE/Lead Auditor/Date 2-1-89	Branch Manager/Date 1 Feb 89
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date D. Keaney 5-26-89	Branch Manager/Date 30 May 89

22 Remarks See Attached Block 22 Remarks for Verification
JW 5/30/89

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	5/30/89	30 May 89	5/30/89 for

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.

Remedial/Investigative Action(s)

Procurement evaluation documents are proprietary at LLNL. However, the intent of the QA Plan is to demonstrate qualification of the selected contractor and to resolve or obtain commitment to resolve unacceptable QA conditions before contract award.

Contractors selected by LLNL to perform QA Level I or II work under the contractor's own QA Program and management will be reviewed to assure qualification based upon (as applicable):

- o Technical considerations
- o Suppliers' personnel
- o Supplier's production capabilities, when applicable
- o Supplier's past performance
- o Alternates (proposed by the contractor)
- o Exceptions (proposed by the contractor)

Effective Date: 4/01/89

Cause of the Condition & Corrective Action to Prevent Recurrence

LLNL procedures do not provide adequate interface between LLNL-YMP and LLNL Procurement in the areas of contractor qualification. Procedures will be revised to provide for contractor qualification prior to award.

LLNL-YMP will prepare a QA specification for use in Level I & II procurement. This specification will include provision for the contractor to address the following subjects, as applicable:

- o Technical considerations
- o QA Requirements
- o Suppliers' personnel
- o Supplier's production capabilities, when applicable
- o Supplier's past performance
- o Alternates (proposed by the contractor)
- o Exceptions (proposed by the contractor)

Prior to award of contract, the bidder selected will be evaluated for qualification in consideration of the applicable subject areas listed above. This evaluation will be documented and retained as a QA Record.

Personnel will be trained to revised procedures.

Effective Date: 5/01/89

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. Procedure 033-YMP-QP 4.0 "Procurement Control and Documentation" Rev. 0 now addresses that contractor qualifications are performed prior to contract award (refer to paragraphs 4.0.5.7.c and 4.0.5.8).

2. Procedure 033-YMP-QP 4.0 Rev. 0, paragraph 4.0.5.7.c addresses the basis for the qualification of suppliers.

3. The requirements of procedure 033-YMP-QP 4.0, paragraph 4.0.5.7.c were verified to be included as part of the Babcock and Wilcox Subcontract No. 9172105 by a "QA Levels I and II Subcontractor Evaluation" form which was signed by the Task Leader and the QA Manager on April 17, 1989.

4. LLNL has prepared a specification titled "LLNL Yucca Mountain Project Quality Assurance Requirements Specification (QARS) for Babcock and Wilcox" No. QARS-001A dated February 10, 1989. This specification addresses the requirements of procedure 033-YMP-QP 4.0 and is now part of the contract.

   LLNL has also issued QARS No. 001B and 001C for Argonne National Laboratory and Pacific Northwest Laboratory.

5. LLNL has not awarded any new subcontracts since the revision of procedure 033-YMP-QP 4.0 Rev. 0. Therefore, the implementation of the procedural requirements for the qualification evaluation of bidders prior to the award of a contract could not verified.

6. Training to procedure 033-YMP-QP 4.0 Rev. 0 was verified to be completed.

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988	2 Severity Level ☐ 1 ☐ 2 X 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. 239 Rev. 0
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 15-7)
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

9 Deficiency
Contrary to the above requirement, LLNL procedure 033-NWMP-P 15.01, Rev. 0, "Non-conformances", does not require the distint use of the specific repair and use-as-is terminology, thereby making the need for WMPO approval subject

10 Recommended Action(s): ☒ Remedial ☐ Investigative ☐ Corrective

1. Determine if this procedural violation has had an adverse impact on the sceintific investigation and design work done.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J.C. Friend [signature] 11/14/88	H. H. Caldwell [signature] NOV 14 1988	James Blaylock 11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

(See Attached)

18 Signature/Date [signature] 12/23/88 [signature] 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Reject ☐ Amended Response	QAE/Lead Auditor/Date [signature] 2-1-89	Branch Manager/Date [signature] 1 Feb 89
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date G. Heaney 5-25-89	Branch Manager/Date [signature] 25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	[signature] 5/25/89	[signature] 25 May 89	For [signature] 5/30/89

8 Requirement (continued)

documented". Paragraph 15.3 further states "Nonconformances for QA level I and II activities ... shall have WMPO approval before disposition is implemenmted 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.

Remedial/Investigative Action(s)

The nineteen Nonconformance Reports issued at NWMP have been reviewed by the QA organization. There were no dispositions identified that would have required a YMPO approval of repair or use-as-is disposition. Consequently, the deficiency did not result in an adverse impact on quality. No remedial action is necessary.

Effective Date: N/A

Cause of the Condition & Corrective Action to Prevent Recurrence

This condition was caused by a failure of the existing NWMP procedure to categorize specific types of resolutions for nonconforming conditions.

The forthcoming procedure QP 15.0, Control of Nonconforming Items, will include specific direction related to the types of dispositions and the requirements for YMPO approval, as required. Personnel will receive appropriate training consistent with the QA program update schedule.

Effective Date: 5/01/89

SDR NO. 239, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. Procedure 033-YMP-QP 15.0 "Nonconforming Items, Procedural Nonconformances and Conditions Adverse to Quality" Rev. 0 has been revised to include the "Repair" or "Use-as-is" disposition terminology. NCR's with these dispositions are required by the procedure to be sent to the Project Office for approval.

2. Personnel training records were verified to be completed for procedure QP 15.0 Rev. 0.

3. NCR nos. 8-14 were reviewed to ensure they did not have a "Repair" or "Use-as-is" disposition requiring a Project Office approval.

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988 | 2 Severity Level ☐ 1 ☐ 2 ☒ 3 | Page 1 of 2

3 Discovered During	3a Identified By	3b Branch Chief Concurrence Date	4 SDR No.
Audit 88-05	C.M. Thompson		240 Rev. 0

5 Organization	6 Person(s) Contacted	7 Response Due Date is 20 Working Days from Date of Transmittal
LLNL	R. Oberle	

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...

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 orginal disposition was revised but not approved in the same

10 Recommended Action(s): ☒ Remedial ☐ Investigative ☐ Corrective

1. Determine if this program violation has had an adverse impact on the quality of the scientific investigations and design work done.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend [signature] 11/14/88	H. H. Caldwell [signature] NOV 14 1988	James Blaylock 11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

(See Attached)

15 Effective Date _____

16 Cause of the Condition & Corrective Action to Prevent Recurrence

(See Attached)

17 Effective Date _____

18 Signature/Date [signature] 12/23/88 [signature] 12/23/88

Comp. by Orig. QA Org.

		QAE/Lead Auditor/Date	Branch Manager/Date
19 Response	☒ Accept ☐ Reject ☐ Amended Response	[signature] 1/9/89	[signature] 9 Jan 89
20 Amended Response	☐ Accept ☐ Reject		
21 Verification	☒ Satisfactory ☐ Unsatisfactory	G. Heaney 5-25-89	[signature] 25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date
	[signature] 5/25/89	[signature] 25 May 89	for 5/31/89 Wendell B. Mansel

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 orginal 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.

Remedial/Investigative Action(s)

All NCRs issued by NWMP have been reviewed by the QA organization, including NCR 11. No adverse impact was identified. Further, upon review of NCR 11, no revision of the NCR's original disposition was identified.

Remedial action is not planned since no problem was identified with NCR 11.

Effective Date: 12/07/88

Cause of the Condition & Corrective Action to Prevent Recurrence

This condition could conceivably occur because procedure 033-NWMP-P15.0, Rev. 0, does not include specific instructions for changing the content of Nonconformance Reports.

The forthcoming procedure QP 15.0, Control of Nonconforming Items, will include specific instructions related to the requirements for changes to NCRs. Personnel will receive appropriate training consistent with the QA program update schedule.

Effective Date: 5/01/89

SDR NO. 240, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions were verified to be complete:

1. Procedure 033-YMP-QP 15.0 "Nonconforming Items, Procedural Nonconformances and Conditions Adverse to Quality" Rev. 0, paragraph 15.0.6 has been revised to include requirements for changes to NCR's.

2. Personnel training records were verified to be completed for procedure 033-YMP-QP 15.0 Rev. 0.

3. NCR-11 was reviewed and no revision of its original disposition was observed.

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date Nov 7, 1988 | 2 Severity Level ☒ 1 ☐ 2 ☐ 3 | Page 1 of 2

3 Discovered During	3a Identified By	3b Branch Chief Concurrence Date	4 SDR No.
Audit 88-05	C.M. Thompson		241 Rev. 0

5 Organization	6 Person(s) Contacted	7 Response Due Date is 20 Working Days from Date of Transmittal
LLNL	R. Oberle/R. Schwartz	

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 requiremnet, 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): ☒ Remedial ☒ Investigative ☒ Corrective

1. Determine the impact of this programmatic failure on the scientific investigation and design work performed under the purview of LLNL.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend 11/14/88	H. H. Caldwell 15 Nov 88	11/15/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

(See Attached)

18 Signature/Date 12/23/88 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Amended ☐ Reject Response	QAE/Lead Auditor/Date 2-1-89	Branch Manager/Date 15 Feb 89
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date S-25-89	Branch Manager/Date 25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date for 5/30/89
	5/25/89	25 May 89	

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.

Remedial/Investigative Action(s)

The Corrective Action System being used at LLNL-YMP is being upgraded as part of the overall revision to the QA Program. Training and calibration will be addressed on readiness review checklists.

No QA Level I or II testing or laboratory investigations have been conducted at LLNL to date, therefore, calibration programs have had no impact upon work activities performed.

Effective Date: 5/01/89

Cause of the Condition & Corrective Action to Prevent Recurrence

This condition was caused by failure of the applicable procedures to provide analysis criteria, and mechanisms for tracking and follow-up on corrective actions and by failure of management to take precipitous action.

Effective "Corrective Action" should have included formal action to preclude performance of QA Level I and II activities (which required calibrations) pending the establishment of calibration programs. Although no work was performed, no formal direction from management was issued at the time. To preclude recurrence a formal process for placing work on hold will be implemented.

The forthcoming procedures QP 15.0 and QP 16.0, and an additional procedure for trend analysis, will contain specific guidance concerning the need for timely and effective corrective action and follow-up. A new procedure is being developed to specifically address corrective action documents that originate outside of LLNL-YMP, such as SDRs. This procedure will provide instructions for timely action related to these documents. QP 18.0, the QA Audit procedure, will contain more specific instructions related to follow-up of previously identified deficiencies and associated corrective actions.

Training of personnel will be conducted as the revised procedures are approved and issued.

Further, timeliness of follow-up actions by the QA organization has been hampered by the diversion of QA personnel to records functions, training functions, and repetitious QA Plan changes. Line managers are being assigned primary responsibility for records management and training as well as the implementation of the Program. Dedicated, qualified QA personnel are being assigned to QA surveillance, audit, and follow-up of corrective actions committed.

Effective Date: 5/01/89

SDR NO. 241, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions have been verified to be complete:

1. Procedures 033-YMP-QP 15.0 "Nonconforming Items, Procedural Nonconformances and Conditions Adverse to Quality" Rev. 0, 033-YMP-QP 16.0 "Corrective Action" Rev. 0, and 033-YMP-QP 16.2 "Trend Analysis" Rev. 0 have been issued and contain requirements for timely corrective action and follow-up.

2. Procedure 033-YMP-QP 16.1 "Processing of Externally Originated Corrective Action Documents" Rev. 0 has been issued and provides instructions for timely processing of external corrective action documents (i.e. SDRs).

3. Procedure 033-YMP-QP 18.0 "Audits" Rev. 0 now includes the consideration of previous audit results in the preparation of forthcoming audits (refer to paragraph 18.0.5.4).

4. Personnel training records for procedures QP 15.0 Rev. 0, QP 16.0 Rev.0, QP 16.1 Rev. 0, and QP 18.0 Rev. 0 were verified to be complete.

5. Training and calibration checklist items have been included on readiness review checklists (refer to attached example).

6. Training to procedure 033-YMP-QP 16.2 "Trend Analysis" has been determined not to be required (refer to attached letter Schwartz to Stockdale dated April 25, 1989).

UNIVERSITY OF CALIFORNIA
Lawrence Livermore
National Laboratory

ATTACHMENT TO
SDR NO. 241, REV.0

YUCCA MOUNTAIN PROJECT

READINESS REVIEW CHECKLIST

Activity: H-20-5 Container Closure Process Development.
Subcontract 9172105, B&W R&DD.

Readiness Review Board Member: _____

Item No.		ITEM	Responsible Organization	Satisfactory	Unsatisfac.	Open
1.	Question:	Are test procedures (Technical, Administrative and Quality Assurance) identified, completed, and approved?	B&W			
	Answer:					
	Comments:					
2.	Question:	Is the Technical Plan for Container Closure Process Development complete and approved?	B&W			
	Answer:					
	Comments:					
3.	Question:	Is the Activity Plan complete and approved?	LLNL			
	Answer:					
	Comments:					

ATTACHMENT TO
SDR NO. 241, REV. 0

			Responsible Organization	Satisfactory	Unsatisfac.	Open
4.	Question:	Is the SIP approved?	LLNL			
	Answer:					
	Comments:					
5.	Question:	Has Calibration Equipment (M&TE) been identified and steps taken to assure Calibrated M&TE will be used?	B&W			
	Answer:					
	Comments:					
6.	Question:	Have personnel been selected for YMP participation and Personnel Qualification Records been established and verified?	B&W			
	Answer:					
	Comments:					
7	Question:	Has a Personnel Training Program been established and training conducted and documented?	B&W			
	Answer:					
	Comments:					
8.	Question:	Has a Quality Assurance Indoctrination Program been developed, implemented, and documented?	B&W			
	Answer:					
	Comments:					

Interdepartmental letterhead

Mail Station L 204

Ext: 3-4627

ATTACHMENT TO
SDR NO. 241 REV.0

QA: 89/944
25 April 89

TO: W. Stockdale

FROM: Ronald Schwartz R. Schwartz

SUBJECT: **Training Requirements for QP 16.2, Trend Analysis**

I do not believe that training is required for the implementation of QP 16.2 for the following reasons:

1. The two QA personnel who actively implement the procedure, Ron Oberle and Gary DeLeon, are its authors;

2. The LLNL-YMP Management personnel who are identified in the procedure have duties that are limited to review the Trend Analysis Reports;

3. As QA Manager, my major function in the procedure is to initiate Corrective Action Reports when an adverse quality trend is identified in the analysis; and

3. No other project personnel have a responsibility specified in the procedure.

If you concur with my analysis, please assure that this letter remains on file for the benefit of future auditors.

Concur. W.K. Stockdale
Training coordinator
4/26/89

xc:
B.Bryan
R.K. Dann, KE
CF
CF
RF

University of California
Lawrence Livermore
National Laboratory

Completed by Originating QA Organization

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

1 Date Nov 7, 1988	2 Severity Level ☒ 1 ☐ 2 ☐ 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 representive 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): ☒ Remedial ☒ Investigative ☒ 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

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
J. C. Friend [signature] 11/14/88	H. H. Caldwell [signature] NOV 14 1988	James Blaylock 11/15/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date ______

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date ______

(See Attached)

18 Signature/Date [signature] 12/23/88 [signature] 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Amended Response ☐ Reject	QAE/Lead Auditor/Date [signature] 2-1-89	Branch Manager/Date [signature] 1 Feb 89
20 Amended Response	☒ Accept AMENDMENT ☐ Reject Not Requested by YMP	QAE/Lead Auditor/Date [signature] 2-24-89	Branch Manager/Date [signature] 2-24-89
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date D. Haney 5-25-89	Branch Manager/Date [signature] 5-26-89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date [signature] 5/26/89	Branch Manager/Date [signature] 5/26/89	PQM/Date For 05/30/89 Wendell B. Mansel

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 sceintific investigation and design work done to date.
3. Perform training as needed. Document the training in accordance with the LLNL QAPP.

SDR #243

Remedial/Investigative Action(s)

LLNL-YMP is precluded from performing independent audits of PNL and of ANL by the DOE. This does not, however, preclude performance of independent audits by the DOE to YMP QA Plan requirements. DOE will be requested to conduct "independent" audits and to allow LLNL QA representative(s) to participate.

Impacts will be assessed based upon the result of "independent" audits performed.

LLNL-YMP has restricted the performance of further QA Level I and II activities at ANL and PNL pending resolution of outstanding QA Program implementation and audit issues. (Reference: NWM 89-060)

Effective Date: 5/01/89

Cause of the Condition & Corrective Action to Prevent Recurrence

The responsibility for implementation must reside with DOE. LLNL-YMP will submit a formal request to DOE to schedule periodic, independent audits of PNL and ANL to YMP QA Requirements, and to allow LLNL-YMP QA representative(s) to participate.

LLNL-YMP management will request DOE audits be conducted for LLNL-YMP should this unusual circumstance recur.

Effective Date: 1/31/89

0497J/12/20/88

AMENDED RESPONSE

SDR #243

Remedial Investigative Action(s)

LLNL-YMP was precluded from performing independent audits of PNL and of ANL by the DOE. This did not, however, preclude performance of independent audits by the DOE to YMP QA Plan requirements. DOE was requested to conduct "independent" audits and to allow LLNL QA representative(s) to participate.

The LLNL-YMP has subsequently received DOE approval to audit ANL and PNL directly.

LLNL-YMP has restricted the performance of further QA Level I and II activities at ANL and PNL pending resolution of outstanding QA Program implementation and audit issues. (Reference: NWM 89-060)

Effective Date: 5/01/89

Cause of the Condition & Corrective Action to Prevent Recurrence

The LLNL-YMP committed to submit a formal request to DOE to schedule periodic, independent audits of PNL and ANL to YMP QA requirements, and to allow LLNL-YMP QA representative(s) to participate. Instead, DOE concurred with LLNL-YMP performing direct audits.

In the future, formal requests will be submitted until a satisfactory response is obtained.

Surveillances will be conducted by the LLNL-YMP QA staff and readiness reviews will be conducted by LLNL-YMP Project management prior to restart of QA Level I or II activities at ANL and PNL.

SDR NO. 243, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

The following corrective actions have been verified to be complete:

1. LLNL has received permission to lead audits of Pacific Northwest Laboratory (PNL) and Argonne National Laboratory (ANL) per the attached memoranda.

2. PNL and ANL are included on the LLNL FY89 audit schedule.

3. LLNL has restricted performance of QA Level I and II activities at PNL and ANL (refer to attached correspondence).

4. LLNL has performed surveillances at ANL (surveillance no. S89-08) and Babcox and Wilcox (surveillance nos. S89-11 and S89-12). The surveillance at PNL has been scheduled to be conducted during the week of May 22-26, 1989. Readiness reviews are planned to be conducted at each facility prior to authorizing the restart of QA Level I or II work activities at each subcontractor facility.

United States Government — Department of Energy

memorandum

ATTACHMENT TO
SOR NO. 243, REV.0

DATE: JAN 13 1989

REPLY TO ATTN OF: San Francisco Operations Office (DP)

SUBJECT: LLNL Audits of PNL QA Program

TO: Joe J. Sutey, Director, Research and Development Division, RL

We understand that we have concurrence from your office for the Lawrence Livermore National Laboratory (LLNL) to lead audits of the Quality Assurance Programs at the Pacific Northwest Laboratory (PNL). These audits will be conducted in direct support of the Yucca Mountain Project. Currently these activities are covered in the SANL Contract #810005 "Spent Fuel Dissolution and Oxidation" with PNL. The audit schedule and details will be established with PNL by LLNL to comply with the quality assurance requirements of the Yucca Mountain Project in Nevada.

This understanding is based on the telephone discussions between Ms. Debbie Kenyon, RL and Mr. Filbert Fong, SAN. If you have any questions, please call me on FTS 536-4320 or Filbert Fong on FTS 536-7836.

Roger R. Liddle for

Michael K. Hooper
Director

cc: D. Kenyon, RL
E. Wilmot, NV
J. [illegible], NV
J. [illegible]ten, SAN-ESQA
L. [illegible], LLNL-(L-206)

Department of Energy

memorandum

RON-FYI

ATTACHMENT TO SDR NO. 243, REV. 0

RECEIVED BY JAN 24 1989 LLNL YUCCA MTN. PROJECT

DATE: JAN 13 1989

REPLY TO ATTN OF: San Francisco Operations Office (DP)

SUBJECT: LLNL Audits of ANL QA Program

TO: Jay O. Hunze, Director, Technology Management Division, CH

We understand that we have concurrence from your office for the Lawrence Livermore National Laboratory (LLNL) to lead audits of the Quality Assurance Programs at the Argonne National Laboratory (ANL). These audits will be conducted in direct support of the Yucca Mountain Project. Currently, these activities are covered under the following SANL contracts with ANL:

SANL No.	Title
810006	Spent Fuel Dissolution
810007	Glass Waste Form Testing
810008	Radiation Chemistry Surrounding Containers
810009	Stress Corrosion Cracking and Ranking of Candidate Materials

The audit schedule and details will be established with ANL by LLNL to comply with the quality assurance requirements of the Yucca Mountain project in Nevada.

This understanding is based on the telephone discussions between Mr. Joel Haugen, CH, and Mr. Filbert Fong, SAN. If you have any questions, please call me on FTS 536-4320 or Fil Fong on FTS 536-7836.

Michael K. Hooper for
Director

J. Haugen, CH
E. Wilmot, NV
J. Baylock, NV
J. Juetten, SAN ESQA
L. Ballou, LLNL (L-206)

ATTACHMENT TO
SDR NO. 243, REV. 0

FY 89 LLNL-YMP EXTERNAL AUDIT SCHEDULE
REVISION 1

Month	Audit No:	Subject:	Requirements
Note 1	89-14	Pacific Northwest Laboratory	Procurement QA Specification
May	89-15	Babcock and Wilcox	Procurement QA Specification
June	89-16	LLNL Mechanical Calibration Facility	QP 12.0
	89-17	LLNL Electronic Calibration Facility	QP 12.0
July	89-18	Techtronics, LLNL Calibration Facility	QP 12.0
	89-19	Techtronics, Santa Clara Facility	QP 12.0
August	89-20	Techtronics, Beaverton Facility	QP 12.0
September	89-21	Argonne National Laboratory	Procurement QA Specification
February	89-22	SIMCO, Santa Clara Facility	NNWSI/88-9, Rev.2 Sect XII
March	89-23	CEESI, Nunn Co Facility	NNWSI/88-9, Rev. 2 Sect XII

The audit of LLNL has been postponed to a later date due to pending review of their QA Program and a Readiness Review activities.

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Lawrence Livermore National Laboratory
Energy Program
L-209, P.O. Box 808
Livermore, CA 94550
415-422-6454

ATTACHMENT TO
SDR NO. 243, REV.0

January 11, 1989
LTH 89-028

John Bates
Argonne National Laboratory
9700 So. Cass Avenue
Argonne, ILL 60439

SUBJECT: Reduction of Work at Argonne National Laboratory

SANL 810-006 - Activity D-20-42 - Spent Fuel Dissolution PI - E. Veleckis
SANL 810-007 - Activity D-20-27 - Conduct Unsaturated testing of WVDP & DWPF Glass

Dear Dr. Bates:

Lyn Ballou, acting Technical Project Officer for the LLNL-Yucca Mountain Project, has directed, in response to findings generated by a recent Project audit, that all QA Level I and II work, with the exception of data collection for in-process tests, be stopped at LLNL and its subcontractor sites. Further, no new QA Level I or II work is to start until authorized.

The Yucca Mountain Project has recently issued a new QA project plan (NNWSI/88-9, Revision 2) that contains new requirements. In addition, new procedures for the assignment of quality levels are being prepared by the YMP which will require that all present and planned activities be reassessed as to their quality levels. As part of the implementation of these requirements, LLNL-YMP is withholding authorization for Argonne National Laboratory to proceed with QA Level I and II work identifiec above. Work authorization cannot be given until the following conditions have been met.

1. A procurement QA specification that reflects the requirements of NNWSI/88-9, Rev. 2., is prepared, approved and distributed by LLNL-YMP to Argonne.

2. LLNL-YMP verifies that the Argonne QA Plan implements the requirements of NNWSI/88-9, Rev. 2.

[illegible] conducts a readiness review to [illegible] that Argonne is ready to proceed.

[illegible] will issue to Argonne the QA [illegible]fications that are mandatory for [illegible]nce to NNWSI/88-9, Revision 2 and will [illegible] tentative agreements of sched[illegible] compliance and for performance of readiness reviews by LLNL-YMP. Preparation of plans and procedures will be permitted to continue in all QA Level I and II activities to ensure fulfillment of quality assurance objectives.

These steps are not intended as a reflecton on the capabilities of Argonne or the quality of the work performed at ANL. Rather, these steps are necessitated by commitments made by

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ATTACHMENT TO
SDR NO. 243 REV.0

LLNL-YMP to the DOE Project Office as part of our plan for developing and implementing a fully qualified quality assurance program.

Upon receipt of this letter you are therefore directed to take the action listed above. We will be working closely with you to assure that the ANL program is returned to full operation as quickly as possible.

If you require further information, please feel free to call Ron Schwartz, LLNL QA Manager at FTS 543-4627.

Ron Schwartz
QA Manager
Nuclear Waste Management Program

RES:LJH:lr

xc: L. B. Ballou
L. J. Hansen
G. Kugler, L-202
R. N. Schock
R. E. Schwartz
H. F. Shaw
D. W. Short
Special Materials Office

Lawrence Livermore National Laboratory
Energy Program
L-209, P.O. Box 808
Livermore, CA 94550
415-422-6454

ATTACHMENT TO
SOR NO. 243 REV. 0

January 11, 1989
LTH 89-027

Steven C. Marschman
Battelle Pacific Northwest Laboratories
P. O. Box 999
Richland, Washington 99352

SUBJECT: Reduction of Work at Battelle Pacific Northwest Laboratories
SBPNL 810-005
- Activity D-20-42. Series 4 tests
- Activity D-20-44. D-20-45, TGA tests
- Activity D-20-45 Oven Oxidation tests
- Activity D-20-46. Fluoride Interactions
- Activity D-20-46. Pressurized tube tests
- Activity D-20-48. ^{14}C Radial distribution tests, and ^{14}C release tests

Dear Mr. Marschman:

Lyn Ballou, acting Technical Project Officer for the LLNL-Yucca Mountain Project, has directed, in response to findings generated by a recent Project audit, that all QA Level I and II work, with the exception of data collection for in-process tests, be stopped at LLNL and its subcontractor sites. Further, no new QA Level I or II work is to start until authorized.

The Yucca Mountain Project has recently issued a new QA project plan (NNWSI/88-9, Revision 2) that contains new requirements. In addition, new procedures for the assignment of quality levels are being prepared by the YMP which will require that all present and planned activities be reassessed as to their quality levels. As part of the implementation of these requirements, LLNL-YMP is withholding authorization for Battelle Pacific Northwest Laboratories to proceed with QA Level I and II work identified above. Work authorization cannot be given until the following conditions have been met.

1. A procurement QA specification that reflects the requirements of NNWSI/88-9, Rev. 2., is prepared, approved and distributed by LLNL-YMP to Battelle Pacific Northwest

2. LLNL-YMP verifies that the Battelle Pacific Northwest QA Plan implements the requirements of NNWSI/88-9, Rev. 2.

3. LLNL-YMP conducts a readiness review to verify that Battelle Pacific Northwest is ready to proceed.

The LLNL-YMP will issue to Battelle Pacific Northwest Laboratories the QA specifications that are mandatory for compliance to NNWSI/88-9, Revision 2 and will obtain tentative agreements of schedules for compliance and for performance of readiness reviews by

"BEST AVAILABLE COPY"

ATTACHMENT TO
SOR NO. 243 REV.0

LLNL-YMP. Preparation of plans and procedures will be permitted to continue in all QA Level I and II activities to ensure fulfillment of quality assurance objectives.

These steps are not intended as a reflection on the capabilities of Battelle Pacific Northwest or the quality of the work performed at Battelle Pacific Northwest. Rather, these steps are necessitated by commitments made by LLNL-YMP to the DOE Project Office as part of our plan for developing and implementing a fully qualified quality assurance program.

Upon receipt of this letter you are therefore directed to take the action listed above. We will be working closely with you to assure that the Battelle Pacific Northwest Laboratories program is returned to full operation as quickly as possible.

If you require further information, please feel free to call Ron Schwartz, LLNL QA Manager at FTS 543-4627.

/for

Ron Schwartz
QA Manager
Nuclear Waste Management Program

RES:LJH:lr

xc: L. B. Ballou
L. J. Hansen
G. Kugler, L-202
R. N. Schock
R. E. Schwartz
H. F. Shaw
D. W. Short
Special Materials Office
David Langstaff, DOE/Richland

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date November 7, 1988	2 Severity Level ☐ 1 ☐ 2 ☒ 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

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): ☒ Remedial ☒ Investigative ☒ Corrective

1.) Document and implement the requirements for use of technical specialist on audits.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
11/14/88	1 1988	11/19/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s) — 15 Effective Date _____

(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence — 17 Effective Date _____

(See Attached)

18 Signature/Date 11/23/88 12/23/88

Comp. by Orig. QA Org.

19 Response	☒ Accept ☐ Reject ☐ Amended Response	QAE/Lead Auditor/Date 2-1-89	Branch Manager/Date 1 Feb 89
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☒ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date D. Yeaney 5-24-89	Branch Manager/Date 25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date for
	5/25/89	25 May 89	5/30/89

8 Requirement (continued)

for the use of technical specialist

10 Recommended Actions (continued)

SDR #244

Remedial/Investigative Action(s)

A deficiency exists in the current procedure. The forthcoming procedure QP 18.0, Audits, will include specific requirements related to the use of Technical Specialists during QA Audits.

The Lead Auditors for the audits conducted during FY 88 where Technical Specialists were used will submit justification for the use of the selected personnel.

Effective Date: 5/01/89

Cause of the Condition & Corrective Action to Prevent Recurrence

This condition was caused by the failure to identify specific requirements related to the use of Technical Specialists during QA Audits in the procedure.

QP 18.0, Audits, will provide for the use of Technical Specialists during the conduct of future QA Audits.

Personnel will be trained to revised procedures.

Effective Date: 5/01/89

SDR NO. 244, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

1. Procedure 033-YMP-QP 18.0 "Audits" Rev. 0 has been revised to include the use of technical specialists in audits.

2. LLNL has provided justification for the use of the technical specialists utilized during audits performed during FY 88.

3. Personnel training records were verified to be completed for procedure 033-YMP-QP 18.0 Rev. 0.

ATTACHMENT TO SDR
NO. 244 REV.0

Basis for Qualification and Assignment of Technical Specialists - SDR #244

ANSI/ASME NQA-1 requires that for each audit performed, there must be a Lead Auditor, and if only one auditor is involved in the audit, the auditor must be a qualified Lead Auditor. The audits in question were led by a qualified lead auditor and included a technical specialist on the team to audit/evaluate technical activities.

The objectives of a quality program audit include assessing the effectiveness of various quality assurance elements or controls and also assuring that technically oriented or programmatic deficiencies are identified and corrected. In order to provide a thorough evaluation of technical elements of the audited tasks, the Lead Auditor may select a technical specialist capable of understanding the technical aspects of a task, including the performance of field, design or laboratory work activities.

For example, Frank Fenzel, who has a BA and MA in Geology and has completed post graduate work in Hydrogeology, was selected to participate in LLNL Audit 88-03, Glass Waste Form Testing, in order to evaluate the adequacy of technical procedures and that the performance of laboratory or test activities are in accord with procedural requirements. Mr. Fenzel's twenty years experience in geology and hydrology were considered adequate for his selection as a technical specialist.

For Audit LLNL 88-09, Geochemical Modeling Code, Sheau Tain (Wally) Hsu, was selected to participate as a Technical Specialist based on his extensive experience in computer modeling, analysis, and simulation of geometric and material non-linear systems. Mr. Hsu has B.S. and M.S. Degrees in Mechanical Engineering and is knowledgeable in the quality measures that must be implemented during the code development and maintenance phases of computer codes.

Audit LLNL-88-16 did not utilize a Technical Specialist that audit.

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WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date November 7, 1988 | 2 Severity Level ☐ 1 ☐ 2 ☒ 3 | Page 1 of 2

3 Discovered During	3a Identified By	3b Branch Chief Concurrence Date	4 SDR No.
Audit 88-05-01	K. Sommer/N. Frank		245 Rev. 0

5 Organization	6 Person(s) Contacted	7 Response Due Date is 20 Working Days from Date of Transmittal
LLNL	R. Oberle	

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): ☒ Remedial ☒ Investigative ☒ Corrective
1.) Implement program requirements and include in all future audits.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
11/14/88	NOV 14 1988	11/14/88

Completed by Organization in Block 5

14 Remedial/Investigative Action(s) — 15 Effective Date _____
(See Attached)

16 Cause of the Condition & Corrective Action to Prevent Recurrence — 17 Effective Date _____
(See Attached)

18 Signature/Date 12/15/88 12/23/88

Comp. by Orig. QA Org.

		QAE/Lead Auditor/Date	Branch Manager/Date
19 Response	☒ Accept ☐ Amended ☐ Reject Response	2-1-89	1 Feb 89
20 Amended Response	☐ Accept ☐ Reject		
21 Verification	☒ Satisfactory ☐ Unsatisfactory	5-25-89	25 May 89

22 Remarks SEE ATTACHED BLOCK 22 CONT'D FOR VERIFICATION DETAILS

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date for
	5/25/89	25 May 89	5/30/89

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.

Remedial/Investigative Action(s)

QA Audits will include an assessment of the effectiveness of the implementation of the QA Program.

Audits will include provisions for assessing the status and effectiveness of previously identified corrective actions related to the activities being audited.

Effective Date: 12/02/88

Cause of the Condition & Corrective Action to Prevent Recurrence

This condition was caused by a lack of adequate procedural guidance concerning the accomplishment of effectiveness evaluations and the follow-up of previously identified corrective actions.

The forthcoming QP 18.0, Audits, will include specific guidance concerning these matters. Personnel who participate in the audit process will be trained in the implementation of these requirements.

In addition, a Trend Analysis procedure will be developed and implemented to compile information related to deficiencies and nonconformances. The results of this trend analysis will be used to support management's overview of the effectiveness of corrective actions. Further, the annual Management Assessment of project activities to ascertain the overall effectiveness of the implementation of the QA Program requirements will be performed with the benefit of trend analysis results from the QA organization.

Personnel will be trained to revised procedures.

Effective Date: 5/01/89

SDR NO. 245, REV. 0 (CONT'D)

BLOCK 22 REMARKS (cont'd)

1. Procedure 033-YMP-QP 18.0 "Audits" Rev.0 now contains guidance to accomplish effectiveness evaluations during the performance of audits (refer to paragraphs 18.0.5.5.2 and 18.0.5.6).

2. Procedure 033-YMP-QP 18.0 Rev.0 now includes the consideration of previous audit results in the preparation of future audits (refer to paragraph 18.0.5.4).

3. Personnel training records were verified to be completed for procedure 033-YMP-QP 18.0 Rev. 0.

4. A trend analysis procedure 033-YMP-QP 16.2 "Trend analysis" Rev. 0 has been issued for analizing adverse trends related to deficiencies and nonconformances.

5. Procedure 033-YMP-QP 2.3 "Management Assessment" Rev. 0 has been issued and contains requirements to conduct management assessments at least once a year to evaluate the effectiveness of the QA program.

6. Training to procedure 033-YMP-QP 16.2 has been determined not to be required (refer to letter Schwartz to Stockdale, dated April 25, 1989).

7. Personnel training records were verified to be completed for procedure 033-YMP-QP 2.3 Rev. 0.

8. A management assessment is currently being prepared by LLNL to assess the effectiveness of the QA program.

9. Audit reports 89-01, 89-02, and 89-03 were reviewed and did include an effectiveness statement based upon the results of the audits.

10. Audit checklists reviewed now require a review of past audit findings and observations to verify the effectiveness of corrective action (refer to attached example).

Interdepartmental letterhead

Mail Station L 204
Ext. 3-4627

ATTACHMENT TO
SDR NO. 245 REV.0

QA: 89/944
25 April 89

TO: W. Stockdale

FROM: Ronald Schwartz R. Schwartz

SUBJECT: **Training Requirements for QP 16.2, Trend Analysis**

I do not believe that training is required for the implementation of QP 16.2 for the following reasons:

1. The two QA personnel who actively implement the procedure, Ron Oberle and Gary DeLeon, are its authors;

2. The LLNL-YMP Management personnel who are identified in the procedure have duties that are limited to review the Trend Analysis Reports;

3. As QA Manager, my major function in the procedure is to initiate Corrective Action Reports when an adverse quality trend is identified in the analysis; and

3. No other project personnel have a responsibility specified in the procedure.

If you concur with my analysis, please assure that this letter remains on file for the benefit of future auditors.

Concur. W.K. Stockdale
Training coordinator
4/26/89

xc:
B.Bryan
R.K. Dann, KE
CF
CF
RF

ITEM NO.:	REFERENCE	REQUIREMENT (AUDIT ELEMENT) METHOD OF ACCOMPLISHMENT	RESULT	DATA/NOTES	AUDITOR INITIALS
25.	22.0.5	For review of Technical Publications, verify documentation that demonstrates: Review for technical content Review for Technical approval Review for Project approval Review for Sponsor approval Review for NWMP Administrative approval Review for QA Provedure approval Review for existance of sufficient QA records			
26.	22.0.6.2	Verify that publications submitted by subcontractors as deliverables are subject to the reviews specified in 22.0.5			
[redacted]		Review past audit findings and [redacted]			

ATTACHMENT TO SDR NO. 245 REV.0