Department of Energy
Yucca Mountain Site Characterization
Project Office
P. O. Box 98608
Las Vegas, NV 89193-8608

WBS 1.2.9.3
QA

DEC 20 1990

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CLOSURE OF STANDARD DEFICIENCY REPORTS (SDRS) 537, 541, AND 544, REVISIONS 0, RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION AUDIT 90-02 OF LAWRENCE LIVERMORE NATIONAL LABORATORY

SDRs 537, 541, and 544, Revisions 0, have been closed based on satisfactory verification of completed corrective actions. Copies of the SDRs are enclosed for your files.

If you have any questions, please contact either Catherine E. Hampton at (702) 794-7973 or FTS 544-7973 or Richard L. Maudlin of Science Applications International Corporation at (702) 794-7290 or FTS 544-7290.

Donald G. Horton, Director
Yucca Mountain Quality Assurance Division

YMQAD:CEH-1288

Enclosure:
SDRs 537, 541, and 544, Revisions 0

cc w/encl:
John Lee, SAN
K. R. Hooks, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
D. W. Short, LLNL, Livermore, CA
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

cc w/o encl:
J. W. Gilray, NRC, Las Vegas, NV

1/1

YMP-5
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PDR WASTE
WM-11 PDR

FULL TEXT ASCII SCAN

ADD: K. Hooks

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WM-11
NH03

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YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization

1 Date May 18, 1990 | 2 Severity Level ☐ 1 ☒ 2 ☐ 3 | Page 1 of 2

3 Discovered During: YMP Audit 90-02

3a Identified By: A. Arejo ma 11-15-90, R. Maudlin

4 SDR No. 537 Rev. 0

5 Organization: LLNL

6 Person(s) Contacted: W. L. Clark, B. Bryan

7 Response Due Date is 20 Working Days from Date of Transmittal

8 Requirement (Audit Checklist Reference, if Applicable)

PART A

LLNL Procedure 033-YMP-QP 2.1 "Preparation, Approval and Revision of Quality Procedures and Requirements", Rev. 1, para. 2.1.4.3 states in part:

9 Deficiency

PARTS A & B

There was no objective evidence available during the audit to assure the that the review process described in QP 2.1 or the LLNL QAPP was followed as

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

PARTS A & B

1. Issue a memo to the appropriate document review files acknowledging this

Aprvl.

11 QAE/Lead Auditor/Date: Gerard Heaney 5-23-90

12 Division Manager/Date: N/A

13 Project Quality Mgr./Date: Catherine Haraf 5-29-90

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: David W. Stuart 6/29/90

Comp. by Orig. QA Org.

19 Response Accepted	QAE/Lead Auditor/Date: G. Heaney 7-9-90	Division Manager/Date: N/A	Project Quality Mgr./Date: Catherine Haraf 7-10-90
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date: Robert W. Craig 11/6/90	Division Manager/Date: N/A.	Project Quality Mgr./Date: Catherine Haraf 12-4-90

21 Remarks: Response rec'd 7/6/90 - QA-90/125
Accept Response 7/26/90 - YMP:CEH-4299
Extension Request dtd 8/10/90 - LLYMP900-8083 - Accepted 8/24/90 - QA:CEH-4643
TIP-1 THRU TIP-7 & SIP-WF-1 WERE REVISED.
033-YMP-QP 2.1 REV. 2. ISSUED 10/17/90
YMP SPENT FUEL WASTE FORM TESTING (WBS 1.2.2.3.1.1) REV. 6 WAS REVIEWED & APPROVED AS NOTED. LBP 11/2/90

22 QA CLOSURE	QAE/Lead Auditor/Date: Robert W. Craig 12/4/90	Division Manager/Date: N/A.	PQM/Date: Catherine Haraf for 12/4/90

8 Requirement (continued)

1. "Review copies are distributed by the originator for review as identified in Exhibit A."
2. "Review copies are accompanied by a memo identifying the comments due date, clarifying information and any special instructions."
3. "The originator prepares a package of review copy pages with major comments and submits the memo and the package to the Local Records Center with the Records Transmittal."

LLNL Procedure 033-YMP-QP 17.0 "Quality Assurance Records", Rev. 1,para. 17.0.5.2 states in part: "When an activity has been completed, the Task Leader will collect and transmit to the LRC records generated by that activity not previously submitted."
(Refer to audit checklist item nos. 5-2 and 17-1)

PART B
The LLNL QAPP 033-YMP-R 3, Rev. 0, para. 1.3.1 states in part: "The LLNL-YMP conducts a technical review of the scientific investigation planning document.... The results of this technical review, and the resolution of any comments by the reviewer or reviewers, are documented, and become a part of the QA records.
(Refer to audit checklist item no. 3-11)

9 Deficiency (continued)

evidenced by the lack of document review packages at the LRC for the documents listed below:

Document	Revision	Approval Date	Issue Date
TIP-CM-01	0	10/09/89	10/09/89
TIP-CM-02	0	10/17/89	10/17/89
TIP-CM-03	0	10/17/89	10/17/89
TIP-CM-04	0	10/17/89	10/17/89
TIP-CM-05	0	12/21/89	01/22/90
TIP-CM-06	0	01/17/90	01/22/90
TIP-CM-07	0	01/26/90	01/26/90
SIP for Spent Fuel Waste Form Testing	0.5	05/23/89	

10 Recommended Actions (continued)

SDR.
2. Instruct appropriate personnel to procedural requirements identified in this SDR.
3. Review to ensure that the appropriate review was performed although a review package might not exist for the reviews performed.
4. Determine the impact on quality due to the SDR.

14. Remedial/Investigative Action:

The Deputy Project Leader reviewed the documentation and interviewed the reviewers for the seven TIPs and the one SIP cited above. Based on this review, document packages are being assembled and filed in the LRC for these eight documents. The conclusion of the review is that the appropriate reviews took place, but that the documentation was incomplete. As much as possible of the documentation is being reestablished. The document packages for these activities will be filed in the LRC by COB 3 July 1990.

15. 3 July 1990

16. Cause of Condition:

The incomplete documentation resulted from several causes. The SIP is still not approved by YMPO more than a year after it was submitted, and thus the package is incomplete. There was confusion as to whether the author (who was the Technical Area Leader) or the LRC should store the package pending YMPO approval. In the interim, the TAL left YMP, and the package was inadvertantly lost. For the TIPs, the documentation was turned over to a quality engineer who subsequently left the program. The documentation was not located in the LRC or in the files turned over by the quality engineer.

Corrective action includes revision of the quality procedure governing planning document review (QP-2.1). The revision includes additional forms to be used for the documentation, and specifies that interim packages will be stored by the publications manager until the complete package is ready for submission to the LRC. In addition, corrective action includes increased awareness by the management and QA staff of LLNL-YMP.
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17. 31 July 1990

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1 Date May 18, 1990 | 2 Severity Level ☐ 1 ☒ 2 ☐ 3 | Page 1 of 2

3 Discovered During: YMP Audit 90-02 | 3a Identified By: M. Diaz | 4 SDR No. 541 Rev. 0

5 Organization: LLNL | 6 Person(s) Contacted: D. Short | 7 Response Due Date is 20 Working Days from Date of Transmittal

8 Requirement (Audit Checklist Reference, if Applicable)
The LLNL QAPP Section 033-YMP-R 18, Rev. 0, para. 1.0 states in part: "All deficiencies, nonconformances, and potential quality problems identified during the audit are documented and monitored until verification of effective

9 Deficiency
Contrary to the above requirements, LLNL Procedures 033-YMP-QP 18.0 "Audits", Rev. 0 and 033-YMP-QP 18.1 "Surveillances", Rev. 1 did not require observations that were generated as a result of audits and surveillances

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

1. Perform a review to establish how many audit and surveillance generated observations have been issued to date. Establish which of those have

Aprvl.

11 QAE/Lead Auditor/Date: Gerard Heaney 5-23-90 | 12 Division Manager/Date: N/A | 13 Project Quality Mgr./Date: Catherine Tompkins 5-29-90

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 N/A

See attached.

18 Signature/Date: David W. Short 6/29/90

Comp. by Orig. QA Org.

19 Response Accepted	QAE/Lead Auditor/Date: G. Heaney 7-9-90	Division Manager/Date: N/A	Project Quality Mgr./Date: 8/29/90
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date: 12/4/90	Division Manager/Date: N/A	Project Quality Mgr./Date: 12/10/90

21 Remarks Response rec'd 7/6/90 - QA:90-225
Amended Response dtd 7/18/90 - LLYMP9007126
Extension Request 8/10/90 - LLYMP9008083 - Accepted 8/24/90 - QA:CEH-4643
Accept Response + Extension 8/31/90 - QA:CEH-4761
DISCUSSIONS WITH AUDITORS & REVIEW OF AUDIT CHECKLISTS INDICATE USE OF PREVIOUS AUDIT & SURVEILLANCE REPORTS TO BE USED FOR FUTURE AUDITS & SURVEILLANCES AS PER PROCEDURAL REQUIREMENTS RBE 11/4/90.

22 QA CLOSURE	QAE/Lead Auditor/Date: 12/4/90	Division Manager/Date: N/A	PQM/Date: 12/10/90

8 Requirement (continued)

corrective action is made."
Para. 2.0 of the same QAPP Section states in part: "All deficiencies, nonconformances, and potential quality problems identified during surveillances are documented and monitored until verification of effective corrective action is made.

(Refer to audit checklist item no. 18-4-1)

9 Deficiency (continued)

to be monitored until verification of effective corrective action was made.

Note: During the course of the audit, LLNL revised the procedures to incorporate the above listed requirements (Refer to Change Notice No. 18.0-1-1 issued to QP 18.0 "Audits", Rev. 0 and Change Notice No. 18.1-1-2 issued to QP 18.1 "Surveillances" Rev. 1). However, this SDR is being issued to accomplish remedial and investigative action as there have been over 75 observations issued to date. LLNL has not documented the monitoring or follow-up of all of these observations.

10 Recommended Actions (continued)

had documented follow-up (i.e., have been recorded onto surveillance or audit checklists).

2. Perform follow-up to those observations which have not yet had documented follow-up (i.e., perform a documented surveillance).

3. Train appropriate personnel to revised procedural requirements.

14. Remedial/Investigative Action(s)

Quality procedures were changed May 18, 1990 to incorporate the now obsolete requirement that potential quality problems be documented in audit and surveillance reports. QA staff training was completed June 16, 1990.

Observations as defined in the LLNL-YMP QA program represent opinions of the auditor. During exit meetings for both surveillances and audits, auditors discuss the observations for management consideration. Management of the audited organization may make improvements or clarifications to the quality assurance program after considering the observations. Actions are not required.

A review in late May '90 of 11 audits and 14 surveillances performed since February 1989 determined the number and status of observations. Some of the observations had documented follow-up even though the follow up was not specifically called for by the procedures in effect. Of the remaining 75 observations, 11 have had follow-up since the review or are currently being followed upon in on-going audits and surveillances.

LLNL-YMP intends to revise its quality assurance program to be in compliance with the recently approved (May 13, 1990) revision of the OCRWM Quality Assurance Requirements Document and perform audits and surveillances to verify implementation through revised procedures. The requirement to address "potential quality problems" has been removed from the higher tier QA document and the LLNL-YMP QA program will reflect this change, too. Sufficient remedial actions related to this SDR are, therefore, complete in light of the new QA requirements.

15. Effective date: June 29, 1990

16. Cause of the Condition

Reference to both documentation of "potential quality problems" and monitoring until verification of completion of corrective action was intentionally omitted from audit and surveillance quality procedures because of the flawed logic of the requirement. For potential problems there can be no actions taken to restore proper conditions or remove errors or faults (corrective actions) since there are no identified deficiencies. Logically, the quality assurance organization cannot monitor or verify corrective action for non problems. No further corrective action beyond that already taken to remedy the short term condition is planned in light of the new QA requirements.

14. [add this paragraph after paragraph 3]

LLNL-YMP routinely uses previous audit and surveillance reports as basis material in the planning stages for subsequent audits and surveillances. This is stated in our quality procedures. This planning direction provides for monitoring any potential quality problems that previous auditors may have expressed in the reports.

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1 Date May 18, 1990 | 2 Severity Level ☐ 1 ☒ 2 ☐ 3 | Page 1 of 2

3 Discovered During: YMP Audit 90-02 | 3a Identified By: M. Diaz | 4 SDR No. 544 Rev. 0

5 Organization: LLNL | 6 Person(s) Contacted: D. Short, E. DeLeon | 7 Response Due Date is 20 Working Days from Date of Transmittal

8 Requirement (Audit Checklist Reference, if Applicable)

The LLNL QAPP, Section 033-YMP-R 16, Rev. 0, para. 1.1 states in part: "Upon discovering or receiving notification that a significant condition adverse to quality or an unusual occurence exists, the LLNL-YMP assures that immediate

9 Deficiency

Contrary to the above,

A) LLNL implementing procedure 033-YMP-QP 15.0 "Nonconforming Items, Procedural Nonconformances and Conditions Adverse to Quality", Rev. 0, does

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

1. Revise LLNL Procedure QP 15.0 to include time limits for the evaluation of an NCR from its date of discovery.

Aprvl.

11 QAE/Lead Auditor/Date: Gerard Heaney 5-30-90 | 12 Division Manager/Date: N/A | 13 Project Quality Mgr./Date: [signature] 5-31-90

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

Not applicable. DOE

~~See attached.~~

17 Effective Date _____

18 Signature/Date: David W. Short 6/29/90

Comp. by Orig. QA Org.

19 Response Accepted	QAE/Lead Auditor/Date: G Heaney 7-9-90	Division Manager/Date: D/A	Project Quality Mgr./Date: [signature] 7-16-90
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date: [signature] 11/2/90	Division Manager/Date: N/A	Project Quality Mgr./Date: [signature] 12/10/90

21 Remarks: Response rec'd 7/6/90 - QA:90/225
Accept Response 7/26/90 - YMP:CEH-4299
Extension Request dtd 8/10/90 - LLYMP900803-Accepted 8/24/90 - QA:CEH-4643
QP 15.0 REV. 2; QP 16.0 REV. 2; QP 16.1 REV. 2; QP 16.2, QP 18.0 REV. 2, QP 18.1 REV 2 ARE IN EFFECT TO ASSURE COMPLIANCE. TRAINING WAS REQUIRED AS APPROPRIATE.
RBC 11/2/90

22 QA CLOSURE	QAE/Lead Auditor/Date: [signature] 12/10/90	Division Manager/Date: N/A	PQM/Date: [signature] 12/10/90

8 Requirement (continued)

actions are taken to remedy the specific conditions."

In addition, the LLNL QAPP, Section 033-YMP-R 5, Rev. 0, states in part: "....These documents (instructions, procedures) include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities are satisfactorily accomplished."

(Refer to audit checklist item no. 16-1)

9 Deficiency (continued)

not contain qualitative or quantitative criteria establishing the time limits from the origination of a nonconformance report to the evaluation of the nonconformance report for determination if the identified deficiency is minor or serious, or a significant condition adverse to quality exists (therefore requiring the issuance of a Corrective Action Report per QP 16.0).

B) LLNL implementing procedure 033-YMP-QP 16.0 "Corrective Action", Rev. 1, does not contain qualitative or quantitative criteria establishing the time limits for the QA Manager to complete Part 1 of the Corrective Action Report from initiation to distribution.

10 Recommended Actions (continued)

2. Revise LLNL Procedure QP 16.0 to include time limits for the QA Manager to complete Part 1 of the CAR from discovery to distribution.

3. Train appropriate personnel to revised procedures.

14. Remedial/Investigative Action(s)

The interpretation by the auditor that the requirement quoted from 033-YMP-R 5, Rev. 0 to "include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities are satisfactorily accomplished" is also verbatim from NQA-1, Basic Requirement 5. This requirement is intended to be implemented through technical instructions, procedures, etc. related to activities such as testing and inspection. Acceptance criteria, both qualitative and quantitative, are also related to equipment operations, manufacturing processes, and production activities (e.g., statistical process control).

To conclude that this requirement implies that time limits must be prescribed for management evaluations of possible conditions adverse to quality is a minor opinion and is not commonly accepted. Quality implementing procedures of many organizations do not place "time limits" on the management evaluation of possible deficiencies. Organizations such as DOE-OCRWM, DOE-YMPO, USGS, LANL, SNL, FSN, Kaiser Engineering, and Cygna Corporation do not interpret this NQA-1 requirement in such a manner.

The LLNL-YMP quality assurance procedures incorporate the requirement for prompt identification and correction of conditions adverse to quality as soon as practical. Once a decision is made that conditions adverse to quality exist, actions are taken (with prescribed time limits) to remedy the adverse conditions. Significant conditions adverse to quality are handled immediately.

LLNL-YMP is improving quality procedures 15.0, 16.0, 18.0, and 18.1 to allow nonconformance reports, corrective action reports, and adverse finding reports to be issued independently of the related audit or surveillance reports. These modifications should provide for improvements in the process to correct adverse conditions.

Affected personnel with be trained to the improved procedures.

15. Effective date: August 15, 1990