



Department of Energy

Yucca Mountain Project Office

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Las Vegas, NV 89193-8608

WBS 1.2.9.3

QA

JUL 26 1990

Leslie J. Jardine
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ACCEPTANCE OF RESPONSES TO STANDARD DEFICIENCY REPORTS (SDRS) 536, 537, 540, AND 544, REVISIONS 0, RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT 90-02 OF LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL)

The Project Office QA staff has evaluated and accepted your responses to SDRs 536, 537, 540, and 544, Revision 0, generated as a result of Project Office QA Audit 90-02 of LLNL. The SDRs will be closed after verification of satisfactory completion of the specified corrective actions. Copies of the SDRs are enclosed for your information.

Verification of completion of your corrective action will be performed after the effective dates that were provided. Any extension to these due dates must be requested in writing with appropriate justification prior to the due date. Please send copies of the extension request to Nita J. Brogan, Science Applications International Corporation, 101 Convention Center Drive, Las Vegas, Nevada 89109.

If you have any questions, please contact Catherine E. Hampton at (702) 794-7973 or FTS 544-7973 of the Yucca Mountain Project QA staff.

James Blaylock for
Donald G. Horton, Director
Quality Assurance
Yucca Mountain Project Office

YMP:CEH-4299

Enclosures:
SDRs 536, 537, 540, and 544

YMP-5

9008030216 900726
PDR WASTE
WM-11 PDC

102.7
WM-11
NH03

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
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Completed by Originating QA Organization	1 Date May 18, 1990		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
	3 Discovered During YMP Audit 90-02		3a Identified By R. Maudlin		4 SDR No. 536 Rev. 0
	5 Organization LLNL		6 Person(s) Contacted J. Blink, D.Short		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) Project Procedure AP-5.13Q "Readiness Review" Rev. 0, para. 4.5 states in part: "The Board approves the completed checklist and the Review Record Memorandum."				
Completed by Organization in Block 5	9 Deficiency Contrary to the above, for several readiness review files reviewed during the audit:				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Issue a memo to the appropriate readiness review files acknowledging this SDR.				
	11 QAE/Lead Auditor/Date <i>Gerard Heaney 5-23-90</i>		12 Division Manager/Date N/A		13 Project Quality Mgr./Date <i>David W. Short 5-29-90</i>
Comp. by Orig. QA Org.	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 <i>David W. Short 6/29/90</i>				
19 Response Accepted	QAE/Lead Auditor/Date <i>S. Heaney 7-9-90</i>	Division Manager/Date N/A	Project Quality Mgr./Date <i>David W. Short 7-19-90</i>		
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
21 Remarks <i>Response rec'd 7/6/90 - LLNL # 660410 - GF - 90/225</i>					
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

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8 Requirement (continued)

AF-5.132 Rev. 0, para. 5.2.1 states in part: "The Readiness Review Board Chairperson performs the following:

1. Determines the technical disciplines to be used to accomplish the scope and purpose of the review.
2. Establishes minimum qualifications (e.g., education, experience and independence) needed by Review Board members to provide the technical disciplines to accomplish the scope and purpose of the review.

(Refer to audit checklist item no. 3-8)

9 Deficiency (continued)

1. No objective evidence could be provided to reflect approval of the Review Record Memorandum by the Readiness Review Board.
2. No objective evidence could be provided to identify that the Readiness Review Board Chairperson: a) made a determination of the technical disciplines to be used; and b) established the minimum qualifications needed by Readiness Review Board members for technical disciplines to be used.

10 Recommended Actions (continued)

2. Establish and document the technical disciplines to be used to accomplish the scope and purpose of the review.
3. Establish and document the qualifications (education, experience, and independence) needed by Review Board Members.
4. Review the qualifications of the personnel who performed readiness reviews to ensure adequacy for each specific readiness review performed. Annotate each file accordingly.
5. Evaluate the impact on quality as a result of this SDR.

14. Remedial/Investigative Action(s)

Readiness Review Record Memoranda will be approved (signed) by Board Members.

Readiness Review records will be supplemented with statements by the Readiness Review Board Chair concerning the determination of technical disciplines used in the reviews and the establishment of minimum qualification of Board members to accomplish the scopes and purposes of the reviews.

The validity of the review results and the recommendations sent by the Board members to the Technical Project Officer are unaffected. These nonconformances do not represent conditions adverse to quality.

15. Effective date: July 31, 1990

16. Cause of the Condition & Corrective Action to Prevent Recurrence

Cause of the Condition

The lack of Board member approval on the Review Record Memoranda was an error of omission, a procedural nonconformance.

Corrective Action to Prevent Recurrence

If LLNL-YMP is specifically directed to perform readiness reviews in accordance with Administrative Procedure 5.13Q, future training will emphasize the documentation requirements. Any checklists and instructions developed for use will incorporate the procedural requirements.

However, since LLNL-YMP is now permitted to perform readiness reviews according to the LLNL-YMP quality assurance program, we intend to discontinue use of the cumbersome AP 5.13Q.

17. Effective date: Not applicable

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Completed by Originating QA Organization	1 Date May 16, 1990		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
	3 Discovered During YMP Audit 90-02		3a Identified By A. Areco R. Maudlin		4 SDR No. 537 Rev. C
	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:				
Completed by Organization in Block 5	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): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective PARTS A & B 1. Issue a memo to the appropriate document review files acknowledging this				
	11 QAE/Lead Auditor/Date <i>Bernard Heaney 5-23-90</i>		12 Division Manager/Date N/A		13 Project Quality Mgr./Date <i>Catherine [Signature] 5-29-90</i>
Completed by Org. QA Org.	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 <i>David W. Short 6/29/90</i>					
19 Response Accepted		QAE/Lead Auditor/Date <i>B. Heaney 7-9-90</i>	Division Manager/Date N/A	Project Quality Mgr./Date <i>[Signature]</i>	
20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
21 Remarks <i>Response rec'd 7/6/90 - GA-90/225</i>					
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

**YMP-0 STANDARD DEFICIENCY REPORT
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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 inadvertently 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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	3 Discovered During YMP Audit 90-02		3a Identified By S. Crawford		4 SDR No. 340 Rev. C
	5 Organization LLNL		6 Person(s) Contacted D. Short, J. Blink		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 3, Rev. 0, para. 1.1.2 states in part: "Scientific planning documents consist of Scientific Investigation Plans for all other activities (other than site characterization activities).				
	9 Deficiency The Scientific Investigation Plan for Metal Barrier Selection and Testing, Rev. 0 (WBS 1.2.2.3.2); Activity Plans for sub-activities E-20-15, E-20-18a, E-20-18c, E-20-18d; and related Technical Implementing Procedures were not				
Completed by Organization in Block 5	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Review and revise all Scientific Investigation Plans, Activity Plans, and Technical Implementing Procedures for the Metal Barrier Activity				
	11 QAE/Lead Auditor/Date <i>Bernard Heaney 5-23-90</i>		12 Division Manager/Date <i>U/A</i>		13 Project Quality Mgr./Date <i>5-29-90</i>
	14 Remedial/Investigative Action(s) See attached.				15 Effective Date <u>July 31, 1990</u>
	16 Cause of the Condition & Corrective Action to Prevent Recurrence See attached.				17 Effective Date <u>July 31, 1990</u>
	18 Signature/Date <i>David W Short 6/29/90</i>				
Comp. by Orig. QA Org.	19 Response Accepted		QAE/Lead Auditor/Date <i>S. Heaney 7-9-90</i>	Division Manager/Date <i>U/A</i>	Project Quality Mgr./Date <i>7-18-90</i>
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
	21 Remarks <i>Response rec'd 7/6/90 - QA: 7/22/90</i>				
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

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8 Requirement (continued)

These documents also identify additional planning documents called Activity Plans which are prepared for each activity or a combination of activities. Activity Plans provide the sequence and details of how the work is performed and how applicable QA procedures are implemented."

(Refer to audit checklist item no. 3-14)

9 Deficiency (continued)

fully consistent for experiment requirements and quality assurance levels. In addition, the planning documents and technical procedures did not reflect current plans for the investigation, although readiness reviews had been conducted and the activities had been authorized to restart.

Examples include:

1. Candidate materials identified by the SIP for "Metal Barrier Selection and Testing" (WES 1.2.2.3.2) Rev. 0, TIP-CM-1 Rev. 0, and TIP-CM-5 Rev. 0 include alloys CDA 102 copper and CDA 613 aluminum-bronze. The actual alloys used to fabricate test coupons for plane-strain fracture toughness (Activity E-20-18c) and threshold stress intensity for stress corrosion cracking (Activity E-20-18d) are CDA 122 and CDA 614. Although the substituted alloys are closely related, the technical basis and justification for deviating from the designated candidate materials should be documented at the SIP or Activity Plan Level.
2. Activity Plan E-20-18c as amended by Change Notice E-20-18c-0-1 included material tests (J1c). These tests are not detailed in TIP-CM-1, which is the applicable TIP for the activity. TIP-CM-1 provides details for performing material tests (K1c) which, although described in Activity Plan E-20-18c, are not intended to be performed. The test coupon configuration shown in TIP-CM-1, Figure 7, is for K1c tests and is not the same test coupon configuration to be actually used for the J1c tests.
3. Activity Plans E-20-18c and E-20-18d identify the fracture toughness and threshold stress intensity tests as QA Level II. The attached statement of work (Appendix II) for subcontracted services identifies Task 3 as QA Level I. Although this discrepancy is no longer a concern because the subcontractor assigned to perform the work will no longer be used, Readiness Reviews RR005 and RR006 had identified the discrepancy and the resolution was that the activity plan has been modified to incorporate this change. The activity plan was not corrected.

10 Recommended Actions (continued)

1. to ensure consistency and accurate reflection of the technical work to be performed.
2. Investigate to determine if the inconsistencies have had an adverse impact to the quality of the work performed.

SDR #540
Response

14. Remedial/Investigative Actions

Technical Implementing Procedures were inconsistent in experimental requirements and quality assurance levels. Changes in test planning had been conceived and discussed but not implemented and no work had been started. Alloy substitutions had not been documented as to technical basis.

16. Cause of the Condition & Corrective Action to Prevent Recurrence

Changes in planned activities took place after Readiness Review had authorized work and were not reflected in plans.

Activity plans and Technical Implementing Procedures will be revised no later than July 31, 1990 to reflect actual plans and technical basis for alloy substitutions documented and reviewed. QA assignments will be corrected as required.

There is no adverse impact on the quality of the subject Tasks because no work had begun.

NOTE : LLNL HAS PREVIOUSLY SUBMITTED A REVISED SIP
TO THE PROJECT OFFICE FOR APPROVAL.

G. Heaney 7-9-90

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Completed by Originating QA Organization	1 Date May 18, 1990		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 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 occurrence exists, the LLNL-YMP assures that immediate				
Completed by Organization in Block 5	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): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective 1. Revise LLNL Procedure QP 15.0 to include time limits for the evaluation of an NCR from its date of discovery.				
	11 QAE/Lead Auditor/Date <i>Gerard Heaney 5-30-90</i>		12 Division Manager/Date <i>N/A</i>		13 Project Quality Mgr./Date <i>Catherine [unclear] 5-31-90</i>
	14 Remedial/Investigative Action(s) See attached.				
Comp. by Orig. QA Org.	15 Effective Date _____				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence ²⁰⁰⁸ Not applicable. See attached.				
	17 Effective Date _____				
18 Signature/Date <i>David W. Short 6/29/90</i>					
19 Response Accepted		QAE/Lead Auditor/Date <i>G. Heaney 7-9-90</i>	Division Manager/Date <i>DA</i>	Project Quality Mgr./Date <i>[unclear] 7/6/90</i>	
20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
21 Remarks <i>Response rec'd 7/6/90 - CA: 911225</i>					
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date	

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8 Requirement (continued)

actions are taken to remedy the specific conditions."

In addition, the LLNL QAPP, Section (33-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 will be trained to the improved procedures.

15. Effective date: August 15, 1990

Leslie J. Jardine

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JUL 26 1990

cc w/encls:

John Lee, SAN

W. Zimmerman, NWPO, Carson City, NV

K. R. Hooks, NRC, Washington, DC

D. W. Short, LLNL, Livermore, CA

cc w/o encls:

J. W. Gilray, NRC, Las Vegas, NV

N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

S. R. Dippner, SAIC, Las Veas, NV, 517/T-08

Gerard Heaney, SAIC, Las Vegas, NV, 517/T-06