



Department of Energy

Yucca Mountain Project Office

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AUG 09 1990

WBS 1.2.9.3

QA

To: K. Hooks

Leslie J. Jardine
Technical Project Officer
for Yucca Mountain Project
Lawrence Livermore National Laboratory
P.O. Box 5514, L-217
Livermore, CA 94551

ACCEPTANCE OF RESPONSES TO OBSERVATIONS 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 the responses to Observations
90-02-01 through 06, generated as a result of Project Office QA Audit 90-02
of LLNL. The responses to these observations are acceptable. Copies of the
observations are enclosed for your information.

If you have any questions, please contact either Catherine E. Hampton at
(702) 794-7973 or FTS 544-7973 or Frank J. Kratzinger at (702) 794-7163 or
FTS 544-7163 of the Yucca Mountain Project QA staff.

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

QA:CEH-4441

Enclosure:
Observations 90-02-01 through 06

cc w/encl:
D. E. Shelor, HQ (RW-30) FORS
John Lee, SAN
S. W. Zimmerman, NWPO, Carson City, NV
K. R. Hooks, NRC, Washington, DC
D. W. Short, LLNL, Livermore, CA

cc w/o encl:
J. W. Gilray, NRC, Las Vegas, NV
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08
S. R. Dippner, SAIC, Las Vegas, NV, 517/T-08
F. J. Kratzinger, SAIC, Las Vegas, NV, 517/T-06

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YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 90-02-01

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: YMP Audit 90-02		3 Identified By: R. Maudlin		4 Date: May 18, 1990	
	5 Organization: LLNL		6 Person(s) Contacted: J. Blink, D. Short		7 Response Due Date is 20 Days from Date of Transmittal	
	8 Discussion: The application of procedure 033-YMP-QP 2.1 "Preparation, Approval and Revision of Quality Procedures and Requirements", Rev. 1 for the technical review of Scientific Investigation Plans, Study Plans, Activity Plans, and Technical Implementing Procedures does not appear to appropriately address sufficient requirements to assure technical adequacy. QP 2.1, para 2.1.1 (Purpose) states: "This procedure describes the requirements for preparation, review, approval, and revision of Quality Procedures (QP) and Quality Assurance Program Plan (QAPP)." The only specific review criteria directed specifically					
Completed by Responder	9 QAE/Lead Auditor <i>Gerard Heaney</i>		Date 6-4-90		10 Branch Manager <i>Arthur J. Hampton</i>	
					Date 6-5-90	
Completed by QA Org.	11 Response: See Attachment					
	12 Signature: <i>Jan Abled</i> Date: 5-16-90					
Completed by QA Org.	13 Response Receipt Acceptable <input checked="" type="checkbox"/>					
	Initiator <i>Maudlin</i>	Date 08-02-90	QA Lead Auditor <i>Arthur J. Hampton</i>	Date DQA 8/2/90		
14 Remarks:						

Page

1 of 2

ENCLOSURE

8 Discussion: (continued)

at the review of SIPs, Study Plans, Activity Plans, TIPs requires that these documents be reviewed for:

- o repeatability of the activity
- o impact on the site waste isolation capability
- o interface with site characterization

In contrast, a review of procedure 033-YMP-QP 2.4 "Technical Review", Rev. 0, para. 2.4.1 states in part: "This procedure describes the requirements for the technical review of Quality Level I and II activities performed under the direction of the Yucca Mountain Project." Para. 2.4.4.5 states in part: "The technical review is a detailed review process intended to provide assurance that the design/investigation is correct and satisfactory. As a minimum, the following are considered:"

- A) Whether the design/investigation inputs are correctly selected.
- B) Whether the assumptions necessary to perform the activity are adequately described and are reasonable.
- C) Whether an appropriate method(s) has been used.
- D) Whether or not the design/investigation inputs are correctly incorporated into the activity.
- E) Whether the design outputs are reasonable when compared to the inputs.
- F) Whether the necessary design outputs and verification requirements for interfacing organizations have been specified in the study/design documents or in supporting procedures or instructions.
- G) Whether the computer programs used for analysis are identified and verified.

It is difficult to rationalize why a scientific notebook is reviewed to QP 2.4, but a SIP or Activity Plan which provides overall technical criteria for implementing the requirements of the SCP is reviewed to the less stringent requirements contained within QP 2.1.

It is recommended that all SIPs, Activity Plans, Study Plans, and TIPs be reviewed in accordance with the requirements of QP 2.4.

July 20, 1990

11. LLNL-YMP QP 2.1 is the proper QP to review technical planning documents; QP 2.4 is intended to review completed or in-progress technical work documented in scientific notebooks and other documents. QP 2.1, which was originally written for use in preparing quality procedures, was adapted to include technical planning documents. The general guidance given in QP 3.0 (paragraph 3.0.8: "... Review is for in-depth technical and programmatic content...") was used in addition to the short checklist in QP 2.1 to guide reviewers. QP 2.1 is being revised to independently guide reviewers. The revision contains a more detailed checklist that can be used to review both quality and planning documents. The revision of LLNL-YMP QP 2.1 is expected to be published in mid-August.

2005

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 90-02-02

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: YMP Audit 90-02		3 Identified By: R. Maudlin		4 Date: May 18, 1990	
	5 Organization: LLNL		6 Person(s) Contacted: D. Short		7 Response Due Date is 20 Days from Date of Transmittal	
	8 Discussion: Procedure 033-YMP-QP 2.1 "Preparation, Approval, and Revision of Quality Procedures and Requirements", Rev. 1 does not provide sufficient detail to assure that technical reviews of Scientific Investigation Planning documents (SIPs) and Activity Plans are adequately documented to the extent that all steps are traceable to the point of resolution and incorporation into the affected document. This observation was determined by review of the technical review documentation for the SIP and the Activity Plan for "Waste Package Performance Assessment", Rev. 0. Examples of concerns found were:					
Completed by Respondee	9 QAE/Lead Auditor <i>Gerard Heaney</i>		Date 6-4-90		10 Branch Manager <i>John D. [unclear]</i>	
					Date 6-5-90	
	11 Response: See Attachment					
Completed by QA Org.	12 Signature: <i>[Signature]</i> Date: <i>Jul 6, 20, 90</i>					
	13 Response Receipt Acceptable <input checked="" type="checkbox"/>					
	Initiator <i>[Signature]</i>		Date 08-02-90		QA/Lead Auditor <i>[Signature]</i>	
14 Remarks:						Date 8/2/90
						Page 1 of 2

8 Discussion: (continued)

- A) Several comments could not be traced back to the originator of the comments.
- B) Where comments were rejected, the basis for rejection was not documented.
- C) It was unclear as to who resolved the comments.
- D) Documentation was not available to reflect that the comments had been appropriately resolved and that a review was performed to verify that resolutions to the comments were adequately incorporated.

These concerns appear to stem from the lack of clear procedural guidance for documenting the review process.

It is recommended to consider revising QP 2.1 to provide detailed guidance on how the technical review process is to be documented. Provide such details as:

- A) Signature of the reviewer and the date the review was performed.
- B) Clear accept/reject of each comment by the document originator and signature and date of the originator resolving the comments.
- C) Where a comment is rejected, document the justification for rejection and concurrence of the person who provided the comment.
- D) Signed and dated review attesting that all comments have been appropriately incorporated.

July 20, 1990

11. LLNL-YMP QP 2.1 is being revised to address the issues raised during YMPO audit 90-02. For technical review of planning documents, a multi-step form is being added to the procedure. This form requires reviewers to designate pages with major comments, requires another submission of the document to reviewers with major comments, and requires those reviewers to sign the form concurring with the final draft. In the event that reviewers do not concur with the final draft, the TPO will resolve the issue and provide additional documentation of the process. The completed reviewer forms (one per reviewer) will be filed as part of the QA review record package. The package also includes the review disposition memo that summarizes the review process. The revision of the LLNL QP 2.1 is expected to be published in mid-August.

JWS

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 90-02-03N-QA-012
4/89

Completed by Originating Organization	2 Noted During: YMP Audit 90-02	3 Identified By: M. Diaz	4 Date: May 18, 1990
	5 Organization: LLNL	6 Person(s) Contacted: D. Short, G. DeLeon	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: LLNL has adopted the practice of processing all identified deficiencies as nonconformances through the process defined in procedure 033-YMP-QP 15.0 "Nonconforming Items, Procedural Nonconformances and Conditions Adverse To Quality". This procedure does not define interfaces or make reference to procedure 033-YMP-QP 16.0 "Corrective Action". QP 16.0 would be used to generate a Corrective Action Report if a nonconformance report was evaluated and found to be considered a significant condition adverse to quality.		
Completed by Respondee	9 QAE/Lead Auditor <i>Gerard Heaney</i>	Date <i>6-4-90</i>	10 Branch Manager <i>Cather Thompson</i>
	Date <i>6-5-90</i>		
Completed by QA Org.	11 Response: See Attached.		
	12 Signature: <i>[Signature]</i> Date: <i>July 20, 90</i>		
Completed by QA Org.	13 Response Receipt Acceptable <input checked="" type="checkbox"/>	QA Lead Auditor	
	Initiator <i>Wain Lee</i>	Date <i>7-30-90</i>	Date <i>8/2/90</i>
14 Remarks:			
Page 1 of 1			

July 19, 1990

OBSERVATION 90-02-03

11. RESPONSE:

Identified deficiencies are processed as nonconformances in accordance with procedure 033-YMP-QP 15.0. This procedure defines all interfaces including responsibilities and sequence of processing of a nonconformances. It refers to procedure 033-YMP-QP 16.0, "Corrective Action", for cases where repetitive or recurring nonconforming conditions are identified that might require further programmatic corrective action to preclude repetition. The majority of identified deficiencies can be processed from origination to final resolution, including corrective and preventive actions, through the use of a "Nonconformance Report." A serious deficiency can also be handled through a "Nonconformance Report."

2105

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 90-02-04

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: YMP Audit 90-02		3 Identified By: S. L. Crawford		4 Date: May 18, 1990							
	5 Organization: LLNL		6 Person(s) Contacted: W. Clarke, J.E. Lauen		7 Response Due Date is 20 Days from Date of Transmittal							
	8 Discussion: Calibration of Instron equipment to be used for material testing of waste package candidate materials (WBS 1.2.2.3.2) was performed by Instron personnel as an on-site technical service per purchase order B112969B and LLNL procedure 033-YMP-QP 4.0 "Procurement Control and Documentation" Rev.1, para. 4.0.5.11c. The requirements of QP 4.0 were met, however, since the calibration service is expected to recur on an annual basis, LLNL should: 1) Obtain a copy of the Instron MIL-STD-45662A quality program description to											
	9 QAE/Lead Auditor <i>Gerard Heaney</i>		Date <i>6-4-90</i>		10 Branch Manager <i>Catherine Anderson</i>		Date <i>6-8-90</i>					
Completed by Respondee	11 Response: See attachment											
	12 Signature: <i>J. Able</i> Date: <i>July 20, 90</i>											
Completed by QA Org.	13 Response Receipt Acceptable <input checked="" type="checkbox"/>		Initiator <i>Frank [Signature]</i>				Date <i>7/30/90</i>		QA/Lead Auditor <i>[Signature]</i>		Date <i>8/2/90</i>	
	14 Remarks:											

Page

1 of 2

8 Discussion: (continued)

assure administrative controls supporting personnel qualifications and NIST traceability are adequate.

- 2) Include Instron on the LLNL YMP Qualified Supplier List.

July 19, 1990

OBSERVATION 90-02-04

11. RESPONSE:

1. A copy of the INSTRON MIL-STD-45662A quality program description is not a requirement to procure the technical services and related documentation for verification of INSTRON test equipment and support system components.
(See attached memo, June 6, 1990, QA:90/202, to L. Jardine from D. Short)

However, it is noted that information from Mr. David Fahy, Director of Quality is that INSTRON is currently completely revising this QA Manual. Completion is expected by the end of September. A copy will be forwarded to LLNL-YMP at that time.

2. Refer to the attached memo which states that INSTRON is approved as a supplier of technical services and will be added to the LLNL-YMP Qualified Supplier's List (QSL).

2008

Interdepartmental letterhead

Mail Station L- 204

Ext: 21287

June 6, 1990
QA:90/202

TO: L. Jardine
FROM: D. Short *Daniel Short*
SUBJECT: Approval of Instron Corporation as a Qualified Supplier
of Technical Services

Based on the information below, the Instron Corporation is approved as a supplier of technical services and will be added to the LLNL-YMP Qualified Suppliers List (QSL).

This Quality Assurance approval was based upon Instron Corporation conforming to the following:

- the provisions of QP 4.0, "Procurement", Sections 4.0.5.9 and 4.0.5.11c.
- the quality requirements of QP 12.0, "Measuring & Test Equipment."
- a quality review of all issued Certificates of Verification and applicable calibration date plus traceability per paragraph 3.5 of MIL 45662 A.
- verification of calibration procedures.

This approval covers the procurement of technical services and related documentation for verification of Instron test equipment and support system components.

Authorization for these services would be similar to that previously provided by LLNL-YMP Purchase Order B112969B, December 11, 1989.

cc: L. Ballou
W. Clarke
J. Estill
D. McCright
P. VanLehn
OF (E. Lauen)
CF
RF

University of California

 Lawrence Livermore
National Laboratory

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 90-02-05

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: YMP-Audit 90-02		3 Identified By: S.L. Crawford		4 Date: May 18, 1990	
	5 Organization: LLNL		6 Person(s) Contacted: W. Clarke, D. McCright		7 Response Due Date is 20 Days from Date of Transmittal	
	<p>8 Discussion:</p> <p>LLNL Technical Implementing Procedure TIP-CM-05 "Determination of Threshold Stress Intensity for Stress Corrosion Cracking Using Modified WOL Specimens" Rev. 0, para. 6.4 provides for verification of critical dimensions for modified WOL material test specimens.</p> <p>1) Although the material test specimens have not been used for Activity E-20-18d yet, the dimensional measurements have not been obtained and recorded.</p>					
Completed by Respondee	9 QAE/Lead Auditor <i>Gerard Heaney</i>		Date <i>6-4-90</i>		10 Branch Manager <i>Cathy Hunter</i>	
					Date <i>6-5-90</i>	
Completed by QA Org.	11 Response: See Attached.					
	12 Signature: <i>[Signature]</i> Date: <i>Jul 20, 90</i>					
	13 Response Receipt Acceptable <input checked="" type="checkbox"/>					
Completed by QA Org.	Initiator <i>F. Smith</i>		Date <i>7/30/90</i>		QA/Lead Auditor <i>[Signature]</i>	
					Date <i>8/2/90</i>	
14 Remarks:						
						<p>Page <u>1</u> of <u>2</u></p>

8 Discussion: (continued)

- 2) Related procedure TIP-CM-1 "Determination of Plane-Strain Fracture Toughness and the Threshold Stress Intensity for Stress Corrosion Cracking" Rev. 0 does not provide for verification of critical dimensions for plane-strain fracture toughness J_{Ic} material test specimens.

July 19, 1990

OBSERVATION 90-02-05

11. RESPONSE:

- 1) The dimensional measurements of the modified WOL material test specimens are currently being measured and recorded in the laboratory notebook. Measurement technique and accuracy are being evaluated for possible revision of TIP-CM-05.
- 2) Similarly, the dimensions of the fracture toughness test specimens (TIP-CM-01 for activity E-20-18c) are being measured and recorded. QA Level II work in this activity has been suspended, pending revision of the activity plan. Measurement technique and accuracy are being evaluated for possible revision of TIP-CM-01.

205

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 90-02-06

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: YMP Audit 90-02		3 Identified By: S. L. Crawford		4 Date: May 18, 1990	
	5 Organization: LLNL		6 Person(s) Contacted: W. Clarke		7 Response Due Date is 20 Days from Date of Transmittal	
	8 Discussion: The final readiness review checklists for LLNL activities E-20-15, E-20-18a, E-20-18c, and E-20-18d which incorporated Readiness Review Board resolved comments, were not completed with checks in the "Accept" column and were not signed by the Readiness Review Board members. The previous version of the readiness review checklists and the Readiness review Comment Record forms were signed by the Readiness Review Board members. The specific checklists that were not completed or signed are:					
Completed by Responsee	9 QAE/Lead Auditor <i>Gerald Heaney</i>		Date <i>6-4-90</i>		10 Branch Manager <i>John H. Hays</i>	
					Date <i>6-5-90</i>	
Completed by QA Org.	11 Response: See Attached.					
	12 Signature <i>Don A. Bell</i> Date: <i>July 20, 90</i>					
Completed by QA Org.	13 Response Receipt Acceptable <input checked="" type="checkbox"/>		Initiator <i>Frank Westgate</i> Date <i>7/30/90</i>			
	14 Remarks:		QA/Lead Auditor <i>John H. Hays</i> Date <i>8/1/90</i>			

8 Discussion: (continued)

Activity	Checklist Rev.	Document No.	RR Package No.
E-20-15	B (8/1/89)	LLYMP8912111G	RR003 E-20-15
E-20-18a	B (7/31/89)	LLYMP8912089G	RR004 E-20-18a
E-20-18c	B (7/31/89)	LLYMP8912110G	RR005 E-20-18c
E-20-18d	B (7/31/89)	LLYMP8912109G	RR006 E-20-18d

The readiness review packages were transmitted to and accepted by the LLNL Local Records Center.

July 19, 1990

OBSERVATION 90-02-06

11. RESPONSE:

Although the "final" readiness review checklists for the four activities in question were not completed with checks in the "Accept" column and were not signed by the Readiness Review Board members, there was no degradation in the compliance with the requirements in any aspect of the preparation and approval of such checklists. All required checks and signatures are present on revision A (previous revision) of the checklists and the few comments that were generated as a consequence of the review were resolved and accepted (with appropriate initials) on the Comment Record form. These comments were incorporated into revision B but these checklists were not signed again. Such signatures would have been redundant and the process of checking and signing them again would have been a redundant process. Revision B of these checklists did not have to be generated and its absence from the packages would not have been noticed. As a consequence, no Observation would have resulted. No action is required at this time.

2008