



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

WBS 1.2.9.3
 QA

SEP 10 1991

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 Site Characterization Project
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EVALUATION OF AMENDED RESPONSE TO CORRECTIVE ACTION REQUEST (CAR) YM-91-041
 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION (YMQAD) AUDIT 91-03
 OF LOS ALAMOS NATIONAL LABORATORY (LOS ALAMOS)

The YMQAD staff has evaluated the amended response to CAR YM-91-041. Overall, the response has been determined to be satisfactory. However, there is one area of your amended response with which YMQAD takes exception. This exception to your amended response is the deletion of the Los Alamos Quality Assurance Program Plan (QAPP). The deletion of the Los Alamos QAPP is unacceptable at this time. Verification of completion of the corrective action will be performed after October 30, 1991, for revision of Los Alamos procedures TWS-QAS-QP-02.5 and LANL-YMP-QP-04.5, the effective date provided in the amended response. Verification of all other corrective action will be performed six months subsequent to issuance of the new Quality Assurance Requirements Document being issued. No further extensions will be granted for this CAR.

If you have any questions, please contact either Catherine E. Hampton at (702) 794-7973 or FTS 544-7973, or John S. Martin at (702) 794-7881 or FTS 544-7881.

Catherine E. Hampton
 Donald G. Horton, Director
 Yucca Mountain Quality Assurance Division

YMQAD:CEH-5584

Enclosure:
 CAR YM-91-041

cc w/encl:
 K. R. Hooks, NRC, Washington, DC
 S. W. Zimmerman, NWPO, Carson City, NV
 S. L. Bolivar, LANL, Los Alamos, NM
 Michael Clevenger, LANL, Los Alamos, NM
 J. L. Day, LATA, Los Alamos, NM

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ADD: Ken Hooks Ltr Encl.
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 NH03

Richard J. Herbst

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SEP 10 1991

cc w/o encl:

J. W. Hines, NWQA, AL
A. R. Chernoff, MSD, AL
J. B. Tillman, LAAO
J. W. Gilray, NRC, Las Vegas, NV
N. J. Brogan, SAIC, Las Vegas, NV, 517/T-08

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**OFFICE OF CIVILIAN
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WASHINGTON, D.C.**

14CAR NO.: YM-91-041
DATE: 04/01/91
SHEET: 1 OF 2
QA
WBS No.: 1.2.9.3

CORRECTIVE ACTION REQUEST

1 Controlling Document LANL-YMP-QAPP, Rev. 5		2 Related Report No. Audit No. 91-03	
3 Responsible Organization Los Alamos National Laboratory		4 Discussed With R. Herbst, S. Bolivar	
10 Response Due 30 Days From Issue	11 Responsibility for Corrective Action R. Herbst	12 Stop Work Order Y or N No	
5 Requirement: LANL-YMP-QAPP, Rev. 5, Sect. 1.2 states in part: "... Implementation of the requirements of the QAPP shall be accomplished through quality implementing procedures (QPs)..." LANL-YMP-QP-5.2, Rev. 0 "Preparation, Review and Approval of Quality Administrative Procedures, Para. 4.4 states: "QPs are documents that describe the methods used to conduct LANL YMP activities that affect quality. QPs implement the QA program requirements of the LANL QAPP."			
6 Adverse Condition: QAPP requirements are not being consistently reflected in QPs. DISCUSSION: The following representative examples illustrate the adverse condition. 1. LANL-YMP-QAPP, Rev. 5, Section 15.5.3 states in part, "Persons responsible for dispositioning the NCR shall ensure that the following requirements are met...The disposition shall document action needed to preclude recurrence of the nonconforming condition." Los Alamos QP TWS-QAS-QP-15.2, Rev. 1, "Deficiency Reporting" only requires documentation of actions to preclude recurrence of significant conditions adverse to quality (i.e., the QP does not require documentation of action needed to preclude recurrence of all nonconforming conditions).			
7 Recommended Action(s): 1. Take necessary action to resolve the representative examples identified in the CAR. 2. Investigate to determine the extent of inconsistencies and resolve all inconsistencies found. 3. Evaluate results of investigation to determine if preventative action is necessary.			
8 Initiator J.S. Martin and J.P. Fox <i>J.S. Martin</i> REPone		9 Severity Level - 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	
Date: 04/01/91		13 Approved By: OQA <i>James B. Layton Jr.</i> Date: 4/3/91	
15 Verification of Corrective Action:			
16 Corrective Action Completed and Accepted: OAR _____ Date _____		17 Closure Approved By: OQA _____	

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**CORRECTIVE ACTION REQUEST
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6 Adverse Condition (continued)

2. LANL-YMP-QAPP, Rev. 5, Section 7.1.3 "Bid Evaluation" states in part, "Bid evaluation shall determine the extent of conformance to the procurement documents. The evaluation, by the designated organizations, shall consider the following, as applicable to the type of procurement:

- o technical considerations
- o QA requirements
- o personnel
- o production capabilities
- o past performance
- o alternatives
- o exceptions

Los Alamos QP LANL-YMP-QP-04.5, Rev. 0, "Procurement of Noncommercial-Grade Items and Services," Para. 6.2.1 limits the evaluation of supplier's capability to provide an item or service in accordance with the technical and QA requirements of the procurement documents. (i.e., Personnel, production capabilities, past performance, alternatives, and exceptions are not addressed in the QP.)

3. LANL-YMP-QAPP, Rev. 5, Section 7.1.6, "Control of Documents Generated by Suppliers," states, "Documents generated by suppliers shall be submitted in accordance with requirements of the procurement documents and shall be handled, approved, and controlled according to LANL QPs for document control. The documents shall be evaluated against the criteria for procurement acceptance."

Los Alamos QP LANL-YMP-QP-04.5, Rev. 0, "Procurement of Noncommercial-Grade Items and Services" does not address this section of the QAPP.

4. LANL-YMP-QAPP, Rev. 5, Section 2.2.2, "Use of Data Not Generated Under Quality Assurance Controls," states in part, "For use in licensing activities, the QA Program for the LANL YMP provides some data or data integrations that were not generated under a program that meets the requirements of 10 CFR 60, Subpart G...A LANL QP shall be prepared to implement these requirements..."

No Los Alamos QP could be found that addresses this subject.

5. LANL-YMP-QAPP, Rev. 5, Section 2.5.2, "Indoctrination" states in part, "Personnel assigned to perform activities affecting quality shall first be indoctrinated to the purpose, scope, methods of implementation, and applicability of the following documents (including revisions and changes) as they relate to the work to be accomplished:

- o QAPPs
- o implementing procedures and work instructions (applicable to the individual's responsibilities)
- o regulations, and
- o Project-level documents..."

LANL-YMP-QAPP, Rev. 5, Section 3.1.1, "Preparation of Scientific Investigation Planning Documents," states in part, "Scientific investigations affecting quality shall be planned and documented to ensure a systematic approach..."

No QP or group of QPs could be found that clearly addresses control of activities performed by personnel who are not assigned to the YMP.

- e.g. In support of a publication, (Eus. J. Mineral, 1990, 2, 771-777, Long-term Thermal Stability of Clinopliolite: The Development of a "B" Phase, by David L. Bish), a Los Alamos employee not assigned to the YMP performed an analysis. No objective evidence could be found within the LANL YMP organization that this Los Alamos employee had received appropriate orientation and training or that the analysis was performed using appropriately calibrated instruments and approved procedures.

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CAR YM-91-041

A. EXTENT - NA

B. ROOT CAUSE

We will matrix existing Quality Procedures (QPs) with the revised Quality Assurance Program Plan (QAPP) to bound the problem identified in CAR-041. We will then make a root cause determination. This will be completed 30 days after YMQAD acceptance of the revised QAPP.

C. REMEDIAL ACTION

The QAPP will be revised for compliance with the latest revision of the Quality Assurance Requirements Document (QARD) and paragraphs, or sections, needing revision will be identified. This effort will take 3 months; estimated date of completion will be July 30, 1991.

The QAPP will be revised and submitted to YMQAD for approval by September 30, 1991.

Existing QPs will be matrixed against the new QAPP. Any QPs that need to be revised to meet QAPP requirements will be identified and scheduled for revision. This task will be completed by October 15, 1991.

An evaluation will be made on a case by case basis regarding the need to stop work until affected QPs are revised.

Training to the new QAPP will commence after YMQAD acceptance. Training to revised QPs will be on a case by case basis, as needed.

The responsible individual for rewriting and obtaining approval for the new QAPP will be S. Bolivar, the QAPL. The individual responsible for training to the new QAPP will be Karen West (acting Training Coordinator).

The specific problems identified in the five representative examples (listed in the CAR) will be resolved by the above actions. Specifically:

1. Example 1 in CAR-041 is a QAPP over commitment. The QP 15.2 (Deficiency Reporting) meets QARD/NQA-1 requirements and the QAPP went beyond these requirements. The QAPP will be revised as per the time schedule described above.

After the QAPP revision is accepted by the YMQAD, it will be matrixed against QP 15.2. A revision to QP 15.2, if necessary, will be completed after the QAPP has been accepted by YMQAD.

File dtd 5/5/91 - TWS - EES - 13 - 05 - 91 - 029

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2. QP 4.5 will be revised to create a section titled Bid Evaluations. The evaluation of bid evaluations will include technical considerations, QA requirements, personnel, production capabilities, past performance, alternatives and exceptions. A QP Action Request to withdraw QP 4.5 will be submitted by May 15. The QP will be revised by July 30, 1991.

Since there have been no procurements requiring bid evaluations, there has been no impact on the quality program.

3. To resolve example 3, the QAPP will be revised. In section 7.1.6 of the QAPP, 'documents' will be changed to 'quality-affecting documents'. The revised QAPP will be submitted to the YMQAD by September 30, 1991.

QP 4.5 will be revised to address this section of the QAPP. A QP Action Request to withdraw QP 4.5 will be submitted by May 15. The QP will be revised by July 30, 1991.

4. The QAPP requires a QP be written to handle the use of data not generated under QA controls. Since no LANL personnel have attempted to qualify this type of data, the lack of a procedure has had no impact on the LANL QA program. The QAPP will be revised to identify that LANL personnel will follow the appropriate AP or APQ. The revised QAPP will be submitted to the YMQAD by September 30, 1991.

5. Example 5 states that no QP exists that addresses control of activities performed by personnel who are not assigned to the YMP. QP 2.5 (Selection of Personnel) will be revised by July 30, 1991 to address this issue. Until this procedure is rewritten, personnel not assigned to the YMP will not be allowed to conduct quality-affecting work on YMP.

D. CORRECTIVE ACTION TO PREVENT RECURRENCE

The requirement to matrix is in the QARD, R4, paragraph 2.7. This will be addressed in the revised QAPP, which will be submitted to the YMQAD by September 30, 1991.

CAR 041 Response Approved

[Signature]
LANL QAPL S.L. Bolivar

5/6/91
Date

CAR 041 Response Approved

[Signature]
LANL TPO R.J. Herbst

5/7/91
Date

CAR 041 Response Approved

[Signature]
YMQAD

5-17-91
Date

Response Approved

[Signature]
QAR
YMQAD

5-17-91
Date

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AMENDED RESPONSE NO. 1
CAR NO. YM-91-041
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A. EXTENT - NA

B. ROOT CAUSE

Existing LANL YMP Quality Administrative Procedures (QPs) will be matrixed with the new quality assurance requirements document using the matrix provided by the Project Office, to bound the adverse condition identified in Section 6 of this CAR. A root cause determination will then be made. This will be completed within 180 days of receipt of the new quality assurance requirements document requirements matrix from the Project Office.

C. REMEDIAL ACTION

Implementation of the remedial actions will be the responsibility of the LANL YMP Quality Assurance Project Leader.

- > Upon receipt of YMQAD approval of this revised response, the LANL YMP Quality Assurance Program Plan (QAPP) will be deleted.

Existing QPs will be matrixed with the new quality assurance document. Any LANL YMP exceptions to the requirements matrix will be noted thereon. Any QPs that need to be revised to implement the new quality assurance requirements document will be identified and revised as necessary. This task will be completed within six months of receipt of the new quality assurance requirements document from the Project Office except as noted in the representative examples below. Any LANL YMP QPs that are issued prior to the receipt of the new quality assurance requirements document will be matrixed to the existing QARD, Revision, 4.

An evaluation will be made on a case by case basis regarding the need to stop work until affected QPs are revised.

Training to revised QPs will be on a case by case basis, as needed.

The five representative examples listed in Section 6 of this CAR will be resolved by the above actions. Specifically:

1. This is a QAPP over commitment to QARD requirements. To ensure that QP TWS-QAS-QP-15.2, Revision 1, "Deficiency Reporting" meets QARD/NOA-1 requirements it will be matrixed with the new quality assurance document, and revised as necessary.

Ltr dtd 8/20/91 - TWS-EES-13-08-91-016

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2. LANL-YMP-QP-04.5, Revision 0, "Procurement of Non-commercial Grade Items and Services" will be revised to create a section titled Bid Evaluations. The evaluation of bid evaluations will include technical considerations, QA requirements, personnel, production capabilities, past performance, alternatives, and exceptions. A QP Action Request to withdraw this QP was submitted on May 15, 1991. A draft of this procedure was completed on July 30, 1991 and it will be issued as soon as possible, but no later than October 30, 1991.
3. LANL-YMP-QP-04.5, Revision 0, "Procurement of Non-commercial Grade Items and Services" will be matrixed with the new quality assurance requirements document and revised as necessary.
4. Since no LANL YMP personnel have attempted to qualify data not generated under QA controls, the lack of a QP has had no impact on the LANL YMP QA program. LANL YMP personnel will follow the appropriate AP or APQ for use of data not generated under QA controls. This will be identified in the new quality assurance requirements document requirements matrix.
5. TWS-QAS-QP-02.5, Revision 0, "Selection of Personnel" has been revised to address this issue. A draft of this procedure was completed on July 30, 1991 and it will be issued as soon as possible, but no later than October 30, 1991. Until this revised procedure is issued, personnel not assigned to the LANL YMP will not be allowed to conduct quality-affecting work on the LANL YMP.

D. CORRECTIVE ACTION TO PREVENT RECURRENCE

The implementation of the corrective action to prevent recurrence will be the responsibility of the LANL YMP Quality Assurance Project Leader.

The existing QPs will be matrixed with the new quality assurance requirements document and revised as necessary. The root cause(s), if any, of the adverse condition will be determined and corrected.

Response Approved	<u>Steph L Bolten</u> LANL OAPL / S. L. Bolten	8/21/91 Date
Response Approved	<u>R. J. Herbst</u> LANL TPO - R. J. Herbst	7/21/91 Date
Response Approved * <i>see attachment to amended response by YMGAD exception to response</i>	<u>John Martz</u> OAR	9-5-91 Date
Response Approved	<u>Catherine Langstender</u> YMGAD	9-5-91 Date

9-5-91

CAR YM-91-041

YMQAD

ATTACHMENT TO AMENDED RESPONSE DATED AUG. 20, 1991, (TWS-EES-13-08-91-016)

An evaluation of LANL amended response was performed by YMQAD on August 30, 1991. This evaluation found the amended response to be acceptable with the exception of "REMEDIAL ACTION" second sentence which reads as follows: " Upon receipt of YMQAD approval of this revised response, LANL YMP Quality Assurance Program Plan (QAPP) will be deleted.". Deletion of the LANL QAPP is unacceptable at this time. As such, LANL Quality Assurance has been notified that the rest of the response is acceptable, however; approval is not granted to delete the LANL QAPP. A new amended response is not required of at this time. In addition, in review of the LANL amended response it was noted that an extension has been requested to previously committed corrective action that was to be completed by July 30, 1991, for procedure revisions. LANL YMP Quality Assurance has been notified via telecommunication that no further extensions will be granted.

In follow-up to the amended response YMQAD requested and received from LANL draft procedures for TWS-QAS-QP-02.5 and LANL-YMP-QP-04.5 and the STOP WORK order issued by LANL against procurement.

QAR

A handwritten signature in black ink, appearing to read "John S. Mand", is written over a horizontal line.