



→ DCC
+ cc: Hooks

Department of Energy
Washington, DC 20585

JAN 22 1991

[Handwritten signature]
Should this be included?
REB
1/28/91

Mr. Robert Browning
Director, Division of High-Level
Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Browning:

This letter is to notify you of the Department of Energy's (DOE) acceptance of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Programs for the Technical and Management Support Services (T&MSS) and Los Alamos National Laboratories (LANL) and to request NRC's acceptance, consistent with our agreements regarding OCRWM program participant QA program acceptance. It is the position of DOE that T&MSS and LANL QA programs are acceptable to initiate activities supporting new site characterization associated with Midway Valley Trenching and Calcite-Silica activities. The bases for this acceptance are in the enclosed DOE memoranda; Horton to Shelor, dated December 21, 1990.

Should you have any questions, please contact me at
(202) 586-6046.

Sincerely,

[Handwritten signature: Dwight E. Shelor]

Dwight E. Shelor
Acting Associate Director for
Systems and Compliance
Office of Civilian Radioactive
Waste Management

2 Enclosures:

1. Memorandum from Director, Office of Quality Assurance, to Acting Associate Director for Systems and Compliance, Subject: U.S. Department of Energy Office of Civilian Radioactive Waste Management Acceptance of the Technical and Management Support Services Quality Assurance Program, dated December 21, 1990.

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2. Memorandum from Director, Office of Quality Assurance, to Acting Associate Director for Systems and Compliance, Subject: U.S. Department of Energy Office of Civilian Radioactive Waste Management Acceptance of the Los Alamos National Laboratories Quality Assurance Program, dated December 21, 1990.

cc:

- C. Gertz, YMP
- R. Loux, State of Nevada
- S. Bradhurst, Nye County, NV
- D. Bechtel, Clark County, NV
- M. Baughman, Lincoln County, NV



Department of Energy
Washington, DC 20585

WBS 1.2.9.3
QA

DEC 21 1990

**Dwight E. Shelor, Acting Associate Director, Systems and Compliance,
HQ (RW-30) FORS**

**U.S. DEPARTMENT OF ENERGY (DOE) OFFICE OF CIVILIAN RADIOACTIVE WASTE
MANAGEMENT (OCRWM) ACCEPTANCE OF THE TECHNICAL AND MANAGEMENT SUPPORT
SERVICES (T&MSS) QUALITY ASSURANCE (QA) PROGRAM**

**References: (1) Letter, Horton to Nelson, dtd. 10/26/90
(2) Letter, Horton to Nelson, dtd. 12/7/90
(3) Letter, Blue to Distribution, dtd. 10/6/89**

The purpose of this letter is to document the bases (current as of the date of this letter) for the OCRWM acceptance of the T&MSS QA Program. This letter also addresses the five conditions for acceptance of the DOE Program Participants' QA Programs in the March 21, 1990, Bimonthly DOE/U.S. Nuclear Regulatory Commission (NRC) QA meeting as stipulated by the NRC. The DOE OCRWM acceptance of the T&MSS QA Program is based upon the following:

- 1. OCRWM QA has approved the T&MSS QA Program Description Document (QAPD), Revision 1, based upon their review which determined that it is consistent with the requirements of the OCRWM QA Requirements Document (QARD), Revision 4 (see reference 1).**
- 2. OCRWM QA has completed the T&MSS QA Program Qualification Audit 90-08, which was conducted November 13-19, 1990 (see reference 2). This audit concluded that the QA Program is adequate for the initiation of quality-affecting activities. Since that audit, T&MSS support to the Yucca Mountain Site Characterization Project Office (YMPO) has not changed in either scope of work or level of effort. Hence, the implementation of the T&MSS QA Program has not changed since November 1990.**
- 3. OCRWM QA has reviewed all open T&MSS QA Program deficiencies and found no items that could have technical or quality impact on output products with one exception. This exception is a Severity Level I Standard Deficiency Report (SDR) 449. The deficiency identified by this SDR was the conduct of software-related activities without procedures. When the T&MSS Software QA Program documents that T&MSS will implement have been issued, this SDR will be closed. The T&MSS Software QA Program has been listed as an exception to the acceptance of the T&MSS QA Program and is discussed later in this letter.**

Dwight E. Shelor

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NOTE: For this review, the Severity Level Checklist criteria established in YMPO Quality Management Procedure 16-03, Revision 1, and OCRWM QA Administrative Procedure 16.1, Revision 3, were used to determine impact of the open deficiencies (SDRs and Corrective Action Reports [CARs], respectively). If the deficiency did not meet Severity Level I criteria, it was regarded as not being significant or not having significant impact on the continued implementation of the T&MSS QA Program.

4. There are no areas of the T&MSS QA Program currently effected by a stop work. However, the area of calibration was determined to be ineffective during the T&MSS QA Program Qualification Audit and the T&MSS Software QA Program documents that T&MSS will use are not yet issued. These items have been identified as exceptions and are discussed later in this letter.
5. The Privacy Act issue did not have an impact on acceptance of the T&MSS QA Program.

OCRWM determined the effectiveness of the T&MSS QA Program by the qualification audit. The activities examined and the results of this audit were able to verify the effectiveness of the QA Program for ten of the 18 areas included in the T&MSS QA Program. Deficiencies discovered in any area were documented on CARs. The effective areas of the T&MSS QA Program were evaluated against the work (air quality/meteorology and radiological monitoring) that T&MSS will perform as general support for the two proposed upcoming new site characterization efforts, Midway Valley Trenching and Calcite-Silica Activities. Based on this evaluation, the effectiveness was determined to be adequate to support the performance of these two proposed upcoming new site characterization efforts.

In summary, OCRWM has concluded that the T&MSS QA Program is in compliance with the applicable requirements of the T&MSS QAPD, Revision 1. Also, based on the evaluation of the effectiveness and the exceptions noted below, OCRWM finds the T&MSS QA Program acceptable to initiate the two proposed upcoming site characterization efforts, Midway Valley Trenching and Calcite-Silica Activities. However, before the T&MSS QA Program can be accepted for additional new site characterization activities, the following exceptions must be addressed:

1. Software QA Program - The T&MSS Software QA Program documents that T&MSS will implement are in the review and approval cycle. Therefore, this will remain an exception until these documents are issued. Controls are in place to ensure no implementation will occur prior to issuing these documents for use (see reference 3).

Dwight E. Shelor

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2. Calibration - The T&MSS Qualification Audit found that the requirements in the calibration procedure were not being appropriately implemented and this area of the program was determined to be ineffective. Since three T&MSS Quality Finding Reports (QFRs) (QFR-13, 14, and 15) adequately addressed the audit team concerns, no deficiency documents were issued by the audit team. This exception will remain in place until these QFRs have been closed.
3. Effectiveness Determinations - The Qualification Audit identified six QA Program Criteria (8, 11, 13, 14, 19 and 20) where effectiveness was indeterminant due to lack of sufficient implementation. Also, Criterion 4 was identified as marginally effective and Criterion 12 was identified as ineffective. The effectiveness of these criteria will be evaluated as future activities performed under the T&MSS QA Program provides the opportunity to verify this attribute, or when identified deficiencies are resolved, as appropriate.

OCRWM QA will verify and document resolution of these exceptions as they are completed. In addition, OCRWM will notify the NRC staff of the resolution of these exceptions, and receive NRC acceptance of the appropriate exception resolution prior to the start of any additional new site characterization work that might be adversely affected by these exceptions. It is OCRWM's intent to resolve all exceptions and request NRC acceptance of this action so all conditions on the acceptance of the T&MSS QA Program can be removed for implementation of new site characterization activities.

Please transmit this letter to the NRC requesting their review and acceptance of the T&MSS QA Program with exceptions as noted herein.

If you have any questions, please contact either Nancy A. Voltura at (702) 794-7972 or FTS 544-7972 or Richard E. Spence of Science Applications International Corporation at (702) 794-7543 or FTS 544-7543.

N. Voltura for
 Donald G. Horton, Director
 Office of Quality Assurance

OQA:NAV-1334

CC:

Debra Butler, HQ (RW-131) FORS
 H. W. Washington, HQ (RW-3) FORS
 J. W. Gilray, NRC, Las Vegas, NV
 R. E. Spence, Harza, Las Vegas, NV, 517/T-08
 S. R. Dippner, SAIC, Las Vegas, NV, 517/T-08
 J. B. Harper, SAIC, Las Vegas, NV, 517/T-22
 K. B. Johnson, SAIC, Las Vegas, NV, 517/T-22
 J. H. Nelson, SAIC, Las Vegas, NV, 517/T-04



Department of Energy
Washington, DC 20585

WBS 1.2.9.3
QA

DEC 21 1990

**Dwight E. Shelor, Acting Associate Director, Systems and Compliance,
HQ (RW-30) FORS**

**U.S. DEPARTMENT OF ENERGY (DOE) OFFICE OF CIVILIAN RADIOACTIVE WASTE
MANAGEMENT (OCRWM) ACCEPTANCE OF THE LOS ALAMOS NATIONAL LABORATORIES
(LOS ALAMOS) QUALITY ASSURANCE (QA) PROGRAM**

**References: (1) Letter, Linehan to Stein, dtd. 11/1/89
(2) Letter, Horton to Herbst, dtd. 5/21/90**

The purpose of this letter is to document the bases (current as of the date of this letter) for the OCRWM acceptance of the Los Alamos QA Program. This letter also addresses the five conditions for acceptance of DOE Program Participants' QA programs in the March 21, 1990, Bimonthly DOE/U.S. Nuclear Regulatory Commission (NRC) QA meeting as stipulated by the NRC. This DOE OCRWM acceptance of the Los Alamos QA Program is based upon the following:

1. The NRC has accepted the Los Alamos QA Program Plan (QAPP) based upon a safety evaluation letter (reference 1). All NRC staff comments were resolved prior to issuance of the safety evaluation letter.
2. OCRWM QA has completed the Los Alamos QA Program Qualification Audit 90-01, which was conducted March 26-30, 1990, and April 2, 1990, (reference 2). The audit concluded that the program is adequate for the initiation of quality affecting activities. Since that audit, Los Alamos support to the Yucca Mountain Site Characterization Project Office (YMFO) has not changed in either scope of work or level of effort. Hence, the implementation of the Los Alamos QA Program has not changed since April 1990.
3. OCRWM QA has reviewed all Los Alamos open QA Program deficiencies and found no items that could have a technical or quality impact on output products. This review also verified that all other significant deficiencies previously identified by OCRWM QA have been resolved.

NOTE: For this review, the Severity Level Checklist criteria established in OCRWM Quality Management Procedure 16-03 was used to determine impact of the open deficiencies (enclosure 1). If the deficiency did not meet Severity Level I criteria, it was regarded as not being significant or not having significant impact on the continued implementation of the Los Alamos QA Program.

4. There is one area of the Los Alamos QA Program currently affected by a stop work order (SWO-LA01). The stop work order was written against the Los Alamos Software QA Program. The Software QA Program was also an unresolved item from the April 1990, Qualification Audit. Additionally, the conditions related to the lack of an approved software QA program was documented on Standard Deficiency Report (SDR) 222. On December 20, 1990, SDR 222 was closed on the basis that the Los Alamos Software QA Plan had been approved by OCRWM QA. When Los Alamos receives formal notification of the closure of SDR 222, they will lift their stop work order and work can proceed in this area. Since the Los Alamos Software QA Program is now approved and the administrative details are anticipated to be complete within a few days, YMPO QA considers this item to have no impact on the implementation of the Los Alamos QA Program.

No other unresolved items have been identified by surveillances since the April 1990, Qualification Audit 90-01. However, deficiencies identified by those surveillances have been documented on SDRs and are listed with their current status in Enclosure 2. It should be noted that while there is still one open SDR as a result of the surveillances, OCRWM QA views this as a normal function of processing these documents and is to be expected.

5. OCRWM QA has surveilled Los Alamos QA Program procedures which has verified their adequacy to control the subject activities and conformance with applicable Los Alamos QAPP requirements (see enclosure 2 for surveillance report numbers, scope, and summary of results for those surveillances performed after the Los Alamos QA Program Qualification Audit 90-01, conducted March 26-30, 1990, and April 2, 1990).
6. The Privacy Act issue did not have an impact on acceptance of the Los Alamos QA Program.

In summary, OCRWM has determined the effectiveness of the Los Alamos QA Program by audits, surveillances, and verification for closure of deficiency documents. The activities examined and the results of these audits, surveillances, and deficiency document closure performed since the April 1990, Qualification Audit, have verified that Los Alamos has continued to implement an effective QA program that addresses their assigned scope of work.

Therefore, based on information presented, OCRWM has concluded that the Los Alamos QA Program is in compliance with the applicable requirements of the Yucca Mountain Site Characterization Project QA Plan, NNWSI/88-9, Revision 2, and is acceptable to support the start of new site characterization activities.

DEC 21 1990

Dwight E. Shelor

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Please transmit this letter to the NRC requesting their review and acceptance of the Los Alamos QA Program.

If you have any questions, please call either Nancy A. Voltura at (702) 794-7972 or FTS 544-7972 or Richard E. Spence of Science Applications International Corporation at (702) 794-7543 or FTS 544-7543.

James B. Blaylock for
Donald G. Horton, Director
Office of Quality Assurance

OQA:NAV-1413

Enclosures:

1. SDR Severity Level Checklist
2. Surveillances of the Los Alamos
QA Program Performed after
April 2, 1990

cc w/encls:

- J. W. Gilray, NRC, Las Vegas, NV
- P. R. Guthals, LANL, Los Alamos, NM
- H. P. Nunes, LANL, Los Alamos, NM
- S. R. Dippner, SAIC, Las Vegas, NV, 517/T-08
- R. E. Spence, SAIC, Las Vegas, NV, 517/T-08

SDR SEVERITY LEVEL CHECKLIST

N-QA-037
4/89

I. ASSIGN A SEVERITY LEVEL OF 1 IF ONE OR MORE OF THE FOLLOWING IS TRUE.

- | | Yes | No |
|--|-----|-----|
| 1. Did the deficiency result in significant damage to natural barriers, structures, systems, or components that will require extensive evaluation, extensive redesign, or extensive repair in order to assure public health and safety? | ___ | ___ |
| 2. Does the deficiency involve loss of essential data or information needed for licensing? | ___ | ___ |
| 3. Does the deficiency constitute a significant deficiency in design, construction, testing, or performance assessment that were detected subsequent to formal quality verification and acceptance? | ___ | ___ |
| 4. Does the deficiency constitute a significant deficiency in design as approved for construction such that the design deviates extensively from design criteria and bases? | ___ | ___ |
| 5. Does the deficiency constitute a significant deviation from performance objectives or specifications that will require extensive evaluation, extensive redesign, or extensive repair to establish the adequacy of a natural barrier, structure, system, or component to meet design criteria and bases? | ___ | ___ |
| 6. Does the deficiency constitute a significant error detected in a computer program after it has been released for use? | ___ | ___ |
| 7. Does the deficiency constitute a significant breakdown in a participant's QA program and/or repetitive, programmatic and hardware deficiencies for which previous corrective action has not been reasonably prompt or effective? | ___ | ___ |

II. ASSIGN A SEVERITY LEVEL OF 2 IF THE ANSWERS TO ALL QUESTIONS IN PART I ARE NO AND ONE OR MORE OF THE FOLLOWING IS TRUE:

- | | Yes | No |
|--|-----|-----|
| 1. Could failure to correct deficiency have a potentially adverse impact on the health or safety of operations personnel? | ___ | ___ |
| 2. Does the deficiency constitute operating outside the scope of the quality program or approved quality procedures where both remedial and corrective actions are required? | ___ | ___ |
| 3. Does the deficiency constitute a repetitive hardware deficiency for which no previous corrective action measures exist? | ___ | ___ |

III. ASSIGN A SEVERITY LEVEL OF 3 IF THE ANSWERS TO ALL QUESTIONS TO PARTS I AND II ARE NO.

QAE/Lead Auditor

QA Division Manager

PQM

Signature/Date

Signature/Date

Signature/Date

ENCLOSURE

SURVEILLANCES OF THE LOS ALAMOS QA PROGRAM

PERFORMED AFTER APRIL 2, 1990

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 1 of 4

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-028 (5/7-9/90)	<p>The main purpose and scope of this surveillance was to follow-up on the commitments obtained through Los Alamos Audit No. 90-01 performed by the Project Office during the period from March 26 through 30, 1990. This also permitted verification of the progress obtained in the affected areas. In addition, implementation of the following criteria/procedures was verified for compliance:</p> <p>QAPP, Revision 4.3, Section 1.0, Organization</p> <p>QAPP, Revision 4.3, Section 2.0, Quality Assurance Program</p> <p>QAPP, Revision 4.3, Section 5.0, Instructions, Procedures, Plans and Drawings</p> <p>QAPP, Revision 4.3, Section 16.0, Corrective Action</p> <p>TWS-QAS-QA-15.2, Revision 1, Deficiency Reporting</p> <p>TWS-QAS-QA-18.1, Revision 2, Audits</p> <p>TWS-QAS-QA-18.2, Revision 1, Surveys</p> <p>TWS-QAS-QA-18.3, Revision 1, Auditor Qualification</p>	<p>This surveillance constituted a review of the status of a new organizational chart and the revision of the implementing procedures for Quality Assurance (QA) training activities, Corrective Action, Audits, and Surveillance activities.</p> <p>Overall implementation of the Los Alamos Corrective Action Program is considered indeterminate. Los Alamos should provide close management attention to this area. Implementation of Audits and Surveillances is considered marginal. Other areas covered during this surveillance appear to be in accordance with Los Alamos management's schedule and commitments to previous Standard Deficiency Reports (SDRs).</p> <p>Five observations were documented to indicate the inadequacies found in areas covered by the surveillance.</p>	NONE

SURVEILLANCES OF THE LOS ALAMOS QA PROGRAM

PERFORMED AFTER APRIL 2, 1990

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 2 of 4

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-032 (7/9-12/90)	<p>The purpose of this surveillance was to: 1) evaluate LANL compliance to internal procedures that had not been fully implemented at the time of Project Office QA Audit 90-01, and 2) to verify implementation of corrective action identified in accepted responses to Project Office SDRs that have reached or are past effective dates.</p> <p>The following LANL procedures were reviewed for implementation to stated requirements:</p> <p>PROCEDURE: TITLE:</p> <p>TWS-QAS-QP-02.7, RO, PERSONNAL TRAINING</p> <p>TWS-QAS-QP-05.1, R3, PREPARATION OF QUALITY ADMINISTRATIVE PROCEDURES</p> <p>TWS-QAS-QP-15.2, R1, DEFICIENCY REPORTING</p> <p>TWS-QAS-QP-17.3, R0, PROCEDURE FOR LANL YMP RECORDS MANAGEMENT</p> <p>TWS-QAS-QP-18.1, R3, AUDITS</p> <p>TWS-QAS-QP-18.2, R2, SURVEYS</p> <p>TWS-QAS-QP-18.3, R2, AUDITOR QUALIFICATION AND CERTIFICATION</p>	<p>This surveillance by the Yucca Mountain Project Office (Project Office) QA Division, which was conducted at Los Alamos National Laboratories (LANL), New Mexico, indicated adequate implementation of the QA Program for those areas examined, with the exception of the area of Corrective Action, which resulted in an issuance of one SDR. In addition, as a result of concerns identified during the surveillance, a Deficiency Report (DR) was issued by LANL to document inadequate training of personnel in Procedure Change Requests.</p>	SDR-562 (Closed)

SURVEILLANCES OF THE LOS ALAMOS QA PROGRAM

PERFORMED AFTER APRIL 2, 1990

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 3 of 4

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-91-02 (10/9-12/90)	<p>The purpose of this surveillance was to determine the adequacy and effectiveness of the implementation of selected Los Alamos QA Procedures. The scope of the surveillance covered the procedures and activities associated with the following criteria:</p> <p>IV Procurement XII Control of Measuring and Test Equipment XV Nonconformances XVI Corrective Action</p> <p>Criterion XV, "Nonconformances" and XVI, "Corrective Action" are combined by Los Alamos into a single procedure, "Deficiency Reporting". The following Los Alamos implementing procedures were examined during the course of the surveillance:</p> <p>TWS-QAS-QP-04.1, R2, PROCEDURE FOR PROCUREMENT</p> <p>TWS-QAS-QP-04.2, R2, PROCEDURE FOR ACCEPTING THE PERFORMANCE OF PROCURED SERVICES</p> <p>TWS-QAS-QP-04.3, R1, QUALIFICATION OF SUPPLIERS OF ENGINEERED ITEMS AND SERVICES</p>	<p>This surveillance determined that there was satisfactory implementation for all areas except deficiency reporting and trending. For the area of deficiency reporting, Los Alamos agreed to amend the response to an existing SDR (*SDR-562) to address the conditions identified. For the area of trending, SDR-597 was issued to address the conditions identified for this issue.</p> <p>*NOTE: SDR-562 was issued as the result of surveillance YMP-SR-90-032. A summary of this surveillance is included in this enclosure.</p>	SDR-597 (Open)

SURVEILLANCES OF THE LOS ALAMOS QA PROGRAM

PERFORMED AFTER APRIL 2, 1990

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 4 of 4

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-91-02 (10/9-12/90) (Continued)	TWS-QAS-QP-12.1, R4, PROCEDURE FOR CONTROL OF MEASURING AND TEST EQUIPMENT TWS-QAS-QP-15.2, R1, DEFICIENCY REPORTING TWS-QAS-QP-16.2, R0, PROCEDURE FOR TRENDING In addition to the above procedures, the surveillance included the attempt to verify the corrective action and closure of all SDRs identified by Los Alamos as ready for closure.		