



Department of Energy

Washington, DC 20585

September 12, 1990

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

- References:
- (1) Letter, Stein to Browning, dated 03/12/90; subject USGS Acceptance
 - (2) Letter, Stein to Browning, dated 04/06/90; subject SNL Acceptance
 - (3) Letter, Stein to Browning, dated 04/13/90; subject REEGo Acceptance
 - (4) Letter, Stein to Browning, dated 04/13/90; subject FSN Acceptance
 - (5) Letter, Stein to Browning, dated 04/13/90; subject LLNL Acceptance
 - (6) Letter, Stein to Browning, dated 04/13/90; subject H&N Acceptance

Dear Mr. Browning:

The purpose of this letter is to provide you with an update of the DOE-OCRWM acceptance of the above OCRWM participant QA programs. This update addresses both the five conditions for acceptance of OCRWM participants' QA programs as discussed in the March 21, 1990, bimonthly DOE/NRC QA meeting and performance of surveillances to verify further implementation of participant QA program requirements, as stipulated by the NRC.

Therefore, based on information previously provided in the above referenced letters and the updates addressed in enclosures 1 and 2 (letters Horton to Shelor, dated August 15, 1990) and enclosures 3 through 6 (letters Horton to Shelor, dated August 23, 1990), DOE-OCRWM concludes that the above referenced participant QA programs are acceptable to support initiation of new site characterization activities, with noted exception as indicated in the enclosures.

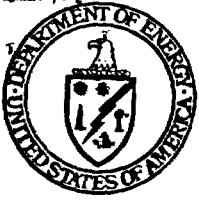
If you have any questions, please contact me at 586-6046.

Ralph Stein, Associate Director
Office of Systems Integration and
Regulations
Office of Civilian Radioactive
Waste Management

Enclosures

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PDR WASTE
WM-1 PDC

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WM-1
NH01



Department of Energy

Yucca Mountain Project Office

P. O. Box 98608

Las Vegas, NV 89193-8608

AUG 15 1990

WBS 1.2.9.3

QA

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

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) ACCEPTANCE OF THE FENIX AND
SCISSON OF NEVADA (FSN) QUALITY ASSURANCE (QA) PROGRAM

- References:
- (1) Letter, Gertz to Shelor, dtd. 3/1/90
 - (2) Letter, Linehan to Stein, dtd. 10/24/89
 - (3) Letter, Blaylock to Bullock, dtd. 5/5/89
 - (4) Letter, Linehan to Stein, dtd. 5/18/89
 - (5) Letter, Bullock to Design Leads, dtd. 8/17/89
 - (6) Letter, Regenda to Bullock, dtd. 9/11/89

The purpose of this memorandum is to provide an update (current as of the date of this letter) on documenting the Project Office acceptance of the QA Program of FSN. This update also addresses the five conditions for acceptance of the U.S. Department of Energy (DOE) Program Participants' QA Programs in the March 21, 1990, Bimonthly DOE/U.S. Nuclear Regulatory Commission (NRC) Quality Assurance meeting as stipulated by the NRC. This DOE acceptance of the QA Program is based upon the following:

1. The NRC has accepted the FSN QA Program Plan (QAPP) based upon a safety evaluation letter (see reference 2). All NRC staff comments were resolved prior to issuance of the safety evaluation letter.
2. Project Office QA has completed the FSN QA Program Qualification Audit 89-1, which was conducted April 10-14, 1989 (see reference 3). Responses have been provided to NRC observations generated as a result of the audit (reference 4). This audit concluded that the QA Program is capable of identifying, tracking, and closing deficiencies. Since that audit, FSN support to the Project Office has not increased in either scope of work or level of effort. Hence, the implementation of the FSN QA Program has not changed since April 1989.
3. Project Office QA has reviewed all FSN open QA Program deficiencies and found no items that could have technical or quality impact on output products. This review also verified that significant deficiencies previously identified by DOE have been resolved.

NOTE: For this review, the Severity Level Checklist criteria established in Project Office 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 FSN QA Program.

4. There are no areas of the FSN QA Program effected by a stop work at the present time. The unresolved items from Audit 89-1, FSN Software QA and procurement, are discussed as exceptions later on in this letter.

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5. Project Office QA has surveilled the FSN QA Program procedures which verified their adequacy to control the subject activities and conformance with applicable FSN QAPP requirements (reference enclosure 2 for surveillance report numbers, scope, and summary of results for those surveillances performed after the FSN QA Program Qualification Audit 89-1, conducted April 10-14, 1989).
6. The Privacy Act issue did not have an impact on acceptance of the FSN QA Program.

In summary, DOE has determined the effectiveness of the FSN QA Program by audits and surveillances. The activities examined and the results of these surveillances performed since the April 1989 Qualification Audit have verified that FSN has continued to implement an effective QA program that addresses their assigned scope of work.

Therefore, based on information presented, the Project Office has concluded that the FSN QA Program is in compliance with the applicable requirements of the Yucca Mountain Project QA Plan, NNWSI/88-9, Revision 2, and is acceptable to initiate new site characterization activities with the following exceptions:

1. Software QA - The Project Office has approved the FSN Software QA Plan for use to develop and issue the implementing procedures related to the plan. The implementing procedures have been completed and are waiting for approval of an associated computer hardware and software procurement procedure before they will be approved and issued. Controls are in place to ensure no implementation will occur prior to approval of the Software QA Program (see reference 5).
2. Procurement - Two observations, 89-1-18 and 89-1-19, were identified in the Project Office Qualification Audit 89-1 of FSN. Based on the acceptable responses provided by FSN to the noted observations, procurement of quality-affecting items will not occur until this activity has been sufficiently addressed in the QA Program. Items requiring action in the two noted observations have been partially completed. Administrative Procedure AP-4.1Q, Revision 0, has been issued by the Project Office and FSN is generating additional procurement procedures which are presently in the review and approval cycle. Controls are still in place to prohibit procurement of quality-related items (see reference 6).

Project Office QA will verify and document resolution of these exceptions by performing surveillances.

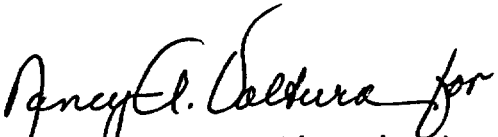
Please transmit this letter, with enclosures, to the NRC for their review.

AUG 15 1990

Dwight E. Shelor

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If you have any questions or comments regarding the Project Office position on this matter, please call Nancy A. Voltura of my staff at (702) 794-7972 or FTS 544-7972.


Donald G. Horton, Acting Director
Office of Quality Assurance

QA:NAV-4502

Enclosure:
Surveillances of the FSN QA Program
performed after April 14, 1989

cc w/encl:

J. W. Gilray, NRC, Las Vegas, NV
R. L. Bullock, FSN, Las Vegas, NV
M. J. Regenda, FSN, Las Vegas, NV
D. J. Tunney, FSN, Las Vegas, NV
R. E. Spence, Harza, Las Vegas, NV, 517/T-08
S. R. Dippner, SAIC, Las Vegas, NV, 517/T-06

SUR 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

SURVEILLANCES OF THE FSN QA PROGRAM

PERFORMED AFTER APRIL 14, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 1 of 2

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-89-108 (8/28/89 Thru 9/1/89)	<p>This Yucca Mountain Project Office (Project Office) surveillance was performed to review and verify the Project-wide implementation of design control activities.</p> <p>The FSN portion of this surveillance included the implementation of procedures for quality assurance level, grading, design control, data management, and configuration management.</p>	<p>The activities performed by FSN covered by the scope of this surveillance have been satisfactorily conducted in accordance with approved procedures. Personnel interviewed were well-informed on procedure policy. FSN also has an ongoing active training program as evidenced by the training records of FSN personnel implementing design control procedures. This surveillance covered the areas surveilled only to the extent the program was being applied.</p>	NONE

ENCLOSURE 2

SURVEILLANCES OF THE FSN QA PROGRAM

PERFORMED AFTER APRIL 14, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 2 of 2

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-004 (11/20/89)	The purpose of this surveillance was to determine the readiness of FSN to implement procedures for the control of purchased items and services.	FSN has made significant progress in developing sufficient implementing procedures for control of purchased items and services as committed to in Observation 89-1-19. However, there are still insufficient procedures for purchasing quality related items. In this area, the FSN QA program is not fully developed.	NONE



Department of Energy

Yucca Mountain Project Office

P. O. Box 98608

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WBS 1.2.9.3

QA

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

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) ACCEPTANCE OF THE
LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL) QUALITY ASSURANCE (QA)
PROGRAM

References: (1) Letter, Gertz to Shelor, dtd. 3/1/90
(2) Letter, Linehan to Stein, dtd. 10/24/89
(3) Letter, Wilmot to Jardine, dtd. 7/2/89

The purpose of this memorandum is to provide an update (current as of the date of this letter) on documenting the Project Office acceptance of the QA Program of LLNL. This update also addresses the five conditions for acceptance of U.S. Department of Energy's (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 acceptance of the LLNL QA Program is based upon the following:

1. The NRC has accepted the LLNL QA Program Plan (QAPP) based upon a safety evaluation letter (reference 2). All NRC staff comments were resolved prior to issuance of the safety evaluation letter.
2. Project Office QA has completed the LLNL QA Program Qualification Audit 89-06, which was conducted June 5-9, 1989 (reference 3). This audit concluded that the QA Program is adequate for the overall control of quality-related activities. Since that audit, LLNL support to the Project Office has not changed in either scope of work or level of effort. Hence, the implementation of the LLNL QA Program has not changed since June 1989.
3. Project Office QA has reviewed all LLNL open QA Program deficiencies and found no items that could have technical or quality impact on output products. This review also verified that significant deficiencies previously identified by DOE have been resolved.

NOTE: For this review, the Severity Level Checklist criteria established in Project Office 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 LLNL QA program.

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4. There are no areas of the LLNL QA Program effected by a stop work at the present time. In addition, the unresolved items from Audit 89-06, LLNL Software QA Plan and QA Level Assignments and grading efforts, have been addressed. The LLNL Software QA Plan was approved by the Project Office on December 20, 1989. The QA Level Assignment and grading efforts have been modified by the Project Office with the issuance of Administrative Procedure (AP)-5.28Q, "Quality Assurance Grading" (effective 3/30/90), and AP-6.17Q, "Determination of the Importance of Items and Activities" (effective 3/19/90). The LLNL implementing procedure for these activities is 033-YMP-QP 2.8, "QA Grading." This procedure has recently been revised to address the new Project Office procedures and is presently in the review and approval process.

No other unresolved items have been identified by audits and surveillances since the June 1989 Qualification Audit 89-06. However, deficiencies identified by those audits and surveillances have been documented on Standard Deficiency Reports (SDRs) and are listed with their current status in Enclosures 2 and 3. It should be noted that while there are some SDRs that are still open as a result of the audits and surveillances, Project Office QA views this as a normal function of processing these documents and is to be expected.

5. Project Office QA has surveilled the LLNL QA Program procedures and verified their adequacy to control the subject activities and conformance with applicable LLNL QAPP requirements (see enclosure 2 for surveillance report numbers, scope, and summary of results those surveillances performed after the LLNL QA Program Qualification Audit 89-06, conducted June 5-9, 1989).
6. Project Office QA performed a scheduled LLNL QA Program Audit 90-02 (see enclosure 3 for audit report number, scope, and summary of results), conducted May 14-18, 1990, which concluded that the implementation of the LLNL QA Program is sufficiently effective, both technically and programmatically, for the work activities audited.
7. The Privacy Act issue did not have an impact on acceptance of the LLNL QA Program.

In summary, DOE has determined the effectiveness of the LLNL QA Program by audits and surveillances. The activities examined, and the results of these audits and surveillances performed since the June 1989 Qualification Audit, have verified that LLNL has continued to implement an effective QA program that addresses their assigned scope of work.

Therefore, based on information presented, the Project Office has concluded that the LLNL QA Program is in compliance with the applicable requirements of the Yucca Mountain Project QA Plan, NNWSI/88-9, Revision 2, and is acceptable to initiate new site characterization activities.

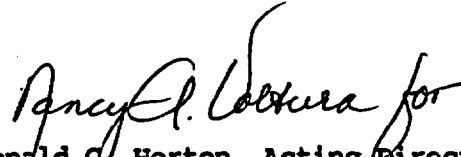
AUG 15 1990

Dwight E. Shelor

-3-

Please transmit this letter with enclosure to the NRC for their review.

If you have any questions or comments regarding the Project Office position on this matter, please call Nancy A. Voltura of my staff at (702) 794-7972 or FTS 544-7972.



Donald G. Horton, Acting Director
Office of Quality Assurance

QA:NAV-4501

Enclosures:

1. SDR Severity Level Checklist
2. Surveillances of the LLNL QA Program
Performed after June 9, 1989
3. Audits of the LLNL QA Program
Performed after June 9, 1989

cc w/encls:

J. W. Gilray, NRC, Las Vegas, NV
D. W. Short, LLNL, Livermore, CA
L. J. Jardine, LLNL, Livermore, CA
R. E. Spence, Harza, Las Vegas, NV, 517/T-08
C. H. Prater, SAIC, Las Vegas, NV, 517/T-06

DEFICIENCY 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 I

SURVEILLANCES OF THE LLNL QA PROGRAM

PERFORMED AFTER JUNE 9, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 1 of 7

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-89-096 (5/15-17/89)	<p>This surveillance was performed to verify implementation of the following procedures:</p> <p>033-YMP-QP 2.9, R0, Indoctrination and Training</p> <p>033-YMP-QP 2.10, R0, Qualification of Personnel</p> <p>033-YMP-QP 4.0, R0, Procurement Control and Documentation</p> <p>033-YMP-QP 4.1, R0, Quality Assurance (QA) Requirements Specification</p> <p>033-YMP-QP 6.0, R0, Document Control</p> <p>033-YMP-QP 15.0, R0, Nonconforming Items, Procedural Nonconformances and Conditions Adverse to Quality</p> <p>033-YMP-QP 16.0, R0, Corrective Action</p> <p>033-YMP-QP 17.0, R0, Quality Assurance Records</p>	<p>The following information summarizes the results for the procedures surveilled:</p> <p>Implementation of 033-YMP-QP 2.9 and 2.10 was acceptable.</p> <p>Implementation of 033-YMP-QP 4.0 and 4.1 was considered acceptable for the limited work done since the procedures' issuance.</p> <p>Procedure 033-YMP-QP 6.0, failed in tracking issuance of new procedures and some recalled procedures.</p> <p>Procedure 033-YMP-QP 15.0 was not reviewed since no NCR had been written since the issuance of the procedure.</p> <p>Implementation of 033-YMP-QP 16.0 was acceptable.</p> <p>Implementation of 033-YMP-QP 17.0 was considered acceptable except in the area of records management training.</p>	<p>SDR-399 (Closed)</p> <p>SDR-340 (Closed)</p>

ENCLOSURE 2

SURVEILLANCES OF THE LLNL QA PROGRAM
PERFORMED AFTER JUNE 9, 1989
(COMPLETION DATE OF QUALIFICATION AUDIT)

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-001 (10/24-26/89)	<p>This surveillance was performed to verify implementation of the following procedures:</p> <p>033-YMP-QP 2.1, R1, Preparation, Approval, and Revision of Quality Procedures and Requirements</p> <p>033-YMP-QP 4.0, R1, Procurement Control and Documentation</p> <p>033-YMP-QP 5.0, R0, Technical Implementation Procedures</p> <p>033-YMP-QP 6.0, R0, Documentation Control</p> <p>033-YMP-QP 14.0, R0, Inspection, Test, and Operative Status</p> <p>033-YMP-QP 17.0, R0, QA Records</p>	Implementation of all examined procedures was found to be acceptable with the exception of 033-YMP-QP 4.0 which was deficient in the area of passing on QA requirements to suppliers.	SDR-457 (closed)

SURVEILLANCES OF THE LLNL QA PROGRAM

PERFORMED AFTER JUNE 9, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-007 (11/13-14/89)	The purpose of the surveillance was two-fold. The first was to assess the effectiveness of the self-imposed stop work order as it applied to software and the adequacy of the record(s) of its implementation in this area. The second was to determine the usefulness of ongoing QA Level III software development and use.	<p>The surveillance of software development and use at LLNL resulted in no SDRs and no Observations. The self-imposed stop work order on all QA Level I and II activities was found to have been effectively implemented in the software area, and is still in effect. Its documentation is adequate.</p> <p>The mechanism for the transition from ongoing QA Level III development to QA Level I or II activity will meet all the current requirements of the lifecycle concept of the software development described in NNWSI/88-9, Revision 2.</p>	NONE

SURVEILLANCES OF THE LLNL QA PROGRAM

PERFORMED AFTER JUNE 9, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-012 (1/8-11/90)	<p>This surveillance was performed to verify implementation of the following procedures:</p> <p>033-YMP-QP 1.0, R0, Organization</p> <p>033-YMP-QP 2.10, R0, Qualification of Personnel</p> <p>033-YMP-QP 3.0, R0, Scientific Investigation Control</p> <p>033-YMP-QP 4.0, R1, Procurement Control and Documentation</p> <p>033-YMP-QP 7.0, R0, Control of Purchased Items and Services</p> <p>033-YMP-QP 17.0, R0, Quality Assurance Records</p> <p>033-YMP-QP 18.0, R0, Audits</p> <p>033-YMP-QP 18.1, R0, Surveillances</p> <p>033-YMP-QP 18.2, R0, Qualification of Quality Assurance Audit Personnel</p> <p>033-YMP-QP 12.0, R1, Control of Measuring and Test Equipment</p>	<p>Implementation of the examined procedures was found to be acceptable with the following exceptions:</p> <p>1. 033-YMP-QP 4.0, Revision 1, Purchase Order to a calibration contractor did not require QA requirements to be passed along to subcontractors.</p> <p>2. 033-YMP-QP 12.0, Revision 1, was added to the scope while following calibration contractor procurement. Out of tolerance, calibration conditions were not reported as required.</p>	<p>SDR-479 (Closed)</p> <p>SDR-480 (Closed)</p>

SURVEILLANCES OF THE LLNL QA PROGRAM

PERFORMED AFTER JUNE 9, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-024 (4/2-6/90)	<p>This surveillance was performed to verify implementation of the following procedures:</p> <p>033-YMP-QP 4.0, R1, Procurement Control and Documentation</p> <p>033-YMP-QP 7.0, R0, Control of Purchased Items and Equipment</p> <p>033-YMP-QP 12.0, R1, Control of Measuring and Test Equipment</p> <p>033-YMP-QP 18.0, R0, Audits</p> <p>Verification of Corrective Action to SDRs 038, 090, 479, and 480</p> <p>YMP-AP-1.7Q, R2, Records Management added while following subcontractor requirements</p>	<p>YMP-AP-1.7Q, Revision 2, LLNL procurement documents do not require that subcontractors follow the requirement for Yucca Mountain Project records.</p> <p>033-YMP-QP 4.0, R1, 033-YMP-QP 7.0, R0, 033-YMP-QP 12.0, R1, 033-YMP-QP 18.0, R0 were all found to be acceptable.</p> <p>Verification of corrective action to SDRs 038, 090, 479, and 480 could not be accomplished.</p>	SDR-507 (Open)

SURVEILLANCES OF THE LLNL QA PROGRAM

PERFORMED AFTER JUNE 9, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 6 of 7

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-89-096 (8/6-9/90)	<p>The purpose of this surveillance was to evaluate the effectiveness of implementation of selected QA Procedures. The scope of the surveillance covered those procedures and activities associated with the QA Program; Instructions, Procedures, and Plans; Document Control; Corrective Action; and QA Records. During the surveillance, implementation of the following procedures were verified for compliance:</p> <p>033-YMP-QP 2.3, R0, "Management Assessments"</p> <p>033-YMP-QP 2.9, R0, "Indoctrination and Training"</p> <p>033-YMP-QP 2.10, R1, "Qualification of Personnel"</p> <p>033-YMP-QP 2.1, R, "Preparation, Approval, and Review of Quality Procedures and Requirements"</p> <p>033-YMP-QP 5.0, R, "Technical Implementing Procedures"</p> <p>033-YMP-QP 6.0, R1, "Document Control"</p> <p>033-YMP-QP 16.0, R1, "Corrective Action"</p>	<p>This report has not been issued as of the date of this letter and therefore, the summary of results has not been provided. Preliminary results indicate that the LLNL QA Program is being implemented satisfactorily.</p>	SDR-567 (Open)

SURVEILLANCES OF THE LLNL QA PROGRAM

PERFORMED AFTER JUNE 9, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 7 of 7

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-89-096 (8/6-9/90) (Continued)	033-YMP-QP 17.0, R1, "Quality Assurance Records" In addition to the above, the surveillance was to include the verification of implementation of corrective action and closure of (3) three SDRs which had been identified by LLNL as ready for closure. The SDRs were numbers 536, 537, and 540.		

AUDIT OF THE LLNL QA PROGRAM

PERFORMED AFTER JUNE 9, 1990

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 1 of 1

ENCLOSURE NO. 3

AUDIT NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
90-02 (5/14/-18/90)	<p>The scope of the audit was to verify that the LLNL QA program meets the requirements of LLNL QAPP, Revision 0, dated December 13, 1988, and to verify the adequacy of implementation of the QA program. This was done by verifying that LLNL quality-affecting activities performed in support of the Yucca Mountain Project are being performed in compliance with requirements contained within LLNL QAPP, Revision 0, and supporting implementing procedures.</p> <p>The following program elements were audited:</p> <ul style="list-style-type: none">1.0 Organization2.0 Quality Assurance (QA) Program3.0 Scientific Investigation Control4.0 Procurement Document Control5.0 Instruction, Procedures, Plans, and Drawings6.0 Document Control7.0 Control of Purchased Items and Services8.0 Identification and Control of Items, Samples, and Data12.0 Control of Measuring and Test Equipment13.0 Handling, Shipping, and Storage15.0 Control of Nonconforming Items16.0 Corrective Action17.0 Quality Assurance Records18.0 Audits	<p>The audit team found the Lawrence Livermore National Laboratory (LLNL) implementation of the QA program to be sufficiently effective, both technically and programmatically. This was based on the limited work activity since the last Yucca Mountain Project (Project Office) Quality Assurance (QA) audit (Audit NO.89-06).</p> <p>The LLNL QA Program could be strengthened in the area of Criteria V "Instructions, Plans, Procedures and Drawings," which involves the generation and maintenance of plans and procedures, including the document review process. Technical and programmatic effectivity should be expected to improve as the LLNL QA Program develops and matures. Subsequent audits should provide additional insight into LLNL's ability to sustain continued improvement.</p> <p>As a result of this audit, seven Standard Deficiency Report (SDRs) and six Observations were issued.</p>	SDR-536 (Open) SDR-537 (Open) SDR-538 (Closed) SDR-539 (Open) SDR-540 (Open) SDR-541 (Open) SDR-544 (Open)

ENCLOSURE 3



Department of Energy

Yucca Mountain Project Office
P. O. Box 98608
Las Vegas, NV 89193-8608

WBS 1.2.9.3
QA

AUG 23 1990

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

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) ACCEPTANCE OF THE
U.S. GEOLOGICAL SURVEY (USGS) QUALITY ASSURANCE (QA) PROGRAM

References: (1) Letter, Gertz to Shelor, dtd. 3/1/89
(2) Letter, Linehan to Stein, dtd. 10/24/89
(3) Letter, Wilnot to Hayes, dtd. 10/16/89
(4) Letter, Horton to Shelor, dtd. 8/15/90

This letter is a revision of my earlier letter (reference 4) on this subject and has been written to clarify Project Office QA actions upon resolution of the Privacy Act issues.

The purpose of this memorandum is to provide an update (current as of the date of this letter) on documenting the Project Office acceptance of the QA Program of USGS. This update also addresses the five conditions for acceptance of U.S. Department of Energy's (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 acceptance of the USGS QA Program is based upon the following:

1. The NRC has accepted the USGS QA Program Plan (QAPP) based upon a safety evaluation letter (reference 2). All NRC staff comments were resolved prior to issuance of the safety evaluation letter.
2. Project Office QA has completed the USGS QA Program Qualification Audit 89-04 conducted August 14-23, 1989 (reference 3). This audit concluded that all of the quality-implementing procedures were either found to meet, or were amended to meet (during the course of the audit), the requirements of NNWSI/88-9, Revision 2. Since that audit, USGS support to the Project Office has not changed in either scope of work or level of effort. Hence, the implementation of the USGS QA Program has not changed since August 1989.
3. Project Office QA has reviewed all USGS open QA Program deficiencies and found no items that could have a technical or quality impact on output products with one exception. This exception is a Severity Level I Standard Deficiency Report (SDR) 489, issued as a result of Project Office QA Surveillance YMP-SR-90-017. However, since this condition adverse to quality has been identified on an SDR, and

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Dwight E. Shelor

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efforts are currently ongoing to resolve the identified conditions, Project Office QA has determined that this item will have no significant impact on the overall implementation of the USGS Quality Program. This review also verified that all other significant deficiencies previously identified by DOE have been resolved.

NOTE: For this review, the Severity Level Checklist criteria established in Project Office 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 USGS QA Program.

4. There are no areas of the USGS QA Program effected by a stop work at the present time. The unresolved item from Audit 89-04, Privacy Act issue (personnel qualifications) is discussed as an exception later on in this letter.

No other unresolved items have been identified by audit and surveillances since the August 1989 Qualification Audit 89-04. However, deficiencies identified by the audit and surveillances have been documented on SDRs and are listed with their current status in Enclosures 2 and 3. It should be noted that while there are SDRs that are still open as a result of the audit and surveillances, Project Office QA views this as a normal function of processing these documents and is to be expected.

5. Project Office QA has surveilled USGS QA Program procedures and has verified their adequacy to control the subject activities and conformance with applicable USGS QAPP requirements (see enclosure 2 for surveillance report numbers, scope, and summary of results for those surveillances performed after the USGS QA Program Qualification Audit 89-04, conducted August 14-23, 1989).
6. Project Office QA performed a scheduled USGS QA Program Audit 90-03 (see enclosure 3 for audit report number, scope and summary of results), conducted June 25-29, 1990 and July 2-3, 1990. This audit concluded that the effectiveness of implementation of the USGS QA Program was considered satisfactory, except in the areas of training, nonconformance control and records, to the extent activities were performed since the last USGS audit. These identified areas of weakness have been documented on SDRs and observations. However, they do not in any way represent a significant breakdown in the QA program.

In summary, DOE has determined the effectiveness of the USGS QA Program by audits and surveillances. The activities examined and the results of these audits and surveillances performed since the August 1989 Qualification Audit have verified that USGS has continued to implement an effective QA program that addresses their assigned scope of work.

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Dwight E. Shelor

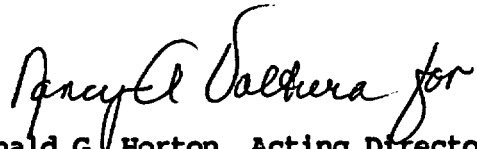
-3-

Therefore, based on information presented, the Project Office has concluded that the USGS QA Program is in compliance with the applicable requirements of the Yucca Mountain Project QA Plan, NNWSI/88-9, Revision 2, and is acceptable to initiate new site characterization activities with the following exception:

Personnel Qualification - Upon resolution of the Privacy Act issues, the Project Office QA will verify and document resolution of this exception by performing audits or surveillances.

Please transmit this letter, with enclosures, to the NRC for their review.

If you have any questions or comments regarding the Project Office position on this matter, please call Nancy A. Voltura of my staff at (702) 794-7972 or FTS 544-7972.



Donald G. Horton, Acting Director
Office of Quality Assurance

QA:NAV-4455

Enclosures:

1. Severity Level Checklist
2. Surveillances of the USGS QA Program
Performed after August 23, 1989
3. Audit of the USGS QA Program
Performed after August 23, 1989

cc w/encls:

- J. W. Gilray, NRC, Las Vegas, NV
- D. H. Appel, USGS, Denver, CO
- L. R. Hayes, USGS, Las Vegas, NV
- R. E. Spence, Harza, Las Vegas, NV, 517/T-08
- S. R. Dippner, SAIC, Las Vegas, NV, 517/T-06

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

USGS SURVEILLANCES PERFORMED AFTER

AUGUST 23, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 1 of 6

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-89-133 (8/30-31/89)	This surveillance was conducted to determine the status and potential discrepancies of USGS Study Plans and Technical Reviews not specifically identified by SDR-417. The surveillance was conducted in accordance with QMP-18-02, Revision 1, including Interim Change Notices (ICNs) 1 through 5.	<p>Only one Study Plan other than those previously submitted to the Yucca Mountain Project Office (Project Office) had Technical Review comments incorporated. (SP 8.3.1.2.2.1); the Technical Review dates and lack of documented reviewer's comment resolution were the same type of discrepancies identified by SDR-417. The discrepancies were considered adequately controlled by the recommended corrective action of SDR-417.</p> <p>Four Study Plans had Technical Reviews performed by reviewers. Comments had not been incorporated by the USGS Principal Investigators (PIs). Since the reviews were considered to be still "in process" at USGS, the discrepancies found, such as unsigned or undated reviews, were not formally documented, but were identified to USGS personnel for correction. These areas will be rechecked during SDR-417 verification. No SDRs or Observations were issued as a result of the surveillance.</p>	NONE

USGS SURVEILLANCES PERFORMED AFTER

AUGUST 23, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 2 of 6

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-006 (11/14/89)	This surveillance was performed to verify the implementation of USGS Technical Procedure HP-62, "Method for Measuring Sub-Surface Moisture Content Using a Neutron Moisture Meter", Revision 4. The surveillance consisted of an assessment of equipment calibration and calibration records, procedure compliance, and the resulting quality assurance records.	A Campbell Pacific Nuclear Neutron Moisture Meter (SN 5715) and radioactive source (50 mCi Am-214 Be), and cable (SN5715) were verified as the proper equipment required for the logging operations and calibration status was current. The surveillance team verified that the logging of the borehole for moisture content was performed in accordance with USGS Technical Procedure HP-62. The surveillance team was impressed with the manner in which Mr. Blout and the USGS personnel conducted this particular activity.	NONE

USGS SURVEILLANCES PERFORMED AFTER

AUGUST 23, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 3 of 6

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-017 (1/22-25/90)	<p>The purpose of this surveillance was to determine the adequacy of implementation of specific attributes of certain USGS procedures to obtain resolution of SDR-418.</p> <p>The following procedures were reviewed for implementation to stated requirements:</p> <p>YMP-USGS-QMP-1.01, Rev. 3, Organization Procedure</p> <p>YMP-USGS-QMP-4.01, Rev. 3, Procurement Document Control</p> <p>YMP-USGS-QMP-5.01, Rev. 2, Preparation of Technical Procedures</p> <p>YMP-USGS-QMP-7.01, Rev. 4, Control of Purchased Items and Services</p> <p>YMP-USGS-QMP-12.01, Rev. 3, Instrument Calibration</p> <p>YMP-USGS-QMP-17.01, Rev. 3, YMP-USGS Records Management</p> <p>YMP-USGS-QMP-18.01, Rev. 3, Audits</p> <p>YMP-USGS-QMP-18.02, Rev. 0, Surveillances</p>	<p>The surveillance by the Project Office QA of USGS indicated adequate implementation of the QA program for those areas examined, however, concern exists regarding the technical adequacy of calibration procedures. Two SDRs addressing calibration and eight Observations concerning procurement, calibration, and QA records, were issued.</p>	<p>SDR-488 (Open)</p> <p>SDR-489 (Open)</p>

USGS SURVEILLANCES PERFORMED AFTER
AUGUST 23, 1989
(COMPLETION DATE OF QUALIFICATION AUDIT)

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-019 (2/20-23/90)	<p>This surveillance evaluated the implementation of the YMP-USGS-QMP-3.03, Revision 1, and YMP-USGS-QMP-3.14, Revision 2, by the USGS.</p> <p>The USGS Software Configuration Status Accounting (CSA) Log lists 75 computer codes in the Software Configuration Management (SCM) System. The surveillance team selected four of the nine software products for which a complete set of lifecycle documentation was available. (Two of the remaining five had been previously examined in Audit 89-4.) The surveillance team also selected five of the ten software products that have some portion of the lifecycle process completed for verification of procedural implementation.</p>	<p>This surveillance verified the implementation by the USGS of its procedures YMP-USGS-QMP-3.03, "Software Quality Assurance," and YMP-USGS-QMP-3.14, "Software Configuration Management System." The implementation of both procedures was judged to be adequate. Five observations were issued, but no SDRs resulted from the surveillance.</p>	NONE

USGS SURVEILLANCES PERFORMED AFTER

AUGUST 23, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 5 of 6

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-026 (4/17-19/90)	<p>This surveillance was performed to verify compliance and implementation of their approved implementing procedures in the areas of Study Plans and Corrective Action.</p> <p>During this surveillance, implementation of the following procedures was verified for compliance:</p> <ol style="list-style-type: none">1. AP-1.10Q, Rev. 1 and Rev. 0, "Preparation, Review, and Approval of SCP Study Plans"2. YMP-USGS-QMP-3.07, Rev. 2, "YMP-USGS Review Procedure"3. YMP-USGS-QMP-15.01, Rev. 4, "Control of Nonconforming Items"4. YMP-USGS-QMP-16.01, Rev. 3, "Control of Corrective Action Reports"5. YMP-USGS-QMP-18.01, Rev. 3, "Audits"6. YMP-USGS-QMP-18.02, Rev. 0, "Surveillances"	<p>The surveillance team reviewed five completed Study Plans which had been transmitted to the Project Office for review and comment. In addition, the status of open USGS internal CARS, NCRs, and Audit findings including Project Office SDRs were reviewed during this surveillance. Overall implementation of the USGS Corrective Action Program and corrective action as it relates to audits and surveillances was considered satisfactory. There were four SDRs and seven Observations documented during this surveillance. The results of the surveillance did not indicate any significant inadequacies in the preparation and review of Study Plans or implementation of the QA Program.</p>	<p>SDR-528 (Open)</p> <p>SDR-529 (Open)</p> <p>SDR-530 (Open)</p> <p>SDR-531 (Open)</p>

USGS SURVEILLANCES PERFORMED AFTER

AUGUST 23, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 6 of 6

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-029 (5/3-4/90)	<p>The purpose of this surveillance was to determine the effectiveness of compliance to selected USGS implementing procedures. The scope of the surveillance covered the review of current USGS organizational charts, technical procedures, technical publication preparation and review, and the distribution and control of controlled documents.</p> <p>During this surveillance, implementation of the following procedures was verified for compliance:</p>	<p>In addition to reviewing five technical publications, the YMP-USGS organizational chart was examined and found to be identified as "Draft" and has not been approved. Thirteen technical procedures were selected for review to verify procedural compliance in the area of procedure preparation and two sets of controlled documents were selected for review to determine if they were properly identified and if document revisions were current.</p> <p>Overall implementation of the areas referenced in the Purpose and Scope section of this report were considered adequate and effective for the limited work performed. Only two Observations were documented.</p>	NONE
	<ol style="list-style-type: none">1. YMP-USGS-QMP-1.01, Rev. 3, "Organization Procedure"2. YMP-USGS-QMP-3.04, Rev. 2, "Technical Review, Approval, and Distribution of YMP-USGS Publications"3. YMP-USGS-QMP-5.01, Rev. 3, "Preparation of Technical Procedures"4. YMP-USGS-QMP-5.05, Rev. 1, "Scientific Notebook Control of Technical Activities" (Including Mod 01, Rev.0)5. YMP-USGS-QMP-6.01, Rev. 5, "Document Control"		

AUDITS OF THE USGS QA PROGRAM

PERFORMED AFTER AUGUST 23, 1989

AUDIT NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
90-03 (6/25/90 Thru 7/3/90)	<p>The scope of the audit was to evaluate the effectiveness of implementation of the USGS QA Program. This was accomplished through the verification of compliance to the USGS implementing procedures which are applied to meet the requirements of YMPO 88/9 and the USGS Quality Assurance Program Plan (QAPP).</p> <p>The following QA Program elements were audited to assess compliance with the USGS implementing procedures and applicable Project Office APQs.</p> <ul style="list-style-type: none"> 1.0 Organization 2.0 Quality Assurance Program 3.0 Scientific Investigation Control and Design Control/Software Quality Assuran 4.0 Procurement Document Control 5.0 Instruction, Procedures, Plans, Drawings 6.0 Document Control 7.0 Control of Purchased Items, and Services 8.0 Identification and Control of Items, Samples, and Data 12.0 Control of Measuring and Test Services 13.0 Handling, Shipping, and Storage 15.0 Control of Nonconforming Items 16.0 Corrective Action 17.0 Quality Assurance Records 18.0 Audits 	<p>In the opinion of the Project Office audit team, the effectiveness of implementation of the USGS QA Program was considered satisfactory, except in the areas of training, nonconformance control, and records to the extent of activities performed since the last USGS Audit. In the area of Audits, due to the problems noted, the effectiveness is considered indeterminate and needs to be evaluated during future audits.</p> <p>The areas of weakness identified above do not in any way represent a significant breakdown in the QA Program, but do indicate areas where management attention is needed. The deficiencies and observations generated during this audit should not prevent USGS from continuing in ongoing activities for the Yucca Mountain Project. However, the Project Office audit team recommends that in-depth USGS internal surveillances and audits be performed in these areas, as well as all other areas, to gain confidence that the corrective actions taken by management to resolve implementation deficiencies are effective and compliance to procedures is achieved.</p>	<p>SDR-553 (Open)</p> <p>SDR-554 (Open)</p> <p>SDR-555 (Open)</p> <p>SDR-556 (Open)</p> <p>SDR-557 (Open)</p> <p>SDR-558 (Open)</p> <p>SDR-559 (Open)</p> <p>SDR-560 (Open)</p> <p>SDR-561 (Open)</p>



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WBS 1.2.9.3

QA

AUG 23 1990

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

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) ACCEPTANCE OF THE
SANDIA NATIONAL LABORATORIES' (SNL) QUALITY ASSURANCE (QA) PROGRAM

References: (1) Letter, Gertz to Shelor, dtd. 3/1/90
(2) Letter, Linehan to Stein, dtd. 10/24/89
(3) Letter, Wilmot to Hunter, dtd. 10/12/89
(4) Letter, Horton to Shelor, dtd. 8/15/90

This letter is a revision of my earlier letter (reference 4) on this subject and has been written to identify the deficiencies issued as a result of a recent surveillance.

The purpose of this memorandum is to provide an update (current as of the date of this letter) on documenting the Project Office acceptance of the QA Program of SNL. This update also addresses the five conditions for acceptance of U.S. Department of Energy's (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 acceptance of the SNL QA Program is based upon the following:

1. The NRC has accepted the SNL QA Program Plan (QAPP) based upon a safety evaluation letter (reference 2). All NRC staff comments were resolved prior to issuance of the safety evaluation letter.
2. Project Office QA has completed the SNL QA Program Qualification Audit 89-03 which was conducted September 11-12, 1989 (reference 3). This audit concluded that the QA Program is adequate for the overall control of quality-related activities. Since that audit, SNL support to the Project Office has not changed in either scope of work or level of effort. Hence, the implementation of the SNL QA Program has not changed since September 1989.
3. Project Office QA has reviewed all SNL open QA Program deficiencies and found no items that could have a technical or quality impact on output products with two exceptions. These exceptions are Severity Level I Standard Deficiency Reports (SDRs) 502 and 552. However, since these conditions adverse to quality have been identified on SDRs, and efforts are currently ongoing to resolve the identified conditions, Project Office QA has determined that these items will have no significant impact on the overall implementation of the SNL Quality Program. This review also verified that all other significant deficiencies previously identified by DOE have been resolved.

AUG 23 1990

Dwight E. Shelor

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NOTE: For this review, the Severity Level Checklist criteria established in Project Office 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 SNL QA Program activities.

4. There are no areas of the SNL QA Program affected by a stop work at the present time. The unresolved item from Audit 89-03, unapproved Software Quality Assurance Plan (SQAP), has been addressed. The SNL SQAP was approved by the Project Office on April 18, 1990.

No other unresolved items have been identified by surveillances since the September 1989 Qualification Audit 89-03. 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 are SDRs that are still open as a result of the surveillances, Project Office QA views this as a normal function of processing these documents and is to be expected.

5. Project Office QA has surveilled SNL QA Program procedures and has verified their adequacy to control the subject activities and conformance with applicable SNL QAPP requirements (see enclosure 2 for surveillance report numbers, scope, and summary of results for those surveillances performed after the SNL QA Program Qualification Audit 89-03, conducted September 11-12, 1989).
6. The Privacy Act issue did not have an impact on acceptance of the SNL QA Program.

In summary, DOE has determined the effectiveness of the SNL QA Program by audits and surveillances. The activities examined, and the results of these audits and surveillances performed since the September 1989 Qualification Audit, have verified that SNL has continued to implement an effective QA program that addresses their assigned scope of work.

Therefore, based on information presented, the Project Office has concluded that the SNL QA Program is in compliance with the applicable requirements of the Yucca Mountain Project QA Plan, NWSI/88-9, Revision 2, and is acceptable to initiate new site characterization activities.

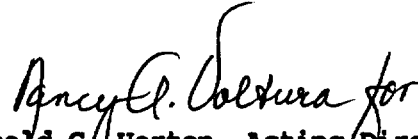
Please transmit this letter, with enclosures, to the NRC for their review.

Dwight E. Shelor

-3-

AUG 23 1990

If you have any questions or comments regarding the Project Office position on this matter, please call Nancy A. Voltura of my staff at (702) 794-7972 or FTS 544-7972.



Donald G. Horton, Acting Director
Office of Quality Assurance

QA:NAV-4651

Enclosures:

1. SDR Severity Level Checklist
2. Surveillances of the SNL QA Program
Performed after September 12, 1989

cc w/encls:

J. W. Gilray, NRC, Las Vegas, NV
T. O. Hunter, SNL, 6310, Albuquerque, NM
R. R. Richards, SNL, 6310, Albuquerque, NM
R. E. Spence, Harza, Las Vegas, NV, 517/T-08
S. R. Dippner, SAIC, Las Vegas, NV, 517/T-05

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

SURVEILLANCES OF THE SNL QA PROGRAM

PERFORMED AFTER SEPTEMBER 12, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-005 (11/27-29/89)	This surveillance was performed as a part of the corrective actions associated with Yucca Mountain Project Office (Project Office) Quality Assurance (QA) Standard Deficiency Report (SDR) 102, Revision 0. Its purpose was to verify that SNL/PSL calibration files demonstrate traceability to the National Institute of Standards and Technology (NIST) or other nationally recognized standards as required by the Yucca Mountain Project QA Plan, NNWSI/88-9.	The surveillance team verified that PSL calibration files exhibit traceability to the NIST or other nationally recognized standards as required by the Project QA Plan. YMP participating organizations provided the Project Office with a list of 77 PSL file numbers. These files had to show documented evidence of calibration activities for instruments that were used to perform Quality Level I or II work on the Project. The surveillance team randomly chose 19 of those files as a sample size. Each file in the sample size was successfully traced back to a NIST or other national standard certification or test number. The surveillance team reviewed over 100 PSL files that were part of the calibration traceability trees for the sample size selected. Based on the results of the surveillance, SDR-102, Revision 0 is closed.	NONE

SURVEILLANCES OF THE SNL QA PROGRAM

PERFORMED AFTER SEPTEMBER 12, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-015 (1/30-2/13/90)	<p>The purpose of this surveillance was to perform an implementation surveillance for activities associated with procurement, training, audits and surveillances, and calibration. During this surveillance, the following procedures were observed and verified for compliance:</p> <ol style="list-style-type: none">1. QAP 2-5, Rev. C, "Training and Familiarization Procedures"2. QAP 7-3, Rev. A, "Evaluation of Contractor QA Program Documents"3. DOP 4-1, Rev. C, "Procurement Document Requirements"4. DOP 7-1, Rev. C, "Procurement Planning"5. DOP 7-2, Rev. B, "Evaluation for Acceptance of Purchased Items or Services"6. QAP 2-7, Rev. D, "Qualification of Quality Assurance Program Audit Personnel"7. QAP 10-1, Rev. B, "Surveillances"8. QAP 18-1, Rev. B, "Quality Assurance Audits"9. DOP 2-6, Rev. C, "Qualification and Certification of Project Personnel"10. DOP 12-1, Rev. D, "Measuring and Test Equipment Control"	<p>Areas reviewed at SNL included training, audits/surveillances, calibration, and procurement. This surveillance indicated effective implementation of the SNL training program and the audits/surveillances performed to date. Due to limited procurement activity by SNL since the newly revised procedures have been in place, the results are inconclusive. Procurement procedures appear to be adhered to, however, there were four observations made on potential problems.</p> <p>The final area observed by the surveillance team was the calibration procedures practiced by SNL at their headquarters located in Albuquerque, New Mexico and of their sub-contractor, EG&G, at the Nevada Test Site (NTS). This area generated the most concern of ineffectiveness.</p> <p>There were two SDRs and one Observation generated concerning the calibration program. Based on this, this area will require future surveillances that assure problems detected have been satisfactorily resolved.</p>	SDR-492 (Open) SDR-493 (Open)

SURVEILLANCES OF THE SNL QA PROGRAM

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-016 (1/8-11/90)	<p>This surveillance was performed for three purposes. The first was to evaluate the adequacy of the process by which the SNL TPO's management directive regarding Software Quality Assurance was implemented. The second was to determine the degree of compliance to that directive. In each case, the surveillance was restricted to software development and use. The third was to assess the adequacy of backup and protection for computer software and the hardware on which it is used.</p> <p>For the scope of this surveillance, a broad sampling of software development and use activities was required to determine compliance with the management directive. The surveillance team therefore conducted interviews with individuals responsible for the planning and conduct of essentially all the work identified as the responsibility of SNL. The current revision (November 1989) of the Work Breakdown Structure (WBS) was used as the basis for the organization and conduct of the surveillance.</p>	<p>The surveillance of software development, use, and protection by SNL, at Albuquerque, New Mexico resulted in no SDRs and one Observation. SNL's management directive to curtail all QA Level I and II activities related to all software development and use, has been effectively implemented. Software protection is adequate. The single Observation addresses the revision and availability of a QA Level I code SPECTRUM-349 after the issuance of the management directive.</p>	NONE

SURVEILLANCES OF THE SNL QA PROGRAM

PERFORMED AFTER SEPTEMBER 12, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-023 (3/5-8/90)	<p>The purpose of this surveillance was to review the adequacy of implementation of selected SNL procedures. The following procedures were reviewed as the basis for the surveillance:</p> <ol style="list-style-type: none">1. DOP 4-1, "Procurement Document Requirements"2. DOP 7-1, "Procurement Planning"3. DOP 7-2, "Evaluation for Acceptance of Purchased Items"4. QAP 7-3, "Evaluation of Contractor QA Program Documents"5. QAP 10-1, "Surveillance"6. DOP 12-1, "Measuring and Test Equipment Control" <p>In addition, corrective action to SDRs 430 through 441, 444, and 445 was reviewed to determine suitability for SDR closeout.</p>	<p>The Project Office QA Surveillance of SNL identified program weaknesses in the areas of calibration sub-contractor control, calibration procedures, calibration records, and timeliness of corrective action. Six SDRs and four Observations were issued.</p>	SDR-499 (Open) SDR-500 (Closed) SDR-501 (Open) SDR-502 (Open) SDR-503 (Open) SDR-504 (Open)

SURVEILLANCES OF THE SNL QA PROGRAM

PERFORMED AFTER SEPTEMBER 12, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-027 (4/23-26/90)	The purpose of this surveillance was to review the adequacy of implementation of selected SNL procedures and to determine the status of open SDRs. The following procedures were reviewed as the basis for the surveillance: <ol style="list-style-type: none">1. QAP 16.1, "Corrective Action"2. DOP 2-2, "Study Plan Requirements"3. DOP 3-4, "Design Investigation Control"4. DOP 3-13, "Independent Technical and Management Reviews of Documents"5. DOP 5-2, "Technical Procedures Requirements"6. DOP 6-1, "Document Control System"7. DOP 12-1, "Measuring and Test Equipment Control"	The Project Office QA Surveillance of SNL identified program deficiencies in the area of document review which has resulted in an ineffective document review process. Three SDRs and three Observations were issued.	*SDR-532 (Open) SDR-533 (Open) SDR-534 (Open) *NOTE: SDR-552 was issued to resolve the untimely responses to this SDR. At the present time, satisfactory response has been provided for both SDRs

SURVEILLANCES OF THE SNL QA PROGRAM

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(COMPLETION DATE OF QUALIFICATION AUDIT)

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-030 (5/29-6/1/90)	<p>The purpose of this surveillance was to determine the adequacy of the implementation of specific SNL Yucca Mountain Project procedures that are utilized by SNL in the implementation of their procurement and training programs.</p> <p>The following SNL procedure activities were surveilled for implementation to stated procedure requirements.</p> <ol style="list-style-type: none">1. QAP 2-5, Rev. C, "Training and Familiarization Procedures"2. DOP 4-1, Rev. C, "Procurement Document Requirements"3. DOP 7-1, Rev. C, "Procurement Planning"4. QAP 7-3, Rev. A, "Evaluation of Contractor QA Program Documents"5. QAP 15-1, Rev. A "Nonconformance Control and Reporting"6. DOP 17-1, Rev. C, "Records Management System"	<p>The areas reviewed at SNL included training, procurement document processing, and nonconformances and records pertaining to procurement activities. This surveillance indicated the training program and training staff levels to be effective; however, the Privacy Act is currently impacting the processing of training records into the LRC. Although procurement procedures are apparently being properly observed, the results of the review are inconclusive in this regard due to the limited procurement activity by SNL since the newly revised procedure became effective and the number of records not present in the procurement documents sampled. Based on the single procurement NCR issued, but primarily because of the limited evidence, the overall results of the review at this time are inconclusive.</p>	<p>SDR-545 (Closed)</p> <p>SDR-546 (Open)</p> <p>SDR-547 (Open)</p>

SURVEILLANCES OF THE SNL QA PROGRAM

PERFORMED AFTER SEPTEMBER 12, 1989

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-034 (7/9-13/90)	<p>The scope of this surveillance was to evaluate seismic monitoring activity at SNL to determine technical and programmatic adequacy as imposed by controls established by the SNL Quality Management Program Plan and by the Experimental Procedure (EP) 0004 and by Technical Procedures (TPs) 82 through 88. The emphasis of the surveillance concerned calibration records and tractability to the seismic monitoring data records. Software was not evaluated as part of the surveillance.</p> <p>In addition, the corrective action program was evaluated.</p>	<p>This report has not been issued as of the date of this letter and, therefore, the summary of results has not been provided. Preliminary results indicate that there will be no Severity Level I SDRs written or stop work action as a result of this audit.</p>	<p>SDR-568 (Open)</p> <p>SDR-569 (Open)</p> <p>SDR-570 (Open)</p>



Department of Energy

Yucca Mountain Project Office
P. O. Box 98608
Las Vegas, NV 89193-8608

WBS 1.2.9.3
QA

AUG 23 1990

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

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) ACCEPTANCE OF THE
REYNOLDS ELECTRICAL & ENGINEERING CO., INC. (REECo), QUALITY ASSURANCE
(QA) PROGRAM

References: (1) Letter, Gertz to Shelor, dtd. 3/1/90
(2) Letter, Linehan to Stein, dtd. 10/3/89
(3) Letter, Wilmot to Pritchett, dtd. 10/24/89
(4) Letter, Horton to Shelor, dtd. 8/15/90

This letter is a revision of my earlier letter (reference 4) on this subject and has been written to specifically identify the remaining issue related to the Privacy Act in regard to the acceptance of the REECo Program.

The purpose of this memorandum is to provide an update (current as of the date of this letter) on documenting the Project Office acceptance of the QA Program of REECo. This update also addresses the five conditions for acceptance of U.S. Department of Energy's (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 acceptance of the REECo QA Program is based upon the following:

1. The NRC has accepted the REECo QA Program Plan (QAPP) based upon a safety evaluation letter (reference 2). All NRC staff comments were resolved prior to issuance of the safety evaluation letter.
2. Project Office QA has completed the REECo QA Program Qualification Audit 89-5, which was conducted September 25-29, 1989 (reference 3). This audit concluded that all quality implementing procedures were either found to meet, or were amended to meet (during the course of the audit), the requirements of NNWSI/88-9, Revision 2. Since that audit, REECo support to the Project Office has not changed in either scope of work or level of effort. Hence, the implementation of the REECo QA Program has not changed since September 1989.
3. Project Office QA has reviewed REECo open QA Program deficiencies and found no items that could have technical or quality impact on output products. This review also verified that significant deficiencies previously identified by DOE have been resolved.

AUG 23 1990

Dwight E. Shelor

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NOTE: For this review, the Severity Level Checklist criteria established in Project Office 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 REECO QA Program.

4. There are no areas of the REECO QA Program effected by a stop work at the present time. However, restricted access to proficiency evaluations is impacting the complete resolution of personnel qualifications. This stems from the fact that REECO is using their annual appraisals and performance evaluations (which includes such information as salary changes, personal history, etc.) to satisfy the requirement for annual proficiency evaluations. These proficiency evaluations are required for employees performing quality-related activities. While this practice had been accepted by Project Office QA, the Privacy Act issue now restricts access to this type of information and our QA auditors cannot verify the records that document the completion of these required proficiency evaluations. Resolution is in process for this item. It is also discussed as an exception to the acceptance of the REECO QA Program later on in this letter.

No other unresolved items have been identified by the surveillance performed since the September 1989 Qualification Audit 89-05. However, the deficiency identified by this surveillance has been documented on a Standard Deficiency Report (SDR) and is listed with its current status in Enclosure 2.

5. Project Office QA has surveilled the REECO QA Program procedures and has verified their adequacy to control the subject activities and conformance with applicable REECO QAPP requirements (see enclosure 2 for surveillance report number, scope, and summary of results for the surveillance performed after the REECO QA Program Qualification Audit 89-5, conducted September 25-29, 1989).

In summary, DOE has determined the effectiveness of the REECO QA Program by audits and surveillances. The activities examined and the results of the surveillance performed since the September 1989 Qualification Audit, have verified that REECO has continued to implement an effective QA Program that addresses their assigned scope of work.

Therefore, based on information presented, the Project Office has concluded that the REECO QA Program is in compliance with the applicable requirements of the Yucca Mountain Project QA Plan, NNWSI/88-9, Revision 2, and is acceptable to initiate new site characterization with the following exception:

AUG 23 1990

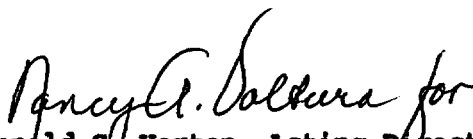
Dwight E. Shelor

-3-

Personnel Qualification - Upon resolution of the Privacy Act issues, Project Office QA will verify and document resolution of this exception by performing audits or surveillances.

Please transmit this letter, with enclosures, to the NRC for their review.

If you have any questions or comments regarding the Project Office position on this matter, please call Nancy A. Voltura of my staff at (702) 794-7972 or FTS 544-7972.


Donald G. Horton, Acting Director
Office of Quality Assurance

QA:NAV-4662

Enclosures:

1. SDR Severity Level Checklist
2. Surveillance of the REECO QA Program
Performed after September 29, 1989

cc w/encls:

J. W. Gilray, NRC, Las Vegas, NV
M. A. Fox, REECO, Las Vegas, NV
R. F. Pritchett, REECO, Las Vegas, NV
R. E. Spence, Harza, Las Vegas, NV, 517/T-08
S. R. Dippner, SAIC, Las Vegas, NV, 517/T-06

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

REECO SURVEILLANCES PERFORMED AFTER

SEPTEMBER 29, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 1 of 1

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-020 (2/12-14/90)	<p>This surveillance covered REECO's QA procedural implementation which was evaluated against the requirements set forth in Criteria I, II, XVI, XVII, and XVIII to include all Quality Procedures found in these areas.</p> <p>The individual REECO Quality Procedures and related documents whose implementation were evaluated were:</p>	<p>The surveillance by the Yucca Mountain Project Office (Project Office) Quality Assurance (QA) Department of Reynolds Electrical and Engineering Company (REECO) on February 12-14, 1990 indicates adequate implementation of procedures in the areas examined (Criteria I, II, XVI, XVII, and XVIII) with two exceptions. These exceptions resulted in the issuance of one Standard Deficiency Report (SDR) in the area of Management Review requirements of Criterion II and one Observation concerning pre and post audit meetings requirements of Criterion XVIII.</p>	SDR-494 (Closed)
	<ol style="list-style-type: none">1. QP 1.0, R6, Organization2. QP 1.1, R3, Resolution of Disputes3. QP 1.2, R1, Stop Work Order4. QP 2.0, R5, Quality Assurance Program5. QP 2.1, R4, Certification of Inspection and Test Personnel6. QP 2.2, R5, Personnel Qualification and Certification7. QP 2.3, R1, Management Assessment8. QP 2.4, R1, Indoctrination and Training9. QP 16.0, R7, Corrective Action10. QP 16.2, R2, Trend Analysis11. QP 17.0, R4, Quality Assurance Records12. QP 18.0, R6, Audits13. 568-DOC-115, R8, Quality Assurance Program Plan14. IM-LRC-IP-01, R0, Yucca Mountain Project Records Management	<p>The overall adequacy of the REECO procedural implementation program of the above Criteria was quite satisfactory and exhibited areas of exemplary application and implementation.</p>	

ENCLOSURE 2



Department of Energy

Yucca Mountain Project Office
P. O. Box 98608
Las Vegas, NV 89193-8608

WBS 1.2.9.3
QA

AUG 23 1990

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

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) ACCEPTANCE OF THE
HOLMES & NARVER, INC. (H&N) QUALITY ASSURANCE (QA) PROGRAM

References: (1) Letter, Gertz to Shelor, dtd. 3/1/90
(2) Letter, Linehan to Stein, dtd. 10/3/89
(3) Letter, Blaylock to Calovini, dtd. 5/24/89
(4) Letter, Linehan to Stein, dtd. 7/31/89
(5) Letter, Gertz to Calovini, dtd. 10/23/89
(6) Letter, Horton to Shelor, dtd. 8/15/90

This letter is a revision of my earlier letter (reference 6) on this subject and has been written to include the results of a recent audit.

The purpose of this memorandum is to provide an update (current as of the date of this letter) on documenting the Project Office acceptance of the QA Program of H&N. This update also addresses the five conditions for acceptance of U.S. Department of Energy's (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 acceptance of the H&N QA Program is based upon the following:

1. The NRC has accepted the H&N QA Program Plan (QAPP) based upon a safety evaluation letter (reference 2). All NRC staff comments were resolved prior to issuance of the safety evaluation letter.
2. Project Office QA has completed the H&N QA Program Qualification Audit 89-02, conducted April 24-28, 1989 (reference 3). Responses have been provided to NRC observations generated as a result of the audit (reference 4). This audit concluded that the QA Program appeared adequate to support the initiation of Title II design. Since that audit, H&N support to the Project Office has not increased in either scope of work or level of effort. Hence, the implementation of the H&N QA Program has not changed since April 1989.
3. Project Office QA has reviewed H&N open QA Program deficiencies and found no items that could have technical or quality impact on output products. This review also verified that significant deficiencies previously identified by DOE have been resolved.

AUG 23 1990

Dwight E. Shelor

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NOTE: For this review, the Severity Level Checklist criteria established in Project Office Quality Management Procedure 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 H&N QA Program.

4. There are no areas of the H&N QA Program effected by a stop work at the present time. However, aspects of procurement and software QA are not yet fully developed. These items are discussed as exceptions later on in this letter.

Unresolved items from Audit 89-02, Organization and the Control of Nonconforming Items, not in compliance with NNWSI QA Plan 88-9, Revision 2, were addressed on Standard Deficiency Reports (SDRs) 322 and 333, respectively, and have been resolved. No other unresolved items have been identified by audits and surveillances since the April 1989 Qualification Audit 89-02. 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 one SDR that is still open as a result of these surveillances, Project Office QA views this as a normal function of processing these documents and is to be expected.

5. Project Office QA has surveilled the H&N QA Program procedures and verified their adequacy to control the subject activities and conformance with applicable H&N QAPP requirements (see enclosure 2 for surveillance report numbers, scope, and summary of results for those surveillances performed after the H&N QA Program Qualification Audit 89-02, conducted April 24-28, 1989).
6. Project Office QA performed a scheduled H&N QA Program audit (see enclosure 3 for audit report number, scope and summary of results), conducted July 21-August 2, 1990. This audit concluded that Criteria 1, 2, 12, 16, 17, and 18 were found to be satisfactory and effectively implemented by H&N.
7. The Privacy Act issue did not have an impact on the acceptance of the H&N QA Program.

In summary, DOE has determined the effectiveness of the H&N QA Program by audit and surveillances. The activities examined, and the results of these surveillances performed since the April 1989 Qualification Audit, have verified that H&N has continued to implement an effective QA program that addresses their assigned scope of work.

AUG 23 1990

Dwight E. Shelor

-3-


Therefore, based on information presented, the Project Office has concluded that the H&N QA Program is in compliance with the applicable requirements of the Yucca Mountain Project QA Plan, NNWSI/88-9, Revision 2, and is acceptable to support the initiation of new site characterization activities with the following exceptions:

1. Procurement - The Project Office (reference 5) has directed H&N not to engage in any procurement of quality-related items or services until such time as H&N's procedures are adequate to fully implement all procurement requirements.
2. Software QA Program - H&N has been directed (reference 4) not to perform quality-related software activities until Project Office acceptance of H&N's Software QA Program.

The Project Office QA will verify and document resolution of these exceptions by performing audits or surveillances.

Please transmit this letter, with enclosures, to the NRC for their review.

If you have any questions or comments regarding the Project Office position on this matter, please call Nancy A. Voltura of my staff at (702) 794-7972 or FTS 544-7972.


Donald G. Horton, Acting Director
Office of Quality Assurance

QA:NAV-4556

Enclosures:

1. SDR Severity Level Checklist
2. Surveillances of the H&N QA Program
Performed after April 28, 1989
3. Audit of the H&N QA Program
Performed after April 28, 1989

cc w/encls:

J. W. Gilray, NRC, Las Vegas, NV
J. C. Calovini, H&N, Las Vegas, NV
C. O. Wright, H&N, Las Vegas, NV
R. E. Spence, Harza, Las Vegas, NV, 517/T-08
S. R. Dippner, 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

SURVEILLANCES OF THE H&N QA PROGRAM

PERFORMED AFTER APRIL 28, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

Page 1 of 3

ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-89-108 (8/22-25/89)	<p>This Yucca Mountain Project Office (Project Office) surveillance was performed to review and verify the Project-wide implementation of design control activities.</p> <p>The H&N portion of the surveillance included the implementation of procedures for quality assurance level/grading, design control, and configuration management. The surveillance reviewed implementation of requirements documents and implementing procedures as they apply to design control documents, such as the Reference Information Base (RIB) and Subsystems Design Requirements Document (SDRD), Design Basis Document (DBD), Quality Assurance Level Assignment Sheets (QALAS), Quality Assurance Requirements Assignment Record (QAR) grading packages, drawing design analyses, calculations, specifications, etc. The review included the flow of design information from organization to organization and the use of interface controls. Also included was the design control activities and records related to the Initial Site Preparation and Mobilization Design package per NETWORK #EHP-001, Rev. 3, (ACTIVITY NODES 91M2 through (91M4).</p>	<p>The activities performed by H&N covered by the scope of this surveillance have been, in general, satisfactorily conducted in accordance with approved procedures. Interviews with supervisors in regard to selected activities indicated they were aware of applicable procedure requirements. One Observation was issued concerning the objective evidence for the required steps in preparing and reviewing specifications by responsible personnel. This surveillance covered the areas surveilled only to the extent the program was being applied.</p>	NONE

SURVEILLANCES OF THE H&N QA PROGRAM

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-022 (2/20-23/90)	<p>The purpose of this surveillance was to determine the adequacy of implementation of specific H&N YMP Procedures which were utilized by H&N in the development of Design Package #1.</p> <p>The following H&N procedures were reviewed for implementation to stated requirements:</p> <p>PROCEDURE: TITLE:</p> <p>YMP-120, R0 WORK INITIATION YMP-140, R0 INTERFACE CONTROL YMP-260, R0 ASSIGNMENT OF QA LEVELS YMP-270, R0 APPLICATION OF GRADED QA YMP-310, R0 DESIGN BASIS DOCUMENT PREPARATION & CONTROL YMP-320, R0 DESIGN INPUT CONTROL YMP-321, R0 DESIGN DRAWING PREPARATION & CONTROL YMP-322, R0 SPECIFICATION PREPARATION & CONTROL YMP-330, R0 DESIGN ANALYSIS YMP-390, R0 QA DRAWING & SPECIFICATION REVIEW</p>	<p>This surveillance which was conducted at H&N, Las Vegas, NV, and indicated adequate implementation of the QA Program for those areas examined, with the exception of Interface Control (YMP-140). This resulted in the issuance of one Standard Deficiency Report (SDR). Additionally, four Observations concerning Quality Levels, documentation confirming drawing examination, QAG reports, and verification of drawings were also issued.</p>	SDR-495 (Open)

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ENCLOSURE NO. 2

SURVEILLANCE NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
YMP-SR-90-025 (3/26-30/90)	<p>The purpose of this surveillance was to determine the adequacy of implementation of specific H&N procedures.</p> <p>The following procedures were reviewed for implementation to the stated requirements:</p> <p>PROCEDURE: TITLE:</p> <p>YMP-410, R0 PROCUREMENT YMP-1610, R0 CORRECTIVE ACTION YMP-1620, R0 TREND ANALYSIS YMP-1710, R0 RECORDS MANAGEMENT YMP-1720, R0 MICROFILMING AND ARCHIVAL STORAGE SERVICES FACILITY (MASSF) YMP-1810, R0 AUDITS YMP-1820, R0 SURVEILLANCE ACTIVITIES</p>	<p>This surveillance of H&N indicated adequate implementation of the QA program for those areas examined. One SDR was issued. The SDR addresses the microfilming process.</p>	SDR-505 (Closed)

AUDITS OF THE H&N QA PROGRAM

PERFORMED AFTER APRIL 28, 1989

(COMPLETION DATE OF QUALIFICATION AUDIT)

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ENCLOSURE NO. 3

AUDIT NUMBER	PURPOSE AND SCOPE	SUMMARY OF RESULTS	DEFICIENCY REPORTS ISSUED
90-06 (7/31/90 Thru 8/2/90)	<p>The following program elements were audited to assess compliance with the H&N Quality Assurance Program Plan (QAPP), Revision 4, and to verify the implementation of the QA program as it relates to the Yucca Mountain Project:</p> <ul style="list-style-type: none">1.0 Organization2.0 Quality Assurance Program8.0 Identification and Control of Items, Samples, and Data12.0 Control of Measuring and Test Equipment13.0 Handling, Shipping, and Storage16.0 Corrective Action17.0 Quality Assurance Records18.0 Audits	<p>The activities audited for implementation of the requirements for Criteria 1, 12, 16, 17, and 18 were found to be satisfactory and effectively implemented by H&N.</p> <p>The activities audited for implementation of the requirements for Criterion 2 were found to be satisfactory and effectively implemented in the areas of selection, indoctrination, and training of personnel and the procedures for maintaining records of personnel qualification evaluations, indoctrination, training, and proficiency evaluation. However, the implementation of the procedures for Management Assessment and Readiness Review was marginally effective.</p> <p>Criteria 8 and 13 could not be evaluated for effectiveness, since no QA Level I or II work has been performed by H&N.</p>	NONE