

Received w/Ltr Dated 3/30/90

P.D. James Conway
From: S. Dana, SAIC

YMP AUDIT 90-1

LOS ALAMOS

OBSERVERS

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PDR WASTE
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ATTACHMENT

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BINDER/VOLUME #:

ATTACHMENT

Received w/Ltr Dated 3/30/90

ADDITIONAL SECTIONS OF CHECKLIST 90-1-02, AS NOTED BELOW, WILL BE PROVIDED AT THE TEAM/OBSERVER MEETING ON 03/26/90:

<u>WBS NUMBER</u>	<u>TITLE</u>
1.2.3.2.5	POSTCLOSURE TECTONICS
1.2.3.2.1.1.1	MINERALOGY, PETROLOGY AND ROCK CHEMISTRY OF TRANSPORT PATHWAYS
1.2.3.4.1.3	RADIONUCLIDE RETARDATION BY PRECIPITATION PROCESSES
1.2.3.4.1.5.2	DEMONSTRATION OF APPLICABILITY OF LABORATORY DATA

102.7



Department of Energy

Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518
MAR 06 1990

WBS 1.2.9.3
QA

Richard J. Herbst
Technical Project Officer for Yucca Mountain Project
Los Alamos National Laboratory
University of California
N-5, Mail Stop J521
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Los Alamos, NM 87545

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT
90-1 OF LOS ALAMOS NATIONAL LABORATORY (LOS ALAMOS) SUPPORT OF THE YUCCA
MOUNTAIN PROJECT

Please be advised that a team from the Project Office will conduct a QA audit of the Los Alamos QA Program Plan and quality-related activities March 26 through March 30, 1990. Current plans call for the audit team to hold an entrance meeting on March 26, 1990, beginning at 10:30 a.m. Please arrange for the appropriate personnel at your Los Alamos facility to attend this pre-audit conference. The post-audit conference is tentatively scheduled for 2 p.m. on March 30, 1990.

The audit will focus on the following areas:

QA Program Elements

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Scientific Investigation Control and Design Control
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans, and 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 Equipment
- 13.0 Handling, Shipping and Storage
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

MAR 06 1990

Technical Areas

Technical specialists will review and evaluate the following technical activities:

<u>WBS NUMBER</u>	<u>SCP REFERENCE</u>	<u>TITLE</u>
1.2.3.2.5	8.3.1.8	Postclosure Tectonics
1.2.3.2.1.1.1	8.3.1.3.2.1	Mineralogy, Petrology and Rock Chemistry of Transport Pathways
1.2.3.4.1.3	8.3.1.3.5	Radionuclide Retardation by Precipitation Processes
1.2.3.4.1.5.2	8.3.1.3.7.2	Demonstration of Applicability of Laboratory Data

In addition, the technical specialists will evaluate the above activities to determine adequacy in the following areas:

1. Technical qualifications of scientific investigation personnel.
2. Understanding of procedural requirements as they pertain to scientific investigation activities.
3. Adequacy of technical procedures.
4. Development of study plans, work supporting the Site Characterization Plan, and any related work products.

If the audit team identifies a need to verify additional programmatic or technical areas during the audit, they will be added to the audit checklist(s) and verified accordingly.

The audit team will consist of:

Stephen R. Dana - Science Applications International Corporation (SAIC),
Las Vegas, Nevada, Audit Team Leader
Sidney L. Crawford - SAIC, Las Vegas, Nevada, Auditor
Amelia I. Arceo - SAIC, Las Vegas, Nevada, Auditor
Anthony E. Cocoros - MAC Technical Services Company (MACTEC),
Las Vegas, Nevada, Auditor
Richard L. Maudlin - MACTEC, Las Vegas, Nevada, Auditor
Mario R. Diaz - Project Office, Las Vegas, Nevada, Auditor
Terry W. Noland - Westinghouse, Las Vegas, Nevada, Auditor-in-Training
Martha J. Mitchell - SAIC, Las Vegas, Nevada, Lead Technical Specialist

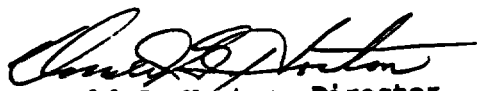
MAR 06 1990

Richard J. Herbst

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Observers from the State of Nevada, U.S. Nuclear Regulatory Commission, U.S. Department of Energy/Headquarters, or other interested parties may also accompany the audit team.

If you have any questions, please contact James Blaylock of my staff at (702) 794-7913 or FTS 544-7913, or Stephen R. Dana of SAIC at (702) 794-7176 or FTS 544-7176.


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

YMP:JB-2260

Enclosure:
Audit Plan 90-1

cc w/encl:

Ralph Stein, HQ (RW-30) FORS
D. E. Shelor, HQ (RW-3) FORS
James Tillman, LAO
H. P. Nunes, LANL, Los Alamos, NV
P. R. Guthals, LANL, Los Alamos, NV
A. E. Cocoros, MACTEC, Las Vegas, NV
R. L. Maudlin, MACTEC, Las Vegas, NV
A. R. Shernoff, MSD, Albuquerque, NM
J. E. Kennedy, NRC, Washington, DC
Ken Hooks, NRC, Washington, DC
J. W. Gilray, NRC, Las Vegas, NV
Susan Zimmerman, NWPO, Carson City, NV
J. H. Hines, NWQA, Albuquerque, NM
A. I. Arceo, SAIC, Las Vegas, NV, 517/T-06
J. J. Brogan, SAIC, Las Vegas, NV, 517/T-12
S. L. Crawford, SAIC, Las Vegas, NV, 517/T-06
S. R. Dana, SAIC, Las Vegas, NV, 517/T-06
R. J. Hutton, SAIC, Las Vegas, NV, 517/T-24
M. J. Mitchell, SAIC, Las Vegas, NV, 517/T-06
C. H. Prater, SAIC, Las Vegas, NV, 517/T-06
T. W. Noland, W, Las Vegas, NV, 517/T-06

BUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE)

QUALITY ASSURANCE (QA) AUDIT PLAN

AUDIT 90-1

MARCH 26 THROUGH MARCH 30, 1990

1.0 SCOPE

The scope of this audit is to evaluate the Los Alamos Quality Assurance Program to determine whether it meets the requirements and commitments imposed by the Project Office. This will be done by verifying implementation and effectiveness of the systems in place, as well as verifying compliance with requirements.

2.0 ORGANIZATION TO BE AUDITED

Los Alamos National Laboratory (Los Alamos), Los Alamos, New Mexico

3.0 AUDIT SCHEDULE

Pre-Audit Team Meeting	10:00 a.m.; March 22, 1990, Las Vegas, NV
Team/Observers Badging	8:00 a.m., March 26, 1990 Los Alamos, NM
Pre-Audit Team/Observers Meeting	9:00 a.m., March 26, 1990, Los Alamos, NM
Pre-Audit Conference	10:30 a.m., March 26, 1990, Los Alamos, NM
Los Alamos Audit Activities	12:00 p.m. to 4:00 p.m., March 26, 1990
Los Alamos Audit Activities	8:30 a.m. to 4:00 p.m., March 27 - 29, 1990
Los Alamos Audit Activities	8:30 a.m. to 11:30 p.m. March 30, 1990
Post-Audit Conference	2:00 p.m., March 30, 1990, Los Alamos, NM

4.0 REQUIREMENTS TO BE AUDITED AND APPLICABLE REFERENCES

The requirements to be audited are contained in the programmatic and technical checklists. These checklists were developed from the following documents:

- o NWSI/88-9, Revision 3.
- o Los Alamos QAPP and Implementing Procedures.
- o NWSI Administrative Procedures (APQs)

The conduct of the audit will be guided by the documents listed below:

- o YMP/QMP-18-01, "Audit System for the Yucca Mountain Project Office," Revision 3.
- o YMP/QMP-16-3, "Standard Deficiency Reporting System," Revision 1.
- o YMP Quality Assurance Audit Task Organization.
- o YMP Audit Observer Inquiry.
- o Policy for Participation of State, Tribal and NRC Representatives as Observers on Department of Energy (DOE) Audits, dtd. July 14, 1987.
- o Headquarters Observation of YMP Quality Assurance.

5.0 ACTIVITIES TO BE AUDITED

The activities to be audited during this audit include:

Programmatic Elements:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Scientific Investigation and Design Control
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans, and Drawings
- 6.0 Document Control
- 7.0 Control of Purchased Items, Samples, and Data
- 8.0 Identification and Control of Items, Samples, and Data
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Shipping, and Storage

5.0 ACTIVITIES TO BE AUDITED (CONTINUED)

- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

Technical Areas

Technical Specialists will review and evaluate the following technical activities:

<u>WBS NUMBER</u>	<u>SCP REFERENCE</u>	<u>TITLE</u>
1.2.3.2.5	8.3.1.8	Postclosure Tectonics
1.2.3.2.1.1.1	8.3.1.3.2.1	Mineralogy, Petrology and Rock Chemistry of Transport Pathways
1.2.3.4.1.3	8.3.1.3.5	Radionuclide Retardation by Precipitation Processes
1.2.3.4.1.5.2	8.3.1.3.7.2	Demonstration of Applicability of Laboratory Data

In addition, the Technical Specialists will evaluate the above activities to determine adequacy in the following areas:

- o Technical qualification of scientific investigation personnel.
- o Understanding of procedural requirements as they pertain to scientific investigation activities.
- o Adequacy of technical procedures.
- o Development of Study Plans, work supporting the Site Characterization Plan, and any related work products.

If the audit team identifies a need to verify additional programmatic or technical areas during the audit, they will be added to the audit checklist(s) and verified accordingly.

6.0 AUDIT TEAM MEMBERS

Stephen R. Dana - SAIC, Las Vegas, Nevada, Audit Team Leader
 Sidney L. Crawford - SAIC, Las Vegas, Nevada, Auditor

6.0 AUDIT TEAM MEMBERS (CONTINUED)

Amelia I. Arceo - SAIC, Las Vegas, Nevada, Auditor
Ed Cocoros - MACTEC, Las Vegas, Nevada, Auditor
Richard L. Maudlin - MACTEC, Las Vegas, Nevada, Auditor
Mario Diaz - YMP, Las Vegas, Nevada, Auditor
Terry W. Noland - Westinghouse, Las Vegas, Nevada, Auditor-in-Training
Martha J. Mitchell - SAIC, Las Vegas, Nevada, Lead Technical Specialist

7.0 AUDIT CHECKLISTS, ANNEXES, AND ATTACHMENTS

90-1-1 Programmatic checklist.

90-1-2 Technical checklist.

Annex A - DOE Procedure on Observer Protocol (July 1987).

Annex B - NRC/QA Procedure For Observing DOE/OGR/HLWR Program Audits.

Annex C - DOE/HQ/OGR Observation of YMP Quality Assurance Audits (Drafts).

Attachment 1 - YMP Audit Observer Inquiry.

Attachment 3 - Objective for the Technical Phase of the QA Audit.

Prepared By: Stephen R. Dana
Stephen R. Dana, Audit Team Leader

Date: 3/5/90

Approved By: James Blaylock
James Blaylock, Branch Chief
Quality Assurance Division
Yucca Mountain Project Office

Date: 3/5/90

Approved By: Donald G. Horton
Donald G. Horton, Director
Quality Assurance Division
Yucca Mountain Project Office

Date: 3/5/90



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QA

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YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA)
AUDIT 89-7 RESULTS OF LOS ALAMOS NATIONAL LABORATORY (LOS ALAMOS) SUPPORT OF
THE YUCCA MOUNTAIN PROJECT (NN1-1990- 0662)

As a result of the Project Office QA Audit 89-7 of Los Alamos, conducted November 13 through November 17, 1989, at Los Alamos, New Mexico, and November 27 and 28, 1989, at Las Vegas, Nevada, the Project Office has determined that areas of the Los Alamos QA Program are inadequate or indeterminate as detailed below:

1. Some procedures are inadequate, i.e., they do not contain sufficient guidance to assure effective implementation of the Los Alamos QA Program. In addition, based on the number of procedural deficiencies identified during the audit, the overall review process should be reevaluated and a consistent approach developed to assure that the process is capable of identifying procedural weaknesses and inconsistencies.

Examples of procedures which do not contain sufficient guidance are listed below:

TWS-QAS-QP-01.1, Revision 1
TWS-QAS-QP-02.1, Revision 1
TWS-QAS-QP-16.1, Revision 1
TWS-QAS-QP-16.2, Revision 0
TWS-QAS-QP-18.1, Revision 1
TWS-QAS-QP-18.2, Revision 0

2. Training and qualification procedures are not consistently followed. For example, documentation and forms for training and qualification are not consistent among the various Los Alamos organizational elements, and some personnel were not fully aware of their training responsibilities. Therefore, the effectiveness of the training and qualification process is indeterminate.

DEC 11 1989

Richard J. Herbst

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3. Technical review of procedures is inadequate. There is not a consistent approach as to how a technical review is defined or how the review should be documented.
4. The corrective action program is inadequate.
5. Based on the number of deficiencies identified during the audit and the inadequate or indeterminate areas identified in Items 1 through 4 above, the Los Alamos audit and surveillance Implementation Program is inadequate in effectively identifying and assessing program deficiencies or weaknesses.

Based on the above, additional actions are required by Los Alamos to assure sufficient controls are in place for the overall control of its quality related activities. As a part of the Project Office evaluation to determine the adequacy of the Los Alamos QA Program, the actions described below shall be taken.

1. Address the five items described above.
2. Resolve all Standard Deficiency Reports identified as a result of the Project Office Audit 89-7.

The above actions shall be resolved and completed by Los Alamos no later than February 16, 1990. The Project Office shall be notified when the actions have been completed. At that time, a supplemental audit will be scheduled to reevaluate the Los Alamos QA Program with specific emphasis on the areas found to be inadequate or indeterminate during the Project Office Audit 89-7, as detailed above.

If you have any questions, please contact James Blaylock of my staff at (702) 794-7913 or FTS 544-7913.

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

YMP:JB-1086

Richard J. Herbst

-3-

CC:

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WBS 1.2.9.3.2.T.1
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DEC 20 1989

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YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA)
AUDIT 89-7 OF LOS ALAMOS NATIONAL LABORATORY (LOS ALAMOS) (NN1-1990-0772)

Enclosed is the report for QA Audit 89-7. The audit was conducted by the Project Office at the Los Alamos facilities in Los Alamos, New Mexico, on November 13-17, 1989, and in Las Vegas, Nevada, on November 27-28, 1989.

During the course of the audit, the audit team generated 12 standard deficiency reports (SDRs) and 18 observations.

Responses to the SDRs (which were transmitted via separate letter) are due within 20 working days of the date of the transmittal letter. Responses to the observations are due within 20 working days of the date of this letter. The subject audit is considered completed as of the date of this letter; however, any open SDRs will continue to be tracked until each one has been closed to the satisfaction of the Lead Auditor and the Project Office.

Please address your responses to me and concurrently send the original of each observation response to Nita J. Brogan, Science Applications International Corporation (SAIC), Las Vegas, Nevada.

If you have any questions, please contact James Blaylock of my staff at (702) 794-7913 or FTS 544-7913, or Stephen R. Dana of SAIC at (702) 794-7176 or FTS 544-7176.

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

YMP:JB-1262

Enclosure:
QA Audit 89-7 Report

DEC 20 1989

cc w/encl:

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T. W. Noland, W, Las Vegas, NV, 517/T-06

PROJECT OFFICE QUALITY ASSURANCE AUDIT REPORT FOR

THE YUCCA MOUNTAIN PROJECT OFFICE AUDIT OF

LOS ALAMOS NATIONAL LABORATORY

AUDIT NO. 89-7

CONDUCTED NOVEMBER 13-17, 1989

AND

NOVEMBER 27-28, 1989

Prepared By: S. Dana Date: 12/13/89
Stephen R. Dana
Audit Team Leader/Lead Auditor

Approved By: Dale Hedges Date: 12-13-89
Dale Hedges, Manager
Quality Assurance Verification Department

Approved By: James Blaylock Date: 12/20/89
Donald G. Horton, Director
Quality Assurance Division
Yucca Mountain Project Office

ENCLOSURE

EXECUTIVE SUMMARY

PROJECT OFFICE AUDIT REPORT NO. 89-7

LOS ALAMOS NATIONAL LABORATORY

LOS ALAMOS, NEW MEXICO

NOVEMBER 13-17, 1989

AND

LAS VEGAS, NEVADA

NOVEMBER 27-28, 1989

In the opinion of the Yucca Mountain Project Office (Project Office) audit team, the Los Alamos National Laboratory (Los Alamos) Quality Assurance (QA) Program is inadequate or indeterminate as detailed below:

1. Some procedures are considered to be inadequate (i.e., they do not contain sufficient guidance to assure effective implementation of the Los Alamos QA program). In addition, based on the number of procedural deficiencies identified during the audit, the overall review process should be re-evaluated and a consistent approach developed to assure that the process is capable of identifying procedural weaknesses and inconsistencies.
2. Training and qualification procedures are not consistently followed. For example, documentation and forms for training and qualification are not consistent among the various Los Alamos organizational elements, and some personnel were not fully aware of their training responsibilities. Therefore, the effectiveness of the training and qualification process is considered to be indeterminate.
3. Technical review of procedures is considered to be inadequate. There is not a consistent approach as to how a technical review is defined or how the review should be documented.
4. In as much as numerous deficiencies were identified relative to the Los Alamos QA Program Plan (QAPP), Revision 4.4, Section 16, "Corrective Action", the Corrective Action program is considered to be inadequate.

5. Based on the number of deficiencies identified during the audit and the inadequate or indeterminate areas identified in items 1 through 4 above, the Los Alamos audit and surveillance implementation program is considered to be inadequate in effectively identifying and assessing program deficiencies or weaknesses.

Additional actions are required by Los Alamos to assure that sufficient controls are in place for the overall control of its quality-related activities.

It should be noted that the Los Alamos Software Quality Assurance Plan (SQAP) has not been approved by the Project Office. Therefore, the audit team was unable to verify that the Los Alamos QA software program met the provisions of the Project Office QA Plan (QAP), NNWSI/88-9, Revision 2.

Issued during the course this audit were 12 Standard Deficiency Reports (SDRs). In addition, a total of 18 Observations were also issued. It should be noted that during the course of the audit, Los Alamos was able to correct nine concerns identified by the auditors. The nine concerns and the actions taken to correct them are described in this report.

It was apparent to the audit team that Los Alamos had put forth a considerable effort to bring their program into compliance with the requirements of NNWSI/88-9, Revision 2. Los Alamos is to be commended for the effort that was put forth during the audit to accommodate the audit team. Of particular note is the amount of time and effort expended by the Los Alamos personnel to correct potential deficiencies identified during the audit.

1.0 INTRODUCTION

This report contains the results of a quality assurance audit of the Los Alamos Yucca Mountain Project activities. The audit was conducted at the Los Alamos facilities in Los Alamos, New Mexico, November 13-17, 1989 and at Las Vegas, Nevada, November 27-28, 1989. The audit was conducted in accordance with the requirements of Quality Management Procedure QMP-18-01, Revision 3, "Audit System for the Waste Management Project Office." The QA program requirements to be verified were taken from the Yucca Mountain Project Office (Project Office) QA Plan, NNWSI/88-9, Revision 2.

2.0 AUDIT SCOPE

The following program elements were audited to assess compliance with NNWSI/88-9, Revision 2, and the Los Alamos Quality Assurance Program Plan (QAPP), Revision 4.4:

- 1.0 Organization
- 2.0 Quality Assurance Program
- 3.0 Scientific Investigation Control and Design Control
- 4.0 Procurement Document Control
- 5.0 Instructions, Procedures, Plans, and 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 Equipment
- 13.0 Handling, Shipping, and Storage
- 15.0 Control of Nonconforming Items
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

The following program elements, described in the Los Alamos QAPP, were reviewed prior to the audit and found to be not applicable to the activities assigned to Los Alamos at this time:

- 9.0 Control of Processes
- 10.0 Inspection
- 11.0 Test Control
- 14.0 Inspection, Test, and Operating Status

The scope of this audit also included a review of the following technical activities:

- 1. Technical qualification of scientific investigators and design personnel.

2.0 AUDIT SCOPE (CONTINUED)

2. Understanding of procedural requirements as they pertain to scientific investigation and design control activities.
3. Adequacy of technical procedures.
4. Development of study plans and work supporting the Site Characterization Plan (SCP).

<u>SCP Section</u>	<u>Title</u>
8.3.1.3.2.2	History of Mineralogic and Geochemical Alteration of Yucca Mountain
8.3.1.3.2.1	Mineralogy, Petrology, and Chemistry of Transport Pathways
8.3.1.8.1.1	Probability of a Volcanic Eruption Penetrating the Repository
8.3.1.8.5.1	Characterization of Volcanic Features
8.3.1.3.3.2	Kinetics and Thermodynamics of Mineral Evolution
8.3.1.3.5.1	Dissolved Species Concentration Limits (Solubility Determination)
8.3.1.3.4.1	Sorption
8.3.1.2.3.1	Characterization of the Site Saturated-Zone Ground Water Flow Study (Activity 7, Testing of C Well Sites with Reactive Tracer)
8.3.1.3.4.2	Biological Sorption and Transport

3.0 AUDIT TEAM PERSONNEL

Stephen R. Dana	Audit Team Leader
James Blaylock	Audit Manager
Frank J. Kratzinger	Auditor
Amelia I. Arceo	Auditor
Sidney L. Crawford	Auditor

3.0 AUDIT TEAM PERSONNEL (CONTINUED)

Frederick J. Ruth	Auditor
Mario R. Diaz	Auditor
Kenneth T. McFall	Auditor-In-Training
Jane Hadden	Auditor-In-Training
Dean B. Eppler	Lead Technical Specialist
Carolyn Rutland	Technical Specialist
Paul L. Cloke	Technical Specialist
Martha J. Mitchell	Technical Specialist
John Marchand	Observer, DOE/HQ
Janet Docka	Observer, DOE/HQ
Kenneth Hooks	Observer, (Lead) NRC
Tilak Verma	Observer, NRC
Jeffrey Pohle	Observer, NRC
Michael Gonzalez	Observer, NRC
Susan Zimmerman	Observer, State of Nevada
Don Shettel	Observer, State of Nevada
Maurice Morganstein	Observer, State of Nevada
Larry Ortiz	Observer, DOE/Albuquerque Operations Office
Martha Pendelton	Observer, SAIC
Joe Caldwell	Observer, MACTEC

4.0 SUMMARY OF AUDIT RESULTS

4.1 STATEMENT OF PROGRAM EFFECTIVENESS

In the opinion of the Project Office audit team, the Los Alamos QA program is inadequate or indeterminate in the following areas:

1. Procedures (inadequate)
2. Training and Qualification (indeterminate)
3. Technical Review of Procedures (inadequate)
4. Corrective Action (inadequate)
5. Audit and Surveillance Implementation Program (inadequate)

Based on the above, additional actions are required by Los Alamos to assure that sufficient controls are in place for the overall control of its quality-related activities.

4.2 SUMMARY OF TECHNICAL ACTIVITIES

The technical specialists interviewed principal investigators and members of the Los Alamos scientific staff, and examined samples of various documents to assess the technical adequacy of the implementing plans and procedures for meeting the requirements of the Project Office QA Plan NWSI/88-9, Revision 2.

In summary, each of the investigators interviewed had a detailed knowledge of their particular program and were aware of the need for maintaining quality throughout their investigations. In all technical discussions, the investigators had an excellent knowledge of the rationale behind their investigations, the uses and limitations of the data their investigations will produce, and of the quality requirements necessary to ensure traceability and reproducibility of their data. It is our opinion that this program is maintaining the high standards seen in previous audits.

4.3 SUMMARY OF FINDINGS

A total of 12 Standard Deficiency Reports (SDRs) were generated as a result of this audit. Information copies of the SDRs are included in Enclosure 3. Eighteen Observations were also issued to Los Alamos which are included in Enclosure 2. A synopsis of SDRs and Observations is discussed in Section 6 of this report. Additionally, this synopsis includes nine concerns that were corrected during the course of the audit.

5.0 AUDIT MEETINGS

5.1 PRE-AUDIT CONFERENCE

A pre-audit conference was held with the Los Alamos Technical Project Officer (TPO) and his staff at 10:30 a.m. on November 13, 1989. The purpose, scope, and proposed agenda for the audit were presented and the audit team was introduced. A list of those attending is provided in Enclosure 1.

5.2 PERSONS CONTACTED DURING THE AUDIT

See Enclosure 1.

5.3 POST-AUDIT CONFERENCE

The post-audit conference was held at 2:00 p.m. on November 17, 1989, at the Los Alamos offices in Los Alamos, New Mexico. A synopsis of the preliminary SDRs and observations identified during the course of the audit was presented to the TPO and his staff. The audit of SCP Section 8.3.1.8.1.1, "Probability of a Volcanic Eruption Penetrating the Repository," and the Integrated Data System (audited under Criteria 3) were not completed prior to the post-audit conference. These audit elements were completed in Las Vegas, Nevada; therefore, a separate post-audit conference was held at 2:00 p.m. on November 28, 1989 in Las Vegas to discuss results of these two elements. A list of those attending both post-audit conferences is provided in Enclosure 1.

5.4 AUDIT STATUS MEETINGS

Audit status meetings were held with the Los Alamos TPO and his key staff at 8:30 a.m. each day of the audit. A status of how the audit was progressing and identification of discrepancies were discussed.

6.0 SYNOPSIS OF STANDARD DEFICIENCY REPORTS, OBSERVATIONS, AND CONCERNS CORRECTED DURING THE AUDIT

6.1 STANDARD DEFICIENCY REPORTS

SDR No. 460 The responsibility and authority of each subcontractor for interface control are not defined and documented in a procedure. Additionally, procedure TWS-QAS-QP-01.1, Revision 0, does not provide sufficient details describing the methods of conducting and documenting interorganizational interfaces.

6.1 STANDARD DEFICIENCY REPORTS (CONTINUED)

- SDR No. 461 An individual was certified on 5/26/89 to four Quality Procedures (QPs) that do not exist.
- SDR No. 462 The qualification files of two individuals did not satisfy the minimum education requirements identified in the applicable position descriptions nor had supervisors documented the basis for accepting "equivalent experience" in lieu of the normal education requirements.
- SDR No. 463 The Functional Requirements Document (FRD), as reviewed, and subsequently as issued, contained numerous errors and inconsistent structure in the logic elements of the Integrated Data System (IDS) that was not identified by the design review process. Additionally, the FRD referenced the design input source as the Exploratory Shaft Facility (ESF) Subsystem Design Requirement Document (SDRD), Benchmark #5 draft. However, the changes of Benchmark #6 impacted the list of U.S. Department of Energy (DOE) orders in the FRD.
- SDR No. 464 Several study plans, submitted to the Project Office subsequent to the effective date of Administrative Procedure AP-1.10Q, had been technically reviewed in a different form and content than the version actually submitted to the Project Office. No check or review was documented to assure that changes occurring between the technical review and submission to the Project Office either did not impact technical content of the study plan or that an additional review of the changes for technical adequacy was performed.
- SDR No. 465 Several Detailed Procedures (DPs) do not address acceptance and rejection criteria or limits or the applicability of this subject to the work covered by the DP.
- SDR No. 466 During a review of controlled manuals, procedures were found which should have been removed or marked obsolete.
- SDR No. 467 There was no documentation to show that a trend report has been issued on Nonconformance Reports (NCRs) since the effective date of the procedure (6/20/89).

6.1 STANDARD DEFICIENCY REPORTS (CONTINUED)

- SDR No. 468 Numerous deficiencies were identified in the corrective action program.
- SDR No. 469 Audit Report LANL-YMP-89-02 contains the following deficiencies:
1. Audit report response was overdue.
 2. Status of the audit findings was not reported to the QA Project Leader (QAPL).
 3. A Corrective Action Report (CAR) was never issued.
- SDR No. 470 Audit plans do not identify organizations to be notified and the applicable documents to be used during the audit. Additionally, audit checklists do not contain the documented evidence reviewed during the audit, or whether objective evidence examined during the audit was acceptable.
- SDR No. 471 TWS-QAS-QP-02.1, Revision 1, does not require position descriptions to identify needed indoctrination or training. Additionally, position descriptions do not generally identify training and indoctrination requirements.

6.2 OBSERVATIONS

1. A Readiness Review to determine Los Alamos and EG&G readiness to start IDS Title II design was performed in accordance with TWS-QAS-QP-02.3. A completed checklist, adding evaluation results, was issued as a "Checklist Summary Ledger" by Los Alamos Memo TWS-EES-1-LV-10-89-33, Attachment II. However, the actual objective evidence, review comments, and reviewer's signature were recorded on "Readiness Review Objective Evidence Documentation" forms, instead of the "Readiness Review Checklist."
2. The Readiness Review Objective Evidence Documentation forms identified several review items as satisfactory although the reviewer's comments indicated that documents were not in place or activities had not been completed. The review items were not included on the list of open items.

6.2 OBSERVATIONS (CONTINUED)

3. Position Descriptions (PDs) are prepared in accordance with Los Alamos procedure TWS-QAS-QP-02.01 to document the minimum education and experience for each Los Alamos person performing activities that affect quality on the Yucca Mountain Project. PDs are not required to be, and have not been, authenticated by signature and date (or revision) to identify the status of the PDs.
4. Los Alamos procedure TWS-QAS-QP-02.1 provides for qualification files of Los Alamos personnel to be maintained by QA Support (QAS) staff. No qualification file was maintained by QAS for an outside Technical Reviewer who is not a Los Alamos employee, but had been certified to perform Yucca Mountain Project activities.
5. Personnel qualification files, maintained in accordance with Los Alamos procedure TWS-QAS-QP-02.1, did not contain direct evidence of personnel education. The only auditable evidence that employees' education has been verified is supervisory sign off on the Los Alamos Project Resume form, indicating supervisors have "contacted" the personnel department. There are no procedural measures in Los Alamos QPs describing personnel department actions to verify employee education, experience, and level of responsibility.
6. Los Alamos procedure TWS-QAS-QP-02.1 provides for annual certification of Los Alamos personnel performing Yucca Mountain Project activities, to include identification of applicable quality and technical procedures and acknowledgment of receipt and understanding of training and/or indoctrination. Documentation of required QPs and DPs was not consistent in the personnel qualification files.
7. Several certification forms (per TWS-QAS-QP-02.1), which are also documentation of annual performance evaluation, were signed by the certifier prior to being signed by the individual. The individual signoff (per QP-02.1, Step 17) is to acknowledge receipt and understanding of indoctrination and training. The supervisor (certifier) signoff (per QP-02.1, Step 19) is to accept the individual's records of indoctrination and training and to document annual proficiency evaluation (QP-02.1, Step 21).

6.2 OBSERVATIONS (CONTINUED)

8. TWS-QAS-QP-18.3, Revision 1, paragraph 6.4, allows point award for lead auditor qualification that are more than allowed by NQA-1 Appendix 2A-3 (Nonmandatory Guidance on the Education and Experience of Lead Auditors). Appendix 2A-3 is identified as a reference by QP-18.3.

TWS-QAS-DP-18.3, Revision 1, paragraph 6.2, does not identify minimum passing lead auditor examination grades.
9. The term "Technical Review" is used in several different contexts, resulting in confusion in review methods, documentation, and resolution of comments.
10. A technical review of a Study Plan was performed, 10/14/88. Comments consisted of one misspelling error and approximately eight line spacing and page break comments, and did not address open (incomplete) items in the study plan.
11. In examining laboratory notebooks, several weaknesses were noted. It was difficult to confirm or locate in the notebooks where procedures that were used are described; the meaning of table entries is not stated; and not all specifications could be read on the photocopy of a spectrum that was affixed into the notebook.
12. LANL-YMP-QAPP, Revision 4.4, identifies several Los Alamos QPs that have not been prepared yet.
13. LANL-YMP-QAPP, Revision 4.4, pages ii through xi, are not identified by revision level. Additionally, page xi and page 42 reference National Bureau of Standards (NBS) instead of National Institute of Standards and Technology (NIST).
14. During a review of DPs, it was noted that technical areas are reviewing DPs differently. Additionally, there was no objective evidence, other than the reviewer's signature on the title page, that a review had been performed.
15. Several Los Alamos DPs do not contain safety information or warnings when hazardous materials or equipment are to be handled as part of the experiment. Procedures should include such information or references to such information in other documents. Technical review of procedures should include the identification of safety issues and such information or references should be added to procedures.

6.2 OBSERVATIONS (CONTINUED)

16. DPs are not required to reference other procedures or documents. This results in a system weakness, in the form of logical disconnects that may eventually lead to implementation errors. This is a possibility particularly when the DP implements higher level QP or programmatic elements. This situation is a problem in the areas of sample management and calibration. Lower level implementing procedures should reference higher level procedures and documents or the lower level procedures must include all information required for implementation of the activity.
17. The extensive number of "to be determined" (TBD) and "open items" in the IDS Functional Requirements Document and the Readiness Review Document indicate weakness in the application of system analysis and system engineering to the activity.
18. In some technical areas, Biological Sorption as an example, the work being done and recorded via the notebook procedure is sufficiently developed and repeated that it could be proceduralized using the DP mechanism. This should be done since it simplifies the information that needs to be recorded in the laboratory notebook and decreases the need for complex referencing in the notebook.

6.3 CONCERNS CORRECTED DURING THE AUDIT

1. The following Los Alamos QPs (for criteria 1, 2, and 3) did not have the Difficulty Importance Frequency (DIF) guidance value of training requirement on the title page:

QP-01.1, Revision 1
QP-02.1, Revision 1
QP-02.2, Revision 2
QP-02.4, Revision 0
QP-03.1, Revision 0
QP-03.3, Revision 0

Los Alamos corrected this deficiency by revising the following procedure:

- o TWS-QAS-QP-05.1, "Preparation of Quality Administrative Procedures," Revision 3, Change Request No. 104.

6.3 CONCERNS CORRECTED DURING THE AUDIT (CONTINUED)

2. Los Alamos procedure TWS-QAS-QP-02.4, Revision 0, did not include the requirement for trending management assessment results and TWS-QAS-QP-16.2, Revision 0, did not reference management assessments as input for trend reports. In addition, TWS-QAS-QP-02.4, paragraph 7.1, did not identify the documentation of recommendation resolution and verification (required by paragraph 6.4) to be part of the management assessment records package. Los Alamos corrected the deficiency by revising the following procedure:
 - o TWS-QAS-QP-02.4, "Procedure for Management Assessment," Revision 0, Change Request No. 101.
3. Los Alamos Purchase Requisition No. 8482Y, dated 8/30/89, did not contain a statement delineating that the Project Office shall have the right of access to subtier contractor facilities. It should be noted that this was the only QA Level I noncommercial purchase requisition available for review. Los Alamos corrected this deficiency by issuing NCR No. LA-0029.
4. Los Alamos was using a system to revise already issued NCRs. However, the method to perform this task is not described in TWS-QAS-QP-15.1, Revision 1. It should be noted the procedure did not address:
 1. What allowed a revision to an NCR disposition.
 2. Who should approve the issuance of a revised NCR.
 3. What kind of additional documentation should be part of the revised NCR.Los Alamos corrected this deficiency by revising the following procedure:
 - o TWS-QAS-QP-15.1, "Procedure for Nonconformances," Revision 1, Change Request No. 096.
5. Los Alamos procedure TWS-LS2-DP-401, Revision 0, did not contain a requirement for "Handling, Shipping, and Storage Requirements," per paragraph 8.3 of the procedure. Los Alamos corrected this deficiency by revising the following procedure:
 - o TWS-LS2-DP-401, "Maintenance of Culture Collection," Revision 0, Change Request No. 100.

6.3 CONCERNS CORRECTED DURING THE AUDIT (CONTINUED)

6. Los Alamos procedure TWS-INC-DP-62, Revision 2, did not require that the sample identifier be attached, as appropriate, to the sample. Los Alamos corrected this deficiency by revising the following procedure:
 - o TWS-INC-DP-62, "Bulk NTS Well Water Samples," Revision 2, Change Request No. 098.
7. Los Alamos procedure TWS-INC-DP-62, Revision 2, did not define long-term storage of samples, as required by procedure TWS-QAS-QP-08.1, Revision 1, and the Los Alamos QAPP, Revision 4.4. Los Alamos corrected this deficiency by revising the following procedure:
 - o TWS-INC-DP-62, "Bulk NTS Well Water Samples," Revision 2, Change Request No. 098.
8. During a review of Los Alamos DPs, the auditor found that some final DP record packages had not been transmitted to the Records Processing Center (RPC). Los Alamos corrected this deficiency by transmitting the DP record packages to the RPC.
9. Los Alamos procedure TWS-QAS-QP-18.2, Revision 0, did not have a method to ensure that deficiencies and/or programmatic weaknesses identified during surveillances are corrected in a timely manner. Los Alamos corrected this deficiency by revising the following procedure:
 - o TWS-QAS-QP-18.2, "Procedure for Surveys," Revision 0, Change Request No. 103.

7.0 RECOMMENDED ACTION

A written response is required for each SDR delineated in Section 6.0. Responses to each SDR are due within 20 working days from the date of the SDR transmittal letter. Upon response, acceptance, and satisfactory verification of all remedial and corrective actions, the SDRs will be closed and Los Alamos notified by letter of closure.

A written response is required for the observations contained in Enclosure 2 of this report. Responses are due within 20 working days from the date of the transmittal letter of this report.

ENCLOSURE 1

LOS ALAMOS NATIONAL LABORATORY
89-7 AUDIT ROSTER

NAME	ORGANIZATION	TITLE	PRE-AUDIT	CONTACTED	
				DURING AUDIT	POST AUDIT
Aldrich, Jim	LANL	Staff Member	X		X
Arceo, Amelia	SAIC	Auditor	X		X
Bacstow, Jack	LANL	HSE-3 DGL	X		
Barber, Janice	LANL	Staff Assistant	X		X
Barr, Donald W.	LANL	Division Leader			X
Bish, David	LANL	Staff	X	X	
Blaylock, James	DOE	Audit Manager	X		X
Bolivar, Stephen	LANL	Staff Member	X	X	X
Bradbury, John	NRC	Observer	X		
Broxton, David	LANL	Staff	X	X	X
Campbell, Katherine	LANL	Staff Member	X		X
Canepa, Julie A.	LANL	PL	X	X	X
Carlos, Barbara	LANL	Principal Investigator	X	X	X
Caughran, Alison	LANL	Editor			X
Chipern, Steve	LANL	Technician	X	X	
Cisneros, Michael	LANL	Chemical Technician			X
Cloke, Paul	SAIC	Technical Specialist	X		
Cole, Eric M.	LATA	QAS	X	X	X
Crawford, Sid	SAIC	Auditor	X		X (1)
Crowe, B.	LANL	Principal Investigator		X	
Curtis, David	LANL	Group Leader	X		
Dana, Stephen	SAIC	Lead Auditor	X		X (1)
Daniels, William R.	LANL	Group leader			X
Day, John L.	LATA	QAS	X	X	X
Diaz, Mario	DOE	Auditor	X		X
Docka, Janet	Weston	Observer	X		
Duffy, Clarence	LANL	Staff Member	X	X	X
Ebinger, Michael H.	LANL	Staff Member			X
Eggert, Kenneth	LANL	Principal Investigator	X		X
Eppler, Dean	SAIC	Lead Tech. Specialist	X		
Essington, Edward H.	LANL	Staff Member		X	X
Foster, Karen L.	LATA	Records Manager	X	X	X
Gainer, Gabriela M.	LATA	QA Support	X	X	X
Gallegos, Don	DOE/LAEO	Health & Safety Mgr.			X
Gancarz, Alex	LANL	Deputy Division Leader	X		
Gabriel, Giday	LANL	Post Doctoral	X		
Gonzalez, Michael	NRC	Observer	X		
Goulding, Patricia F.	LATA	QA Support	X	X	X
Guthals, Paul	LANL	QAO		X	X
Hadden, Jane	KOH Systems	Auditor-in-Training	X		X
Harrington, Charles D.	LANL	Principal Investigator	X	X	X

LOS ALAMOS NATIONAL LABORATORY
89-7 AUDIT ROSTER

<u>NAME</u>	<u>ORGANIZATION</u>	<u>TITLE</u>	<u>PRE- AUDIT</u>	<u>CONTACTED</u>	
				<u>DURING AUDIT</u>	<u>POST AUDIT</u>
Hedges, Dale	SAIC	QAVDM			X
Herbst, Richard J.	LANL	TPO	X	X	X
Hersman, Larry	LANL	Staff	X	X	X
Hobart, David E.	LANL	Principal Investigator	X	X	X
Hooks, Kenneth R.	NRC	Observer	X		X
Jones, Marcia	LANL	Word Processor	X		X
Kratzinger, Frank	SAIC	Auditor	X		X
Levy, Schon	LANL	Principal Investigator	X	X	X
Maassen, Larry	LANL	Staff	X	X	X
Mahoney, Patty	LANL	Safety Engineer	X		
Marchand, John	Weston	Observer	X		X
Martinez, Eva L.	LANL	Secretary	X	X	X
McConville, Jim	HARZA	Observer			(1)
McFall, Kenneth	SAIC	Auditor-in-Training	X		X
Mitchell, Alan	LANL	Chemical Technician	X		
Mitchell, Martha	SAIC	Technical Specialist	X		X (1)
Mogar, Deborah	SAIC	Observer	X		X
Morgan, Terry	LANL	QA Liaison	X	X	X
Morgenstein, Maurice	St. of Nev.	Observer	X		X
Morley, Richard	LANL	QAL	X	X	X (1)
Morris, Wayne	LANL	Staff Member	X		X
Meyer, Arend	LANL	Principal Investigator		X	X
Myers, C. W.	LANL	EES Division Leader		X	X
Newman, Brent D.	LANL	Chemical Technician		X	X
Nunes, Henry P.	LANL	QAPL	X	X	X
Oakley, Donald T.	ET-ERA	Staff Member			X
Oblad, Ross	LANL	Staff Member			(1)
Oliver, Ronald	LANL	Staff Member			(1)
Ortiz, E. Larry	DOE/AL	Observer	X		X
Ortiz, Gabriel	LANL	Record Analyst	X	X	
Otero-Bell, Diane	LATA	Support	X		
Ott, Martin A.	LANL	Mechanical Technician	X		X
Palmer, Phillip	LANL	Chemical Technician	X	X	
Polzer, M. L.	LANL	Staff Member			X
Raymond, Robert	LANL	Staff Member	X		
Robertson, Charles	LANL	Division Leader	X		
Ruth, Frederick	SAIC	Auditor	X		X
Salazar, Loyola	LANL	Group Leader	X		
Schempp, Lloyd	LANL	QA Audit Manager	X		X
Shettel, Don	St. of Nev.	Observer	X		
Simondson, Dan	LATA	QA Support	X		X

LOS ALAMOS NATIONAL LABORATORY
89-7 AUDIT ROSTER

<u>NAME</u>	<u>ORGANIZATION</u>	<u>TITLE</u>	<u>PRE- AUDIT</u>	<u>CONTACTED</u>	
				<u>DURING AUDIT</u>	<u>POST AUDIT</u>
Springer, Everett	LANL	Principal Investigator	X	X	X
Starquist, Virginia	LANL	Collaborator	X		
Thomas, Kimberly	LANL	Deputy Group Leader	X	X	
Tillery, Patricia	LATA	QA Support	X	X	X
Triaz, Ines	LANL	Staff Member		X	X
Vaniman, David	LANL	Staff Member	X		X
Verma, Tilak	NRC	Observer	X		X
Vigil, Rachael	LANL	Secretary	X		X
Watson, Clayton	LANL	QAL-EES-S	X		X
West, Karen	LANL	Staff Member	X	X	
Whetten, John T.	LANL	Associate Director			X
Zimmerman, Susan	St. of Nev.	Observer	X		X

NOTE: (1) Identifies attendance at Post-Audit meeting on November 28, 1989

ENCLOSURE 2

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-01

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: Audit 89-7
(LANL)

3 Identified By: S. L. Crawford

4 Date:
11/28/89

5 Organization: Los Alamos
Nat'l Lab

6 Person(s) Contacted: R. Oliver
R. Morley

7 Response Due Date
is 20 Days from Date
of Transmittal

8 Discussion:

A Readiness Review to determine LANL and EG&G readiness to start IDS Title II design was performed in accordance with LANL procedure TWS-QAS-QP-02.3 (Rev. 0) as directed by LANL letter TWS-EES-13-08-89-103, 8/25/89. QP-02.3 provides for review items, objective evidence, evaluation results, and signature authentication to be recorded on a "Readiness Review Checklist."

The specific review items were listed on a Readiness Review Checklist, issued by LANL memo TWS-EES-1-LV-09-89-62; a completed checklist, adding evaluation

9 QAE/Lead Auditor Date
S. Dan 12/13/89

10 Branch Manager Date

Completed by Respondee

11 Response:

12 Signature: Date:

Completed by QA Org.

13 Response Receipt Acceptable

Initiator Date

QA/Lead Auditor Date

14 Remarks:

8 Discussion: (continued)

results, was issued as a "Checklist Summary Ledger" by LANL memo TWS-EES-1-LV-10-89-33, Attachment II. However, the actual objective evidence, review comments, and reviewer's signature were recorded on "Readiness Review Objective Evidence Documentation" forms (TWS-EES-1-LV-10-89-33, Attachment III), instead of the "Readiness Review Checklist." The Objective Evidence Documentation form is not discussed in QP-02.3; as a result, there is no provision to assure retention of the objective evidence documentation as a part of the Readiness Review Data Package (Reference QP-02.3, para. 4.5, 4.7, 4.8, 6.8).

This is documented as an Observation because the Readiness Review Objective evidence Documentation forms contained the equivalent information required by QP-02.3, para. 6.3.2 and the Objective Evidence Documentation forms were included in the Readiness Review Data Package in process of review and comment by the review panel members.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-02

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: Audit 89-7
(LANL)

3 Identified By: S. L. Crawford

4 Date:
11/28/89

5 Organization: Los Alamos
Nat'l Lab

6 Person(s) Contacted: R. Oliver,
R. Morley

7 Response Due Date
is 20 Days from Date
of Transmittal

8 Discussion:

A Readiness Review was conducted during September-October 1989 to determine LANL and EG&G readiness to start IDS Title II design. The Readiness Review Objective Evidence Documentation forms, transmitted by LANL memo TWS-EES-1-LV-10-89-33, 10/19/89, identified several review items as satisfactory although the reviewers' comments indicated that documents were not in place or activities had not been completed. The review items were not included on the list of open items, although nine items, previously marked "satisfactory," were identified during final review and approval of the completed readiness review package to

9 QAE/Lead Auditor
S. Dana Date
12/13/89

10 Branch Manager
Date

Completed by Respondee

11 Response:

12 Signature: _____ Date: _____

Completed by QA Org.

13 Response Receipt Acceptable
Initiator _____ Date _____

QA/Lead Auditor _____ Date _____

14 Remarks:

8 Discussion: (continued)

remain open due to no objective evidence.

This is documented as an Observation because the Readiness Review Report was still in the review process and had not been issued as a final document. In addition, the preliminary conclusion of the draft transmittal letter is "not ready to start Title II design." Finally, the IDS design effort is being halted per LANL letter TWS-EES-13-11-89-075, 11/20/89.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-03

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: Audit 89-7
(LANL)

3 Identified By: S. L. Crawford

4 Date:
11/16/89

5 Organization: Los Alamos
Nat'l Lab

6 Person(s) Contacted: K. Foster

7 Response Due Date
is 20 Days from Date
of Transmittal

8 Discussion:

Position Descriptions are prepared in accordance with LANL procedure TWS-QAS-QP-02.1 to document the minimum education and experience for each LANL person performing activities that affect quality on the YMP. Position descriptions are not required to be, and have not been, authenticated by signature and date (or revision) to identify the status of the PDs.

9 QAE/Lead Auditor

Date

10 Branch Manager

Date

S. L. Crawford 12/13/89

Completed by Respondee

11 Response:

12 Signature:

Date:

13 Response Receipt Acceptable

Initiator

Date

QA/Lead Auditor

Date

14 Remarks:

Completed by QA Org.

Page

1 of 1

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-04

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: audit 89-1
(LANL)

3 Identified By: S. L. Crawford

4 Date:
11/16/89

5 Organization: Los Alamos
Nat'l Lab

6 Person(s) Contacted: K. Foster

7 Response Due Date
is 20 Days from Date
of Transmittal

8 Discussion:

LANL procedure TWS-QAS-QP-02.1 provides for qualification files of LANL personnel to be maintained by QAS Support (QAS) Staff. No qualification file was maintained by QAS for an outside Technical Reviewer who is not a LANL employee but had been certified to perform YMP activities.

9 QAE/Lead Auditor Date
S. J. Davis 12/13/89

10 Branch Manager Date

Completed by Respondee

11 Response:

12 Signature: Date:

Completed by QA Org.

13 Response Receipt Acceptable
Initiator Date

QA/Lead Auditor Date

14 Remarks:

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-9-05

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: Audit 89-7 (LANL)	3 Identified By: S. L. Crawford	4 Date: 11/16/89	
	5 Organization: Los Alamos Nat'l Lab	6 Person(s) Contacted: K. Foster	7 Response Due Date is 20 Days from Date of Transmittal	
	8 Discussion: Personnel qualification files, maintained in accordance with LANL procedure TWS-QAS-DP-02.1, do not contain direct evidence of personnel education. The only auditable evidence that employees' education has been verified is supervisory sign off on the LANL Project Resume form, indicating supervisors have "contacted" the personnel department. There are no procedural measures in LANL QP's describing personnel department actions to verify employee education, experience, and level of responsibility.			
9 QAE/Lead Auditor <i>S. Dene</i>		Date 12/19/89	10 Branch Manager Date	
Completed by Respondee	11 Response:			
	12 Signature: _____ Date: _____			
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>			
	Initiator _____ Date _____	QA/Lead Auditor _____ Date _____		
14 Remarks:				
Page <u>1</u> of <u>1</u>				

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-06

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: Audit 89-7
(LANL)

3 Identified By: S. L. Crawford

4 Date:
11/16/89

5 Organization: Los Alamos
Nat'l Lab

6 Person(s) Contacted: K. Foster

7 Response Due Date
is 20 Days from Date
of Transmittal

8 Discussion:

LANL procedure TWS-QAS-QP-02.1 provides for annual certification of LANL personnel performing YMP activities, to include identification of applicable quality and technical procedures and acknowledgement of receipt and understanding of training and/or indoctrination. Documentation of required Quality (QP) and Detailed (DP) procedures was not consistent in the personnel qualification files:

1. QPs and DPs typed on the certification form

9 QAE/Lead Auditor

Date

10 Branch Manager

Date

S. J. Davis 12/13/89

Completed by Respondee

11 Response:

12 Signature:

Date:

13 Response Receipt Acceptable

Initiator

Date

QA/Lead Auditor

Date

Completed by QA Org.

14 Remarks:

Page

1 of 2

8 Discussion: (continued)

2. Procedures stated as "attached list," actually attached
3. Procedures stated as "attached list," not attached
4. DPs (only) listed
5. QPs (only) listed
6. Unissued procedures listed (see SDR #461)

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-07

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: Audit 89-7 (LANL)	3 Identified By: S. L. Crawford	4 Date: 11/16/89
5 Organization: Los Alamos Nat'l Lab	6 Person(s) Contacted: K. Foster	7 Response Due Date is 20 Days from Date of Transmittal
8 Discussion: Many certification forms (per TWS-QAS-QP-02.1), which are also documentation of annual performance evaluation, were signed by the certifier prior to being signed by the individual. The individual signoff (per QP-02.1 Step 17) is to acknowledge receipt and understanding of indoctrination and training. The supervisor (certifier) signoff (per QP-02.1 Step 19) is to accept the individual's records of indoctrination and training and to document annual proficiency evaluation (QP-02.1 Step 21).		

9 QAE/Lead Auditor <i>S. Dew</i>	Date 12/13/89	10 Branch Manager	Date
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Completed by Respondee

11 Response:

12 Signature: _____ Date: _____

Completed by QA Org.

13 Response Receipt Acceptable

Initiator	Date	QA/Lead Auditor	Date
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14 Remarks:

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-08

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: Audit 89-7
(LANL)

3 Identified By: S. L. Crawford

4 Date:
11/16/89

5 Organization: Los Alamos
Nat'l Lab

6 Person(s) Contacted: H. Nunes, K. Foster

7 Response Due Date is 20 Days from Date of Transmittal

8 Discussion:

1. TWS-QAS-QP-18.3 Rev. 1, paragraph 6.4 allows point award for lead auditor qualification that are more than allowed by NQA-1 Appendix 2A-3 (Nonmandatory Guidance on the Education and Experience of Lead Auditors). Appendix 2A-3 is identified as a reference by QP-18.3.

A. Education

1). Paragraph 6.4.1 allows 5 credits maximum; Appendix 2A-3

9 QAE/Lead Auditor
S. Davis 12/13/89

10 Branch Manager
Date

Completed by Respondee

11 Response:

12 Signature: _____ Date: _____

Completed by QA Org.

13 Response Receipt Acceptable

Initiator _____ Date _____

QA/Lead Auditor _____ Date _____

14 Remarks:

8 Discussion: (continued)

(and QP-18.3 Attachment 1) allows 4 points maximum.

- 2). Paragraph 6.4.1 allows 1 additional credit for each masters or advanced degree in engineering, physical sciences, business management, or QA; Appendix 2A-3 allows only 1 additional credit (total) for masters or advanced degrees in the above disciplines.

B. Experience

- 1). Paragraph 6.4.2 allows additional credit for each of several categories of specialized nuclear, QA, or auditing experience; Appendix 2A-3 does not allow cummulative credits for these areas.
2. TWS-QAS-DP-18.3, Rev.1, paragraph 6.2 does not identify minimum passing lead auditor examination grades.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-09

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: Audit 89-7
(LANL)

3 Identified By: S. L. Crawford

4 Date:
11/15/89

5 Organization: Los Alamos
Nat'l Lab

6 Person(s) Contacted: R. Herbst

7 Response Due Date
is 20 Days from Date
of Transmittal

8 Discussion:

The term "Technical Review" is used in several different contexts, resulting in confusion in review methods, documentation, and resolution of comments.

1. Technical products (publications)	QP-03.2
2. Study plans	QP-03.2 per QP-03.3
3. Software Records	QP-03.1
4. Scientific Notebooks	QP-03.5
5. Technical Procedures	QP-05.2

9 QAE/Lead Auditor
S. Dan 12/13/89

10 Branch Manager
Date

Completed by Respondee

11 Response:

12 Signature: _____ Date: _____

Completed by QA Org.

13 Response Receipt Acceptable

Initiator _____ Date _____

QA/Lead Auditor _____ Date _____

14 Remarks:

8 Discussion: (continued)

6. Design Products

QP-3.16

QP-03.1, QP-03.5 and QP-05.2 do not identify specific requirements for reviewer qualification, selection, and documentation; technical review elements; and comment documentation and resolution.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-10

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: AUDIT-89-7 (LANL)	3 Identified By: S. L. Crawford	4 Date: 11/15/89	
	5 Organization: Los Alamos Nat'l Lab	6 Person(s) Contacted: A. Meijer	7 Response Due Date is 20 Days from Date of Transmittal	
	8 Discussion: A technical review of a Study Plan (SP 8.3.1.3.4.1 Rev. 0 and SP 8.3.1.3.4.3 Rev. 0 - combined) was performed 10/14/88 in accordance with TWS-QAS-QP-07. Comments consisted of 1 misspelling error and approximately 8 line spacing and page break comments, and did not address open (incomplete) items in the study plan. While it is recognized that there should be no "quota" for comments, the review was clearly an editorial review and did not assess the technical adequacy of the study plan.			
Completed by Respondee	9 QAE/Lead Auditor <i>S. Dan</i>	Date 12/13/89	10 Branch Manager 	
	11 Response:			
Completed by QA Org.	12 Signature:		Date:	
	13 Response Receipt Acceptable <input type="checkbox"/>	Initiator	Date	
	QA/Lead Auditor	Date	Date	
14 Remarks:				
<table border="1"> <tr> <td align="center">Page 1 of 1</td> </tr> </table>				Page 1 of 1
Page 1 of 1				

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-11

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: Audit 89-7 (LANL)	3 Identified By: P. Cloke	4 Date: 11/17/89
	5 Organization: Los Alamos Nat'l Lab	6 Person(s) Contacted: L. Hersman	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: In examining laboratory notebooks in connection with checklist items T-107, T-109, and T-110, several weaknesses were noted. It was difficult to confirm or locate in the notebooks where procedures that were used are described (copies of several pages from the notebooks are attached). On page 52 (see Attachment, page 1 of 2), 12 May 89, there is not a statement as to the origin for the instructions. It was stated that this was from a telephone call to the supplier. This should have been stated and followed-up by a written copy of the instructions. On page 53 (see Attachment, page 2 of 2), 17 May 89, a cross		
	9 QAE/Lead Auditor <i>S. Davis</i>	Date 12/13/89	10 Branch Manager Date
Completed by Respondee	11 Response:		
	12 Signature:		Date:
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>		
	Initiator Date	QA/Lead Auditor Date	
14 Remarks:			
			Page <u>1</u> of <u>2</u>

8 Discussion: (continued)

reference to pages 52 and top of 53 should have been made. In other instances procedures were described many pages later and no cross reference was provided. The manner in which the 8l was reduced to 210ml is not stated. No cross reference to where run #89 is described is provided. In the third to the last line on page 53, "/" presumably means "and." If such shorthand is to be used, there should be a master list of their definitions. On page 56, some of the writing cannot be read, specifically the entry following "10" on the second line, the word following "and" on the fourth line, and the word following "columns" on the first line under the 22 May 89 entries. Also, on the page the meaning of the table entries is not stated. In view of the text, it is presumed that there are conductivities (units inspected) in fractions eluted through a column. However, guesswork is not adequate and units must be stated. The volume of the fractions also needs to be stated. Finally, on this page, the balance on which the weighings was made must be given.

On other pages examined, not all specifications could be read on the xerox copy of a spectrum that was affixed into the notebook. Moreover, there was no legible vertical scale (if any at all) nor indication of units or attenuation on that scale.

These are considered weaknesses rather than deficiencies since Dr. David Updegraff has been able to read and understand the notebooks. However, in the future this should be avoided. It is suggested that the style of entry used by other investigators at LANL be examined (e.g., those used by D. Hobart and similar practices followed in the Biological Sorption Task).

10 May 89

Added 20 ml of Chelex H₂O to (#1) organic Extraction to help separate allowed to go overnight again

ACID vials J.S. 510-89 washed glass ware made 500 ml of each ingredient for media and passed through a Chelex column

-Johnny A Saloy

11 May 89

Made 8 l of new media for run #8

run #88 was not completed, because (#1) organic Extraction didn't separate on time for next Extraction.

Johnny A Saloy

12 May 89

Instruction for Packing P-2 Column

How to regenerate P2 Beads Before Packing Column use a .050 M sodium Phosphate Buffer with pH around neutral and equilibrate the P-2 beads for about 4 to 6 hours or overnight

To Pack the P-2 column Put 20% of the Buffer then start pouring the gel till you get to the height you would like

12 May 89

To Clean P-2 B Column use a 1M Sodium hydroxide. Pass it through the column at least 3 times the length of the column. then rinse the column with Chelex H₂O one time the length of the column then pass your Buffer at least 5 to 7 times the length of the column before you pass your sample through.

Sodium Phosphate Buffer: For 50 mL
Ex.

Sodium Phosphate Monobasic

$$.025 M \times MW. 137.99 \times \frac{500}{1000} = 1.73 g$$

Sodium Phosphate Dibasic

$$.025 M \times MW. 141.96 \times \frac{500}{1000} = 1.77 g$$

in 1000 mL
of H₂O

gives you
pH around 7
Johny A Salzer

17 May 89

packed a P-2 Column (Extra fine mesh)
used a Sodium Phosphate Buffer.

Reduced the volume of run # 89 & L down to 210 mL of unbuffered media then filtered through a Whatman # 54 filter.

Organic Extraction

(1) Added 105 mL of Chloroform / 105 mL of Phenol to the 210 mL of the unbuffered media and allowed to separate overnight.

Johny A Salzer

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-12

N-QA-012
4/89

Completed by Originating Organization

2 Noted During: Audit 89-7
(LANL)

3 Identified By: S. L. Crawford

4 Date:
11/15/89

5 Organization: Los Alamos
Nat'l Lab

6 Person(s) Contacted: R. Herbst,
H. Nunes

7 Response Due Date
is 20 Days from Date
of Transmittal

8 Discussion:

LANL-YMP-QAPP, R4.4, identifies several LANL QPs that have not been prepared yet:

- Qualification of Data (AP-5.9Q) - QAPP, Par. 2.1.2
- Graded QA (AP-5.17Q) - QAPP, Par. 2.2.2 (pending PO position)
- QA Level Assignment (AP-5.4Q) - QAPP, Par. 3.2.1.1 (pending PO position)

The QAPP should be clarified or a schedule for procedure preparation

9 QAE/Lead Auditor

Date

10 Branch Manager

Date

S. Davis

12/13/89

Completed by Respondee

11 Response:

12 Signature:

Date:

13 Response Receipt Acceptable

Initiator

Date

QA/Lead Auditor

Date

14 Remarks:

Completed by QA Org.

Page

1 of 2

8 Discussion: (continued)
established.

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-13

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: Audit 89-7 (LANL)	3 Identified By: S. L. Crawford	4 Date: 11/15/89	
	5 Organization: Los Alamos Nat'l Lab	6 Person(s) Contacted: R. Herbst, H. Nunes	7 Response Due Date is 20 Days from Date of Transmittal	
	8 Discussion: <ul style="list-style-type: none"> 1. LANL-YMP-QAPP, R4.4, pages ii through xi, (Policy, Contents, List of Figures and List of Tables, List of Acronyms) are not identified by Revision level. 2. LANL-YMP-QAPP, R4.4, page xi (Acronyms) and page 42 (Par. 12.3.2) reference NBS (National Bureau of Standards) instead of NIST (National Institute of Standards and Technology). 			
9 QAE/Lead Auditor <i>S. Davis</i>		Date 12/13/89	10 Branch Manager Date	
Completed by Respondee	11 Response:			
	12 Signature: _____ Date: _____			
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>			
	Initiator _____ Date _____	QA/Lead Auditor _____ Date _____		
14 Remarks:				
Page <u>1</u> of <u>1</u>				

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-14

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: Audit 89-7 (LANL)	3 Identified By: F. Ruth	4 Date: 11/17/89
	5 Organization: Los Alamos Nat'l Lab	6 Person(s) Contacted: T. Morgan, G. Ortiz	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: In a review of Detailed Procedures (DPs), it was noted that all three (3) technical areas are reviewing DPs differently. In addition, there was no objective evidence, other than the reviewer's signature on the procedure title page, that a review and comment resolution had been performed (except for HSE). The following DPs were reviewed: <p align="center">TWS-EES-DP-601, Rev. 0</p>		
Completed by Respondee	9 QAE/Lead Auditor	Date	10 Branch Manager
	<i>S. Davis</i>	12/13/89	
Completed by QA Org.	11 Response:		
	12 Signature:		
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>		
	Initiator	Date	QA/Lead Auditor
14 Remarks:			Date
			Date

8 Discussion: (continued)

TWS-INC-DP- 62, Rev. 2
TWS-INC-DP- 82, Rev. 0
TWS-INC-DP- 78, Rev. 0
TWS-INC-DP- 75, Rev. 0
TWS-HSE-12-DP-311, Rev. 1
TWS-HSE-12-DP-314, Rev. 0

The preparation, review, and comment resolution of Detailed Procedures should be the same as Quality Procedures (QPs), as outlined in TWS-QAS-QP-05.1, Rev. 3, Paragraph 6.2, "Review," and Paragraph 6.3, "Comment Resolution Process."

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-15

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: Audit 89-7 (LANL)	3 Identified By: M. Mitchell	4 Date: 11/17/89
	5 Organization: Los Alamos Nat'l Lab	6 Person(s) Contacted: H. Nunes	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: Several Los Alamos DPs do not contain safety information or warnings when hazardous materials or equipment are to be handled as part of the experiment. Procedure should include such information or references to such information in other documents. Technical review of procedures should include the identification of safety issues and such information or references should be added to procedures. NO RESPONSE REQUIRED		
Completed by Respondee	9 QAE/Lead Auditor <i>S. Jara</i>	Date 12/15/89	10 Branch Manager
	11 Response:		
Completed by QA Org.	12 Signature: _____		Date: _____
	13 Response Receipt Acceptable <input type="checkbox"/>	Initiator _____ Date _____	QA/Lead Auditor _____ Date _____
14 Remarks:			

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-16

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: Audit 89-7 (LANL)	3 Identified By: M. Mitchell	4 Date: 11/17/89
	5 Organization: Los Alamos Nat'l Lab	6 Person(s) Contacted: H. Nunes	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: DPs are not required to reference other procedures or documents. This results in a system weakness, in the form of logical disconnects that may eventually lead to implementation errors. This is a possibility particularly when the DP implements higher level Quality Procedures or programmatic elements. This situation is a problem in the areas of sample management and calibration. Lower level implementing procedures should reference higher level procedures and documents or the lower level procedures must include all information required for implementation of the activity.		
	9 QAE/Lead Auditor <i>S. Jara</i>	Date 12/13/89	10 Branch Manager Date
Completed by Respondee	11 Response:		
	12 Signature: _____ Date: _____		
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>	Initiator _____ Date _____	QA/Lead Auditor _____ Date _____
	14 Remarks:		

YUCCA MOUNTAIN PROJECT OFFICE
1 YMPO OBSERVATION NO. 89-7-17

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: Audit 89-7 (LANL)	3 Identified By: M. Mitchell	4 Date: 11/28/89
	5 Organization: Los Alamos Nat'l Lab	6 Person(s) Contacted: R. Oliver, R. Mosley	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: During the Los Alamos audit element of the readiness review for the IDS, there was uncertainty on the part of the LANL staff involved in the activity concerning what items were requirements for start and which could be made part of the activity. This uncertainty caused large numbers of open items to be left in the readiness review checklists. An example of this was the QA grading package for the activity. The issue of prerequisites for activities need to be thought out and evaluated during readiness evaluations. This appears to be a result of insufficient attention to systems analysis and the early stages of		
9 QAE/Lead Auditor <i>S. Davis</i>		Date 12/13/89	10 Branch Manager Date

Completed by Respondee	11 Response:
	12 Signature: _____ Date: _____

Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>	
	Initiator _____ Date _____	QA/Lead Auditor _____ Date _____
14 Remarks:		
Page <u>1</u> of <u>2</u>		

8 Discussion: (continued)

system engineering. This situation and the extensive number of "TBDS" in the Functional Requirements Document indicates the lack of early involvement of the system users (with the use of interviews and questionnaires as part of system analysis activities) rather than just involving the users as part of the review process. More attention should be given to systems engineering, analysis of needs, and evaluation of options in design areas such as the IDS.

YUCCA MOUNTAIN PROJECT OFFICE
YMPO OBSERVATION NO. 89-7-18

N-QA-012
4/89

Completed by Originating Organization	2 Noted During: Audit 89-7 (LANL)	3 Identified By: M. Mitchell	4 Date: 11/17/89
	5 Organization: Los Alamos Nat'l Lab	6 Person(s) Contacted: L. Hessman	7 Response Due Date is 20 Days from Date of Transmittal
	8 Discussion: In some technical areas, Biosorption as an example, the work being done and recorded via the notebook procedure is sufficiently developed and repeated that it could be proceduralized using the detail procedure mechanism. This should be done since it simplifies the information that needs to be recorded in the laboratory notebooks and decreases the need for complex referencing in the notebooks.		
	9 QAE/Lead Auditor <i>S. Dana</i>	Date 12/13/89	10 Branch Manager Date
Completed by Respondee	11 Response:		
	12 Signature: _____ Date: _____		
Completed by QA Org.	13 Response Receipt Acceptable <input type="checkbox"/>	Initiator _____ Date _____	QA/Lead Auditor _____ Date _____
	14 Remarks:		

ENCLOSURE 3

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 11/17/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
	3 Discovered During Audit 89-7		3a Identified By M. Diaz		4 SDR No. 460 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted R. Herbst, H. Nunes		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Item 1-1) NNWSI/88-9, Rev. 2, Para. 1.0, states "The organizational structure, lines of communication, authority, and duties of persons and organizations performing				
Completed by Organization in Block 5	9 Deficiency Contrary to the requirements in Item 8 above, the responsibility and authority of each subcontractor for interface controls are not defined and documented in a procedure. Additionally, TWS-QAS-QP-01.1, Rev. 0, does not provide suffi-				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Identify the cause of the condition and the planned action to				
	11 QAE/Lead Auditor/Date <i>S. Diaz 11/30/89</i>		12 Division Manager/Date <i>M. Diaz 12-1-89</i>		13 Project Quality Mgr./Date <i>[Signature] 12/1/89</i>
	14 Remedial/Investigative Action(s)				
Comp. by Org. QA Org.	15 Effective Date _____				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence				
	17 Effective Date _____				
18 Signature/Date					
19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
21 Remarks					
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 460

Rev. 0

Page 2 of 2

8 Requirement (continued)

activities affecting quality shall be clearly established and delineated in writing. These activities affecting quality include both the performing functions of attaining quality objectives and the QA functions."

LANL QAPP, Rev. 4.4, Para. 1.4, states "When more than one LANL subcontractor organization is involved in activities affecting quality, the responsibility and authority of each organization for interface, as well as changes thereto, shall be clearly established and documented and any shared responsibilities shall be defined and documented. To support these interfaces, required interface documentation shall be defined in the administrative procedures. The YMP administrative procedures (APs) shall provide the implementing interface controls used by LANL. A LANL QP shall describe the methods of conducting and documenting interorganizational interfaces."

9 Deficiency (continued)

cient details describing the methods of conducting and documenting interorganizational interfaces.

10 Recommended Actions (continued)

prevent recurrence.

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 11/16/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
	3 Discovered During AUDIT 89-7		3a Identified By S. L. Crawford		4 SDR No. 461 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted K. Foster		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (Q#2-5) TWS-QAS-QP-02.1, Rev. 1, Para. 6.5, step 16, requires a record of personnel indoctrination and training to be entered on a Project Certification Form. Step 17 requires the individual to sign the				
	9 Deficiency An individual (Co-PI, Dynamic Transport Column experiments, and Technical Reviewer, Batch Sorption Studies) was certified 5/26/89 to four (4) Quality Procedures that do not exist:				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Investigate the program, process, activities, or documentation to				
Completed by Organization In Block 5	11 QAE/Lead Auditor/Date <i>S. Jones 11/30/89</i>		12 Division Manager/Date <i>Kate Hedges 12-1-89</i>		13 Project Quality Mgr./Date <i>[Signature] 12/1/89</i>
	14 Remedial/Investigative Action(s)				15 Effective Date _____
	16 Cause of the Condition & Corrective Action to Prevent Recurrence				17 Effective Date _____
Comp. by Orig. QA Org.	18 Signature/Date				
	19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks				
22 QA CLOSURE					
QAE/Lead Auditor/Date		Division Manager/Date		PQM/Date	

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 461

Rev. 0

Page 2 of 2

8 Requirement (continued)

certification acknowledging receipt and understanding of indoctrination and training. Step 19 requires the individual's supervisor to sign the certification accepting the indoctrination and training for the individual's qualification.

9 Deficiency (continued)

TWS-QAS-QP-03.10

TWS-QAS-QP-03.11

TWS-QAS-QP-03.12

TWS-QAS-QP-03.13

10 Recommended Actions (continued)

determine the extent and depth of similar deficient conditions listed as examples on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 11/16/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
	3 Discovered During Audit 89-7		3a Identified By A. I. Arceo, S. L. Crawford		4 SDR No. 462 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted L. Hersman, K. Foster		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (C #2-3). LANL-YMP-QAPP, Rev. 4.4, para. 2.5.1 provides "The initial capabilities of an individual shall be based on an evaluation of his education, experience, and training and compared to those established for the				
Completed by Organization In Block 5	9 Deficiency The qualification record files of the following two individuals did not satisfy the minimum education requirements identified in the applicable position descriptions nor had supervisors documented the basis for accepting				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Investigate the program, process, activities, or documentation,				
	11 QAE/Lead Auditor/Date <i>S. Dana 11/30/89</i>		12 Division Manager/Date <i>L. Hersman 12-1-89</i>		13 Project Quality Mgr./Date <i>[Signature] 12/1/89</i>
Comp. by Orig. QA Org.	14 Remedial/Investigative Action(s)				
	15 Effective Date _____				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence				
17 Effective Date _____					
18 Signature/Date					
19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
21 Remarks					
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 462

Rev. 0

Page 2 of 2

8 Requirement (continued)

position."

TWS-QAS-QP-02.1, Rev. 1, Para. 6.2, Step 9, requires "Supervisors are responsible for determining and documenting that the personnel selected have relevant experience commensurate with the minimum requirements specified in the position description." Para. 6.3, Step 10, requires supervisors to "...verify resumes of employees or potential employees for accuracy and conformance to position description requirements, by reviewing the Project resume against the position description, and document verification of relevant education and experience by signing and dating the Project Resume Form...."

9 Deficiency (continued)

"equivalent experience" in lieu of the stated formal education requirements.

o Project Leader (EES-13)

Required: MS or equivalent

Actual: BS ChE

o Lab Technician (LS-2)

Required: BS or equivalent

Actual: No degree

10 Recommended Actions (continued)

to determine the extent and depth of similar deficient conditions listed as examples on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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1 Date 11/27/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
Completed by Originating QA Organization	3 Discovered During LANL Audit 89-7		3a Identified By S. L. Crawford		4 SDR No. 463 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted R. Oblad, R. Morley		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Item 3-7) TWS-QAS-QP-03.15, para. 6.3 and 6.4 provide for review of design documents. LANL letter TWS-EES-1-09-89-16, 9/8/89 transmitted the Integrated Data System (IDS) Functional Requirements Document (FRD) for review				
	9 Deficiency 1. The FRD, as reviewed, and subsequently, as issued (10/04/89, TWS-EES-13-10-89-004) contained numerous errors and inconsistent structure in the logic elements of the IDS that was not identified by the				
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Identify the cause of the condition and the planned action to					
Completed by Organization in Block 5	11 QAE/Lead Auditor/Date <i>S. J. Davis</i> 12/1/89		12 Division Manager/Date <i>R. Oblad</i> 12-1-89		13 Project Quality Mgr./Date <i>[Signature]</i> 12/1/89
	14 Remedial/Investigative Action(s)				15 Effective Date _____
	16 Cause of the Condition & Corrective Action to Prevent Recurrence				17 Effective Date _____
18 Signature/Date					
Comp. by Orig. QA Org.	19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks				
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

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8 Requirement (continued)

per QP-03.15, para. 6.3. The transmitted letter requested the reviewers to assure:

1. The FRD is correct.
2. The FRD is consistent with the ESF SDRD.
3. The FRD is concisely and logically structured.
4. The FRD fulfils its purpose adequately to start Title II design.
5. The FRD complies with the LANL QA plan.

9 Deficiency (continued)

design review process. (See attached List of Discrepancies)

2. The FRD referenced the design input source as the ESF SDRD, Benchmark #5 draft. Although, that was the issued version at the time of FRD preparation, Benchmark #6 changes had been approved by DOE/HQ (02/21/89) issued by YMPO (08/07/89) for incorporation into the SDRD. The changes of Benchmark #6 impacted the list of DOE orders in para. 2.2 of the FRD.
3. It is noted that QP-03.15, Rev. 0, was the correct procedure for design review at the time of FRD review; subsequently, QP-03.15, Rev. 1, 10/12/89 directs design reviews to be performed in accordance with QP-03.16, Rev. 0, 10/12/89.

10 Recommended Actions (continued)

prevent recurrence.

LANL AUDIT 89-7

LIST OF DISCREPANCIES
INTEGRATED DATA SYSTEM (IDS) FUNCTIONAL REQUIREMENTS DOCUMENT (FRD)

<u>PAGE</u>	<u>REFERENCE</u>	<u>DISCREPANCY</u>
1. 2	para 2.2	DOE Order 1330 Draft is 1330.1B Draft per SDRD BM6.
2. 2	para 2.2	DOE Order 1450.1C, listed in SDRD BM5 and BM6, is not listed in the FRD.
3. 2	para 2.2	DOE Order 5310.1A is not listed in SDRD BM5 or BM6 and DOE Order 5300.1B, listed in SDRD BM6, is not listed in the FRD.
4. 11	fig. 3.2.1	Element 1.1.1.5 is identified as "IDS Installation Tests" on logic tree, but "IDS Installation Checks" on page 12.
5. 13	fig.3.2.1	Element 1.1.1.6 and 1.1.1.7 are identified as "System Configuration" and "Instrument Configuration" on logic tree, but "System Configuration Input" and "Instrument Configuration Input" on page 11 (fig. 3.2.1) and page 12.
6. 17	fig. 3.2.4	Element 1.2.1.2 is identified as "Verify" on logic tree, but "Protect" on page 15 (fig. 3.2.3) and page 16.
7. 19	fig. 3.2.5	Element 1.2.1.2 is identified as "Verify" on logic tree; same as comment 6 above.
8. 20	para 3.2.5	"Test Controls" is identified as element 1.1.3, a part of element 1.1, "ACQUIRE"; fig. 3.1.2 (page 5) and fig. 3.2.5 (page 19) show the elements as 1.2 "PROCESS" and 1.2.3 "Test Controls."
9. 22	para. 3.2.6	Paragraph "Store" is a 2nd level element; previous paragraphs and figures are 3rd level elements. The paragraph title should be "IDS Data Archive". A new paragraph 3.2.7, "On-Line" should be inserted.
10. 22	para. 3.2.6	"STORE" is identified as element 1; the correct element designation is 1.3.
11. 24	para. 3.2.7	Paragraph "Distribute" is a 2nd level element; same as comment 9.

12. 25 fig. 3.2.8 Figure does not include 5th level elements 1.5.1.1.1, 1.5.1.1.2, 1.5.1.2.1, 1.5.1.2.2, 1.5.1.2.3; 5th level elements are presented on fig. 3.2.3 (page 15), fig. 3.2.4 (page 17), and fig. 3.2.5 (page 19).
13. 26 para. 3.2.8 "Malfunction Alarm" and subelements are identified as 1.5.1.4, 1.5.1.4.1, etc. The correct elements designations are 1.5.1.2, 1.5.1.2.1, etc.
14. 27 fig. 3.2.9 Figure does not include 5th level elements 1.5.2.3.1, 1.5.2.3.2; same as comment 12 above.
15. 28 para. 3.2.9 "Instrument Malfunction Alarm" subelements are identified as 1.5.2.4.1 and 1.5.2.4.2; the correct element designations are 1.5.2.3.1 and 1.5.2.3.2
16. 29 fig. 3.2.10 Element 1.6.3.2 is identified as "Provide Data I/O Terminals"; para. 3.2.10 (page 30) identifies the element title as "Provide Data I/O Terminals and Remote Access."
17. 30 para. 3.2.10 Paragraph "Operate" is a 2nd level element; same as comment 9 above.
18. 30 para. 3.2.10 "Maintenance and Operations" and subelements are identified as 1.6.4, 1.6.4.1, etc. The correct element designations are 1.6.3, 1.6.3.1, etc. Also "Maintenance and Operations" should be italicized.
19. 49 Appdx. B "National Bureau of Standards" (NBS) should be "National Institute of Standards and Technology" (NIST). NIST was correctly identified on pages 12 and 16.
20. 52 Appdx. E "NBS" should be "NIST"; same as comment 19 above.

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	3 Discovered During Audit-89-7		3a Identified By S.L. Crawford		4 SDR No. 464 Rev. 0		
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted R. Herbst, various PI's		7 Response Due Date is 20 Working Days from Date of Transmittal		
	8 Requirement (Audit Checklist Reference, if Applicable) (Q#3-1, 3-2) YMP AP-1.10Q, Rev. 0, paras. 5.1.2 and 5.1.5 require project participants to perform a technical review of SCP study plans prior to submittal to the Project Office. LANL TWS-QAS-QP-03.3, Rev. 0, para 6.2.1,						
Completed by Organization in Block 5	9 Deficiency Several study plans, submitted to the Project Office subsequent to the effective date of AP-1.10Q, had been technically reviewed in a different form and content than the version actually submitted to the Project Office. No						
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action to be taken to correct the deficiencies noted in block 9. Identify the cause of the condition and the planned action to						
	11 QAE/Lead Auditor/Date S. Jones 11/30/89		12 Division Manager/Date R. Herbst 12-1-89		13 Project Quality Mgr./Date W. ... 12/1/89		
	14 Remedial/Investigative Action(s)						
Comp. by Org. QA Org.	15 Effective Date _____						
	16 Cause of the Condition & Corrective Action to Prevent Recurrence						
	17 Effective Date _____						
	18 Signature/Date						
19 Response Accepted		QAE/Lead Auditor/Date		Division Manager/Date		Project Quality Mgr./Date	
20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date		Division Manager/Date		Project Quality Mgr./Date	
21 Remarks							
22 QA CLOSURE		QAE/Lead Auditor/Date		Division Manager/Date		PQM/Date	

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8 Requirement (continued)

requires study plans to be "...reviewed technically according to QPS-3.02..."

9 Deficiency (continued)

check or review was documented to assure that changes occurring between the technical review and submission to the Project Office either did not impact technical content of the study plan or that an additional review of the changes for technical adequacy was performed.

It is noted that all study plans having technical reviews performed prior to AP-1.10Q (and prior to QP-03.3) have already been submitted to the Project Office. Only three (3) LANL study plans remain to be submitted.

10 Recommended Actions (continued)

prevent recurrence.

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1 Date 11-17-89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2	
3 Discovered During Audit 89-7		3a Identified By M. J. Mitchell		4 SDR No. 465 Rev. 0	
5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted R. Herbst, H. Nunes		7 Response Due Date is 20 Working Days from Date of Transmittal	
8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Item N/A) LANL-YMP-QAPP, Rev. 4.4, Para. 3.1.6.1, states in part "DPs used for scientific investigations shall provide for the following as appropriate:					
9 Deficiency Many DPs do not address acceptance and rejection criteria or limits or the applicability of this subject to the work covered by the DP. Examples of this condition include:					
10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Investigate the program, process, activities, or documentation to					

Completed by Organization in Block 5

11 QAE/Lead Auditor/Date <i>S. Dem</i> 11/30/89		12 Division Manager/Date <i>N. K. ...</i> 12-1-89		13 Project Quality Mgr./Date <i>...</i> 12/1/89	
14 Remedial/Investigative Action(s)				15 Effective Date _____	
16 Cause of the Condition & Corrective Action to Prevent Recurrence				17 Effective Date _____	
18 Signature/Date					

Comp. by Orig. QA Org.

19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
21 Remarks			

22 QA CLOSURE

22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date
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8 Requirement (continued)

o Acceptance and rejection limits and criteria, including required levels of precision and accuracy."

TWS-QAS-QP-05.2, Rev. 2, Para. 6.3.7.6 states in part "Include criteria (eg., prerequisites and final conditions) for ensuring that DPs have been performed correctly."

9 Deficiency (continued)

TWS-EES-DP-54, Rev. 1
TWS-EES-DP-102, Rev. 1
TWS-EES-DP-114, Rev. 1
TWS-EES-DP-124, Rev. 0
TWS-INC-DP-27, Rev. 0

10 Recommended Actions (continued)

determine the extent and depth of similar deficient conditions listed as examples on the SDR. Identify the deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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Completed by Originating QA Organization	1 Date 11/17/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
	3 Discovered During Audit 89-7		3a Identified By F. Ruth/ J. Hadden		4 SDR No. 466 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted K. Foster		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Item 6-4) TWS-QAS-QP-06.1, Rev. 1, Para. 6.5, states "The holder of a controlled document removes and destroys obsolete documents in accordance with directions				
	9 Deficiency A random sample of the 59 controlled manuals were reviewed in accordance with the latest revision of the table of contents, dated October 13, 1989, to determine if all appropriate procedures had been removed or marked superceded				
Completed by Organization in Block 5	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Investigate the program, process, activities or documentation, to				
	11 QAE/Lead Auditor/Date <i>S. Davis 4/30/89</i>	12 Division Manager/Date <i>Michael DeGuz 12-1-89</i>	13 Project Quality Mgr./Date <i>[Signature] 12/1/89</i>		
	14 Remedial/Investigative Action(s)				15 Effective Date _____
	16 Cause of the Condition & Corrective Action to Prevent Recurrence				17 Effective Date _____
	18 Signature/Date				
Comp. by Orig. QA Org.	19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks				
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

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8 Requirement (continued)

given in the receipt acknowledgement form. If the holder of a controlled document prefers to keep obsolete revisions, he may do so, but he must mark "superceded," "obsolete," or a similar expression on the cover page of the outdated version and note this action on the receipt acknowledgement form."

9 Deficiency (continued)

or obsolete as required. During the review, procedures were found which should have been removed or marked obsolete. In one case (#90), one procedure was missing from the manual.

Note: The following is a list of the controlled manuals that were reviewed and all discrepancies discovered during the review were corrected during the audit:

#4
#5
#27
#40
#48
#50
#85
#86
#90

10 Recommended Actions (continued)

determine the extent and depth of similar deficient conditions listed as examples on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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Completed by Originating QA Organization	1 Date 11/17/89		2 Severity Level <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3		Page 1 of 2
	3 Discovered During Audit 89-7		3a Identified By M. Diaz		4 SDR No. 467 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted P. Goulding		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Item 15-7) NNWSI/88-9, Rev. 2, Section XV, Para. 3.0, states "Nonconformance reports shall be periodically analyzed by the QAS organization to show quality trends"				
	9 Deficiency Contrary to the above requirements, there is no documentation to show that a trend report has been issued on NCRs since the effective date of 6/20/89 of the procedure.				
Completed by Organization in Block 5	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input type="checkbox"/> Corrective Identify the remedial actions to be taken to correct the deficiency(ies) noted in block 9.				
	11 QAE/Lead Auditor/Date <i>J. Jones 11/30/89</i>		12 Division Manager/Date <i>W. H. Hedges 12-1-89</i>		13 Project Quality Mgr./Date <i>W. H. Hedges 12/1/89</i>
	14 Remedial/Investigative Action(s)				
	15 Effective Date _____				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence				
17 Effective Date _____					
18 Signature/Date					
Comp. by Orig. QA Org.	19 Response Accepted		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
	21 Remarks				
	22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date

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8 Requirement (continued)

and to help identify root causes of nonconformances. Results shall be reported to upper management for review and assessment." TWS-QAS-QP-16.2, Rev. 0, Para. 5.2, states "The Quality Assurance Support group generates trending data on a quarterly basis, beginning in January, and delivers these data to the QAPL." TWS-QAS-QP-16.2, Rev. 0, Para. 8.0, states "An approved quarterly trending report is the criterion that demonstrates satisfactory compliance with this QP."

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	3 Discovered During Audit 89-7		3a Identified By A. I. Arceo		4 SDR No. 468 Rev. 0	
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted P. Goulding/H. Nunes		7 Response Due Date is 20 Working Days from Date of Transmittal	
	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Items 16-1, 16-2, 16-3, and 16-4) NNWSI/88-9, Rev. 2, Section XVI, Para. 1.0, and LANL-YMP-QAPP, Rev. 4.4, Para. 16.1, state "The corrective Action System shall ensure that conditions adverse or potentially adverse to					
	9 Deficiency Contrary to the requirements stated above: 1. Actions to prevent recurrence of significant conditions were not					
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Investigate the program, process, activities, or documentation to					
	Completed by Organization in Block 5	11 QAE/Lead Auditor/Date <i>J. Dan 11/30/89</i>		12 Division Manager/Date <i>K. Hedges 12-1-89</i>		13 Project Quality Mgr./Date <i>[Signature] 12/1/89</i>
		14 Remedial/Investigative Action(s)				15 Effective Date _____
		16 Cause of the Condition & Corrective Action to Prevent Recurrence				17 Effective Date _____
		18 Signature/Date				
Comp. by Orig. QA Org.	19 Response Accepted		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	20 Corrective Action Verif. Satisfactory		QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks					
22 QA CLOSURE		QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

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8 Requirement (continued)

quality are identified promptly and corrected as soon as practical." NNWSI/88-9, Rev. 2, Section XVI, Para. 1.1, and LANL-YMP-QAPP, Rev. 4.4, Para. 16.2, state "For significant conditions adverse to quality, the identification, cause, and corrective action taken to prevent recurrence shall be documented and reported to immediate management and upper levels of management for review and assessment... Upon discovering or receiving notification that a significant condition adverse to quality or unusual occurrence exists, each NNWSI Project Participant shall ensure that:

- o Immediate actions have been taken to remedy the specific condition(s).
- o Causative factors have been determined.
- o Controls have been reviewed, implemented, monitored, and revised, if necessary.
- o Affected managers at all levels have been notified of adverse condition(s) and of lessons to be learned to improve conditions or avoid similar occurrences."

NNWSI/88-9, Rev. 2, Section XVI, Para. 1.2, and LANL-YMP-QAPP, Rev. 4.4, Para. 16.3, state "The QA organization shall document concurrence of the adequacy of proposed corrective actions to assure that QA requirements will be satisfied. Follow-up action shall be taken by the QA organization to verify proper implementation of this corrective action and to close out the corrective action. The organization responsible for implementing the corrective action shall assure that the corrective action is completed in a timely manner." NNWSI/88-9, Rev. 2, Sec. XVI, Para, 1.3, and LANL-YMP-QAP Rev. 4.4, Para. 16.4, state "The QA organization shall periodically analyze corrective action reports to establish quality trends. The results shall be reported to the TPO and QAPL for review and assessment." TWS-QAS-QP-16.1, Rev. 1, Para. 6.3, states "A copy of the CAR Log is sent to the RPC annually in the first quarter of the calendar year."

9 Deficiency (continued)

indicated on the CARs reviewed (CAR Nos. 043; 043, Rev. 1; 044; 046; 055, and 055, Rev 1).

2. Verification of corrective action implementation was not documented on the CAR other than the signature of the person who performed the verification. There were no references as to what was performed (survey, desk survey, or audit) or documents reviewed to verify corrective action implementation.
3. CARs were revised; however QP-16.1, Rev. 1, does not provide for revisions to CARs.
4. CARs and CAR Log do not provide information as to why the CARs were revised. The CAR Log showed that the CARs were voided, but in reality,

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9 Deficiency (continued)

the CARs were revised (CAR No. 043, 046, and 055).

5. The CAR Log was not sent to the RPC as required by QP-16.1, Rev. 1.
6. The form used for CAR does not reflect all the information required by the example form in QP-16.1, Rev. 1.
7. Some CARs (043, 044, and 055) were not completed in a timely manner.
8. CARs were not analyzed to establish quality trends.
9. Corrective Action Reports were issued to identify procedural noncompliance instead of "...significant breakdown in the QA Program or repeated nonconformances." Procedural noncompliance should be identified in another deficiency reporting system and when it becomes repetitive, then a CAR should be written.

10 Recommended Actions (continued)

determine the extent and depth of similar deficient conditions listed as examples on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

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	3 Discovered During Audit 89-7		3a Identified By M. Diaz		4 SDR No. 469 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted E. Cole/P. Tillery		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Item 18-5-1) TWS-QAS-QP-18.1, Rev. 1, Para. 6.6.1, states in part "If any findings have been identified, a response is sent to the audit team leader within 20 working				
Completed by Organization in Block 5	9 Deficiency Contrary to the requirements cited above, audit report LANL-YMP-89-02 contains the following deficiencies:				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Investigate the program, process, activities or documentation to				
	11 QAE/Lead Auditor/Date <i>S. Davis 11/30/89</i>		12 Division Manager/Date <i>Walter Edge 12-1-89</i>		13 Project Quality Mgr./Date <i>[Signature] 12/1/89</i>
	14 Remedial/Investigative Action(s) 15 Effective Date _____				
Comp. by Orig. QA Org.	16 Cause of the Condition & Corrective Action to Prevent Recurrence 17 Effective Date _____				
	18 Signature/Date				
	19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
21 Remarks					
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

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8 Requirement (continued)

days of the audit report." Para. 6.7.1 states in part "The status of audit findings for the current year shall be updated monthly by the QAS and reported to the QAPL." LANL-YMP-QAPP, Rev. 4.4, Para. 16.1, states in part "The corrective action system shall ensure that conditions adverse to quality shall be identified promptly, documented on corrective action reports, and corrected as soon as practical."

9 Deficiency (continued)

1. The audit report was issued on July 11, 1989. However, a response was not issued until October 6, 1989, 63 days after the due date.
2. Status of the audit findings was not reported to the QAPL as required.
3. A corrective action report was never issued. However, the affected audit team leader was aware of the situation but did not take any action to identify it nor to document it.

10 Recommended Actions (continued)

determine the extent and depth of similar deficient conditions listed as examples on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 11/17/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
	3 Discovered During Audit 89-7		3a Identified By M. Diaz		4 SDR No. 470 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted E. Cole/P. Tillery		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (Checklist Items 18-2, 18-3-1) NNWSI/88-9, Rev. 2, Section XVIII, Para. 1.3.1, states in part "Audit plans shall identify organizations to be notified, ...applicable documents."				
Completed by Organization in Block 5	9 Deficiency Contrary to the requirements cited above: 1. Audit plans do not identify organizations to be notified and the appli-				
	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Investigate the program, process, activities or documentation, to				
	11 QAE/Lead Auditor/Date <i>S. Dora</i> 11/30/89		12 Division Manager/Date <i>Blakely</i> 12-1-89		13 Project Quality Mgr./Date <i>[Signature]</i> 12/1/89
Comp. by Orig. QA Org.	14 Remedial/Investigative Action(s)				
	15 Effective Date _____				
	16 Cause of the Condition & Corrective Action to Prevent Recurrence				
17 Effective Date _____					
18 Signature/Date					
19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date		
21 Remarks					
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 470

Rev. 0

Page 2 of 2

8 Requirement (continued)

TWS-QAS-QP-18.1, Rev. 1, Para. 6.4.2, states in part "Auditors document their investigations, observations, and names of personnel interviewed on the audit checklist." NNWSI/88-9, Rev. 2, Section XVIII, Para. 1.4, states in part "Objective evidence shall be examined to the depth necessary to determine if these elements are adequate for effective control and to determine whether or not they are being implemented effectively."

9 Deficiency (continued)

cable documents to be used during the audit.

2. Numerous audit checklists do not contain the documented evidence reviewed during the audit.
3. Checklists do not contain qualitative or quantitative criteria to determine whether or not the objective evidence examined during the audit is acceptable to the scope and requirements of the audit.

10 Recommended Actions (continued)

determine the extent and depth of similar deficient conditions listed as examples on the SDR. Identify these deficiencies and provide the measures required to correct them. Identify the cause of the condition and the planned corrective action to prevent recurrence.

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization	1 Date 11/16/89		2 Severity Level <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3		Page 1 of 2
	3 Discovered During Audit 89-7		3a Identified By S.L. Crawford		4 SDR No. 471 Rev. 0
	5 Organization Los Alamos Nat'l Lab		6 Person(s) Contacted K. Foster		7 Response Due Date is 20 Working Days from Date of Transmittal
	8 Requirement (Audit Checklist Reference, if Applicable) (Q #2-2) LANL-YMP-QAPP, Rev. 4.4, para. 2.5 provides "Position descriptions shall establish minimum personnel qualifications and the necessary indoctrination or training or both before a person starts work on activities"				
	9 Deficiency TWS-QAS-QP-02.1, Rev.1, para. 4.2 and para 6.1, step 5, do not require position descriptions to identify needed indoctrination or training. Position descriptions do not generally identify training and indoctrination				
Completed by Organization In Block 5	10 Recommended Action(s): <input checked="" type="checkbox"/> Remedial <input type="checkbox"/> Investigative <input checked="" type="checkbox"/> Corrective Identify the remedial action(s) to be taken to correct the deficiencies noted in block 9. Identify the cause of the condition and the planned action to				
	11 QAE/Lead Auditor/Date <i>S. Dora 11/30/89</i>	12 Division Manager/Date <i>R. H. ... 12-1-89</i>	13 Project Quality Mgr./Date <i>[Signature] 12/1/89</i>		
	14 Remedial/Investigative Action(s)				15 Effective Date _____
	16 Cause of the Condition & Corrective Action to Prevent Recurrence				17 Effective Date _____
	18 Signature/Date				
Comp. by Org. QA Org.	19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date	
	21 Remarks				
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date		

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
12/88

SDR No. 471

Rev. 0

Page 2 of 2

8 Requirement (continued)
that affect quality."

9 Deficiency (continued)

requirements; training matrices, per QP-02.2 are not attached to certifications, resumes, or position descriptions, to show required training prior to annual certification.

10 Recommended Actions (continued)

prevent recurrence.

LANL-YMP-QAPP, R4.4
August 24, 1989

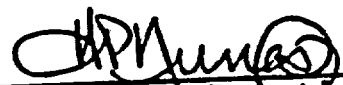
LOS ALAMOS NATIONAL LABORATORY
QUALITY ASSURANCE PROGRAM PLAN
FOR THE
YUCCA MOUNTAIN PROJECT

Effective Date 8/31/89



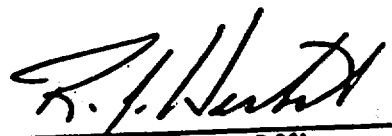
Quality Assurance Support
E. M. Cole

8/28/89
Date



Quality Assurance Project Leader
H. P. Nunes

8/25/89
Date



Technical Project Officer
R. J. Herbst

8/28/89
Date

POLICY

The Los Alamos National Laboratory (LANL) considers quality assurance (QA) an essential element of the Yucca Mountain Project (YMP). LANL will implement sound QA practices as necessary for its contribution toward obtaining a Nuclear Regulatory Commission license for the geologic repository. It is the responsibility of each person working on the YMP for LANL to be familiar with and comply with the requirements and policies established by this Quality Assurance Program Plan (QAPP) and to use the implementing procedures that support it.

This QAPP provides instructions to apply the QA requirements to the technical activities of the LANL YMP. Activities shall be planned, implemented, and maintained as required by this QAPP and shall consistently address the requirements of the YMP QA Plan.



Technical Project Officer
Richard J. Herbst

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LIST OF ACRONYMS

A	Analysis Division
AP	Administrative Procedure
CAR	Corrective Action Request
DOE	Department of Energy
DP	Detailed Technical Procedure
ESS	Earth and Space Sciences Division
HSE	Health, Safety, and Environmental Division
INC	Isotope and Nuclear Chemistry Division
LANL	Los Alamos National Laboratory
LS	Life Sciences Division
NBS	National Bureau of Standards
NCR	Nonconformance Report
NRC	Nuclear Regulatory Commission
OCRWM	Office of Civilian Radioactive Waste Management
PI	Principal Investigator
PMP	Project Management Plan
PQM	Project Quality Manager
QA	Quality Assurance
QAL	Quality Assurance Liaison
QALA	Quality Assurance Level Assignment
QAP	Quality Assurance Plan
QAPL	Quality Assurance Project Leader
QAPP	Quality Assurance Program Plan
QAS	Quality Assurance Support
QP	Quality Procedures
RPC	Records Processing Center
SIP	Scientific Investigation Plan
TPO	Technical Project Officer
WBS	Work Breakdown Structure
WX-4	Technical Engineering Support
YMP	Yucca Mountain Project (formerly NNWSI)

1.0 ORGANIZATION

1.1 Los Alamos National Laboratory Yucca Mountain Project

The Los Alamos National Laboratory (LANL) quality assurance (QA) program detailed in this Quality Assurance Program Plan (QAPP) applies to all items and activities that affect the quality of LANL's YMP activities. Activities affecting quality include both technical activities and QA functions. The technical organizations are responsible for performing technical activities according to technical procedures. The QA organization is responsible for verifying performance of these activities by implementing the appropriate QA procedures.

The Technical Project Officer (TPO) is responsible for the development and implementation of the QA program. The LANL Quality Assurance Project Leader (QAPL) is delegated the authority of establishing the QAPP and directing the QA program delineated therein. The QAPL may delegate to other LANL participants, subcontractors, agents, or consultants the work of establishing and executing the QA program, or any part thereof, but remains responsible for this work. For LANL, verification is conducted by the Quality Assurance Support (QAS) contractor. The TPO is responsible to the Yucca Mountain Project Manager to ensure that LANL activities are performed in accordance with this QAPP and the associated implementing procedures.

1.1.1 Responsibilities of the Technical Project Officer

The TPO shall be responsible for seeing that the management and coordination of LANL activities are consistent with the goals and objectives of the overall Department of Energy (DOE) YMP, including planning, technical direction, cost, and schedule control.

The TPO shall provide overall management of the YMP at Los Alamos, including

- the interaction between LANL and other Office of Civilian Radioactive Waste Management (OCRWM) Program participants by representing LANL at Project Management/TPO meetings and through communications with other YMP participants;
- LANL management support for cost, schedule, and performance measurement, as well as the tracking of deliverables and milestones established by the YMP, to ensure that program goals are being implemented at LANL;
- the preparation of comments on DOE, Nuclear Regulatory Commission (NRC), and Environmental Protection Agency reports as requested by the DOE/YMP; and
- the establishment and implementation of a QA program.

1.1.2 Responsibilities of the Project Leader for the Exploratory Shaft

The Project Leader for the exploratory shaft shall be responsible for providing overall management of LANL's exploratory shaft activities. These activities will result in the access to a selected underground tuff horizon and surrounding strata in the unsaturated zone, allow for the safe and effective acquisition of geotechnical data from the selected underground tuff horizon and surrounding strata, and demonstrate the constructibility of large diameter shafts and underground openings in the selected horizon.

The Project Leader for the exploratory shaft shall have responsibilities for all efforts required to

- organize, plan, schedule, budget, monitor, control, and report LANL's exploratory shaft work;
- integrate the exploratory shaft testing elements with related site, repository, testing, and other elements, including the integration of site activities and test plans with design efforts; and
- coordinate the QA program aspects of exploratory shaft tasks and provide technical interfaces between the YMP and other participating organizations.

1.1.3 Responsibilities of the Project Leader for Geochemistry

The Project Leader for geochemistry is responsible for providing the overall management of technical activities for site characterization to determine the geochemical properties of tuff and the geochemical environment at Yucca Mountain as a basis for predicting the migration of radionuclides to the accessible environment. The Project Leader shall be responsible for all efforts required to

- organize, plan, schedule, budget, monitor, control, and report LANL's geochemical work;
- integrate the geochemical elements with related site, repository, testing, and other elements, including the integration of site activities and test plans with design efforts; and
- coordinate the QA program aspects of the geochemistry tasks and provide technical interfaces between the YMP and other participating organizations.

1.1.4 Responsibilities of the Principal Investigators and Other Contributing Investigators

Principal Investigators (PIs) and Contributing Investigators are responsible for carrying out the specific tasks assigned to them, including satisfying all technical and quality assurance requirements of the LANL YMP. The PI may delegate tasks to contributing investigators as necessary, but the PI maintains overall responsibility for the task. The PI shall be responsible for all efforts required to

- prepare scientific investigation planning documents;
- identify and prepare technical procedures;
- ensure that the LANL YMP QA program requirements are included in the technical procedures, purchase requisitions, and scientific investigation planning documents;
- conduct technical reviews of the milestones and final reports;

- interface with the LANL QAS to resolve quality concerns and coordinate with the QAS/Quality Assurance Liaison (QAL) for audits and surveys; and
- ensure that contributing investigators comply with the LANL YMP technical and QA requirements.

1.2 Quality Assurance Functions

QA functions are those activities designed to ensure that an adequate QA program is established and effectively implemented and to verify that activities affecting quality have been performed correctly. The persons performing QA functions shall have sufficient authority, access to work areas, and organizational freedom to identify quality-related problems; to recommend, initiate, or effect solutions through designated channels; to verify implementation of the solutions; and to ensure that further processing, delivery, installation, or use of nonconforming items, data, or equipment are controlled until the unsatisfactory condition has been corrected. Their responsibilities include the authority to stop unsatisfactory work through established channels. Such persons shall have direct access to responsible management, which shall be at a level where the appropriate authority and organizational freedom (including sufficient independence from cost and schedule) can effect an appropriate action.

1.2.1 Dedicated Quality Assurance Positions

1.2.1.1 Quality Assurance Project Leader

The QAPL is assigned the responsibility and authority to direct and manage the LANL YMP QA program. The QAPL is a LANL staff member independent from cost and schedule with management and QA knowledge and experience. The QAPL shall not be assigned duties that preclude full attention to QA responsibilities or that conflict with the reporting and resolution of QA issues and problems. Figure 1-1 shows the QAPL position within the LANL YMP organization. The QAPL shall have effective communication channels with other management positions.

The QAPL shall be responsible for approving, interpreting, and changing (as necessary) the LANL QAPP, for implementing procedures, and for verifying the adequacy and effectiveness of the QA program and its implementation by LANL and its subordinate organizations. The QAPL shall have the authority to resolve disputes regarding quality.

The QAPL's responsibilities include, but are not limited to,

- assembling, maintaining, and managing an independent QA staff, including training, qualifying, and certifying QA personnel;
- applying appropriate QA requirements to YMP items and activities, depending on the quality level assigned;
- providing and/or directing personnel training to maintain YMP personnel's technical proficiency and awareness of QA requirements;
- establishing interface controls between the participating LANL organizations so that quality objectives are maintained;
- defining the LANL QA program in the LANL Quality Assurance Manual;

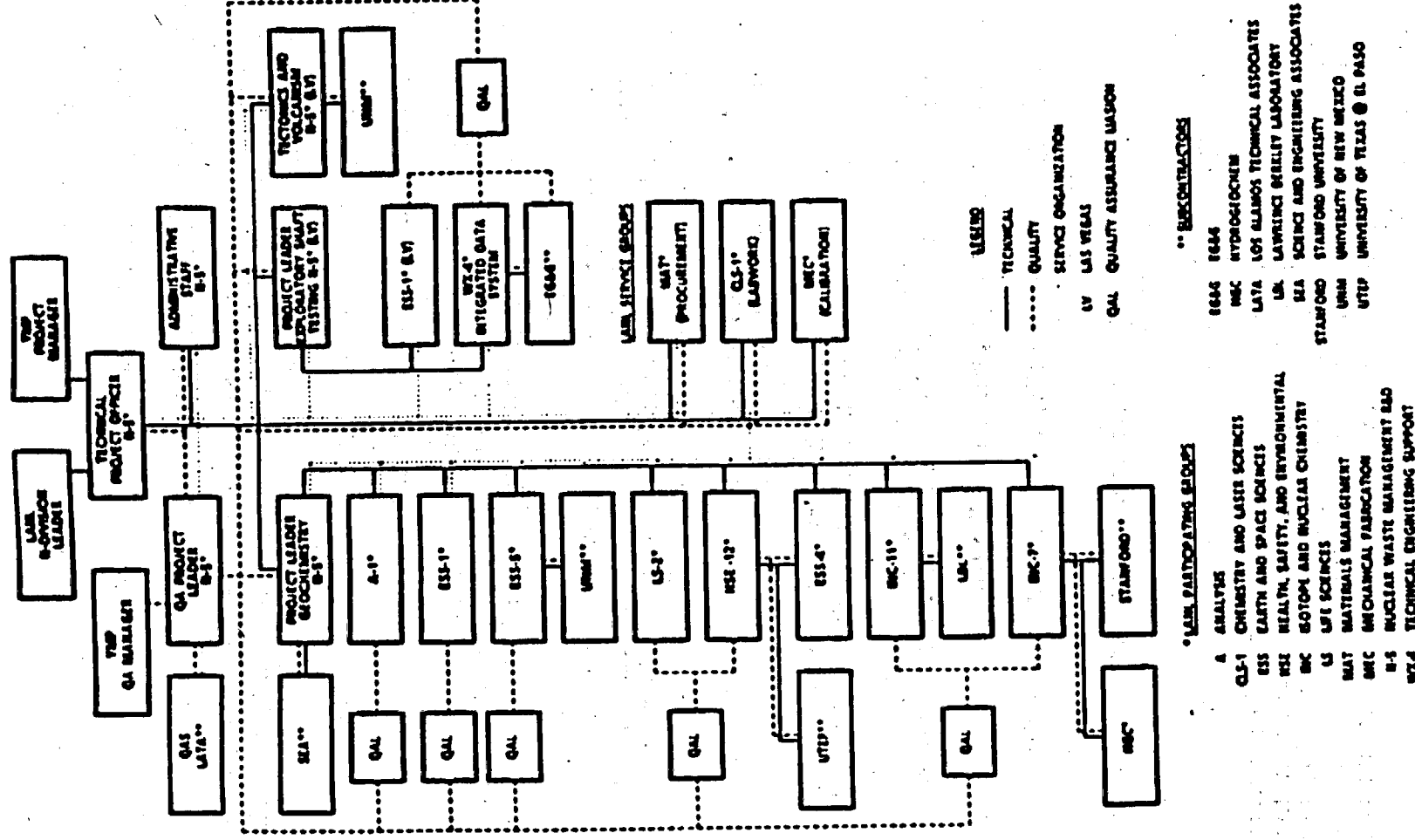


Figure 1-1. LANL Yucca Mountain Project Organizational Chart

- issuing stop work orders; and
- stopping the continuation of unsatisfactory work.

1.2.1.2 Other Dedicated Quality Assurance Positions

The QAS and QAL shall also have effective communication channels with other management positions. The QALs shall have the responsibility and authority to verify the adequacy and effectiveness of QA plans, QA requirements, and QA program implementation. In addition, the QALs shall not be assigned duties that prevent or conflict with the reporting and resolution of QA issues and problems.

QAS responsibilities include, but are not limited to,

- issuing, revising, and controlling the distribution of the LANL Quality Assurance Manual as directed by the QAPL (i.e., when changes occur in policies, practices, or the organization or when technical processes change or are added to the Project);
- ensuring that QA records, which provide objective evidence of the quality of items and activities, are collected, maintained, and stored by the responsible/originating organizations and that these records are transmitted in accordance with contractual requirements;
- performing independent verification and assessment of QA program effectiveness through audits and surveys;
- verifying that interface requirements between the LANL organizations and LANL subcontractors have been appropriately specified and maintained; and
- training LANL staff in appropriate quality administrative procedures (QPs) and orienting the LANL YMP staff to QAPP requirements.

QAL responsibilities include, but are not limited to,

- identifying levels of quality for all YMP items/activities in accordance with LANL QPs, and
- ensuring that LANL subcontract requirements are appropriate for the assigned quality level.

1.2.2 QA Organizational Structure

The structure of the YMP at LANL for organizations performing activities affecting quality is shown in Figure 1-1. Table 1-1 summarizes the assignment of responsibilities for QA implementation and QA support. The organizational structure and responsibility for assignments have been established to achieve, maintain, and verify quality. Organizations assigned QA functions shall have the organizational freedom and authority to accomplish the assigned functions.

1.3 Achievement, Maintenance, and Verification of Quality

Quality shall be achieved and maintained by those performing work. Quality achievement shall be verified by persons or organizations not directly responsible for performing the work. Individuals or groups in the QA organization shall verify

TABLE 1-1

DIVISION OF LANL YMP QA RESPONSIBILITIES^a

Function^b	QAPL	QAS	QAL
Liaison with Project Office QA	X (lead)		
Coordination of program QA document review [Project Office administrative procedures (APs), DOE Orders, and NRC guidance]	X		
Project representative to QA steering committee	X		
Maintenance of DOE and NRC requirements	X (lead)		
Development of LANL QPs		X (lead)	
Approval of QPs	X (lead)		X (review and comment)
Review of detailed technical procedures (DPs) with PIs		X	X (lead) ^c
Approval process for DPs	X		
Maintenance of original versions of internal QA program procedures and control of changes and distribution		X	
Identification of QA problems, initiation of deficiency reports, and recommendation or provision of solutions	X	X	X
Approval of disposition of nonconformance reports (NCRs) and corrective action requests (CARs)	X (lead)	X	X
Trend analysis		X (lead)	X
Day-to-day interpretation of QA requirements for PIs		X	X
Response to internal surveys and audits			X (lead)
Coordination of external audits and internal contacts and response	X (lead) ^d		X

TABLE 1-1

DIVISION OF LANL YMP QA RESPONSIBILITIES^a
 (continued)

Function^b	QAPL	QAS	QAL
Qualification of contractors or vendors		X	X (lead)
Follow-up to audits and surveys		X	
Maintenance of original current organization and personnel certifications			X
Identification of activities or items important to quality [QA level assignment (QALA)]			X
Coordination of Project Office approval of QALAs	X		
Design review control	X		
QA review and approval of procurement documents			X
Approval of sample identification, handling, storage, and control			X
Establishment and verification of controls for measuring equipment		X	X (lead)
Approval of controls for measuring equipment	X		
Measuring equipment calibration report		X	
LANL YMP QA training	X	X	X (lead)
Conflict resolution	X ^e		
Maintenance of QA records before transfer to the LANL Records Processing Center (RPC)	X	X (lead)	X

TABLE 1-1

DIVISION OF LANL YMP QA RESPONSIBILITIES^a
 (concluded)

Function ^b	QAPL	QAS	QAL
Internal survey and audits (coordination with PIs and QALs)		X	
a. Individuals supervising or performing QA functions are the QAPL, QAS, and QAL-- all from participating organizations. The QAPL shall play a major role in all QA functions for the LANL YMP.			
b. The QAPL reports to the TPO; the QAS reports to the QAPL; and the QAL reports to the QAPL or to the line supervisor.			
c. The QAL shall coordinate all reviews and approvals.			
d. The QAPL shall compile the responses to external audits and surveys with substantial input from the QAS and QAL.			
e. The QAPL shall be responsible for resolving all quality-related conflicts that have not been resolved at lower levels. Any person involved in the LANL YMP may appeal a dispute over QA to the TPO. The QAPL may elevate unresolved conflicts to the YMP Quality Manager (PQM). QA personnel can elevate unresolved conflicts through the QAPL to the Program Director of Nuclear Programs at LANL and the PQM. The QAPL also reviews and approves the PQM's comments on the QAPP and QPs.			

conformance with established requirements (unless specifically exempted elsewhere in this QAPP). Allegations of inadequate quality shall be resolved in accordance with the requirements of a YMP Administrative Procedure for Resolution and Reporting of Quality Concerns.

1.4 Interface Between Organizations

Interfaces are defined as exchanges or shared technical requirements of work and organizational liaison with ongoing work. When more than one LANL subcontractor organization is involved in activities affecting quality, the responsibility and authority of each organization for interface, as well as changes thereto; shall be clearly established and documented, and any shared responsibilities shall be defined and documented. The interfaces between internal LANL organizations are documented in this QAPP. To support these interfaces, required interface documentation shall be defined in the administrative procedures. The YMP administrative procedures (APs) shall provide the implementing interface controls used by LANL. A LANL QP shall describe the methods of conducting and documenting interorganizational interfaces.

The interface between LANL and the Project Office is through the TPO. Scientific investigation planning documents shall be used to define interface responsibilities for scientific activities external to LANL. For YMP activities internal to LANL, interface responsibilities shall be either between the TPO and PI or specified by written directives.

2.0 QUALITY ASSURANCE PROGRAM

2.1 Basic Requirements of the Los Alamos National Laboratory Yucca Mountain Project Quality Assurance Program

LANL's QA program consists of the LANL QAPP and QPs. The QAPP shall be submitted to the PQM for review, prior to implementation. When the QAPP is submitted to the Project Office for review, a checklist based on the YMP Quality Assurance Plan (QAP) is included. After the QAPP is reviewed by the PQM and after comments and revisions are resolved, the documents shall be approved by the PQM; the approved QAPP shall be issued. After internal LANL review, comment, and approval; QPs shall be issued for use.

This QAPP complies with the requirements of the Project Office QAP. The LANL YMP and subcontractor activities shall be carried out in accordance with this QAPP and QPs, which shall be applied in a way that is consistent with the importance of the activity.

As part of the QA program, management above or outside of the QA organization shall regularly receive information as to the scope, status, adequacy, compliance, etc., of the QA program. Readiness reviews, as appropriate, shall be performed and shall apply to major scheduled and/or planned activities that could affect quality. Readiness reviews shall be used in verifying that specified prerequisites and programmatic requirements have been identified before a major activity is started.

This QAPP applies to LANL QA Level I and II activities associated with the YMP, including nuclide migration studies; geochemistry; mineralogy; petrology studies; and planning for the exploratory shaft construction, technical direction, and testing program. LANL also provides assistance in accordance with this QAPP to other project organizations in areas of specialized expertise as directed by the Project Office.

The activities covered by this QAPP shall be delineated in the LANL YMP Work Breakdown Structure (WBS), which is maintained at the TPO's office. The QAPP includes the following basic provisions for activities affecting quality.

- Activities affecting quality shall be planned and documented to ensure a systematic approach. Planning results in the documented identification of methods and organizational responsibilities. Planning shall begin as early as practicable and shall be completed no later than the start of those activities.
- Activities affecting quality shall be accomplished under controlled conditions, which include the use of appropriate equipment, the maintenance of environmental conditions suitable for accomplishing the activity, the use of formal procedures for the given activity, and the assurance that all prerequisites for the given activity have been satisfied.
- Procedures for activities affecting quality shall specify any equipment and technical skills necessary to achieve the required quality for that activity.
- Procedures for activities affecting quality shall specify the means to verify quality by peer reviews (Project Office directed), technical review, survey and audit, or a combination of these.
- All LANL YMP personnel performing activities affecting quality shall be indoctrinated and/or trained in both technical and QA requirements of their

assigned task. QA auditors are trained and qualified in accordance with YMP requirements. The certification of YMP personnel shall be documented.

- LANL YMP management shall assess the adequacy and implementation of this QAPP regularly and shall formally report the results on an annual basis to the Project Manager and PQM.
- LANL participants are responsible for interfaces with other major YMP participants as specified in the Work Breakdown Structure (WBS) and outlined in Section 1 of this QAPP.

2.1.1 Verification of the Quality Assurance Program Plan

The QAPL or his appointee shall conduct internal audits of all phases of the application of this QAPP for all LANL YMP activities affecting quality. These internal audits shall assess the continuing implementation, effectiveness, compliance, and adequacy of the QA program. LANL shall prepare a QP for the review of suppliers' QA programs. The procedure shall make provision for the assignments of responsibility for review and approval of the supplier QA program. The procedure shall identify documents for review and approval and the documentation of results. Reviews shall be recorded on checklists that specify the criteria and that indicate conformance or nonconformance.

2.1.2 Use of Data Not Generated under Quality Assurance Controls

For use in licensing activities, the QA program for the LANL YMP provides some data or data interpretations that were not generated under a program which meets the requirements of 10 CFR 60, Subpart G. Specific methods for acceptance of this information will be in YMP AP 5.9Q, "Acceptance of Data and Data Interpretations Not Developed under the Yucca Mountain Project QA Program." Once accepted, these data shall be classified as "primary data" for licensing purposes. A LANL QP shall be prepared to implement these requirements (see also Appendix G).

2.1.3 Approach to Quality Assurance

The YMP uses a graded approach to QA that recognizes the differences between items and activities that may or may not have an effect on radiological health, safety, and waste isolation. The graded approach is designed to ensure that each item or activity is assigned a QA level consistent with its potential impact on, or importance to, radiological health and safety, waste isolation, nonradiological health and safety, achievement of DOE mission objectives, NRC licensing requirements, and operability and maintainability of the repository, including its costs and schedules. The assignment is accomplished by deliberate planning and selective application of QA requirements on the items or activities to be performed. The degrees of QA to be applied depend on the item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations. LANL or the Project Office shall identify QA levels for all items and activities affecting quality that are associated with site characterization, facility and equipment construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. QA levels assigned by LANL are subject to Project Office approval before work begins on the item or activity.

2.2 Application of Graded Quality Assurance

2.2.1 Extent of Application

Graded QA shall apply throughout the life of the YMP in accordance with established policies, procedures, and instructions and shall control activities affecting the quality of identified structures, systems, and components to an extent consistent with their importance. The extent of QA controls shall be determined by the QA staff in combination with the line staff and shall be dependent upon the specific activity, its complexity, and its importance to safety or waste isolation. The QAPP shall apply to all items and activities affecting quality during site characterization of the geologic repository, facility and equipment design, procurement and construction, facility operation, performance confirmation, closure, decommissioning, and dismantling of surface facilities. However, the preparation of administrative and management planning documents [except for documents specifically required by the Nuclear Waste Policy Act of 1982 (as amended) or for licensing] and the procurement of administrative items do not require QALAs.

It may be necessary to exempt certain YMP items and activities from QALAs. Requests for exemptions shall be documented and shall contain sufficient justification to support the exemption request. Such exemptions are subject to approval by the QAPL, the TPO, and the PQM.

2.2.2 Method of Application

Graded QA in the LANL YMP shall be applied according to a LANL QP, which shall define the responsibility, method, and criteria for assigning and documenting QA levels to the LANL activities and items involved in the YMP. This QP shall describe how:

- all YMP activities and items affecting quality are evaluated for QALA;
- QA levels are assigned in a manner consistent with the Project Office APs, the "Q-List" provided by the Project Office, and the YMP/88-9;
- one level (I, II, or III) will be assigned for each technical task that affects quality;
- the justification for the QALA is documented;
- once a QALA has been made, it applies equally to the particular item or activity associated with the QALA by any participant involved, therein; and
- the assigned QALA and QA requirements are submitted to the Project Office for review, resolution of comments, and approval before use.

The LANL QAPP shall apply to QA Levels I and II. Good engineering and scientific practices shall apply to QA Level III unless other requirements are specified. Definitions for each level are contained in Appendix A. Deviations within applicable criteria are permissible for QA Level II items and activities, provided that adequate justification is documented and approved by the Project Office.

QA Level I (refer to Appendix A for definition) is the most stringent level and shall be applied to those items and activities that may affect the ability of the repository to meet the preclosure and postclosure performance objectives specified by the NRC and the Environmental Protection Agency for protecting public health and safety from radiological hazards. QA Level I activities which are on the Q-List will provide the

primary data input to the basis for the NRC to authorize construction and to issue a license for the DOE to receive and process source, special nuclear, and by product material (waste) at the geologic repository. QA Level I control and documentation shall be applied to all activities (i.e., those activities involving near-term safety and long-term isolation, including site characterization, scientific investigation, facility and equipment design, procurement, and construction) specifically concerned with the protection of the public's health and safety with respect to radiological hazards. Therefore, QA Level I shall apply to

- items or activities that could affect preclosure radiological health and safety of the general public (Specifically, this means items and activities that could cause, or result in an accident that could result in a radiation dose, either to the wide body or to any organ, of 0.5 rem or greater, either at or beyond the nearest boundary of the unrestricted area, at any time until the permanent closure of the repository.);
- items or activities that provide primary data that will be relied on for performance assessment of the repository system. These data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research that have a significant impact on site characterization or are an essential part of the data base that directly supports the final design of the repository and waste package performance;
- items or activities that could adversely impact the waste isolation capabilities of the engineered and natural barriers;
- items or activities that are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system;
- the design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) (As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities shall be governed by the QA level assigned to the item.); and
- items or activities whose failure would cause the failure of a QA Level I item or irretrievable loss of a QA Level I items or data.

QA Level II (refer to Appendix A for definition) is the second most stringent level and shall be applied to those items and activities specifically concerned with the nonradiological operation of the exploratory shaft facility and repository and the radiological safety of the repository worker. Therefore, QA Level II shall be applied to items and activities whose failure would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits given in 10 CFR 20 or that

- could have a major impact on the nonradiological health and safety of the public and repository workers,
- could affect the retrievability of waste up to the time of repository closure,

- involve the nonradiological operation, reliability and maintenance of engineered systems,
- involve activities that have a major impact on YMP that delay the achievement of DOE/OCRWM milestones,
- the design phase that involves the comparative technical analysis of alternatives, methods, or equipment to determine which alternatives, methods, or equipment is preferred, shall be assigned a QA Level of II prior to execution. Where a particular item can be identified and defined during this phase, a separate QA Level assignment may be made for that item. Once the QA Level for such an item is identified and approved, design procurement and construction activities shall be governed by the QA Level assigned to the item.
- Where items and activities that, having failed, could result in a major cost overrun.
- Where items and activities that, having failed, could result in a major schedule slippage.

QA Level II activities may have as much importance as QA Level I activities. However, QA Level II activities cannot be subsequently used to support QA Level I activities. If it becomes necessary to use a QA Level II activity to support a QA Level I activity, LANL shall substantiate that QA requirements equivalent to those required for a QA Level I activity were in place at the time of the activity. The other available method to upgrade a QA Level II activity to a QA Level I is through a technical justification process applied in accordance with YMP AP 5.9Q.

QA Level III is the least stringent level of the graded QA system. QA Level III items and activities have no major function in the characterization of the site or design of the repository, but they require good practices for the intended use. Design phases that are purely preliminary and are conducted to define the range of alternatives, methods, and equipment worthy of more detailed study shall be assigned QA Level III before execution. Those activities controlled in accordance with a QA Level III program cannot subsequently be used to directly support QA Level I activities.

In some cases, data or data interpretations generated as a result of activities controlled in accordance with QA Level II or III programs, or activities performed before the complete implementation of the YMP QAP, may be used in the licensing process as background or corroborative information.

2.3 Quality Assurance Activities

LANL shall perform an overview of the QA activities of all organizations, including LANL subcontractors and suppliers of services. The overview shall include a review of the existing QA program before a contract is awarded, method for documenting review and approval action, and a survey(s) and/or an audit(s) to verify the adequacy of and compliance with the QA program during the contract period.

Following LANL's QPs for procurement, the statement of work may require, if appropriate, that the supplier or subcontractor have or create a QA program equivalent to the LANL QAPP or, at the supplier's option, use the QAPP. These procedures shall

Identify the types of documents to be submitted for review and approval, assign responsibility for review, and identify the methods for documenting review and approval action.

2.4 Management Assessment

Management assessments shall be conducted at least annually to verify that the QA program is being effectively implemented; that the system and management controls established to achieve and ensure quality are effective; that the resources and personnel provided to the QA program are adequate; and that personnel are trained to the QA requirements of the program. These assessments shall be performed and reported in accordance with LANL QPs, which shall include the minimum requirements for planning, organizing, performing, and documenting the results.

The assessment procedure shall specify that results be analyzed for quality trends and that reports and recommendations be tracked. Management outside or above the QA organization shall be responsible for the management assessment activity. Copies of the LANL management assessment report shall be transmitted to the Yucca Mountain Project Manager and PQM.

2.5 Personnel Indoctrination and Training Procedures

LANL shall establish requirements for the selection, indoctrination, and training of personnel performing or verifying activities that affect quality. Position descriptions shall establish minimum personnel qualifications and the necessary indoctrination or training or both before a person starts work on activities that affect quality. In addition, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, Appendix F) shall be certified in accordance with those codes and standards.

2.5.1 Position Descriptions and Evaluation of Personnel Qualifications

For the YMP, LANL requires position descriptions specify and generally describe the activities performed for each YMP personnel position. Requirements for formal education and experience shall be stated in these YMP position descriptions for personnel performing and verifying activities that affect quality. The relevant education, experience, and training of personnel shall be verified. The initial capabilities of an individual shall be based on an evaluation of his education, experience, and training and compared to those established for the position. The YMP personnel proficiency evaluations shall be performed and documented at least annually by managers or supervisors responsible for the activities performed. Proficiency evaluations may be performed in conjunction with periodic or day-to-day employee performance evaluations.

2.5.2 Indoctrination

Personnel assigned to perform activities affecting quality shall first be indoctrinated to the purpose, scope, methods of implementation, and applicability of the following documents (including revisions and changes) as they relate to the work to be accomplished:

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

Indoctrination may be effected through the use of a mandatory reading list, classroom presentations, video presentation, or other instructional methods.

2.5.3 Training

Before being assigned activities affecting quality (i.e., assignments where it is deemed necessary to develop and demonstrate initial proficiency), personnel shall undergo training to gain the required proficiency. This training shall encompass the principles, techniques, and requirements of the activity. Such training may include classroom sessions, workshops, on-the-job training, or other instructional methods.

2.5.4 Training and Certification for Auditor

Requirements for training and certification of auditors, lead auditors, and technical observers are addressed in Appendix F of this QAPP.

2.5.5 Records

YMP personnel files shall contain the indoctrination and training records, position descriptions, annual certification forms, initial qualification evaluations for work on the LANL YMP, and supervisors' documentation of the annual YMP proficiency evaluations. These documents shall be retained as QA records.

Records of these activities will include the objective and content of the training or indoctrination dates the name of the instructor, attendees, results of any YMP proficiency evaluations, the initial evaluation, and any other applicable information, shall be maintained as lifetime QA records. The evaluation documents for the proficiency of YMP personnel shall include the name of the employee, the name of the evaluator, evaluation results, date, and activities covered by the evaluation.

The evaluation documents for the qualification of YMP personnel shall include the verification and evaluation of employee education, experience, and training as compared with those required for the position.

3.0 SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL

3.1 Scientific Investigation Control

3.1.1 Preparation of Scientific Investigation Planning Documents

Scientific investigations affecting quality shall be planned and documented to ensure a systematic approach. Before the start of any scientific investigation, the responsible PI shall develop a scientific investigation planning document for that investigation that outlines the work to be performed and delineates the instructions for complying with the requirements of the defined scope of work. Scientific investigations categorized as site characterization activities, as defined in the Nuclear Waste Policy Act (as amended), shall use study plans as the scientific investigation planning document. The requirements for the format and content of study plans are included in Appendix E of this QAPP. QA level assignments will be made in accordance with APs.

At a minimum, the scientific investigation planning document shall include or reference the following:

- a description of the work to be performed, with the scope and proposed methodology clearly defined;
- a discussion of the purpose for the work;
- identification of who is to perform the work;
- instructions on how to perform the work (i.e., using the applicable technical procedures or scientific notebooks); and
- schedule requirements.

The description of the work to be performed in the scientific investigation shall include references to any applicable regulations, requirements, performance criteria, key issues, information needs, planning documents for higher-level scientific investigations, or WBS items for which the work is performed. The study plan will be the controlling document, describe the scope of work, and identify the controls to be used. The description shall identify the known factors and concerns that are important for the planning or the performance of the scientific investigation. Any previous work used in support of the scientific investigation shall be described, including identification of the QA levels or QA controls under which that work was performed. Note: This requirement does not apply to study plans. The scientific investigation planning document shall be attached to documents containing a level of detail that will enable an independent reviewer to determine that the appropriate QA level has been applied to the investigation. LANL scientific investigation planning documents that are approved and in place with approved QALAs will remain in place and active until they are superseded or withdrawn by LANL or the Project Office.

3.1.2 Quality Assurance Level Assignment

Once a scientific investigation planning document has been developed, the associated QALA for each of the activities and built-to-order items in that plan shall be prepared. It may be necessary in some cases to assign QA levels to the supporting activities and built-to-order items in previously prepared plans. Therefore, the QALA is not itself a part of the plans, even though it normally accompanies those plans and goes through the same review and approval process.

3.1.3 Review and Approval of Scientific Investigation Planning Documents

The organization that develops a scientific investigation planning document shall conduct a technical review of it to ensure that

- fabrications, installations, modifications, inspections, experiments, and tests have been incorporated;
- the scientific investigation can be conducted as specified;
- time, resources, and training are sufficient to accomplish the work in accordance with the specified sequential progression of operations; and
- the overall measures to be employed preserve the quality of the work.

The technical review shall be performed by any qualified individual other than those who developed the original scientific investigation planning document. The originator's immediate supervisor may perform the review if the supervisor is the only other technically qualified individual and if the need is documented and approved in advance by the QAPL. The results of the technical review and the resolutions of any comments by the reviewers shall be documented and shall become part of the QA records as prescribed in the QP for document review.

The scientific investigation planning document shall be reviewed per LANL procedures. The TPO or his designee shall then forward the scientific investigation planning document to the Project Office for review and approval by the appropriate branch chief. The scientific investigation planning document will be returned to the TPO upon completion of the Project Office review and approval cycle. Study plans shall also be reviewed and approved by OCRWM prior to implementation. A peer review of the scientific investigation planning document shall be conducted if the Project Office deems it necessary. In the event that any completed research reports or activities are required to have a peer review, they will be referred to the Project Office by the TPO.

All changes in the scientific investigation planning document shall go through this same review and approval process. If modified work is not within the scope of the study plan or the scientific investigation planning documents and

- is not repeatable or
- could potentially impact the waste isolation capability of the site or
- could interfere with other site characterization activities,

then approval shall be obtained from an appropriately qualified reviewer. The PI is responsible for evaluating the effects of such changes on the associated QALAs. Minor changes in the scientific investigation planning document limited to inconsequential editorial corrections need not go through the same review and approval process as a technical change must. However, minor changes shall be reviewed and approved by the appropriate project leader and concurred with by the QAPL before issue. A file of the minor changes made in scientific investigation planning documents shall be maintained in the appropriate resident file.

3.1.4 Scientific Investigation Data Interpretation and Analysis Documents

Interpretation and analysis shall be performed in a planned, controlled and documented manner that shall provide details that will be sufficient for a technically qualified individual to review, understand, and verify the analysis without recourse to the originator. Documentation shall include purpose, method, assumptions, input, references, and qualitative and quantitative units. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer, and date.

Documentation of interpretation and analysis shall include or reference the following:

- a definition of the objective,
- a definition of input and sources,
- a listing of applicable references,
- results of literature searches, or other background data,
- identification of assumptions,

- Identification of any computer calculation; including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem, and
- signatures and dates of review and approval by appropriate personnel.

3.1.5 Use of Computer Programs

Computer programs used to support a license application shall be subject to the requirements of LANL procedures for software QA requirements (See Subsection 3.3, Appendix H of this QAPP and NUREG-0856.)

3.1.6 The Use of Scientific Notebooks Versus the Use of Detailed Technical Procedures

There are two kinds of documentation that can be used for the QA documentation and control of scientific work: the scientific notebook and the detailed technical procedure (DP). Scientific notebooks generally are used by qualified individuals who are largely guided by professional judgment and who use trial and error methods in their work. A DP generally is used when a qualified individual performs repetitive work that is not guided by professional judgement and does not involve trial and error methods. DPs shall be required when deviation from a prescribed sequence of actions endangers the validity of the results. Bound notebooks, logbooks, or appropriate forms shall be used to document the performance of DPs and the control over all other aspects of the work. Documentation of scientific work, i.e., experiments and research, shall be performed to provide a written record of the experiment or research.

3.1.6.1 Detailed Technical Procedures

DPs, together with other supporting documents or notebooks, shall be used whenever the work is repetitive and is performed by individuals who may not be directly supervised by a PI. Modifications of the technical aspects of DPs shall be approved by an appropriately qualified reviewer. DPs shall be developed, reviewed, changed, or modified in accordance with the requirements given in Section 5 of this document.

Acceptance or rejection criteria of the performance of a DP, including required levels of precision and accuracy, shall be provided by the organization responsible for the scientific investigation.

DPs used for scientific investigations shall provide for the following as appropriate:

- Objectives, methods and/or characteristics to be tested or observed.
- Prerequisites such as calibrated instrumentation, adequate and appropriate equipment and instrumentation, suitable and controlled environmental conditions, and provisions for data collection and storage. For activities of long duration, specific provision shall be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions shall be designed to ensure validity of data throughout the scientific investigation.
- Mandatory verification points.
- Acceptance and rejection limits and criteria, including required levels of precision and accuracy. (NOTE: "Accept/reject criteria" means those features or characteristics of a DP that make it possible to determine

whether that the results were produced by work that was performed properly and according to the DP. A data acquisition task produces output that, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject criteria" are simply the conditions and methods stated in the DP.)

- Methods of documenting or recording data and results, including precision and accuracy.
- Methods of data reduction.
- Provision for ensuring that prerequisites have been met.
- Special training or qualification requirements for personnel performing the scientific investigation.
- Personnel responsibilities.

DPs shall be complete to the extent that another qualified individual may, at a later date, repeat the procedure and gather similar results.

The potential sources of uncertainty and error in technical implementation procedures that must be controlled and measured to ensure that scientific investigations are well controlled shall be identified. Parameters that need to be measured and/or controlled to minimize such uncertainties or error and to ensure adequate control shall be addressed explicitly in test procedures.

For instrumentation and/or equipment used in data collection, consideration shall be given to whether failure or malfunction of the instrumentation during scientific investigation will be detectable, either during data collection or by examination of the data. Where ability to detect such failure or malfunction is questionable, procedures will include any special provisions for equipment and instrumentation configuration, installation, and use that can further reduce risk of undetectable failure or malfunction.

Changes to field and laboratory procedures associated with scientific investigations shall be controlled to assure that such changes are subsequently documented and verified in a timely manner by authorized personnel. Any procedural deviation encountered during activities shall be documented, reported, and evaluated for significance.

3.1.6.2 Scientific Notebooks

Bound scientific notebooks may be used with other appropriate documents to record scientific investigations and experiments. A competent technical reviewer will sign the notebook. When using notebooks, documentation shall be sufficiently detailed so that another qualified scientist can trace the investigation and confirm the results or repeat the experiment and achieve similar results without recourse to the PI. Notebooks must be maintained as stipulated in LANL QPs.

When recording results of scientific investigations in notebooks, include the acceptance/rejection criteria for the process of generating the data.

Initial Entries

Initial entries are considered to be the "general" procedure. Modifications to this "general" procedure shall be recorded in the notebook in process entries.

Where appropriate, before initiation of the experiment or research, the following entries shall be made or referenced, as applicable:

- the title of the experiment or research;
- the name of the qualified individual(s) performing the experiment or research;
- a description of the experiment's objective(s);
- equipment and materials to be used during the experiment or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material;
- calibration requirements;
- the dated signature of the individual(s) making the initial entries;
- special training or personnel qualification requirements;
- documentation of suitable and controlled environmental conditions and
- the potential sources of uncertainty and error in scientific investigations which must be controlled and measured to ensure that the investigations are well controlled.

In-Process Entries

In-process entries shall include or reference, as applicable:

- the date and name of the individual making the entry;
- provisions for ensuring that prerequisites have been met;
- a description of the experiment or research attempted, including the detailed step-by-step process followed (reference may be made to the use of a DP if one is used);
- a description of any conditions that may adversely affect the results of the experiment or research;
- identification of samples used and any additional equipment and materials not included as part of the initial entries;
- all data taken during the experiment and a brief description of the results, including notation of any unexpected results;
- any deviations from the planned experiment or research;

- any interim conclusions reached, as appropriate; and
- when final results have been reached, a summary of the outcome of the experiments or research, including a discussion of whether the experiment's objectives as outlined in the initial entries were achieved. The final results and summary shall be included in a report. Reference to the report shall be made in the notebook. The report shall become part of the QA records for the activity.

Final Entries

The final entries of experiments or research require, as a minimum, the signature of the investigator and a competent technical reviewer as described in the LANL implementing procedure.

3.1.6.3 Logbooks

A logbook is associated with a specific activity, an operating device, or sample location. Logbooks and entries thereto shall be controlled according to a LANL QP. Logbooks may also be used to note any pertinent data concerning their assignment, including such entries as data runs and results, calibration runs and results, downtimes, and sample withdrawals.

3.1.7 Interface Control

Internal and external scientific investigation interfaces and efforts shall be coordinated among LANL participants and other YMP participating organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among and within participating organizations for the review, approval, release, distribution, and revision of documents involved with scientific investigations and interfaces. Interfaces within LANL shall be coordinated according to LANL QPs. Interfaces between scientific investigations, or between a scientific investigation and any other YMP activities, shall be coordinated among YMP participants in accordance with LANL QPs. Interfaces between LANL and suppliers shall be controlled in accordance with QPs established in the procurement documents. The transmittal of information or items (including samples of natural or manmade materials) across interfaces shall be documented according to LANL policy.

Ongoing field or laboratory investigations, where several organizations may be involved, shall be identified to preclude inadvertent interruption and to ensure operational compatibility. Such identification shall be clearly evident on the location. Field surveys shall identify the location of the scientific investigation.

3.1.8 Verification of Scientific Investigation

3.1.8.1 Verification Planning

Planning and performance of verification activities shall be accomplished and documented using LANL QPs. Verification procedures shall provide for the following:

- identification of characteristics and activities to be verified;
- a description of the method of verification;
- identification of the individuals or groups responsible for performing the verification;
- acceptance and rejection criteria;

- Identification of required procedures, drawings, and specifications (including revisions used);
- recording identification of the verifier and the results of the verification.

The LANL QA organization shall perform surveys (according to Section 18 of this QAPP) of all scientific investigations, as deemed appropriate for the purposes and the complexity of the work. The QA verification team for a scientific investigation shall consist of one or more technically qualified individuals who are familiar with the scientific investigation planning document and one or more QA personnel. This verification team shall determine the timing and number of surveys.

3.1.8.2 Verification Hold Points

Mandatory verification hold points shall be established as necessary during preparation of the DPs. When such hold points are established, work may not proceed without the specific consent of the QAL. These hold points shall be indicated in appropriate documents controlling the activity. Consent to waive any specified hold point shall be documented before work can be continued beyond the designated hold point.

3.1.8.3 Reporting Independence of Personnel

Verifications shall be performed by personnel who do not report directly to the immediate supervisor(s) who is (are) responsible for performing the activity being verified. If these personnel are not part of the formal QA organization, they shall have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) ensure that further processing, delivery, installation, or use is controlled until proper disposition has occurred. When the persons or organizations who perform the verification activities are not part of the formal QA organization (i.e., part of line management), then the QA organization shall overview and monitor the activity.

3.1.9 Reports, Conclusions, and Recommendations

Technical review of the results and documentation of scientific investigations shall be accomplished in accordance with LANL QPs that specify that all final reports shall be submitted to the Project Office for review and approval.

3.1.10 Close-Out Verification

Because a considerable period of time may pass before data from a completed scientific investigation are used in the licensing process, close-out verification shall be performed upon completion of any scientific investigation to ensure that the QA records for that investigation are adequate and complete. Close-out verifications shall be performed by a team consisting of technically qualified personnel as well as by QA personnel.

3.2 Design Control

LANL, at present, has direct responsibility for design control activities. This section is included for LANL design control activities and for pass through to LANL subcontractors. (Currently this function is performed by EG&G for design of the Integrated Data System.)

3.2.1 General

The design shall be defined, controlled, and verified. The term design refers to specifications, drawings, design criteria, and performance requirements for the natural and engineered components of the repository system. Design control measures shall be applied to conceptual designs, or parts thereof, which may at a later time become part of the final design. Design information and design activities refer to the data collection and analyses used in supporting design development and verification. This includes general plans and technical procedures for data collection and analyses and related information such as test results and analyses. Plans for data collection and analyses shall be complete before performing the data collection and analysis activities. Data collection activities resulting from scientific investigations can produce design input. Data analysis includes the initial step of data reduction as well as broad systems analyses (such as performance assessments), which integrate many other data and analyses of individual parameters.

It is the policy of the YMP that the completed or final design of a facility or item evolves from a sequential order of design activities (or phases) wherein each phase becomes more detailed in nature than the preceding phase. For organizations responsible for design, the number and length of design phases required to complete the design of any particular item or facility may vary according to the timeliness and availability of pertinent information and the complexity of the item or facility. However, producing a unified facility design depends on the coordinated interfaces among all YMP design organizations.

3.2.1.1 Quality Assurance Level Assignment

All design phases shall be assigned a QA level before execution in accordance with the methods specified in LANL QPs.

3.2.1.2 Qualification of Personnel

Personnel performing design work shall be oriented, trained, and qualified in accordance with the requirements of Subsection 2.4 of this document. Instructions, procedures, and drawings for design work shall comply with the requirements of Section 5 of this document.

3.2.1.3 Peer Review

A peer review is an acceptable method of design verification for design activities or design documents that are beyond the state-of-the-art. These design activities or design documents may involve or specify the use of untried testing and design analysis procedures and methods or detailed technical criteria and requirements that do not exist or are being developed. (See also Appendix J of this QAPP.)

The peer review shall meet the requirements of Subsection 3.5 of this QAPP.

3.2.2 Design Input

Applicable design input (such as site characterization data, criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards) shall be identified and documented, and their selection shall be reviewed and approved by the responsible design organization and QA organization. The purpose of this QA review, at the input stage, is to ensure that the documents are prepared, reviewed, and approved in accordance with documented procedures and QA requirements. Changes in approved design input, including the reason for the changes, shall be identified, documented, reviewed, approved, and controlled by the responsible

design organization. Design input (see Appendix B) shall be specified and approved on a timely basis to the level of detail necessary to permit design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

3.2.3 Design Analysis

Design analysis shall be planned, controlled, and documented in sufficient detail, including purpose, method, assumptions, design input, references, and units, to enable a technically qualified person to review, understand, and verify the analysis without recourse to the originator. These documents shall be produced in a form suitable for reproduction, filing, and retrieval. Calculations shall be identified by subject, including structure, system, or component; originator; reviewer; and date.

3.2.3.1 Documentation of Design Analysis

Documentation of design analysis shall include the following:

- a definition of the objective of the analysis;
- a definition of the design input and its sources;
- a listing of applicable references;
- results of literature searches and other background data;
- identification of assumptions and an indication of those that require verification as the design proceeds;
- identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem; and
- signatures and dates of review and approval by appropriate personnel, including QA personnel. The purpose of this QA review, at the analysis stage, is to ensure that the documents are prepared, reviewed and approved in accordance with documented procedures and QA requirements.

3.2.3.2 Use of Computer Programs

Computer programs used to support a license application shall be verified and controlled as specified in QPs for software QA requirements (see Subsection 3.3).

3.2.4 Design Verification

3.2.4.1 Identification and Documentation

The organization responsible for a design shall verify the adequacy of the design in a timely manner, according to the design control measures and shall identify and document the verification method used, the results of the verification, and the personnel involved.

3.2.4.2 Timing of Verification

Verification of the adequacy of the design shall be performed before its release for procurement, manufacture, construction, or release to another organization for use in other design activities. In cases where this timing cannot be met, the portions of the design that have not been verified shall be identified and controlled. In all cases, the verification shall be completed before the component, system, or structure is used.

3.2.4.3 Extent of Verification

The extent of the design verification necessary shall be a function of the importance to the safety of the item under consideration, the complexity of the design, the degree of standardization, and the similarity with previously proven designs. The verification process need not be duplicated for identical designs that have been verified in accordance with the requirements of this section. However, if new design inputs affect the application of standardized or previously proven designs, those designs shall be verified for each application. Known problems affecting the standardized or previously proven designs and their effect on other features shall be considered. The original design and associated verification measures shall be referenced in the files of subsequent applications of the design.

3.2.4.4 Changes in Verified Designs

Changes in previously verified designs shall require further verification steps, including the evaluations of the effects of those changes on the overall design.

3.2.4.5 Persons Performing Verification

Design verification shall be performed by any certified individual(s) or certified group(s) other than those who performed the original design. Those individuals qualified to verify designs include

- individuals or groups from the originator's organization,
- individuals or groups from other organizations contracted for this purpose, and
- the originator's supervisor, providing all of the following requirements are met:
 - the supervisor is the only individual in the organization competent to perform verification;
 - the supervisor did not establish the design input used, specify the design approach, or rule out certain design considerations; and
 - the rationale for satisfying the two requirements above shall be documented and approved by management superior to the supervisor. The QAPL must concur with the rationale.

3.2.4.6 Methods of Design Verification

Design verification shall be accomplished by design reviews, alternate calculations, qualification testing, and/or peer reviews. LANL QPs shall establish responsibilities,

areas and features to be verified, pertinent considerations, and the extent of documentation needed.

Design Reviews

Design reviews shall be detailed critical reviews meant to ensure that the design is correct and satisfactory. At a minimum, the reviewers shall consider the items below and document the results of such deliberations.

- Have the design inputs been selected correctly?
- Have the assumptions used to perform the design activity been adequately described and are they reasonable?
- Upon completion, are the assumptions reverified when necessary?
- Has an appropriate design method been used?
- Have the design inputs been incorporated into the design correctly?
- Is the design output reasonable as compared with the design input?
- Have the design input and verification requirements needed by interfacing organizations been specified in the design documents or in supporting procedures or instructions?
- Have the computer programs used for analysis been identified and verified in accordance with the methods specified in LANL QPs and DPs?

Alternate Calculations

Alternate calculations may be used to determine the adequacy of the original analyses. The use of alternate calculations requires a technical review of the assumptions, inputs, and computer programs or other methods used in the calculation.

Qualification Tests

Qualification tests that involve physical testing of systems, structures, or components may be used to verify the adequacy of a design or a specific design feature. Where design adequacy is to be verified by qualification tests, the tests shall be identified in the design document. The following stipulations shall apply to the use of qualification tests.

- The test configuration shall be clearly defined and documented.
- Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions.
- Other features of the design shall be verified by other means when the test is intended to verify only specific design features.

- Test results shall be documented and evaluated by the organization responsible for the design to ensure that test requirements have been met.
- If qualification testing indicates that modifications of the item are necessary to obtain adequate performance, the modification shall be documented and the item shall be modified and retested or otherwise verified to ensure satisfactory performance.
- When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test shall be subject to error analysis, where applicable, before its use in the final design work.

3.2.5 Design Change Control

Changes in approved designs, including field changes, shall be justified. They shall be subjected to the same control measures applied to the original design and shall be approved by the same organizations that reviewed and approved the original design document. In the case where the organization originally responsible for approving a particular design is no longer responsible, the Project Office will designate a new responsible organization that has demonstrated competence in the specific design area of interest and has an adequate understanding of the requirements and intent of the original design. Errors and deficiencies in approved designs and in design information documents shall be documented, and action shall be taken to correct them. Where a significant design change is necessary, the design process and verification procedure shall be reviewed and the procedure shall be modified as indicated. Additionally, training for needed changes shall be considered and the changes with the required training shall be communicated to all affected groups or individuals.

3.2.6 Design Interface Control

Design interfaces internal and external to LANL shall be identified and controlled, and the design efforts shall be coordinated. Interface controls include the documented assignment of responsibility and the establishment of procedures for the review, approval, release, distribution, and revision of documents involving design interfaces.

Design information transmitted across interfaces shall be documented and controlled. Transmittals shall identify the status of design information or documents provided and, when necessary, identify incomplete items that require further evaluation, review, or approval. Where it is necessary to initially transmit design information informally, the design information shall be confirmed promptly by a controlled document.

3.2.7 Design Output Requirements

Completed designs shall be documented and relate to design input in sufficient detail to permit design verification. This documentation shall identify assemblies or components that are part of the designed item. When such an assembly or component part is a commercial-grade item and is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial-grade item, and the difference is defined and documented.

The design document shall show evidence that the required review and approval cycle has been achieved before its release for use in procurement or construction or release to another organization for use in other design activities. As a minimum, the review and approval cycle shall include the participation of the technical and QA elements of both the responsible design organization and the Project Office. The purpose of the QA review is to ensure that the documents are prepared, reviewed, and approved in accordance with documented procedures and QA requirements.

3.3.8 Design Documents as Quality Assurance Records

Design documentation, including design input, analyses, drawings, specifications and approved changes, evidence of design verification, and records confirming interface control, shall be collected, controlled, stored, and maintained as QA records in accordance with LANL records management procedures.

3.3 Software Quality Assurance Requirements

Appendix H of this QAPP describes the software requirements for the LANL YMP and shall be used in conjunction with the following sections.

For a geologic repository, computer software used to support license application shall be controlled to the same level of requirements as software used to perform direct design analysis. Auxiliary software used to support primary data software shall be controlled at a level commensurate with the complexity of that software.

Where commercial auxiliary software is used, all available documentation from the software supplier shall be obtained. It is recognized that source code is generally not available and controls are limited to unique version identification and user-related manuals. Supplemental, detailed requirements for the development, maintenance, and security of computer software are contained in Appendix H.

3.3.1 Computer Software Documentation and Control

Appendix H to this QAPP provides detailed requirements on the content of software documentation used on the YMP. Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NUREG 0856. This requirement may be met in part by existing documentation, if properly referenced and related to NUREG 0856 requirements.

Software QA documentation is a QA record and shall be controlled as per Section 17 of this QAPP.

3.3.2 Software Description

LANL shall prepare a software QA plan as described in Appendix H to describe its software design, test, and configuration management system. The software QA Plan shall be submitted to the Project Office for review and approval.

3.3.2.1 Baseline Elements

Software shall be placed under configuration management as each baseline element is approved. Software baseline elements shall be uniquely identified to ensure positive control of all revisions; the identification of each code version shall be directly related to the associated documentation.

3.3.2.2 Software Changes

Changes in software shall be systematically evaluated, coordinated, and approved to assure that the impact of a change is carefully assessed before updating the baseline, required action is documented, and the information concerning approved changes is transmitted to all affected organizations. Changes in computer software shall be subject to the same level of approval, verification, and validation as the original software.

3.3.2.3 Software Testing

Testing of software, including new or modified software, shall be performed for those inputs and conditions necessary to exercise the software, to identify boundary conditions, and to provide a suitable benchmark or sample problem for installation. The goal of testing is to develop a set of test cases that have a high probability of detecting the errors in order to determine the conditions under which the software will not perform properly.

3.3.2.4 Qualification of Existing Software

Existing software shall be qualified for use. This qualification shall be based on the ability of the software to provide acceptable results for specific applications and compliance with the requirements of this section and Appendix H.2. Software that has not been developed in accordance with this QAPP may be qualified for use, provided the software is verified, validated, a software baseline is established, and applicable documentation is prepared to support the software.

3.3.2.5 Interface Management

Methods for determining the applicability of requirements and managing interfaces involving software, documentation, configuration management, change, qualification, verification, and validation will be described in the software QA Plan.

3.3.2.6 Software Configuration Management

The minimum requirements for a configuration management QP shall include a unique identification, including software version numbers, whenever feasible, in the output; listings of the software; and a brief chronology of the software versions, including descriptions of the changes made between controlled versions of the software.

3.4 Technical Reviews

Technical reviews shall be performed in accordance with a QP that defines the following:

- the criteria for selection of the technical reviewers,
- the procedure for technical reviews, and
- the method of review documentation.

3.5 Peer Reviews

When applicable, LANL shall institute a peer review process to provide adequate confidence in the work being reviewed. A peer review QP shall meet the requirements of NUREG-1297 and Appendix J of this QAPP.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Procurement Document Requirements

Documents for procurement of material, equipment, and services used in LANL YMP activities shall include or reference applicable regulatory requirements, design or site investigation bases, and other requirements necessary to ensure quality.

Procurement documents shall contain the following information as appropriate:

- a scope of work description,
- the technical requirements for the work,
- QA program requirements,
- a right-of-access provision,
- subcontracting requirements (including the subcontractor's pass through of appropriate QA requirements),
- documentation requirements, and
- nonconformance provisions.

4.1.1 Scope of Work

The procurement documents shall clearly define the scope of the work to be performed by the supplier or subcontractor.

4.1.2 Technical Requirements

The procurement documents shall specify the technical requirements for the work. Where necessary, these requirements shall reference specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including any revisions thereto, that describe the items or services to be furnished. The procurement documents shall identify test, inspection, and acceptance requirements for monitoring and evaluating supplier or contractor performance.

4.1.3 Quality Assurance Program Requirements

For noncommercial-grade procurements, a LANL supplier or subcontractor shall be required to have a documented QA program that implements all the applicable QA requirements of this document as selected by the requester. Subcontractors' QAPPs and related documents, including changes thereto, shall be reviewed and approved by the requester and QA. Upon review, if additional QA elements are required, they shall be specified and incorporated in the subcontractor's QA program before the initiation of procured activities. The extent of the program required depends upon the type and use of the item or service being procured.

In the development of QA requirements for measuring and other equipment, consideration shall be given to whether proper performance of that equipment can be determined during or after its use (i.e., whether failure or malfunction of the equipment can be detected).

4.1.4 Right of Access

QA Level I and II procurement documents shall provide for access to the suppliers' facilities or their subcontractors' facilities and to their records for inspection or audit by the purchaser and appropriate Project Office personnel. When audits of suppliers or

their subcontractors are performed by LANL or other YMP personnel, the LANL procurement organization shall be notified and then coordinate with the requester to arrange access.

4.1.5 Documentation Requirements

Procurement documents shall identify the documentation (reports, manuals, certification, etc.) required from the supplier or their subcontractor's and shall specify the time of submittal. QA Level I procurements from LANL in-house suppliers shall be considered internal supplies and are not documented as procurement but shall be appropriately qualified for its intended use. Measuring and test equipment are qualified for the Project through calibration.

4.1.6 Nonconformance

Procurement documents shall prescribe the requirements for reporting and approving the disposition of nonconformances as appropriate to the specific procurement. Section 15 contains more information on nonconformance.

4.2 Review of Procurement Documents

A review of the procurement requests and of changes in procurement specifications shall be made to ensure that documents transmitted to the prospective supplier or contractor include all appropriate provisions to require that items or services meet the specifications.

Before a contract is awarded, personnel who have access to pertinent information and an adequate understanding of the requirements and intent of the procurement documents shall perform and document the review. The review shall be performed by the requester and QA, as a minimum. The QA review shall ensure that

- the QA requirements are stated correctly and are inspectable and controllable;
- there are adequate acceptance and rejection criteria; and
- the procurement documents have been properly prepared, reviewed, and approved.

4.3 Procurement Document Changes

Changes in procurement documents shall be subject to the same degree of control used in the preparation of the original documents. Changes made as a result of the bid evaluation or precontract negotiations shall be incorporated in the procurement documents. Before a contract is awarded, a review and evaluation of such changes and their effects will be completed, documented and approved by the requester.

The review of changes shall include

- that appropriate content is included within the procurement documents,
- that additional or modified design/site investigation criteria is determined, if applicable; and

- that supplier requested changes or exceptions are evaluated for impact on the intent of the original procurement document.

4.4 Distribution of Procurement Documents

Copies of QA Level I procurement documents and changes therein that state the vendor, the scope of work, and the date when work is to start shall be sent to the Project Office QA Department.

5.0 INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

5.1 General

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, plans, or drawings written according to QPs. LANL procedures consist of QPs and DPs prepared in accordance with this QAPP. These documents, including drawings, shall be developed by qualified personnel, controlled as required by Sections 6 and 17 of this document, and distributed according to QPs. For the production of drawings, the initiating organization shall establish procedures, when directed, for the initiation, review, approval, issue, and change control.

5.2 Criteria

Instructions, procedures, and plans shall specify appropriate quantitative or qualitative criteria for determining satisfactory work performance, QA compliance and identify the QA records to be generated during implementation of the document. The documents shall specify the checkpoints in the work process at which compliance with the criteria shall be determined and verified. Criteria for approval or rejection shall be provided for all inspections of products and for construction and monitoring of methods, and equipment. Means for identifying approved or rejected products or services shall also be provided.

5.3 Reviews

Independent technical reviews of all instructions, procedures, plans, and drawings shall be performed by the originating organization in accordance with QPs before their implementation. The technical adequacy of procedures for conducting scientific investigations shall be reviewed and approved by qualified persons other than those who prepared the procedures. Before instructions, procedures, and plans are implemented at LANL, they shall be reviewed by the QA organization, in accordance with QPs, to ensure that they meet all requirements of this QAPP. Reviews of instructions, plans, procedures, and drawings should consider if the activities described therein (1) are repeatable, (2) will affect waste isolation capabilities, and/or (3) will interfere with other site characterization activities.

5.4 Distribution

The QAPP and all procedures, plans, instructions and drawings shall be maintained and provided to the PQM as part of the controlled distribution for all QA Level I and II activities documents.

6.0 DOCUMENT CONTROL

6.1 Document Preparation, Review, Approval, and Issue

The preparation, review, approval, and issue of documents, such as instructions, administrative procedures, plans, and drawings, including changes therein, shall be controlled to ensure that correct documents are available for use at the proper location. Document control shall be implemented through procedures and shall be applied to documents that contain or specify quality requirements and documents that prescribe activities affecting quality.

The document control system shall be prescribed in a QP, and the QA organization shall provide review, resolution of comments, and approval of quality-related aspects of the documents.

6.2 Implementation of Document Control

Documents shall be controlled according to a QP that

- identifies documents to be controlled;
- assigns responsibility for preparing, reviewing, approving, and issuing documents;
- defines instructions for reviewing documents for adequacy, completeness, correctness, and inclusion of appropriate quality requirements before approval and issue;
- prescribes a method for removing or marking obsolete or superseded documents, in a timely manner, to prevent inadvertent use;
- prescribes a method for ensuring that the correct and applicable documents are available at the location where they are to be used;
- requires a master list or equivalent to identify the correct and updated revisions of documents; and
- delineates interface documents.

6.3 Changes in Documents

Changes in documents shall be reviewed and approved by the same organizations that originally reviewed and approved the document, unless other organizations are specifically designated by the organization responsible for the document. The reviewing organizations shall have access to pertinent background data or information upon which to base their approval. Reviewers shall specifically consider whether changes to the process are not repeatable, have the potential to affect waste isolation capability of the site, or interfere with other site characterization activities.

Minor changes in documents limited to inconsequential editorial corrections do not require the same review and approval as the original documents. Editorial corrections will be verified that they do not substantially change the document before the documents are issued.

6.4 Distribution of Documents

The document control system shall ensure that documents requiring verification are not released before verification or, if they must be released before verification, that they are uniquely identified and controlled in accordance with paragraph 6.2 above. A master list or equivalent used to identify the correct, current, and updated versions of documents shall be submitted to the PQM by the records coordinator. The LANL shall issue to the PQM controlled copies of all LANL implementing procedures, plans, instructions, and the QAPP used for QA Level I and II activities. In addition, procedures, plans, and instructions for QA Level I and II activities shall be accessible for review in the area where the activity is performed.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICE

7.1 General Requirements

Procurement shall be conducted in accordance with LANL QPs. Purchased material, equipment, and services shall conform to the requirements of procurement documents. These methods include source evaluation and selection, the examination of objective evidence of quality, inspection at the contractor or subcontractor source, audit, and examination of products upon delivery as specified in the procurement documents. Organizational responsibilities shall be stated in a QP. This documentary evidence shall be handled as specified in Section 17. Specific requirements for the purchase of items and services are listed below.

7.1.1 Procurement Planning

Procurement activities shall be planned and documented to ensure a systematic approach to procurement. The QA organization shall participate in the qualification of supplier, verification of supplier activities and monitoring receipt inspection. Planning shall be accomplished as early as practicable and no later than the start of YMP procurement activities. Planning shall determine what is done, who does it, how it is done, and when it is to be accomplished.

Planning results in the documented identification of procurement methods, the sequence of actions and milestones that indicate the completion of these activities, and the preparation of applicable procedures before the initiation of each individual activity listed below. Planning considers the following:

- preparation, review, and change control of procurement documents;
- selection of procurement suppliers;
- control of supplier performance;
- verification through survey, inspection, or audit of activities, including specification of hold-and-witness points;
- control of nonconformances;
- execution of corrective action;
- acceptance of an item or service; and
- preparation of QA records.

7.1.2 Evaluation and Selection of Suppliers

Before a contract is awarded, suppliers shall be selected based on an evaluation of their ability to provide items or services in accordance with the requirements of the procurement documents.

Criteria for evaluation and selection of procurement sources, and the results thereof, shall be documented and shall include one or more of the following items:

- an evaluation of the suppliers' histories, including current capabilities, of providing identical or similar products that perform satisfactorily in actual use;
- an evaluation of the suppliers' current QA records supported by documented qualitative and quantitative information that can be objectively evaluated; and
- an evaluation of the suppliers' technical and quality capabilities as determined by a direct evaluation of their facilities and personnel and the implementation of their QA program.

7.1.3 Bid Evaluation

Bid evaluation shall determine the extent of conformance to the procurement documents. The evaluation, by the designated organizations, shall consider the following, as applicable to the type of procurement:

- technical considerations,
- QA requirements,
- personnel,
- production capabilities,
- past performance,
- alternates, and
- exceptions.

Before the contract is awarded, the purchaser shall resolve unacceptable QA conditions identified during the bid evaluation.

7.1.4 Interface Measures

The interface between the supplier and the purchaser includes the following:

- review of supplier documents that are generated or processed during activities fulfilling procurement document requirements,
- require the supplier to identify planning techniques and processes, when applicable;
- methods of exchanging document information; and
- a method of identifying and processing necessary change information. (Measures to control changes in procurement documents shall be established, implemented, and documented in accordance with the requirements of Subsection 4.3 of this QAPP.)

7.1.5 Evaluation of Supplier Performance

7.1.5.1 Verification Measures

The purchaser of items and services shall establish measures to verify the supplier's performance and to establish the extent of source survey and inspection activities. The

extent of verification activities, including planning, is a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the supplier's activities (i.e., a preaward survey).

These verification activities shall be conducted as early as practicable. However, LANL's verification activities do not relieve the suppliers of their responsibilities for verification of quality achievement.

When using another participating organization, LANL will request the PQM to conduct a survey to determine that the item or activity is being produced or performed in accordance with LANL requirements.

7.1.5.2 Record of Evaluation and Verification

Activities shall be performed to verify conformance with requirements of procurement documents and their results shall be recorded. Source surveys and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented. These completed documents shall be considered QA records and shall be controlled in accordance with Section 17 of this QAPP. This documentation is evaluated to determine the supplier's QA program effectiveness.

7.1.6 Control of Documents Generated by Suppliers

Documents generated by suppliers shall be submitted in accordance with requirements of the procurement documents and shall be handled, approved, and controlled according to LANL QPs for document control. The documents shall be evaluated against the criteria for procurement acceptance.

7.1.7 Acceptance of Item or Service

Methods shall be established for the acceptance of items or services being furnished by the supplier. The supplier or contractor shall verify that an item or service complies with the procurement requirements before its submission for acceptance. Documentation of acceptance shall be considered a QA record and maintained in accordance with Section 17 of this QAPP.

Acceptance of services performed shall require documentation of surveys and audits, a technical review of data generated, or other objective evidence of satisfactory performance.

Methods of acceptance for items include

- a supplier certificate of conformance,
- a source verification,
- a receiving inspection,
- a postinstallation test at the facility site, or
- a combination of the above.

7.1.7.1 Certificate of Conformance

The following minimum criteria apply to a certificate of conformance.

- The certificate shall identify the purchased material or equipment.
- The certificate shall identify the specific procurement requirements met by the purchased material or equipment, including codes, standards, or other specifications. Identification shall be accomplished by including a list of the specific requirements or by providing, at the point of receipt, copies of the purchase order, the procurement specifications or drawings, and a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.
- The certificate shall identify any procurement requirements that have not been met, shall explain the nonconformance, and shall propose a means of resolution.
- The certificate shall be validated by a person responsible for this QA function that is described in the supplier's of QA program.
- The certificate system, including the procedures followed in filling out a certificate and the administrative procedures for the review and approval of the certificates, shall be described in the supplier's QA program.
- The validity of supplier certificates and the effectiveness of the certification system shall be verified during the performance of audits of the supplier, or independent inspection, or test of the items. Such verification shall be conducted at intervals commensurate with the supplier's past quality performance.

7.1.7.2 Source Verification

If source verification is performed, it shall be done at intervals that are consistent with the importance and complexity of the item or service. Source verification shall be implemented to monitor, witness, or observe activities. Verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Once the source verification is accepted, LANL, (the receiving destination of the item), and the supplier shall be furnished with documented evidence of acceptance of the item.

7.1.7.3 Receiving Inspection

Purchased items shall be inspected as necessary to verify their conformance to specified requirements. Inspections shall take into account source verification, audit documentation, and the demonstrated quality performance of the supplier. Receiving inspection shall be performed in accordance with LANL QPs. Supplier documentation that material or equipment conform to procurement requirements will be available for review at receipt inspection and/or prior to installation or use. Receiving inspections shall be based on objective evidence criteria, such as physical, dimensional, damage, or other measurable characteristics. Technical personnel, who are familiar with the objectives of the research and have been indoctrinated to the applicable codes, standards and QA requirements; shall perform the receipt inspections. These technical personnel shall have the experience and training commensurate with the scope, complexity or special nature of receipt inspection.

7.1.7.4 Postinstallation Testing

Postinstallation testing requirements and acceptance documentation shall be established between LANL and the supplier in the procurement document.

7.1.8 Procurement of Services

In cases involving procurement of services, including third-party inspections, engineering, analysis, consulting, installation, repair, overhaul, or maintenance work, acceptance shall be made according to the following methods:

- technical verification of data produced;
- a survey and/or audit of the activity; or
- a review of evidence, such as certifications and stress reports, for conformance to the requirements for procurement documents.

7.1.9 Control of Supplier Issued Nonconformances

Requirements involving the control of supplier issued nonconformances for the item or service being procured shall be stipulated in the purchasing document.

The nonconformance report (NCR) issued by the supplier shall contain the following minimal information:

- the technical or material requirement violated, with reference to the procurement document;
- a consideration of whether the nonconformance can be corrected by continuation of the original process or rework;
- an evaluation of nonconforming items;
- a submittal of a nonconformance notice to the requester;
- the process correction proposed, when applicable;
- the recommended disposition (i.e., use-as-is, repair, rework, or reject); and
- technical justification for the disposition.

The submittal of a nonconformance notice shall include a disposition recommendation (e.g., use as is or repair) and technical justification. Supplier dispositions are approved and implementation is verified by the requester in accordance with the LANL QP. Supplier nonconformance reports shall be processed and reviewed by the requestor according to a LANL QP and maintained as QA records.

Disposition of nonconformances by the requester includes

- an evaluation and approval of the supplier's corrective action (if applicable),
- maintenance of records of nonconformance, and
- verification of the corrective actions.

7.2 Commercial-Grade Items

If a design or scientific investigation requires commercial-grade items, then the following requirements and the requirements of Section 4 of this QAPP shall be used to accept the items.

7.2.1 Identification of Commercial-Grade Items

Where the commercial-grade item is to be used it shall be properly identified in approved design or design activity documents and will meet applicable requirements. An alternate commercial-grade item may be supplied if the cognizant organization provides verification that the alternate commercial-grade item will perform the intended function and will meet the requirements applicable to both the replaced item and its application.

7.2.2 Source Evaluation and Selection

Source evaluation and selection shall be in accordance with Subsection 7.1.2 when the requestor determines that such activity is necessary based on the complexity of the item and its importance to safety.

7.2.3 Purchase Order

Commercial-grade items shall be identified in the purchase order by the manufacturer's published product description (e.g., the catalog number).

7.2.4 Receipt of Commercial-Grade Items

Receipt of a commercial-grade item shall determine that

- damage was not sustained during shipment;
- the item received was the item ordered;
- the required receipt inspection or testing is accomplished in accordance with written procedures to ensure conformance with the manufacturer's published requirements, and, if applicable, acceptance of the item may be accomplished by way of a calibration program in accordance with Section 12 of this QAPP and the associated procedure; and
- documentation, as applicable to the item, has been received and accepted.

8.0 IDENTIFICATION AND CONTROL OF SAMPLES AND DATA

8.1 Identification and Control of Samples

These requirements shall apply to samples used in or resulting from scientific investigations.

Samples shall be identified and controlled according to LANL DPs. Such procedures shall define the responsibilities (including interface between organizations) for the collection, identification, handling, storage, and transportation of samples and for the generation of records regarding such.

Samples shall be collected according to LANL DPs to ensure that collection methods produce the intended sample. Sample-handling methods shall be documented and shall be used to ensure that all samples meet the technical objectives dictated by the scientific investigation for which the samples are collected.

Transportation methods shall be described in, and effected by, LANL DPs prescribing appropriate containers, methods of handling, and any other environmental or safety considerations for the sample. Where multiple organizations are involved, appropriate procedures shall define responsibilities and documentation methods to be used.

Controls shall be implemented to ensure that sample identification is verified and maintained when samples are handled, transported, or transferred from one organization's responsibility to another for use or analysis.

Samples shall be identified by placing the identification directly on the sample, on its container, or on records traceable thereto. When it is impractical to place the identification on the samples, an alternative method shall be implemented to ensure that samples are not mixed with like samples and that the correct identification of samples is verified and documented before the samples are released for use.

Physical identification shall be used to the maximum extent possible. Where physical identification cannot be placed on the sample, appropriate alternative identification methods shall be used whereby identification of samples can be traced to the appropriate documentation, such as drawings, specifications, drilling logs, test records, inspection documents, and nonconformance reports.

Samples shall be stored and maintained in predetermined physical conditions commensurate with their intended purpose. Samples intended for long-term storage shall receive treatment to ensure that they do not degrade during storage. "Long term" is defined by the scientific investigation planning document for each sample collection case.

Measures shall be taken to maintain sample identification consistent with the planned duration and conditions of storage. Consideration shall be given to the maximum storage life expected of the sample. Physical segregation of samples to preclude mixing with like samples shall be used to the maximum degree practical.

LANL procedures shall be based upon the YMP AP describing the ultimate storage of all types of samples, including liquids, gases, and solids. The procedures shall, as a minimum, address the transportation, handling, storage, and retrievability of samples and the generation and retention of records. All records generated as a result of the testing of the samples shall be handled in accordance with Section 17 of this document.

8.2 Identification and Control of Data

The requirements included here shall apply to data generated by a LANL YMP scientific investigation. Data generated by a scientific investigation shall be identified to assist in the determination of their correct use. Identification of such data shall be provided in all documents and information systems in which such data appear. The identification of data shall include a reference to the origin of the data (task, test, experiment, report, publication, etc.) and an indication of the QA level assigned to the activity that produced the data.

Control measures shall be implemented to ensure that data are properly identified. These measures shall include verification of the identification of data before their release for use.

Where data are the results of the efforts of more than one organization, QPs describing the organizational responsibilities for those data shall be developed and implemented. The documentation resulting from the scientific investigation involving more than one organization shall be annotated to show which organization produced what portion of the data.

9.0 CONTROL OF PROCESSES

The requirements for process control shall apply to engineered items and scientific investigations; the requirements for special process control apply to engineered items only which are not a part of the LANL scope-of-work. All processes shall be controlled by instructions, procedures, plans, drawings, checklists, travelers, or other appropriate means to ensure that process parameters are controlled and that specific environmental conditions are maintained.

10.0 INSPECTION

The requirements of this section of the Project Office QAP apply to engineered items and do not apply to scientific investigation activities.

11.0 TESTING

LANL does not currently conduct any activities to which testing requirements apply.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Scope of Control Program

Tools, gages, instruments, fixtures, reference or transfer standards, nondestructive test equipment and other measuring and test equipment used in activities affecting quality shall be controlled. They shall be calibrated and adjusted at specified periods to maintain measurement accuracy within specified limits. The scope and methodology of the control program includes all equipment or systems used to calibrate, measure, gage, test or inspect, either to control or to acquire data, to verify conformance to a specified requirement, or to establish characteristics or values not previously known. Calibration and control measures are not required for rulers, tape measures, levels, and other such devices if normal commercial equipment provides adequate accuracy. Procedures shall be established for calibration (technique and frequency), maintenance, and control of measuring and test equipment used for measurement, inspection and monitoring. The review and documented concurrence of these functions shall be identified in the procedures.

12.2 Description of Responsibilities

All organizations using and calibrating measuring and test equipment shall establish and implement a calibration program through DPs. The QAPL shall be responsible for evaluating each program and for ensuring that it is effective and complies with the QP.

12.3 Program Requirements

Calibration programs shall include specifications for selection, calibration, capability, handling, and storage of measuring and test equipment.

12.3.1 Selection

Selection of measuring and test equipment shall be controlled to assure that such equipment is of proper type, range, accuracy, and tolerance to accomplish the intended function. The type, range, accuracy, and tolerance of a measuring device shall be specified in DPs, logbooks, instruction books, or other appropriate places. Each device shall have a unique identification number. This number shall be recorded on the data sheet, log, etc., along with the measurement taken, to ensure traceability.

12.3.2 Calibration

Measuring and test equipment covered by these requirements shall be calibrated against certified equipment having known valid relationships to the National Bureau of Standards (NBS) or other nationally recognized standards and shall be calibrated, adjusted and maintained at prescribed intervals. If no nationally recognized standards exist, the basis for calibration shall be specified and documented in a DP, QP, logbooks, or notebooks. Calibrating standards shall have equal or greater accuracy than that required of the equipment being calibrated. Calibrating standards with the same accuracy may be used, provided they can be shown to be adequate for the requirements and that the basis of acceptance is documented and approved by the principal investigator.

12.3.3 Capability

The method and interval of calibration for each item shall be defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. Measuring and test equipment shall be labeled, tagged, or otherwise documented in a fashion that indicates the due date of the next calibration and that provides traceability to calibration data. If measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented that includes the validity of previously obtained results and the acceptability of previous investigations or data-gathering activities of these items since the expiration of the last calibration. Devices that are out of calibration shall be tagged or segregated and shall not be used until they have been recalibrated. If any measuring and test equipment is found to be consistently out of calibration, then it shall be repaired or replaced. During the normal course of an investigation, calibration shall be performed whenever the accuracy of equipment is suspect.

12.3.4 Handling and Storage

Measuring and test equipment shall be handled and stored according to the manufacturer's recommendation or approved procedures to maintain accuracy.

12.4 Records

Records and documents related to calibration activities shall be maintained as specified in this section and the LANL QPs.

Equipment shall be marked to indicate calibration status. Calibration records shall identify the calibration procedure (including revision) used to perform the calibration.

13.0 HANDLING, SHIPPING, AND STORAGE

13.1 General

Work and inspection instructions, drawings, specifications, shipment instructions, or other procedures, shall be established as necessary to control the packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration. Such instructions shall specify the following:

- special equipment and protective environments,
- specific procedures,
- inspection and testing of any special tools and equipment,
- training of special equipment operators, and
- marking and labeling.

13.2 Special Equipment and Protective Environments

When required for particular items, special equipment (e.g., containers, shock absorbers, and accelerometers), and special protective environments (e.g., an inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified in the pertinent instructions provided by the responsible organization, and their existence shall be verified by the QA organization.

13.3 Specific Procedures

When required for critical, sensitive, perishable, or exceptionally expensive articles, DPs shall be written for handling, storage, packaging, shipping, and preservation. DPs shall be subject to LANL QAPL approval (see Table 1-1).

13.4 Inspection and Testing of Special Tools and Equipment

Any special-handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special-handling tools and equipment shall be inspected and tested in accordance with approved procedures and at specified time intervals to verify that the tools and equipment are adequately maintained.

13.5 Training of Special Equipment Operators

Operators of special-handling and lifting equipment shall be experienced or shall be trained to use the equipment. Verification and documentation of this training shall be maintained as QA records in accordance with LANL QPs.

13.6 Marking and Labeling

Marking and labeling instructions for packaging, shipment, handling, and storage of items shall be specified in LANL DPs to adequately identify, maintain, and preserve the item. Marking requirements for special environments or special controls shall also be specified in LANL DPs.

14.0 INSPECTION, TEST, AND OPERATING STATUS OF ENGINEERED ITEMS

The Project Office QAP requirements of inspection, test, and operating status apply to engineered items and do not apply to scientific investigations.

15.0 CONTROL OF NONCONFORMANCES

15.1 General

Measures shall be established to control nonconforming items and activities and to prevent their inadvertent installation, use or performance. These measures shall include the use of documented procedures for identification, documentation, evaluation, segregation (when practical), disposition, and notification to affected organizations. All LANL YMP personnel shall be responsible for reporting nonconformances in accordance with their approved procedures for nonconformance control. These procedures shall be consistent with the requirements discussed below.

15.2 Identification

Identification of nonconforming items shall be made by marking, tagging, or other methods that do not adversely affect the end use of the item. The identification shall be legible and easily recognizable and shall contain the NCR number. The method for tracking the NCR status and QA organizational responsibilities shall be clearly stated in a QP. Internal and external interfaces shall be clearly defined.

15.3 Nonconformance Control Log

Nonconformances shall be tracked in a nonconformance control log that contains the following information:

- the NCR number (a sequential number preceded by "LANL"),
- a brief description of the nonconforming condition,
- identification of the person or organization responsible for determining and carrying out the nonconformance disposition, and
- the status of each NCR (open or closed).

15.4 Segregation

When practical, nonconforming items shall be segregated by placing them in a clearly identified and designated holding area until their dispositions are accomplished. When segregation is impractical or impossible because of physical conditions, such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of nonconforming items. Tags shall be permitted if they are securely attached to the items, or the items shall be placed within a unique storage area if a place is so designated. Segregation is not applicable to nonconforming activities.

15.5 Disposition

Processing, delivery, installation, use or performance of a nonconformance shall be controlled pending an evaluation and approved disposition by authorized personnel. Recommended dispositions of nonconforming items shall be proposed, reviewed, and approved in accordance with documented procedures. Nonconformance documentation shall be distributed to all affected organizations upon issue and closure.

15.5.1 Responsibility and Authority

The organization using or producing the nonconformance shall be responsible for its evaluation, disposition, and close-out. Those persons who are assigned signature approval of the disposition shall be identified in the QP. The QA responsibilities shall include approval of the disposition and verifying closeout of nonconformances.

15.5.2 Personnel

Persons selected to evaluate nonconformances to determine a disposition shall have demonstrated competence in the specific area under evaluation and an adequate understanding of the requirements, and shall have access to pertinent background information.

15.5.3 Disposition of the NCR

Persons responsible for dispositioning the NCR shall ensure that the following requirements are met.

- Nonconformance documentation shall adequately identify and describe the nonconformance.
- Appropriate justification for the disposition shall be documented. In the case of use-as-is or repair dispositions of the item, technical justification shall be required. Such dispositions shall require the approval of the appropriate YMP Branch Chief and the PQM prior to implementation. The records of as-built items, if such records are required, shall reflect the accepted deviation.
- The NCR shall refer to any approved design documents, procedures, plans, work orders, etc., to be used for the correction of the nonconforming condition.
- The technical details for correction of the nonconforming condition shall be adequate for the recommended disposition.
- If continuance is requested, justification for the continuance will be documented and then approved by the TPO, QAPL, PQM and YMP Branch Chief.
- The disposition shall comply with existing design documents, test plans or procedures, reports, and regulatory requirements.
- If a change is appropriate to reflect the as-built condition of an item, then the disposition shall address the action needed to change the existing design documents, test plans or procedures, reports, etc. Any documents changed shall have a cross reference on the NCR.
- The disposition shall identify and document the correction as repair, rework, use-as-is, or reject/scrap.
- The disposition shall identify the personnel responsible for implementing the disposition.

- The disposition shall describe the cause of the nonconforming condition.
- The disposition shall document action needed to preclude recurrence of the nonconforming condition.

15.5.4 Project Office Notification

Copies of NCRs shall be sent to the PQM upon issuance and closure.

15.5.5 Corrective Action

Action taken to correct the nonconformance shall be verified and documented. Repaired or reworked items shall be re-examined in accordance with applicable procedures and with the original acceptance criteria, unless the disposition has established alternate acceptance criteria.

15.6 Conditional Release

Work on a nonconformance shall be stopped until the NCR disposition is complete. If only a specific portion of an item or activity is in nonconformance, then that specific portion shall be identified and work may proceed on the remaining areas or subtasks. However, work on a nonconformance may continue (conditional release) before implementation of the disposition when approved by the QAPL, TPO, PQM and YMP Branch Chief. Requests for conditional releases on nonconformance shall document that the following conditions are met:

- the nonconformance can be removed or corrected at a later date without damage to, or contamination of, the associated permanent facility equipment or structures;
- if the nonconformance is related to an item, the item shall remain accessible for inspection;
- the nonconformance shall have been evaluated and limitations for use of the equipment or system established; and
- traceability and identification of the nonconformance shall be maintained.

15.7 Nonconformances and Trending

The NCRs shall be periodically analyzed by the QA organization to establish quality trends and to help identify root causes of nonconformances. The results shall be reported to the TPO and QAPL for review and assessment. When repetitive or recurring nonconforming conditions are identified (as a trend), an evaluation shall be made as to whether further programmatic corrective action (Section 16) is warranted to preclude repetition. This corrective action shall be beyond the scope of the action taken for the disposition of the existing NCRs and shall be processed in accordance with LANL corrective action procedures.

16.0 CORRECTIVE ACTION

16.1 General

The corrective action system shall ensure that repetitive nonconformances and/or conditions adverse to quality, including supplier nonconforming activities and services,

shall be identified promptly, documented on corrective action reports, and corrected as soon as practical.

16.2 Significant Adverse Conditions

For significant conditions adverse to quality, the identification, cause, and corrective action taken to preclude recurrence shall be documented and reported to immediate management and upper levels of management for review and assessment. Assessment may result in a stop work order. A significant condition adverse to quality is one that, if not corrected, could have a serious effect on safety or operability. Significant conditions shall include, but shall not be limited to, breakdowns in the QA program and repetitive nonconformances. Upon discovering or receiving notification that a significant condition adverse to quality exists, LANL shall ensure that

- immediate action has been taken to remedy the specific condition(s);
- any root cause has been determined;
- controls are reviewed, implemented, monitored, and revised, if necessary; and
- affected managers at all levels are notified of the adverse condition(s) and of additional training, if necessary, to improve conditions or to avoid similar occurrences.

16.3 QA Follow-Up Action

The QA organization shall document concurrence with the adequacy of proposed corrective actions to ensure that QA requirements are met. Follow-up action shall be taken by the QA organization to verify proper implementation of the corrective action, to document its acceptance, and close-out the action. The organization responsible for implementing the corrective action shall ensure that the corrective action is completed in a timely manner. Failure to properly complete corrective action steps in a timely manner may result in a stop work order.

16.4 Corrective Action Reports

The QA organization shall periodically analyze corrective action reports to establish quality trends. The results shall be reported to the TPO and QAPL for review and assessment. Copies of corrective action reports shall be sent to the PQM by the QAPL upon issue and closure.

17.0 RECORDS

17.1 General

Records that furnish evidence of quality shall be specified, prepared, and maintained in accordance with QPs that meet the requirements of this section. Records management QPs shall be issued at the earliest practical time consistent with the schedule and work activities. The term "records" used in this section means QA records.

17.2 Management, Control, and Preservation of Records

QPs shall be consistent with the Project Office AP 1.7Q, YMP QA Records Management. Responsibilities and methods for record transmittal, distribution, retention, maintenance, retrievability, and status of QA records shall be specified in the QPs.

QPs shall define the implementation of the record system and shall identify and measures for the prevention of delays between record completion and storage at the LANL RPC and for the preservation and safekeeping of the records.

For purposes of record retention, all LANL YMP records, including superseded records, shall be classified as lifetime records and shall be retained for the life of the LANL YMP.

17.3 Minimum Records

Sufficient records shall be specified, prepared and maintained to furnish evidence of the activities that affected quality. All operating logs and the results of reviews, receipt inspections, audits, monitoring of work performance, materials analysis, qualifications of personnel, and procedures shall be maintained as QA records. Final reports shall contain a listing, by unique number, that enables prompt retrieval of all documents used to compile or evaluate the reports. This listing shall include all referenced documents, peer review or other review documents, computer codes, data sheets, procedures, and plans. All documents referenced by final reports, except references readily available to the public, shall be retrievable from the LANL RPC. A list of typical QA records is contained in Appendix E.

17.4 Generation of Records

A document is not considered to be a QA record until it satisfies the definition of a QA record (Appendix A). Records to be generated, supplied, or maintained by or for LANL shall be specified in design documents, procurement documents, implementing procedures, or other documents. Records shall be legible, identifiable, accurate, complete, reproducible on microfilm and other media, and appropriate to the work accomplished. A completed record is defined as a record that will either receive no more entries or whose revision would normally consist of the reissue of the record; and is signed and dated by the originator and, as applicable, by personnel authorized to approve the record. Records shall be completed in accordance with LANL QPs and DPs.

17.5 Validation and Authentication of Records

Records shall be considered valid only if stamped, initialed or signed, and dated by authorized persons or otherwise authenticated in accordance with QPs. Validated records may be originals or reproduced copies.

Record authentication may be a statement by the responsible individual or organization. Handwritten signatures are not required if the record is clearly identified as a statement by the reporting individual or organization. LANL shall maintain a list that contains the signature and initials of the persons authorized to authenticate records.

17.6 Receipt of Records

Each LANL organization that is responsible for the receipt of records shall designate a person to be responsible for receiving the records. The designee shall be responsible for organizing and implementing a system for receipt control of records for dual storage. The receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process. The receipt control system shall include the following:

- a method for designating the required records,
- a method for identifying the records received,

- a method for acknowledging receipt, and
- procedures for receipt and inspection of incoming records.

LANL organizations responsible for receiving records shall provide protection from damage, deterioration, or loss during the time that the records are in their possession. Each LANL group shall process its records and transfer them to the LANL RPC for further processing and transfer to the Project Office without unnecessary delays.

17.7 Records Identification

The YMP approved indexing system shall identify the connection between the record and the item or activity to which it applies. Records shall be identified by a unique number or other designation that is directly traceable to controlling program information (e.g., project, contract number, task number, preparing organization, author, date, title, and subject). This identification number or other designation shall not be repeated anywhere in the YMP. The indexing system shall include the location of the record within the records system.

17.8 Storage of Records

Records shall be controlled from the time they are completed until the time they are stored in a permanent storage facility. Temporary storage, preservation, safe-keeping, and retrievability of completed records shall be done in accordance with a QP describing the permanent storage of records. The QP shall include the following:

- a description of the storage facility,
- the filing system to be used,
- the method for verifying that the records received are legible and are in agreement with the transmittal document,
- the method of verifying that the records are those designated,
- the rules governing access to and control of the files including retrieval times,
- the method for maintaining control of and accountability for records removed from the storage facility, and
- a method for filing supplemental information.

17.8.1 Responsibilities

The RPC shall be responsible for ensuring that the requirements of QPs for the storage of records are met.

17.8.2 Storage Facilities

Methods for the permanent and temporary storage of records and documents shall be stated in QPs. Records and documents shall be stored in dual facilities constructed and maintained in a manner that minimizes the risk of damage or destruction from natural disasters, such as winds, floods, or fires; environmental conditions, such as high and low temperatures and humidity; infestation of insects or rodents; or mold. The dual

facilities shall be predetermined locations sufficiently remote from each other to reduce the chance of simultaneous exposure to a hazard.

17.8.3 Preservation

Records shall be stored in a manner approved by the QAPL. Deterioration of the records shall be precluded by the following.

- Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure.
- Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or shall be placed in containers and stored on shelves.
- Special processed records (radiographs, photographs, negatives, microfilm, magnetic material, etc.) shall be protected from damage caused by excessive light, stacking, electromagnetic fields, temperatures, and humidity.

17.8.4 Safekeeping

The QP shall include safekeeping measures to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism.

17.8.5 Replacement, Restoration, or Substitution

Lost or damaged records shall be replaced, restored, or substituted within 90 days of the discovery of the loss or the determination that the damaged record is incomplete or illegible.

17.9 Corrected Information in Records

Records shall be corrected in accordance with LANL QPs that stipulate appropriate review or approval by the originating organization. The correction shall include the date and the identification of the person authorized to issue such correction and shall not obliterate the corrected data.

17.10 Access to QA Records

A list shall be maintained that designates those personnel who have access to the QA record files. Records maintained by LANL at LANL or at any other location (on an interim or other basis) shall be accessible to the Project Office or its designated alternate.

17.11 Transfer of QA Records

The RPC shall review each group's records turnover and shall acknowledge receipt of, inventory, and transfer the records to the Project Office.

18.0 AUDITS

18.1 General Requirements

All LANL YMP activities are subject to scheduled and planned internal and external audits to ensure that procedures and activities comply with the overall QA program and to determine the program's effectiveness. The audits shall be performed using check lists in accordance with QPs. Qualified personnel who do not have direct responsibility for performing the activities being audited shall conduct the audits. Audit results, including deficiencies, nonconformances, and potential quality problems, shall be documented and monitored, reviewed by the QAPL, and reported to the TPO and monitored until verification of effective corrective action is made. On the form supplied by the audit organization, the audited organization shall describe the corrective action to be taken to address findings and shall submit the completed form to the QAPL and the audited organization's own management. The audit organization shall track audit findings to ensure that all findings are properly closed and to identify quality trends.

Audits shall be performed by the QAS and shall include follow-up action, verification of corrective action, or reaudit of specific areas.

18.2 Audits

LANL shall conduct internal and external audits of activities under its direct control and shall not conduct audits of other participating organizations. These audits shall be scheduled, planned, conducted, and reported as described below and in accordance with QPs.

18.2.1 Scheduling

Internal and external QA audits shall be scheduled annually (date, activity, and requirements) to provide complete coverage of QA program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity and initiated early enough in the activity to ensure effective QA. The audit schedule shall be prepared annually and evaluated periodically and revised as necessary to ensure that coverage is maintained current. Revisions of the audit schedule shall be documented. LANL shall perform or arrange for annual evaluations of suppliers. This evaluation shall be documented and shall take into account, where applicable, (1) review of suppliers' furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions; (2) results of previous source verifications, audits, and receiving inspections; (3) operating experience of identical or similar products furnished by the same supplier; and (4) results of audits from other sources, e.g., customer, American Society of Mechanical Engineers, or NRC audits. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage. The audit schedule, including dates and any revisions thereof, shall be sent to the PQM. The audit schedule shall identify the date of the audit, the activities to be audited, and the requirements to which the activities will be audited.

18.2.2 Internal Audits

All applicable elements of LANL's internal QA program shall be audited at least annually or at least once during the life of the activity, whichever is shorter. The scope of the audit is established by considering the results of any previous audits; the nature and frequency of identified deficiencies; and any significant changes in personnel, organization, or the QA program.

18.2.3 External Audits

Applicable elements of an external organization's QA program shall be audited at least annually or once during the life of the activity, whichever is the shorter period. Exception: If the activity is less than four months in duration, an audit is not required unless it is necessary because of the complexity or importance of the activity being performed. The justification for not performing audits of vendors whose activities are less than four months in duration shall be documented, approved by the QAPL and sent to the PQM.

If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit shall satisfy the needs of all of the purchasers, and the audit report shall be distributed to all the purchasers for whom the audit was conducted. Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.

18.2.4 Audit Plan

An audit plan shall be developed and documented for each audit. This plan identifies the audit scope, audit requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and check lists.

18.2.5 Audit Personnel

Auditors shall be independent of any direct responsibility for the performance of the activities that they are to audit. If the audit is internal, the personnel who have direct responsibility for performing the activities to be audited shall not be involved in the selection of the audit team. Auditors shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. Appendix F defines the requirements for the qualification of QA auditors.

An audit team shall be identified before the beginning of each audit. This team shall contain one or more auditors, one of whom is qualified as a lead auditor, to organize and direct the audit, to coordinate the preparation and issue of the audit report, and to evaluate the responses. The audit team leader identifies technical specialists (if they are necessary) and includes their names in the audit plan. The technical specialists shall have appropriate technical expertise or experience in the work being audited and be independent from the work performed. Multidisciplinary teams shall be used when more than a single technical area is to be audited. The audit team leader shall ensure that the audit team is prepared before the audit begins.

18.2.6 Performance

Audits shall be performed using checklists as early in the life of the activity as practicable and shall be continued at intervals consistent with the schedule for accomplishing the activity. The elements selected for an audit shall be evaluated against specified requirements, including a review of any corrective actions taken on deficiencies identified during previous audits in the area being audited. Objective evidence shall be evaluated to determine whether the selected elements are effective and are being implemented properly. The audit results shall be documented by auditors and shall be reviewed by the management responsible for the area audited. Conditions

that require prompt corrective action shall be reported immediately to the management of the audited organization. Audit findings shall be reviewed with the audited organizations at the closing meeting.

18.2.7 Reporting

The audit report shall be signed by the audit team leader and shall be issued to the audited organization within 30 calendar days of the audit in accordance with LANL QPs. The audit report shall include the following information, as appropriate:

- a description of the audit scope;
- identification of the auditors;
- identification of persons contacted during audit activities;
- a summary of audit results, including an evaluation of the effectiveness of the QA program elements that were audited; and
- a description of each adverse audit finding in sufficient detail to enable the audited organization to take corrective action.

18.2.8 Response

Line management of the audited organization or activity shall investigate any audit finding, shall determine any root cause, shall schedule corrective action that include measures to prevent recurrence, and shall notify the QAS in writing of action taken or planned within 30 calendar days of receipt of the audit report. The adequacy of audit responses shall be evaluated by the QAS.

18.2.9 Follow-Up Action

Follow-up action, including reaudits of specific areas, shall be taken to determine whether corrective action has been accomplished as scheduled and shall be verified by the auditing organization. Audit results shall be analyzed by QAS to identify quality trends. The results of the analysis shall be reported to responsible management for review, assessment, and appropriate action.

18.2.10 Records

Audit records shall include

- identification of the organizations, activities, or items audited and the individuals contacted during the audit;
- a description of any deficiencies, nonconformances, or potential quality problems; and
- audit plans, audit reports, written replies, and the record of completed corrective actions and close-out of the audit.

Qualification records for auditors and lead auditors shall be established and maintained. Records for all auditors shall be updated annually.

18.3 Surveys

The audit program shall be supplemented by survey activities. The purpose of a survey shall be to monitor or observe items or activities to verify conformance to specified requirements. These surveys may be conducted by the QAS and/or a QAL on a scheduled and/or random basis.

Surveys shall be conducted in accordance with a QPs. Surveys shall be scheduled and conducted based on the activity's relative effect on or importance to the YMP. All deficiencies, nonconformances, and potential quality problems identified during surveys shall be documented and monitored to ensure and verify that effective corrective action is made.

18.3.1 Planning

Surveys shall be performed according to written check lists or plans whenever practical. The planning documentation shall identify characteristics; define methods and acceptance criteria; and provide for the recording of objective evidence of results, and the accuracy of the equipment necessary to perform the survey. Acceptance criteria related to surveillances may be as simple as to verify proper implementation of procedures or to verify conformance to requirements.

18.3.2 Reporting Independence

Survey personnel shall not report directly to the immediate supervisors who are responsible for the work being surveyed.

18.3.3 Records

Survey reports shall include the following:

- the identification of the organizations, activities, or items surveyed, including the names of persons contacted;
- the date of the survey;
- the name of the individual performing the survey;
- the survey criteria;
- any equipment used during the survey;
- a description of any deficiencies, nonconformances, and potential quality problems identified during the survey (Nonconformances shall be handled per QAPP Section 15 or 16, as applicable.);
- the survey results; and
- an acceptance statement related to the effectiveness of the QA program as surveyed.

APPENDIX A
TERMS AND DEFINITIONS

ACCEPTANCE CRITERIA: Specified limits that are defined in codes, standards, or other requirements documents and placed on the characteristics of an item, process, or service.

ACCESSIBLE ENVIRONMENT: (1) the atmosphere, (2) the land surface, (3) surface water, (4) oceans, and (5) the portion of the lithosphere that is outside the controlled area.

ACTIVITIES THAT AFFECT QUALITY: Deeds, actions, work, or performance of a specific function or task. The Project Office QA Program applies to activities affecting the quality of all systems, structures, and components important to safety, and to the design and characterization of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation. The QA Level I requirements of this QA Program apply to all activities affecting the quality of structures, systems, and components important to safety and engineered barriers important to waste isolation. These activities include: designing (including such activities as safety analyses, laboratory testing of waste package materials to characterize their performance, and performance assessments), purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying. These types of activities do not need to be identified as part of the Q-List, nor do they require QA level assignment. However, activities related to natural barriers important to waste isolation shall be identified and listed on a Q-List. These activities include: performance assessments, site characterization testing, and activities that may impact the waste isolation capability of the natural barrier. Examples are site characterization activities such as exploratory shaft construction, borehole drilling, and other activities that could physically or chemically alter properties of the natural barriers in an adverse way.

ACTIVITY: Any time-consuming effort (operation, task, function, or service) that influences or affects the achievement or verification of the objectives of the YMP as depicted in the WBS.

AP-YMP ADMINISTRATIVE PROCEDURE: An implementing procedure which identifies the interface control methods which govern Project-wide systems and are implemented by all Project participants. APs that implement QA requirements are identified with a "Q" suffix (i.e., AP 1.1Q).

AUDIT: A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, codes, standards, instructions, drawings, and other applicable requirements, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

AUTHENTICATION (QA RECORDS): Authentication is the act of attesting that the information contained within a document is accurate, complete, and appropriate to the work accomplished. Authentication is accomplished by one of the following methods: (1)

a stamped, initialed, or signed, and dated document; (2) a statement by the responsible individual or organization; or (3) issuing a document which is clearly identified as a statement by the reporting individual or organization. A document cannot become a QA record until it has been authenticated.

AUXILIARY SOFTWARE: (1) Software that may be easily and exactly verified and that performs a simple function such as conversion of units, change in data format, or plotting of data in support of primary analysis software. (2) A stream of commands or a sequence of streams of commands executed to utilize system maintained software in which the system maintained software generates reportable results. Auxiliary software does not generate primary data.

BARRIER: Any material or structure that prevents or substantially delays the movements of water or radionuclides.

BASELINE: As used for computer software: (1) the stage of computer software at a completed and reviewed phase of the software life cycle; (2) approved documentation generated within or as a result of completing a phase of the software life cycle.

CERTIFICATE OF CONFORMANCE: A document signed by an authorized individual that certifies the degree to which items or services meet specified requirements.

CERTIFICATION: The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

CHARACTERISTIC: Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

COMMERCIAL GRADE ITEM: An item satisfying all of the following requirements:

- The item is not subject to design or specification requirements that are unique to mined geologic disposal systems.
- The item is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (i.e., catalog).
- The item is used in applications other than mined geologic disposal systems.

COMPUTER CODE VERIFICATION: Assurance that a computer code correctly performs the operations specified in a numerical model (NUREG 0856). Usually accomplished by comparing code results to a hand calculation, to an analytical solution or approximation, or to a verified code designed to perform the same type of analysis (e.g., benchmarking).

COMPUTER CODE: A set of computer instructions for performing the operations specified in a numerical model.

COMPUTER MODEL VALIDATION: Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (NUREG 0856). Usually accomplished by comparing code results to physical data or to a verified or validated code designed to perform the same type of analysis (e.g., benchmarking with a validated code). Peer review may be used for code validation if it is the only available means.

CONDITION ADVERSE TO QUALITY: An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one that, if not corrected, could have a serious effect on safety or operability.

CONFIGURATION MANAGEMENT: As used for computer software: (1) a system for the orderly control of software, including methods used for labeling, changing, and storing software and its associated documentation. (2) the systematic evaluation, coordination, approval or disapproval, and implementation of all approved changes in an item of software after establishment of its configuration.

CONSEQUENCE ANALYSIS: A method by which the consequences of an event are calculated and expressed in some quantitative way, e.g., money loss, deaths, or quantities of radionuclides released to the accessible environment.

CONTAINMENT: The confinement of radioactive waste within a designated boundary.

CONTAINMENT, PERIOD OF: The period during the first several hundred years following permanent closure of the geologic repository in which radiation and thermal levels are high and the uncertainties of ensuring repository performance are great. During this time, special emphasis is placed upon the ability to contain the wastes by waste packages within an engineered barrier system.

CONTRACTOR: An organization under contract to provide supplies, construction, or services.

CONTROLLED AREA: The surface location, which is to be marked by suitable monuments, that extends horizontally no more than 5 kilometers in any direction from the outer boundary of the underground facility and the underlying subsurface, which is an area that has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure. The controlled area is also known as the site.

CONVERSION REPORT: A written description of all modifications made to the original code or an externally available existing code after it is acquired.

CORRECTIVE ACTION: Measures taken to rectify conditions that are adverse to quality and, where necessary, to preclude repetition.

CORROBORATIVE DATA: Existing data used to support or substantiate other existing data.

CREDIBLE EVENT OR CREDIBLE ACCIDENT: An event or accident scenario which needs to be considered in the design of a geologic repository.

DESIGN: The act of developing designs for construction or of analyzing the performance of repository engineered structures, systems, components, and natural barriers. Design documentation includes, but is not limited to, drawings, specifications, test plans, design reports, test reports, system design descriptions, configuration status listings, design manuals, and manuals describing computer programs used for design or performance analysis.

DESIGN INPUT: Those criteria, parameters, bases, or other requirements upon which the detailed final design is based.

DESIGN OUTPUT: Documents, such as drawings, specifications, and others that define technical requirements of structures, systems, and components.

DESIGN PROCESS: Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

DEVIATION: A departure from specified requirements.

DISCREPANCY: Condition adverse to quality; reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances.

DISPOSITION: The action taken to resolve a nonconforming condition and to restore acceptable conditions.

DOCUMENT: Any written or pictorial information describing, defining, specifying, reporting or certifying activities, requirements, procedures or results. A document is not considered to be a QA Record until it satisfies the definition of QA Record as defined in this appendix.

DOE: The U.S. Department of Energy or its duly authorized representatives.

ENGINEERED BARRIER SYSTEM: The waste package and the underground facility.

ENGINEERED ITEM: Any structure, system, or component identified in design documents as being a functional part of the completed facility.

EXISTING DATA: Data developed prior to the implementation of a 10 CFR 60, Subpart G, QA program by DOE and its contractors, or data developed outside the DOE repository program, such as by oil companies, national laboratories, universities, or data published in technical or scientific publications. Existing data does not include information which is accepted by the scientific and engineering community as established facts (e.g., engineering handbooks, density tables, gravitational laws.)

EXTERNAL AUDIT: An audit of those portions of another organization's QA program that is neither under the direct control nor within the organizational structure for the auditing organization.

FINAL DESIGN: Approved design output documents and approved changes thereto.

FUNCTIONAL CHARACTERISTICS: Those attributes of a repository or its structures, systems, and components that determine its performance with respect to safety, reliability, operability, and other design criteria established in the Office of Geologic Repositories Program or other Federal regulatory documents.

GEOLOGIC REPOSITORY: A system that is either intended to or may be used for the disposal of radioactive wastes in excavated geologic media. A geologic repository includes the geologic repository operations area and the portion of the geologic setting that provides isolation of the radioactive waste.

GEOLOGIC REPOSITORY OPERATIONS AREA: A high-level radioactive waste facility that is part of a geologic repository, including both surface and subsurface areas, in which waste-handling activities are conducted.

IMPORTANT TO SAFETY: Those engineered structures, systems, and components that are essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure.

IMPORTANT TO WASTE ISOLATION: The barriers that must meet the criteria for long-term performance of the engineered and natural barriers to prevent the release of radionuclides from the site to the accessible environment (i.e., for achieving the postclosure performance objectives in 10 CFR 60, Subpart E.)

INDOCTRINATION: Instruction provided to personnel to familiarize them with programmatic and work-oriented documents applicable to the assigned activity.

INSPECTION: Examination or measurement to verify whether an item or activity conforms to specified requirements.

INSPECTOR: A person who performs inspection activities to verify whether or not an item or activity conforms to specified requirements.

INTERNAL AUDIT: An audit of those portions of an organization's QA program that is retained under its direct control and within its organizational structure.

ISOLATION: Inhibiting the transport of radioactive materials so that amounts and concentrations of this material entering the accessible environment will be kept within prescribed limits.

ITEM: An all-inclusive term that is used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, and prototype hardware. This term includes magnetic media and other materials that retain or support data.

LIFETIME RECORDS: QA records that furnish evidence of the quality and completeness of data, items, and activities affecting quality. All YMP QA records are classified lifetime records.

LOGBOOK: A document that may be used to provide a written record of repetitive activities performed in accordance with technical procedures. Examples include calibration, data runs, inventory of controlled materials, etc.

MATERIAL: A term that includes items plus any hardware or geologic samples either used in or resulting from research and development or site investigations on the YMP. Hardware and geologic specimens include but are not limited to test apparatus or equipment, special nuclear material, cores, geologic samples, water and gas samples, etc.

MEASURING AND TEST EQUIPMENT: Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known.

MODEL: A representation of a physical system, based on scientific principles and laws, that transforms a set of input information or data into another set of output information or data.

NONCONFORMANCE: A deficiency in characteristics, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

NONMECHANISTIC FAILURES: Postulated failures which are not based on previously observed models or mechanisms but which are assumed to provide conservatism in safety assessments.

NUMERICAL METHOD: A procedure for solving a problem primarily by a sequence of arithmetic operations.

NUMERICAL MODEL: A representation of a process or system using numerical methods.

NEVADA TEST SITE SUPPORT CONTRACTOR: Organizations that are directly under contract to DOE/NV for activities at the Nevada Test Site and other locations.

OBJECTIVE EVIDENCE: Any documented statement of fact, other information, or record, either quantitative or qualitative, that pertains to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

OPERATIONS, PERIOD OF: Includes the time during which the emplacement of wastes occurs; any subsequent period before permanent closure during which the emplaced wastes are retrievable; and permanent closure, which includes the sealing of shafts.

OVERVIEW: An analysis and assessment by management of the scope, status, adequacy, and effectiveness of the quality achievement and assurance activities for the YMP. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveys, as appropriate.

OWNER: The person, group, company, agency, or corporation that has or will have title to the repository.

PARTICIPATING ORGANIZATION: This term applies to the following: (1) The government agencies external to the DOE, (2) national laboratories, and (3) organizations participating directly in YMP activities.

PEER: A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work.

PEER REVIEW: A documented, critical review performed by peers who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Peer reviews are in-depth, critical reviews and evaluations of documents, material or data that require interpretation or judgement to verify or validate assumptions, plans, results or conclusions or when the conclusions, material or data contained in a report go beyond the existing state of the art. A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work. In contrast to peer review, the term technical review refers to a review to verify compliance to predetermined requirements, industry standards or common scientific, engineering or industry practice.

PEER REVIEW GROUP: A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed and should vary in size based on the subject matter and importance of the subject matter to safety or waste isolation.

PEER REVIEW REPORT: A documented in-depth report of the proceedings and findings of a peer review.

PERFORMANCE ALLOCATION: This term applies to the process of deriving subsystem and component performance goals from performance objectives. A systematic process of assigning confidence levels with their desired, associated performance goals for the mined geologic disposal systems, subsystems, and components.

PERFORMANCE ASSESSMENT: The process of quantitatively evaluating component and system behavior, relative to containment and isolation of radioactive waste, to determine compliance with the numerical criteria associated with 10 CFR Part 60.

PERFORMANCE CONFIRMATION: The program of tests, experiments, and analyses that will evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objectives for the period after permanent closure will be met.

PERMANENT CLOSURE: The sealing of shafts and boreholes. Permanent closure represents the end of active human intervention with respect to the engineered barrier system.

PRIMARY DATA: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable QA Level I requirements and is necessary for the resolution of the NRC performance objectives of 10 CFR 60 in accordance with the YMP Issues Resolution Strategy. This includes information that has been qualified and accepted in accordance with Project Office AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the YMP QA Program."

PRINCIPAL INVESTIGATOR (PI): The individual who has the technical responsibility for a particular technical task. This responsibility includes, but is not limited to, planning and cost control, the day-to-day technical direction and control of the item or activity, and the assembly of a support team to accomplish the item or activity. This term may be synonymous with task leader or project engineer depending upon the YMP participant.

PROCEDURE: A document that specifies or describes the way in which an activity is to be performed.

PROCUREMENT DOCUMENT: Purchase requisitions, purchase orders, letters of intent, work authorization letters, drawings, contracts, specifications, instructions, or any document that provides a means for acquiring possession or ownership of items or right to the use of services by payment.

PURCHASER: The organization responsible for the establishment of procurement requirements and for the issuance, administration, or both, of procurement documents.

Q-LIST: A list of geologic repository engineered structures, systems, and components that have been determined to be important to safety, and engineered barriers important to waste isolation that must be covered under the QA requirements of 10 CFR 60 Subpart G.

QUALIFICATION (of DATA): A formal process intended to provide a desired level of confidence that data are suitable for their intended use.

QUALIFICATION (PERSONNEL): The characteristics or abilities that are gained through education, training, or experience, which are measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

QUALIFICATION TESTING: Demonstration that an item meets design requirements.

QUALIFIED DATA: Data initially collected under a 10 CFR 60, Subpart G quality assurance program or existing data qualified in accordance with Appendix G of this QA Plan.

QUALIFIED PROCEDURE: An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

QUALITY ACTIVITIES LIST: A list of those major activities conducted during site characterization, construction, operation, or closure that relate to natural barriers important to waste isolation. These activities, which must be covered under the program, include data gathering, performance assessments, and those activities that could affect a natural barrier's ability to isolate waste.

QUALITY ASSURANCE (QA): All those planned and systematic actions that are necessary to provide adequate confidence that the geologic repository and its subsystems or subcomponents will perform satisfactorily in service.

QUALITY ASSURANCE RECORD: An individual document or other item that has been executed, completed, and approved and that furnishes evidence of the (1) quality and completeness of data (including raw data), items, and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents such as plans, correspondence, documentation of telecons, specification, technical data, books, maps, papers, photographs, and data sheets; (5) items such as magnetic media; and (6) other materials that provide data and document quality regardless of the physical form or characteristic. A completed record is a document or item (and documentation) that will receive no more entries, whose revisions would normally consist of a reissue of the document (or documentation), and that is signed and dated by the originator and, as applicable, by approval personnel.

QUALITY ASSURANCE LEVEL I: Those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public. Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10 CFR 60, and 40 CFR 191.

QUALITY ASSURANCE LEVEL II: those activities and items related to the systems, structures, and components which require a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE and YMP concerns, and the environment.

QUALITY ASSURANCE LEVEL III: Those activities and items not classified as QA Levels I or II.

QUALITY ASSURANCE PROGRAM PLAN (QAPP): The document that describes the organizations QA program, the applicable QA requirements, and defines how compliance with the QA criteria will be accomplished.

RADIOACTIVE WASTE: High-level waste (HLW) and other radioactive materials that are received for emplacement in a geologic repository.

READINESS REVIEW: An independent, systematic documented review to determine and inform management of the readiness to advance from one phase, process, or activity into another. Readiness reviews are used to coordinate many elements and provide attention to detail, to assure that the project is ready to proceed to the comprehensive review of a total project or a particular segment of a project.

RECEIVING: Taking delivery of an item at a designated location.

RELIABILITY ANALYSIS: An analysis that estimates the reliability of a system or component.

REPAIR: The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

REPOSITORY: See Geologic Repository Operations Area.

RETRIEVAL: The act of intentionally removing radioactive waste from the underground location at which the waste had been emplaced previously for disposal.

REWORK: The process by which a nonconforming item or activity is made to conform to the original requirements by completion or correction utilizing existing approved procedures.

RIGHT OF ACCESS: The right of a purchaser or designated representative to enter the premises of a supplier for the purpose of inspection, survey, or QA audit.

SCENARIO: An account or sequence of a projected course of action or event.

SCIENTIFIC INVESTIGATION: Any research, experiment, test, study, or activity that is performed for the purpose of investigating the natural barriers or the man-made aspects of the geologic repository, including the overall design of the facilities and the waste package. This will include, but will not be restricted to, all geologic, tectonic, seismologic, hydrologic, climatologic, geochemical, chemical, geophysical, physical, geo-mechanical, mechanical, meteorological, metallurgical, environmental, socioeconomic, and transportation studies of activities that are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation, and closure of the geologic repository.

SCIENTIFIC NOTEBOOK: A document which may be used to provide a written record of the results of scientific investigations and experiments when the work involves a high degree of professional judgment or trial and error methods, or both. These notebooks may be used in lieu of a technical procedure.

SERVICE: The performance of activities that include, but are not limited to, site characterization, design, fabrication, investigation, inspection, nondestructive examination, repair, or installation.

SITE: Location of the controlled area.

SITE CHARACTERIZATION: The program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of parameters of a particular site that are relevant to the procedures under 10 CFR 60. Site characterization includes borings, surface excavations, excavation of exploratory shafts, limited subsurface lateral excavations and borings, and in situ testing at depth as needed to determine the suitability of the site for a geologic repository. It does not include preliminary borings and geophysical testing needed to decide whether or not site characterization should be undertaken.

SOFTWARE: A set of computer operations specified in any programming language that can be translated unambiguously into machine language. (Operations specified in machine language are also software.)

SOFTWARE-DEVELOPMENT LIFE CYCLE: A method of project planning and documentation for the development of a software product. Life cycle allows optimal traceability regarding the goals, restrictions, decisions made, and current progress of a code.

SPECIAL PROCESS: A process, the results of which are highly dependent on the control of the process, the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

SUPPLIER: Any individual or organization under contract to provide items or services to the DOE/NV, to a participating organization, or to an Nevada Test Site support contractor for YMP activities.

SURVEY: The act of monitoring or observing to verify whether or not an item or activity conforms to specified requirements.

TECHNICAL PROJECT OFFICER (TPO): The individual within each YMP participant's organization who has been assigned overall responsibility for the organization's scope or work as detailed in the WBS.

TECHNICAL REVIEW: A documented traceable review performed by qualified personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Technical reviews are in-depth, critical reviews, analyses and evaluation of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness.

TESTING: An element of verification that is used to determine the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

TRACEABILITY: The ability to track the history, application, or location of an item and like items or activities by means of recorded identification.

TRAINING: In-depth instruction provided to personnel to develop and demonstrate initial proficiency in the application of selected requirements, methods, and procedures and to adapt to changes in technology, methods, or job responsibilities.

TRAVELER: A document that accompanies and tracks the progress of an item, sample, or activity.

UNDERGROUND FACILITY: The underground structure, including openings and backfill materials, but excluding shafts, boreholes, and their seals.

UNRESTRICTED AREA: Any area, access to which is not controlled for purposes of protection of individuals from exposure to radiation and radioactive materials, and any area used for residential quarters.

USE-AS-IS: A disposition that is permitted for a nonconforming item or service when it can be established that the item is satisfactory for its intended use.

VALIDATION (QA RECORDS): Validation is the act of reviewing a document or document package to ensure it is complete, authenticated, reproducible, and microfilmable.

VERIFICATION: The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

WAIVER: Documented authorization to depart from specified requirements.

YUCCA MOUNTAIN PROJECT OFFICE: The organization to which the DOE/NV has assigned the responsibility of administering and coordinating the activities of various participating organizations and Nevada Test Site support contractors associated with the YMP.

YUCCA MOUNTAIN PROJECT PARTICIPANTS: An all-inclusive term used to describe (generically) the various organizations involved in the YMP. This term includes the Project Office, participating organizations, and NTS support contractors. These contractors are required to have a Project Office approved QA Program Plan (QAPP) for the conduct of their activities.

YUCCA MOUNTAIN PROJECT PERSONNEL: All DOE participating organizations and Nevada Test Site support contractor personnel involved in YMP activities.

YUCCA MOUNTAIN PROJECT QUALITY ASSURANCE PLAN (QAP): The document that describes the planned, systematic QA requirements that are applicable to the YMP.

YUCCA MOUNTAIN PROJECT WORK BREAKDOWN STRUCTURE (WBS) DICTIONARY: A controlled document which establishes a product-oriented framework for organizing and defining work to be accomplished.

WASTE PACKAGE: The waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.

APPENDIX B

B.0 DESIGN INPUTS

B.1 Introduction

Design inputs include many characteristics and functions of an item or system. For a more detailed discussion on design control activities, see Section 3.

B.2 Applicable Design Inputs

Applicable design inputs are identified and documented, and their selection is reviewed and approved by the responsible design and QA organizations. The purpose of the QA review is to ensure that the documents are prepared, reviewed, and approved in accordance with documented procedures and QA requirements. Changes in approved design inputs, including the reason for the changes, are identified, documented, approved, and controlled by the responsible design organization. Although these inputs vary depending on the application, LANL or its subcontractor will consider the following list of inputs as they apply to specific items or systems of the repository:

- basic functions of each structure, system, and component;
- performance requirements such as capacity rating and system output;
- codes, standards, and regulatory requirements, including the applicable issue, agenda, or both;
- design conditions such as pressure, temperature, fluid chemistry, and voltage;
- loads such as seismic, wind, thermal, and dynamic;
- environmental conditions anticipated during storage, construction, and operation, including pressure, temperature, humidity, corrosiveness, site elevation, wind direction, nuclear radiation, electromagnetic radiation, and duration of exposure;
- interface requirements, including definition of the functional and physical interfaces involving structures, systems, and components;
- material requirements, including such items as compatibility, electrical insulation properties, protective coating, and corrosion resistance;
- mechanical requirements such as vibration, stress, shock, and reaction forces;
- structural requirements covering such items as equipment foundations and pipe supports;
- hydraulic requirements such as pump net positive suction heads, allowable pressure drops, and allowable fluid velocities;
- chemistry requirements, including provisions for sampling and limitations on water chemistry;

- **electrical requirements such as source of power, voltage, raceway requirements, electrical insulation, and motor requirements;**
- **layout and arrangement requirements;**
- **operational requirements under various conditions, including repository start-up, normal repository operation, repository emergency operation, special or infrequent operation, system abnormal or emergency operation, and repository decontamination, decommissioning, and dismantling;**
- **instrumentation and control requirements, including indicating instruments, controls, and alarms required for operation, testing, and maintenance (other requirements such as the type of instrument, installed spares, range of measurement, and location of indication are included);**
- **access and administrative control requirements for repository security;**
- **redundancy, diversity, and separation requirements of structures, systems, and components;**
- **requirements for failure effects of structures, systems, and components, including a definition of those events and accidents that these structures, systems, and components must be designed to withstand;**
- **test requirements, including preoperational and subsequent periodic in-service tests and the conditions under which these tests will be performed;**
- **accessibility, maintenance, repair, and in-service inspection requirements for the repository, including the conditions under which these inspections will be performed;**
- **personnel requirements and limitations, including the qualification and number of personnel available for repository operation, maintenance, testing, and inspection, and radiation exposures to the public and repository personnel;**
- **transportability requirements, including size and shipping weight, limitation, and Interstate Commerce Commission regulations;**
- **fire protection or resistance requirements;**
- **handling, storage, cleaning, and shipping requirements;**
- **other requirements to prevent undue risk to the health and safety of the public;**
- **materials, processes, parts, and equipment suitable for application;**
- **safety requirements for preventing injury to personnel, including radiation safety to restrict the use of dangerous materials, escape provisions from enclosures, and grounding of electrical systems;**
- **quality control and QA requirements;**

- reliability requirements of structures, systems, and components, including their interactions, which may impair functions that are important to safety;
- interface requirements between repository equipment and operation and maintenance personnel; and
- requirements for criticality control and accountability of nuclear materials.

APPENDIX C

**C.0 REQUIREMENTS FOR THE QUALIFICATION OF INSPECTION
AND TEST PERSONNEL**

LANL does not currently conduct any YMP activities to which these requirements apply.

APPENDIX D

**D.0 REQUIREMENTS FOR THE QUALIFICATION OF NONDESTRUCTIVE
EXAMINATION PERSONNEL**

LANL does not currently conduct any YMP activities to which these requirements apply.

APPENDIX E

E.0 LIST OF TYPICAL QA RECORDS

Following is a list of typical LANL-YMP QA records. The YMP retention period for these records is defined as lifetime. QA records shall be specified, prepared and maintained in accordance with QAPP Section 17 and the LANL QPs. In addition, the control of QA records shall comply with the applicable requirements of Project Office AP 1.7Q, "Yucca Mountain Project QA Records Management."

E.1 Site Characterization

- Surveys of the underground facility excavations, shafts, and boreholes referenced to readily identifiable surface features.
- Description of the materials encountered.
- Geologic maps and geologic cross section.
- Locations and amounts of seepage.
- Instrument locations, readings, analysis, and reports for in situ testing.
- Technical specifications.
- Sample extraction location maps.
- Site Characterization Report.
- Environmental Assessment.
- Peer review documentation.
- Test plans and procedures, and results.
- Data reduction, evaluations, analyses, and reports for:
 - Geomorphology.
 - Stratigraphy.
 - Tectonics.
 - Seismicity.
 - Geoengineering.
 - Hydrology.
 - Geochemistry.
 - Climatology and Meteorology.
- Environmental Impact Statement.
- Environmental Report.

E.2 Design Records

- Applicable codes and standards used in design.
- Design drawings.
- Design calculations and records of checks.
- Approved design change requests.
- Design deviations.
- Design reports.
- Design verification data.
- Design specifications and amendments.
- Safety analysis report.
- Stress reports for code items.
- Systems descriptions.
- Systems process and instrumentation diagrams.
- Technical analysis, evaluations, and reports.

E.3 Procurement Records

- Procurement specifications.
- Purchase order including amendments.

E.4 Manufacturing Records for Procured Equipment

- Applicable code data reports.
- As-built drawings and records (Note: As-built drawings and records shall correctly identify the installed condition of the item. The type of as-built drawings and records to be maintained shall be specified).
- Certificate of compliance.

E.5 Installation and Construction Records

E.5.1 Receiving and Storage - Nonconformance Reports

E.5.2 General

- **Scientific investigation planning documents.**
- **Quality assurance level assignment documents.**
- **Review and approval documents including comments and resolution.**
- **Data interpretation and analysis documents.**
- **Software configuration management including software quality assurance requirements in accordance with Section 3.3 of this Quality Program**
- **Scientific notebooks and logbooks.**
- **Detailed technical procedures.**
- **Audit and survey documentation.**
- **Verification documentation.**
- **Recommendations.**
- **Close-out verification.**
- **Personnel qualification documents.**
- **Peer reviews.**
- **Design analysis.**
- **Design change control.**
- **Anomalous conditions encountered.**
- **Nonconformance reports.**
- **Corrective Action reports.**
- **Audit reports.**
- **Trending reports.**

APPENDIX F

F.0 REQUIREMENTS FOR THE QUALIFICATIONS OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL

F.1 Introduction

All LANL YMP activities are subject to scheduled and planned internal and external audits to ensure that procedures and activities comply with the overall QA program and to determine the program's effectiveness. This appendix provides requirements for the qualification of lead auditors. A lead auditor organizes and directs audits, reports audit findings, and evaluates corrective actions. This appendix also provides amplified requirements for the qualifications of individuals, hereinafter referred to as auditors, who participate in an audit, including technical specialists, management representatives, and auditors-in-training.

F.1.1 Qualification of Auditors

LANL and its subcontractor will establish the qualifications for audit personnel and the requirements for the use of technical specialists to accomplish the auditing of QA programs. Personnel selected for QA auditing assignments will have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors will either have or will be given appropriate training or orientation to develop their competence to perform required audits. The competence of personnel to perform the various auditing functions will be developed by one or more of the methods listed below.

F.1.1.1 Orientation

Orientation will provide a working knowledge and understanding of this document and procedures used by LANL and its subcontractor for implementing audits and reporting results.

F.1.1.2 Training Programs

Training programs will provide general and specialized instruction in audit performance. General training will include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training will include methods of examining, questioning, evaluating and documenting specific audit items and methods of closing audit findings.

F.1.1.3 On-the-Job Training

On-the-job training, guidance, and counseling will be under the direct supervision of the lead auditor. Such training will include planning, performing, reporting, and follow-up action involved in conducting audits.

F.1.2 Qualification of Lead Auditors

An individual will meet the requirements listed below before being designated a lead auditor.

F.1.2.1 Communication Skills

The prospective lead auditor will have the capability to communicate effectively, both orally and in writing. These skills will be attested to in writing by LANL.

F.1.2.2 Training

Prospective lead auditors will have training to the extent necessary to ensure their competence in auditing skills. Training will be given in the following areas based upon management evaluation of the particular needs of each prospective lead auditor:

- knowledge and understanding of this document, 10 CFR 60, and other nuclear and/or DOE-related codes, standards, regulations, and regulatory guides, as applicable to the YMP;
- general structure of QA programs and applicable elements as defined in this document;
- auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items and procedures for closing out audit findings;
- audit planning in the functions related to quality for the following activities: site characterization (scientific investigations), design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility.
- on-the-job training, including applicable elements of the audit program.

F.1.2.3 Audit Participation

The prospective lead auditor will have participated in a minimum of five QA audits within a period of time not to exceed three years before the qualification date. One of the audits will be a nuclear QA audit that will be made within the year before qualification.

F.1.2.4 Examination

The prospective lead auditor shall pass an examination that shall evaluate his comprehension of and ability to apply the body of knowledge identified in Paragraph F.1.2.2 of this appendix. The test may be oral, written, practical, or any combination of the three types. If any portion of the examination is oral, written documentation of the oral examination questions/content shall be maintained. The development and administration of the examination shall be in accordance with Paragraph F.3 of this appendix.

F.2 Maintenance of Qualification

F.2.1 Maintenance of Proficiency

Lead auditors will maintain their proficiency through regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to a QA program and program auditing; and participation in training programs. Based on an annual assessment, LANL may extend the qualifications, require retraining, or require requalification. These evaluations will be documented.

F.2.2 Requalification

Lead auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. Requalification will include retraining in accordance with the requirements of Subsection F.1.2.2 of this appendix, re-examination in accordance with Subsection F.3.2 of this appendix, and participation as an auditor in at least one nuclear facility QA audit.

F.3 Administration

F.3.1 Organizational Responsibility

Training of auditors will be LANL's responsibility. LANL or its subcontractor will select and assign personnel who are independent of any direct responsibility for the performance of the activities that they will audit. The lead auditor will, before commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

F.3.2 Qualification Examination

The development and administration of the examination for a lead auditor required by Subsection F.1.2.4 of this appendix is LANL's responsibility. LANL may delegate this activity to an independent certifying agency but will retain responsibility for the examination and its administration for conformance to this document. The integrity of the examination will be maintained by LANL or by a certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. LANL will retain copies of the objective evidence regarding the type or types and content of the examination or examinations.

F.4 Certification of Qualification

Each lead auditor will be certified by LANL as being qualified to lead audits. As a minimum, this certification will document the following:

- the employer's name;
- the lead auditor's name;
- the date of certification or recertification;

- the basis of qualification (i.e., education, experience, communication skills, training, and examination); and
- the signature of LANL's designated representative who is responsible for such certification.

APPENDIX G

G.0 REQUIREMENTS FOR QUALIFICATION OF EXISTING DATA NOT GENERATED UNDER A QA PROGRAM MEETING THE REQUIREMENTS OF 10 CFR 60, SUBPART G

G.1 General

This appendix provides the requirements for the qualification for existing data that will be needed to support a license application, which have not been initially generated under a QA Program meeting the requirements of 10 CFR 60, Subpart G.

G.2 Methods for Qualification of Existing Data

Four methods or combinations of methods are acceptable for the process of qualifying existing data:

- The execution of the peer review process in accordance with the requirements of Appendix J of this QAPP.
- The use of corroborating data which are defined as existing data used to support or substantiate other existing data. Inferences drawn to corroborate the existing data shall be clearly identified, justified, and documented. The level of confidence associated with corroborating data is related to the quality of the program under which it developed and the number of independent data sets. The amount of corroborating data needed shall be dealt with on a case-by-case basis in the documented reviews for qualifications.
- The use of confirmatory testing which is defined as testing conducted under a 10 CFR 60, Subpart G QA program which investigates the properties of interest (e.g., physical, chemical, geologic, mechanical) of an existing data base. One example of confirmatory testing is testing conducted under the same environmental conditions and with similar or the same procedures, test material, and equipment as the original test which generated the existing data. Another type of confirmatory testing is testing conducted by different test methods and equipment but which still investigates the same parameter of interest. The amount of confirmatory testing required shall be dealt with on a case-by-case basis in the documented reviews for qualification.
- Demonstrating that the existing data were collected under a QA program which is equivalent to a 10 CFR 60, Subpart G QA program.

G.3 Selection and Documentation of Qualification Methodology

When the methods indicated in the last 3 bullets of Section 2 are utilized to qualify existing data, a technical review shall be conducted to support the quality of the data. Additional confidence/credibility can be achieved when a combination of methods is used.

Documentation of the decision process shall provide an auditable trail of all factors used in arriving at the choice of the qualification method(s), and the decision as to the qualification of the existing data. The level of confidence in the existing data shall be

commensurate with the intended use of the data. Attributes which shall be considered in the qualification process are:

- Qualifications of personnel or organizations generating the data are comparable to qualification requirements of personnel generating similar data under the approved 10 CFR 60, Subpart G program.
- The technical adequacy of equipment and procedures used to collect and analyze the data.
- The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).
- The environmental conditions under which the data were obtained if germane to the quality of data.
- The quality and reliability of the measurement control program under which the data were generated.
- The extent to which conditions under which the data were generated may partially meet Subpart G.
- Prior uses of the data and associated verification processes.
- Prior peer or other professional reviews of the data and their results.
- Extent and reliability of the documentation associated with the data.
- Extent and quality of corroborating data or confirmatory testing results.
- The degree to which independent audits of the process that generated the data were conducted.
- The importance of the data to showing that the proposed repository design meets the performance objectives of 10 CFR 60, Subpart E.
- Replication of test results.

Note: Additional guidance related to this subject can be found in NUREG-1298 "QUALIFICATION OF EXISTING DATA FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES" (February, 1988).

APPENDIX H

H.0 REQUIREMENTS FOR COMPUTER SOFTWARE

H.1 Objectives and Scope

The purpose of this appendix is to describe the requirements for the development, management, control, and documentation of the software used to support the LANL YMP. The software requirements of this appendix are intended to ensure software quality and to provide the NRC with part of the basis on which it will evaluate the soundness of the software used.

This appendix supplements and shall be used in conjunction with Section 3.3 of the QAPP. Appendix A contains the definitions for the terms used in this appendix.

The requirements set forth in this appendix apply to computer software used to produce or manipulate data that is used directly in site-characterization and performance assessment analyses and in the design, analysis, and operation of repository structures, systems, and components. LANL shall prepare QPs that assure the requirements of this appendix are implemented in a consistent and systematic manner. The extent to which these requirements apply is related to the nature, complexity, and importance of the software applications and are defined in LANL's Software QA Plan.

H.2 Verification and Validation

Verification and validation methodologies will be described in the Software QA Plan (SQAP). QPs will be used to implement the chosen methodology. Verification and validation of software shall be performed before the use of such software to perform technical calculations in support of site-characterization, performance assessment analyses, and the design, analysis, and operation of repository structures, systems, and components. In those cases where this requirement cannot be met, the portion or portions of software that have not been verified or validated shall be identified and controlled. In all cases, the verification and validation of software shall be completed before relying on the software to support the license application.

H.2.1 Software Verification

Verification plans shall use methods such as analyses, demonstrations, and test runs to ensure that the software adequately and correctly performs all intended functions and provide confidence that it does not perform any function that, either by itself or in combination with other functions, could degrade the entire system.

Verification activities shall be performed according to QPs and performed relative to specific hardware configurations prior to the use of the software in support of the license application. The amount of verification activity shall be determined by the type and complexity of the software. The results of verification shall be documented according to the QP.

H.2.2 Model Validation

Model validation activities shall be performed according to QPs and will demonstrate that the models embodied in computer software are adequate representations of the process or system for which they are intended. Validation shall be accomplished by comparing software results with verified and traceable data obtained from laboratory experiments, field experiments or observations, or in situ testing. Specific sets of data used in the validation process shall be identified, and justification for their use shall be documented. When data are not available from the sources mentioned above, alternative approaches may be used and shall be documented. Alternative approaches may include peer review and comparisons with the results of similar analyses performed with verified software. The results of model validation, including an evaluation of the degree of validity of the model, shall be documented in accordance with the QP.

Model validation shall be accomplished prior to the use of the software-generated data in final reports used for licensing. Data generated prior to model validation may be used in reports with the designation that the data was generated using models that have not been validated.

H.3 Software Configuration Management

A software configuration management system shall be described in the SQAP with implementation direction contained in QPs to ensure positive identification of software and control of all software baseline changes and provide appropriate documentation to the YMP local records center.

H.3.1 Configuration Identification

Software configuration baseline items shall be identified at the appropriate phase of each code's software life cycle. Approved changes in a baseline shall be added to the baseline as updates. A baseline and its updates shall specify the most recent software configuration. A labeling system for configuration items shall be implemented that

- uniquely identifies each software configuration item or version identifier,
- identifies changes in software configuration items by revision identifiers, and
- facilitates placement of the software configuration item in a relationship with other configuration items.

H.3.2 Configuration Change Control

Changes in software configuration items shall be formally controlled and documented. This documentation shall contain a description of the change, the identification of the originating organization, the rationale for the change, and the identification of affected baselines and software configuration items. The change will be formally evaluated by a qualified individual or organization with the ability to approve or disapprove the proposed change. Assurance shall be provided that only authorized changes are made in software baselines and software configuration items.

H.3.3 Configuration Status Accounting

The information needed to manage software configuration items shall be recorded and reported. This information shall include the approved configuration identification,

the status of formal proposals for changes in software configuration items, the implementation status of approved changes, and all information to support the functions of configuration identification and configuration control.

H.4 Discrepancy Reporting and Corrective Action

QPs shall be prepared to describe the software discrepancy and corrective action reporting system. This discrepancy reporting system shall be integrated with the configuration management system to ensure formal processing of discrepancy resolutions.

Software discrepancy procedures shall ensure that, as a minimum,

- . defects are documented and evaluated for possible corrective action,
- . defects are assessed for impact on previous applications,
- . corrections are reviewed and approved before changes in software configuration items are entered in baselines, and
- . preventive and corrective actions provide for appropriate notification of organizations to which controlled copies have been distributed.

H.5 Media Control and Security

Physical media containing the images of software shall be physically protected to prevent their inadvertent damage, degradation, or loss.

H.6 Software Acquisition, Procurement, and Transfer

Procedures shall be established for controlling the acquisition or procurement of computer software from an outside organization and for the transfer of computer software to an outside organization.

Software requests by LANL groups shall include appropriate criteria to enable the software received to comply, as much as possible, with the requirements of this QAPP. Requirements not satisfied at the time the software is received shall be completed by the organization in the appropriate phase of the applicable software life cycle. For those requirements that are not satisfied, the reasons shall be documented and distributed to the users.

Configuration management requirements shall apply to acquired or procured software using the product originally received as the initial baseline. Configuration management records shall document any conversions, modifications, configuration changes, or additional software needed to make the software functional.

Configuration management change controls shall be established for documenting the conversion of software to be used on a computer system, and/or peripheral hardware, other than that for which it was designed. Conversion includes all modifications and tests made to input/output or the source code or additional software written to run the original software on the new system. Software conversion shall be documented and maintained for the specific version of the software and the computer system on which it is installed. Software conversion changes shall be evaluated and activities performed in accordance with the appropriate configuration management system elements.

H.7 Software Quality Assurance Plan

A LANL SQAP shall be prepared that describes the software design, test and configuration management system for software used to support the design of a geologic repository. This description shall provide criteria for the application of Appendix H requirements, based on the complexity and importance of the software used; indicate the methods used to develop computer program requirements and translate those requirements into a detailed design and executable code; describe the documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use; state the methodology for establishing a software baseline and change control system, which includes change control tracking throughout the life of the software; describe the process used for verification and validation of the software developed; and identify procedures used for reporting and documenting software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determination of the appropriate corrective actions.

The LANL SQAP shall identify the:

- organizational responsibilities for the management, application, control, and acquisition of software, and the interfacing of these activities,
- software products to which the SQAP applies,
- software development life cycle model used, including documentation.
- minimum required documentation,
- software configuration management system used,
- verification and validation methodologies, and
- software review procedures and the attendant documentation.

H.8 Software Life Cycle

Each LANL group shall use the life cycle controls below.

LANL shall adhere to a software life cycle model that requires that software development or acquisition proceed in a traceable, planned, and orderly manner. The relative emphasis placed on the phases of the software life cycle will depend on the nature, complexity, importance, and intended application of the software.

Documentation is required as defined in this portion of the appendix and described in the SQAP. All software documentation is considered to be a QA record.

Documentation produced during software development, acquisition, implementation, testing, and use shall receive the appropriate reviews as described in the SQAP.

Reviews of software life cycle activities shall be performed, as applicable, for each life cycle phase completed. The QPs used for reviews shall identify the reviewers and their responsibilities.

The documentation for all reviews shall contain a record of review comments and the personnel responsible for comment resolution. After review comments have been resolved, the approved documents shall be updated and placed under configuration management.

The following are the life cycle elements that shall apply, as appropriate for the software, as defined, interpreted, and described in the LANL SQAP.

H.8.1 Life Cycle Requirements Phase

During this phase, requirements that pertain to functionality, performance, design constraints, attributes, and external interfaces of the completed software shall be specified, documented, and reviewed. These requirements include the following characteristics:

- format and language that is understood by the programming organization and the user,
- enough detail to allow for objective verification,
- adequate definition to provide for the response of the software to the identified input data, and
- the information necessary to design the software without prescribing the software design itself.

Software requirements documentation shall outline the requirements that the software must fulfill. A specific capability of software should be referred to as a requirement only if its achievement can be verified by a prescribed method. The requirements shall address the following, as applicable to the software application:

- functionality—the functions the software is to perform;
- performance—the time-related issues of software operation such as speed, recovery time, and response time;
- design constraints imposed on implementation—any elements that will restrict design options;
- attributes—non-time-related issues of software operation such as portability, correctness, security, and maintainability; and
- external interfaces—interactions with other participants, hardware, and other software.

The review of software requirements is performed at the completion of the software requirements documentation. This review shall ensure that the requirements are complete, verifiable, and consistent. The review shall also ensure that sufficient detail is available to facilitate definition of the software design or acquisition.

H.8.2 Life Cycle Design Phase

During the design phase, a software design based on the requirements shall be specified, documented, and systematically reviewed. The design specifies the overall structure (control and data flow) and the reduction of the overall structure to physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation.

Verification activities during this phase consist of, but are not limited to

- the planning for design-based test cases,
- the review and analysis of the software design, and
- the verification of the software design.

Software design documentation shall address the following, as applicable to the software application:

- a description of the major components of the software design as they relate to the requirements of the software requirements specification;

- a technical description of the software with respect to control flow, data flow, control logic, and data structure;
- a description of the allowable and tolerable ranges for inputs and outputs;
- the design described in a manner that is easily traceable to the software requirements; and
- a description of life cycle verification activities.

The software design review shall be held at the completion of the software design documentation. This review includes an evaluation of the technical adequacy of the design approach and ensures that the design satisfies all the requirements in the requirements documentation. Depending on the complexity of the software design, the design may require multiple design reviews.

H.8.3 Life Cycle Coding Phase

During this phase, the design is translated into a programming language and the software is debugged. Only minor design issues, if any, should be resolved at this phase.

Verification activities during this phase shall consist of

- the possible modification of test cases necessitated by design changes made during coding and
- the examination of source code listings to ensure adherence to coding standards and conventions.

Software coding documentation shall address the following, as applicable:

- source code listings,
- revised requirements documents, and
- revised design documents.

Any design changes made in the requirements and design phase documents shall be assessed to determine the impact on the design. The revised requirements and design phase documents shall be reviewed at the same review level as that performed for the original documents.

The software coding phase review is an evaluation to determine that the requirements and design specifications are implemented in the completed code. The review is conducted prior to verification and validation.

H.8.4 Life Cycle Testing Phase

The testing phase consists of verification activities. Software verification will be essentially completed during this phase. The verification activities include

- execution of the test cases and evaluation of the results,
- evaluation of the completed software to ensure adherence to the requirements, and
- preparation of a report describing the results of software verification.

Life cycle testing activities shall be documented. Software testing documentation includes a plan that describes the tasks and criteria for accomplishing the verification of the software in this phase. The documentation also specifies the hardware and system

software configuration(s) for which the software is designed. In those cases where testing is used to ensure that requirements have been met in the software design, test documentation shall provide traceability from requirements to design as implemented in the code. This documentation also includes a report on the results of the execution of the life cycle verification activities. The report includes the results of all previous reviews, audits, and tests, and a summary of the status of the software.

Model validation will be conducted in accordance with Section H.2.2 of this appendix. Because model validation is dependent on application, model validation may not be completed at this stage.

The software testing review is an evaluation of the adequacy of completed software life cycle verification activities and model validation plans. The review results in an approval of verification and validation documentation.

H.8.5 Life Cycle Installation and Checkout Phase

During this phase, the software may become part of a system that incorporates other software components, hardware, and production data. The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating data bases, and verifying that all components have been included.

Testing activities during this phase shall consist of the execution of test cases for installation and integration. Test cases from earlier phases may be used for installation testing.

H.8.6 Life Cycle Application and Maintenance Phase

During the application and maintenance phase, the software is approved for operational use. Further activities may consist of maintenance of the software to identify and remove latent errors (corrective maintenance), response to new or revised requirements (perfective maintenance), or adaptation of the software to changes in the software environment (adaptive maintenance). Software modifications shall be approved, documented, tested, and controlled in accordance with software configuration management requirements. User notification of changes and corrections is a vital aspect of the maintenance phase.

LANL shall establish procedures for controlling the application of software that performs technical calculations in support of site characterization and performance assessment analyses and for the design, analysis, and operation of repository structures, systems, and components. These software applications shall be reviewed and approved to ensure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.

LANL shall include in QPs, methods for documenting software applications that perform technical calculations to ensure that these applications and the results of these applications may be independently reproduced.

Procedures shall be established for reviewing these applications to provide reasonable assurance that the software used is appropriate for the intended application and that the results produced are accurate. Documentation appropriate for a given application or analysis shall include the computer code, the input data, the assumptions

or approximations used to develop the input data, and appropriate user documentation for performing the application or analysis.

H.9 Mandatory Documentation

The following documentation is mandatory as applicable to the particular software and is maintained as a QA record (reference Section 3.3.1):

- software summary form,
- software requirements,
- software design and change,
- software verification and validation,
- continuing documentation and code listings,
- mathematic and numerical models,
- user's manual,
- code assessment and support, and
- configuration management support.

Mandatory documents shall be reviewed in accordance with LANL review procedures. These documents shall comply with the documentation requirements of NUREG-0856.

APPENDIX I

1.0 REQUIREMENTS FOR THE IDENTIFICATION OF ITEMS AND ACTIVITIES TO BE INCLUDED ON THE Q-LIST

1.1 Introduction

This appendix provides requirements for the identification of items important to safety and the identification of items and activities important to waste isolation. These items and activities are subject to the highest quality assurance level (QA Level I) of this QAPP, and shall be listed on a "Q-List."

The Project Office will prepare the appropriate AP or APs for determining the items and activities to be placed on the "Q-List." This procedure will describe the Probabilistic Risk Assessment (PRA) techniques and performance allocation methods used for identifying Q-listed items and activities.

1.2 Quality Assurance Criteria for Licensing

The purpose of the geologic repository program is to permanently dispose of high-level nuclear waste. In order to obtain a license for receipt and possession of radioactive material at the geologic repository, it must be demonstrated that the repository system will function as required to protect health and safety of the public and the environment. Requirements for licensing a repository to meet this goal are specified in 10 CFR Part 60. These requirements describe the performance objectives and other technical criteria to assure safe operation during waste emplacement and retrieval (if necessary), as well as effective containment and long-term isolation of waste following permanent closure of the geologic repository. The QA Level I requirements of this QA Plan specify the QA program for those items and related activities important to safety and/or waste isolation to assure that their characterization, design, construction, and operation comply with the requirements of 10 CFR Part 60.

1.2.1 Criteria for the Q-List and Quality Activities List

The QA Level I requirements of this QA Plan apply to items and activities important to safety and/or waste isolation. As derived from 10 CFR Part 60 (60.152), this QA program is based on the 18 criteria of 10 CFR Part 50 Appendix B. These criteria address, in general terms, the basic elements of a QA program, such as organization, design control, test control, inspection, and records management. As noted in 10 CFR 60.152, these criteria are supplemented as necessary to meet the specific requirements of the repository program. In addition to the QA Level I requirements of this QAPP, items important to safety and the waste package are subject to the design criteria of 10 CFR 60.131(b) and 60.135, respectively.

1.2.2 Criteria for Non-Q-List Items

Certain items that are not important to safety and/or waste isolation shall also be addressed in the license application to demonstrate compliance with 10 CFR Part 60 requirements such as those associated with meeting the design criteria in 10 CFR 131 (a) for protection of worker health safety. While these items are not subject to the QA Level I requirements of this QA Plan, QA Level II requirements shall be applied. Additional guidance related to this subject can be found in NUREG-1318, (April, 1988), paragraph 5.1(b).

1.2.3 Data Not Collected Under a 10 CFR 60 Subpart G QA Program

All data collection, interpretations, analyses, and other work to be used to support findings related to "important to safety" and/or "waste isolation" in the licensing process shall be technically and procedurally defensible. "Existing data" shall be qualified in accordance with the requirements of Appendix G of this QAPP. In addition to existing data, some materials that may be important to safety and/or waste isolation may already have been purchased prior to implementation of a 10 CFR 60 Subpart G QA Program. Supporting documentation on these materials (e.g., the technical specifications and QA records) shall be reviewed to determine whether they meet the technical and QA requirements for their designated function. If not, they shall be "qualified" for use to assure they will perform their intended function.

1.3 Identification of Items Important to Safety

Items important to safety are those items essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of unrestricted area at any time until the completion of permanent closure (10 CFR 60.2). The 0.5 rem value is, therefore, the threshold for determining what structures, systems, and components shall be on the Q-list as items important to safety. The rationale for placing a system, structure, or component on the Q-list is to provide added assurance, via application of rigorous QA/QC and design requirements, that they should perform their designated function.

Probabilistic Risk Analysis (PRA) shall be used to the extent practicable, to support the identification of structures, systems, and components important to safety in the license application. Use of this approach for the operations phase of the high-level waste program is consistent with the approach prescribed by the Environmental Protection Agency standard (40 CFR Part 191) for the overall system containment following emplacement of waste in a geologic repository. In cases where data are limited, engineering judgment and conservative bounding assumptions shall be used. Conservative assumptions shall include non-mechanistic failures where information and/or experience are not adequate to reliably determine failure modes and accident scenarios. However, non-mechanistic failures need not be considered where failure modes and mechanisms are understood and failure rates can be determined.

Operator actions or errors which could initiate accidents shall be identified in PRAs or other analysis. These shall be controlled to minimize the probability of occurrence. Other activities which are subject to QA Level I requirements, such as designing, inspecting, and purchasing, will not be identified in PRAs but shall be controlled in accordance with QA Level I requirements.

PRAs shall utilize the following techniques:

System modeling to depict the combination of safety function and system successes or failures which constitute accident scenarios. Two modeling techniques which may be used are event tree analysis, which identifies the sequence of events that may result in an accident, and fault tree analysis, which determines how failures in safety systems may occur. Both techniques are analytical tools which organize and characterize potential accidents in a methodical manner.

An event tree defines a comprehensive set of accident sequences that encompasses the effects of all realistic and physically possible potential accidents. By definition, an initiating event is the beginning point in the sequence. Hence, a comprehensive list of accident-initiating events shall be compiled to ensure that the event trees properly depict all important sequences.

The fault tree examines the various ways in which a system designed to perform a safety function can fail. Each safety system identified in the event tree as involved in an accident shall be examined to determine how failures of components within that system could cause the failure of the entire system.

If failure of a mitigating system should contribute to an offsite dose, individual components within the mitigating system shall be reviewed, using fault tree analysis, to determine the effect of their failure on performance of the overall system. For example, individual components in the ventilation system which may need to be analyzed include dampers, motors, and filters.

Consequence analysis of accident scenarios identified in event/fault tree analyses to determine the amount and kind of radionuclides which may reach the unrestricted area and contribute to an off-site dose. Consequence analysis includes identification of a source term for radioactive releases and evaluation of mechanisms for movement and deposition of radioactive materials released from the high-level waste facility. The energy, magnitude, and timing of radiological releases resulting from various accidents shall be considered in this analysis.

Analysis to assess the effect of uncertainties in the data base and uncertainties arising from modeling assumptions on the PRA findings. The insights gained in the analysis about features that are significant contributors to risk can provide qualitative understanding into system performance.

Additional guidance related to the assessment of pre-closure accidents can be found in NUREG 1318, (April, 1988), paragraph 5.2(a).

1.3.1 Redundancy

The use of redundant structures, systems, and components is a method of providing additional assurance that necessary safety functions will be performed if an accident occurs and that the accident dose limit will not be exceeded. In a redundant system, the failure of one train of the system shall not comprise or prevent the associated safety function from being performed. For the high-level waste repository, 10 CFR 60 [60.131(b) (5) (ii)] addresses requirements for redundancy. The items needed to provide redundancy of items important to safety shall also be on the "Q-list."

1.3.2 Use of Previously Established Guidelines and Standards

Many guidelines and standards have been developed in the nuclear power reactor program and other nuclear programs which may be applicable for the geologic repository program. For example, there are regulatory guides covering design basis earthquakes, floods, and tornado wind velocities which may be used in the design of the HLW facility and developing the Q-list. While some of these guidelines and standards may not be directly applicable to a geologic repository, they shall be considered to the extent practicable, to eliminate the need to develop new approaches.

1.3.3 Retrieval

The option for retrieval of waste is addressed as a performance objective in 10 CFR 60.111(b). If retrieval is found to be necessary, analyses of retrieval operations shall be conducted at that time, to identify Q-list items.

1.4 Identification of Items and Activities Important to Waste Isolation

The term "important to waste isolation" refers to engineered and natural barriers that will be relied on to meet the containment and isolation performance objectives of 10 CFR 60 Subpart E. Four of the performance objectives for waste isolation after permanent closure are stated in 10 CFR 60.112 and 60.113 and include:

- ground water travel time
- waste package containment period
- maximum yearly release rate from the engineered barrier system
- the overall system performance objective in 10 CFR 60.112 for release of radioactive materials to the accessible environment (the Environmental Protection Agency standard in 40 CFR Part 191).

The items and activities important to waste isolation shall include:

- Components of the engineered barrier system relied on to meet the performance objectives.
- Elements of the natural barrier system (e.g., host rock, and geochemical retardation characteristics) relied on to meet the performance objectives.
- Activities necessary to demonstrate that the performance objectives will be met, including collection of data to characterize the site or performance of engineered barriers.
- Activities in the preclosure phase that could affect post-closure performance.

The broad performance objectives for waste isolation provide some flexibility in allocating credit among the various components of the natural and engineered barrier systems to meet each objective. For example, a 300 to 1,000 year lifetime for the waste package might be achieved by a combination of performance from each of the components in the waste package or by a single component, such as the canister. The allocation of performance among the various components of the natural and engineered barrier system for each performance objective will provide the basis for determining which barriers are important to waste isolation. Performance assessments shall be conducted on these barriers to ascertain that those relied on will meet the waste isolation and containment performance objectives of 10 CFR Part 60. The initial allocations of performance will provide a basis for determining what site characterization testing will be needed. The initial allocations of performance among the barriers is likely to change based on the results of performance assessments using data collected during site characterization.

It is expected that most of the data collected during the site characterization phase can potentially be used in the license application performance assessments. During the early phase of characterization in particular, when little is known about the site and the importance of data characterizing it, data collection activities shall be controlled in accordance with the QA Level I requirements of this QAPP. However, there may be cases where it is known that data are not needed for performance assessments, or will be duplicated later in accordance with QA Level I requirements of this QAPP and therefore would not have to be performed in accordance with QA Level I requirements at this time. For example, scoping tests or tests to examine the feasibility and appropriateness of a data collection technique may not need to be performed in accordance with the QA Level I requirements of this QAPP.

Note: Additional guidance related to this subject can be found in NUREG-1318, "TECHNICAL POSITION ON ITEMS AND ACTIVITIES IN THE HIGH-LEVEL WASTE GEOLOGIC REPOSITORY PROGRAM SUBJECT TO QUALITY ASSURANCE REQUIREMENTS" (APRIL 1988).

APPENDIX J

J.0 REQUIREMENTS FOR PEER REVIEW

J.1 Introduction

This appendix provides the requirements regarding the applicability of peer reviews, the structure of peer review groups, acceptability of peers, and the conduct and documentation of peer reviews.

J.2 Applicability of Peer Review

A peer review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and waste isolation cannot otherwise be established through testing, alternate calculations or reference to previously established standards and practices.

In general, the following conditions are indicative of situations in which a peer review shall be considered.

- Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.
- Decisions or interpretations having significant impact on performance assessment conclusions will be made.
- Novel or untried testing, plan, procedure, and/or analyses are or will be utilized.
- Detailed technical criteria or standard industry procedures do not exist or are being developed.
- Results of tests are not reproducible or repeatable.
- Data or interpretations are ambiguous.
- Data adequacy is questionable—such as, data may not have been collected in conformance with an established QA program.

A peer review shall be used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means.

J.3 Structure of Peer Review Group

The number of peers comprising a peer review group shall vary commensurate with the following:

- the complexity of the work to be reviewed,

- its importance to establishing that safety or waste isolation performance goals are met,
- the number of technical disciplines involved,
- the degree to which uncertainties in the data or technical approach exist, and
- the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.

The collective technical expertise and qualifications of peer review group members shall span the technical issues and areas involved in the work to be reviewed, including any differing bodies of scientific thought. The potential for technical or organizational partiality shall be minimized by selecting peers to provide a balanced peer review group. Technical areas more central to the work to be reviewed shall receive proportionally more representation in the peer review group.

J.4 Acceptability of Peers

The technical qualification of the peer reviewers in their review areas, shall be at least equivalent to that needed for the original work under review and shall be the primary consideration in the selection process. Each peer shall have recognized and verifiable technical credentials in the technical area that the peer has been selected to review.

Members of the peer review group shall be independent of the original work to be reviewed. Independence in this case means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed. In some cases (i.e., funding considerations) it may be difficult to meet the independence criteria without reducing the technical quality of the peer review. When the independence criteria cannot be met, a documented rationale shall be included in the peer review report.

J.5 Peer Review Process

Since the peer review process may vary from case to case, a peer review plan shall be prepared prior to initiating a peer review. The peer review plan shall describe the work to be reviewed, the size and spectrum of the peer review group, and the suggested method and schedule necessary to produce a peer review report.

The peer review group shall evaluate and report on:

- validity of assumptions,
- alternate interpretations,
- uncertainty of results and consequences if incorrect,
- appropriateness and limitations of methodology and procedures,
- adequacy of application,
- accuracy of calculations,
- adequacy of requirements and criteria, and
- validity of conclusions.

Documentation shall be prepared to indicate the results of meetings, deliberations, and activities of the peer review process.

J.6 Peer Review Report

A report documenting the results of the peer review shall be prepared and issued under the direction of the peer review group chairperson. The report shall be signed by each peer review group member. The peer review report shall include the following:

- a clear description of the the work or issue that was peer reviewed;
- conclusions reached by the peer review process;
- individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate; and
- listing of the peers and the technical qualification and evidence of independence for each peer, including potential technical and/or organizational partiality.

Note: Additional guidance related to this subject can be found in NUREG-1297, "PEER REVIEW FOR HIGH LEVEL NUCLEAR WASTE REPOSITORIES" (FEBRUARY 1988).

APPENDIX K

K.0 FORMAT AND CONTENT REQUIREMENTS FOR SITE CHARACTERIZATION PLAN STUDY PLANS

K.1 Purpose and Objectives of Studies

- Describe the information that will be obtained in this study. Briefly discuss how this information will be used.
- Provide the rationale and justification for the information to be obtained by the study. The study plan can be justified by (1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the Site Characterization Plan); (2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); and (3) direct Federal, State, and other regulatory requirements for specific studies. Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and that higher level goal.

K.2 Rationale for Selected Study

- Provide the rationale and justification for the selected tests and analyses (including standard tests). Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitations of the various options; and
- Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). This rationale should also identify reasonable alternatives; summarize reasons for not selecting these alternatives, and reference, if available, reports which evaluate alternatives considered.
- Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. Factors to be considered include:
 - potential impacts on the site from testing;
 - whether the study needs to simulate repository conditions;
 - required accuracy and precision of parameters to be measured with test instrumentation;
 - limits of analytical methods that will use the information from the tests;
 - capability of analytical methods to support the study;

- time required versus time available to complete the study;
- the scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field;
- interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and
- interrelationships involving significant interference among tests and exploratory shaft facility design and construction, as appropriate (refer to Section 8.4 of the Site Characterization Plan or its references for specific exploratory shaft facility design information).

K.3 Description of Tests and Analyses

- Because studies comprise tests and analyses, provide the following for each type of test:
 - Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g., spatial location relative to the site, exploratory shaft facility elements, repository layout, stratigraphic units, depth, and test location).
 - Summarize the test methods. Reference any standard procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA Level L. Reference the applicable specific QA requirements that will be applied to the test.
 - Specify the tolerance, accuracy, and precision required in the test, where appropriate.
 - Indicate the range of expected results of the test and the basis for those expected results.
 - List the equipment required for the test and describe briefly any such equipment that is special.
 - Describe techniques to be used for data reduction and analysis of the results.
 - Discuss the representativeness of the test including why the test results are considered representative of future conditions or the spatial

variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results.

- Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests
- Show the relationship of the test to the set performance goals and confidence levels.

• For each type of analysis, do the following:

- State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels.
- Describe the methods of analysis including any analytical expressions and numerical models that will be employed.
- Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA Level L. Reference the applicable QA requirements.
- Identify the data input requirements of the analysis.
- Describe the expected output and accuracy of the analysis.
- Describe the representativeness of the analytical approach (e.g., with respect to spatial variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.

K.4 Application of Results

- Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies).
- For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the Site Characterization Plan) that will use the information produced from the studies described above, and refer to any use of the results for model validation.
- For design uses, refer to, or describe, where the information from the study described above will be used in construction equipment design and development, and engineering system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals).

- For characterization uses, refer to, or describe, where the information from the study described above will be used in planning other characterization activities.

K.5 Schedule and Milestones

- Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing, data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities.
- Describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study.
- Dates for activities or milestones including durations and interrelationships, for the study plans will be provided. These should reference the master schedules provided in Section 8.5 of the Site Characterization Plan.