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Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME I

CONTENTS

QUALITY ASSURANCE PROCEDURES (QP)

NOTE: Please note that the table of contents now reflects new procedural alpha numeric designators. As each procedure is revised, the new designator will be used and ultimately the old designator will be completely removed.

Present Designations	Title	New Designations
TWS-MSTQA-QP-02, R10	Quality Assurance Program Index	Index to be Eliminated
TWS-QAS-QP-02.1, R0	NNWSI Personnel Selection, Training, and Certification	
TWS-QAS-QP-03, R7	Document Control Procedures	TWS-QAS-QP-06.X, R0
TWS-QAS-QP-04.1, R0	NNWSI Procurement Procedures	
TWS-QAS-QP-05.1, R1	Preparation of Quality (Administrative) Procedures	
TWS-QAS-QP-05.2, R0	Preparation of a Detailed Technical Procedure	
TWS-QAS-QP-07, R2	Procedure for Technical Review of Publications	TWS-QAS-QP-03.X, R0
TWS-QAS-QP-09, R0	Records Control Procedure	TWS-QAS-QP-17.1, R0
TWS-MSTQA-QP-10, R0	Document Control of the Exploratory Shaft Test Plan	TWS-QAS-QP-03.X, R0
TWS-MSTQA-QP-11, R1	NNWSI Surveillance Procedure	TWS-QAS-QP-18.2, R0

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Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME I

QUALITY ASSURANCE PROCEDURES (QP) - Concluded

Present Designations	Title	New Designations
TWS-QAS-QP-12.1, R1	NNWSI Instrument Calibrations	
TWS-QAS-QP-13.1, R0	Handling, Storage, and Shipping Procedure	
TWS-MSTQA-QP-14, R1	Research and Development (Experimental) Procedure	TWS-QAS-QP-03.X, R0
TWS-MSTQA-QP-16, R0	NNWSI Control of Nonconformances	TWS-QAS-QP-15.X, R0
TWS-QAS-QP-17, R0	NNWSI QA Audits	TWS-QAS-QP-18.1, R0
TWS-QAS-QP-17.1, R0	Records Management Procedure (Draft QAL Manuals)	
TWS-MSTQA-QP-18, R1	Assignment of Quality Levels for Los Alamos NNWSI Activities and Items	TWS-QAS-QP-02.X, R0
TWS-MSTQA-QP-19, R0	NNWSI Change Requests	TWS-QAS-QP-06.X, R0
TWS-QAS-QP-21, R0	Corrective Action	TWS-QAS-QP-16.X, R0
TWS-QAS-QP-22, R0	NNWSI Supplier Qualification	TWS-QAS-QP-07.X, R0

CHANGE REQUESTS (CR)

CR No. 007	Modifies QP-12,R0 (CR in front of QP)
CR No. 008	Modifies QP-06,R2 (CR in front of QP)
CR No. 009	Modifies QP-18,R1 (CR in front of QP)
CR No. 011	Modifies QP-12,R0 (CR in front of QP)
CR No. 012	Modifies QP alpha numeric code (CR in front of Volume I Table of Contents)
CR No. 013	Modifies QP-16,R0
CR No. 019	Modifies QP-14, R1 (CR in front of QP)
CR No. 024	Modifies QP-16, R1 (CR in front of QP-16, R1)
CR No. 026	Modifies QP-19,R0 (CR in front of QP)

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME II

CONTENTS

DETAILED PROCEDURES (DP)

Isotopic Nuclear Chemistry DPs

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME II

DETAILED PROCEDURES (DP) - Continued

TWS-INC-DP-62, R1	Bulk NTS Well Water Samples
TWS-INC-DP-63, R0	Preparation of NTS Core Samples for NNWSI Crushed Rock Experiments
TWS-INC-DP-65, R0	Procedure for Volcanism Field Studies

Health, Safety, and Environmental Division DPs

TWS-HSE5-DP-201, R0	Air Particulate Sample Preparation Procedure for SEM Evaluation
TWS-HSE5-DP-202, R0	Operating Instructions for Amray Model 1000 Scanning Electron Microscope and Kevex Model 7000 Energy Dispersive X-Ray Analyzer for Evaluation of Air Samples Collected on Nuclepore Filters
TWS-HSE5-DP-206	Fiber Counting Procedure
TWS-HSE5-DP-211, R0	Preparation and use of Air Particulate Filter Sampling Devices
TWS-HSE5-DP-212, R0	Preparation, Calibration, and use of Cascade Impactors
TWS-HSE5-DP-213, R0	Procedure For The Calibration and Use of SKC Personal Sampling Pumps
TWS-HSE5-DP-214, R0	Procedures For The Calibration and Use of Alpha-1 Personal Sampling Pumps
TWS-HSE5-DP-215, R0	Procedures For The Calibration of The Singer Dry Gas Meter

WX-Design Engineering Division DPs

TWS-WX-DP-59, R0	NNWSI Exploratory Shaft Facility Design Control Procedure

CHANGE REQUESTS (CR)

CR No. 006	Modifies DP-35,R0 (CR in front of DP)
CR No. 025	Modifies TWS-INC-DP-35, R0 (CR in front of DP-35, R0)

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME III

CONTENTS

EARTH AND SPACE SCIENCES DPS

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME III

EARTH AND SPACE SCIENCES DPs - Concluded

ENVIRONMENTAL SCIENCE

CHANGE REQUESTS (CR)

QUALITY ASSURANCE PROGRAM INDEX OF PROCEDURES FOR LOS ALAMOS NNWSI PROJECT

This index is prepared and maintained in accordance with TWS-MSTQA-QP-02.

Section No.	Title	NNWSI Procedure Reference
1.	Organization	
2.	Quality Assurance Program	LANL-NNWSI-QAPP Sections 1 and 2. TWS-MSTQA-QP-02 TWS-QAS-QP-02.1 TWS-MSTQA-QP-18
3.	Design Control	LANL-NNWSI-QAPP Section 3. TWS-WX-DP-59
4.	Procurement Document Control	LANL-NNWSI-QAPP Section 4. TWS-QAS-QP-04.1 TWS-QAS-QP-22
5.	Instructions, Procedures, and Drawings	LANL-NNWSI-QAPP Section 5. TWS-QAS-QP-03 TWS-QAS-QP-05.1 TWS-QAS-QP-05.2 TWS-MSTQA-QP-07 TWS-MSTQA-QP-09 TWS-MSTQA-QP-11 TWS-QAS-QP-12.1 TWS-QAS-QP-13.1 TWS-MSTQA-QP-14 TWS-MSTQA-QP-15 TWS-INC-WP-12 TWS-ESS-DP-01 TWS-INC-DP-02 TWS-ESS-DP-03 TWS-ESS-DP-04 TWS-CNC-DP-05

* Procedures affected by this issue have been underscored.

Section No.	Title	NNWSI Procedure Reference
5.	Instruction, Procedures, and Drawings (continued)	TWS-ESS-DP-06
		TWS-ESS-DP-07
		TWS-ESS-DP-09
		TWS-ESS-DP-10
		TWS-ESS-DP-11
		TWS-CNC-DP-14
		TWS-CNC-DP-15
		TWS-ESS-DP-16
		TWS-CNC-DP-17
		TWS-CNC-DP-18
		TWS-ESS-DP-20
		TWS-CNC-DP-22
		TWS-CNC-DP-23
		TWS-ESS-DP-24
		TWS-ESS-DP-25
		TWS-INC-DP-26
		TWS-INC-DP-27
		TWS-ESS-DP-28
		TWS-INC-DP-30
		TWS-INC-DP-34
		TWS-INC-DP-35
		TWS-INC-DP-36
		TWS-INC-DP-37
		TWS-INC-DP-38
		TWS-INC-DP-39
		TWS-INC-DP-40
		TWS-INC-DP-41
		TWS-INC-DP-42
		TWS-INC-DP-43
		TWS-INC-DP-44
		TWS-INC-DP-45
		TWS-ESS-DP-50
		TWS-ESS-DP-51
		TWS-ESS-DP-52
		TWS-ESS-DP-53
		TWS-ESS-DP-54
		TWS-ESS-DP-55
		TWS-ESS-DP-56
		TWS-WX-DP-59
		TWS-INC-DP-60
		TWS-INC-DP-61
		TWS-INC-DP-62
		TWS-INC-DP-63
		TWS-INC-DP-65
		TWS-INC-DP-101
		TWS-ESS-DP-102
		TWS-ESS-DP-103
		TWS-ESS-DP-105
		TWS-ESS-DP-106

* Procedures affected by this issue have been underscored.

Section No.	Title	NNWSI Procedure Reference
5.	Instruction, Procedures, and Drawings (concluded)	TWS-ESS-DP-107 TWS-ESS-DP-110 TWS-ESS-DP-111 TWS-ESS-DP-112 TWS-ESS-DP-113 TWS-INC-DP-114 TWS-ESS-DP-115 TWS-HSE5-DP-201 TWS-HSE5-DP-202 TWS-HSE-5-DP-206 TWS-HSE5-DP-211 TWS-HSE5-DP-212 TWS-HSE5-DP-213 TWS-HSE5-DP-214 TWS-HSE5-DP-215 TWS-HSE12-DP-301
6.	Document Control	LANL-NNWSI-QAPP Section 6. TWS-MSTQA-QP-03 TWS-QAS-QP-07 TWS-MSTQA-QP-10 TWS-MSTQA-QP-19
7.	Control of Purchased Items and Services	LANL-NNWSI-QAPP Section 7. TWS-QAS-QP-04.1
8.	Identification and Control of Items	LANL-NNWSI-QAPP Section 8.
9.	Control of Processes	LANL-NNWSI-QAPP Section 9. TWS-MSTQA-QP-14
10. & 11.	Inspection and Test and Control	LANL-NNWSI-QAPP Sections 10 & 11. TWS-MSTQA-QP-11 TWS-MSTQA-QP-14
12.	Control of Measuring and Test Equipment	LANL-NNWSI-QAPP Section 12. TWS-QAS-QP-12.1, R1

* Procedures affected by this issue have been underscored.

Section No.	Title	NNWSI Procedure Reference
13.	Handling, Storage, and Shipping	LANL-NNWSI-QAPP Section 13. TWS-QAS-QP-13.1
14.	Inspection, Test, and Operating Status	LANL-NNWSI-QAPP Section 14.
15.	Control of Nonconforming Items	LANL-NNWSI-QAPP Section 15. TWS-MSTQA-QP-16
16.	Corrective Action	LANL-NNWSI-QAPP Section 16. TWS-QAS-QP-21
17.	Quality Assurance Records	LANL-NNWSI-QAPP Section 17. TWS-MSTQA-QP-03 TWS-QAS-QP-17.1
18.	Audits	LANL-NNWSI-QAPP Section 18. TWS-QAS-QP-17

* Procedures affected by this issue have been underscored.

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 026

Date April 19, 1988

Procedure No. TWS-MSTOA-QP-19, R0

Change Requested:

(1) Replace 4.4 with the following:

4.4 Reviews for change requests (CRs) to quality procedures (QPs) shall be conducted as reviews for the original QPs--that is, the draft CR will be submitted to the Quality Assurance Liaisons for review and comment. The review, comment, and resolution process shall be accomplished and documented by using the Document Review Sheet or its equivalent. After comments have been returned and resolved, each individual who has made comments will be sent a copy of their comments showing the resolutions. The original Document Review Sheets will be retained in the Quality Assurance Support file and will be submitted to the Records Processing Center as a permanent Nevada Nuclear Waste Storage Investigations (NNWSI) Project record. The requestor shall sign the revised CR before it is transferred to the Quality Assurance Project Leader and Technical Project Officer for review and approval. The approved CR shall be issued in accordance with NNWSI Controlled Document distribution procedures.

(2) Replace Attachment 2 with the form labeled "Los Alamos National Laboratory NNWSI Change Request."

Reason for Change:

(1) This change will bring the CR review and approval requirements in line with the same requirements for QP review and approval.

(2) This form is being changed to follow the change in the text.

Change Requested By Patricia M Tillery **Date** 4/19/88

Reviewed By Henry Paul Haines **Date** 4/19/88

QAPL Approval Karen A West **Date** 4/25/88

TPO Approval D T Oakley **Date** 4/25/88

Effective Date April 25, 1988 **Date** 4/25/88

LOS ALAMOS NATIONAL LABORATORY
QUALITY ASSURANCE PROGRAM PLAN
FOR
NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS

Effective Date 4/25/88

H. P. Nunes
Quality Assurance Support

04/21/88
Date

K. A. West (Acting)
Quality Assurance Project Leader

4/22/88
Date

D. T. Oakley
Technical Project Officer

4/25/88
Date

POLICY

The Los Alamos National Laboratory (LANL) considers quality assurance (QA) an essential element of the Nevada Nuclear Waste Storage Investigations (NNWSI) Project. LANL will implement sound QA practices as necessary for its contribution toward obtaining a Nuclear Regulatory Commission (NRC) license for the geologic repository. It is the responsibility of each person working on the Project 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 implement and apply the QA requirements to the technical activities of the LANL NNWSI Project. Activities shall be planned, implemented, and maintained as required by this QAPP and shall consistently address the requirements of the NNWSI QA Plan.

D T Oakley 4-25-88

TPO, D. T. Oakley

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(concluded)

LIST OF FIGURES

LIST OF TABLES

LIST OF ACRONYMS

A	Analysis Division
AP	Administrative Procedure
ASTM	American Society of Testing and Material
CAR	Corrective Action Request
CDR	Conceptual Design Report
DOE	Department of Energy
DP	Detailed Technical Procedure
EPA	Environmental Protection Agency
ESS	Earth and Space Sciences Division
FDC	Functional Design Criteria
HSE	Health, Safety, and Environmental Division
INC	Isotope and Nuclear Chemistry Division
LANL	Los Alamos National Laboratory
LS	Life Sciences
NBS	National Bureau of Standards
NCR	Nonconformance Report
NDE	Nondestructive Examinations
NNWSI	Nevada Nuclear Waste Storage Investigations
NPSH	Net Positive Suction Heads
NRC	Nuclear Regulatory Commission
NTS	Nevada Test Site
OCRWM	Office of Civilian Radioactive Waste Management
OGR	Office of Geologic Repositories
PI	Principal Investigator
PM	Project Management
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
QASC	Quality Assurance Support Contractor

QP	Quality Procedure
RMS	Records Management System
RPC	Records Processing Center
SIP	Scientific Investigation Plan
T&MSS	Technical and Management Site Support
TPO	Technical Project Officer
WBS	Work Breakdown Structure
WMPO	Waste Management Project Office
WX-4	Technical Engineering Support

1.0 ORGANIZATION

1.1 Los Alamos National Laboratory Nevada Nuclear Waste Storage Investigations 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 Nevada Nuclear Waste Storage Investigations (NNWSI). Activities affecting quality include both technical activities and QA functions. The technical organizations are responsible for performing technical activities according to detailed technical procedures (DPs). 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 Quality Assurance Project Leader (QAPL) is delegated the authority of establishing the QAPP and directing the QA program delineated therein. The LANL QAPL may delegate to other LANL participants, contractors, 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 and inspection activities are conducted by the Quality Assurance Support (QAS) contractor. The TPO is responsible to the WMPO 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 is responsible for seeing that the management and coordination of LANL activities are consistent with the goals and objectives of the overall DOE NNWSI Project, including planning, technical direction, cost, and schedule control.

The TPO provides overall management of the NNWSI Project at Los Alamos, including

- the interaction between LANL and other Office of Civilian Radioactive Waste Management (OCRWM) Program participants by representing Los Alamos at Project Management (PM)/TPO meetings and through communications with other NNWSI Project participants;
- LANL management support for cost, schedule, and performance measurement, as well as the tracking of deliverables and milestones established by the NNWSI Project to ensure that program goals are being implemented at Los Alamos;
- the preparation of comments on DOE, Nuclear Regulatory Commission (NRC), and Environmental Protection Agency (EPA) reports as requested by the DOE/WMPO; 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 is 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 will 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 and provide technical interfaces between the NNWSI Project 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 is 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 and provide technical interfaces between the NNWSI Project 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 the responsibilities for satisfying all technical and quality assurance requirements of the LANL NNWSI Project. The PI may delegate tasks to contributing investigators as necessary, but the PI maintains overall responsibility for the task. The PI is responsible for all efforts required to

- prepare Scientific Investigation Plans (SIPs);
- identify and prepare the DPs;
- ensure that the LANL NNWSI QA program requirements are included in the DPs, purchase requisitions, and SIPs;
- conduct technical reviews of the milestones and final reports;
- interface with the LANL QAS to resolve quality concerns and coordinate the QAS/QAL audits and surveys; and

- ensure that contributing investigators comply with the LANL NNWSI Project technical and QA requirements.

1.2 Quality Assurance Functions

The 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 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 is controlled until the unsatisfactory condition has been corrected. Their responsibilities include the authority to stop unsatisfactory work through established channels. Such persons have direct access to responsible management, which is 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 LANL QAPL is assigned the responsibility and authority to direct and manage the LANL NNWSI QA program. The QAPL is a LANL staff member with management and QA knowledge and experience. The QAPL is not 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 NNWSI organization.

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

The QAPL responsibilities include

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

1.2.1.2 Other Dedicated Quality Assurance Positions

The QAS and Quality Assurance Liaisons (QAL) also have effective communication channels with other management positions. The QALs have the responsibility and

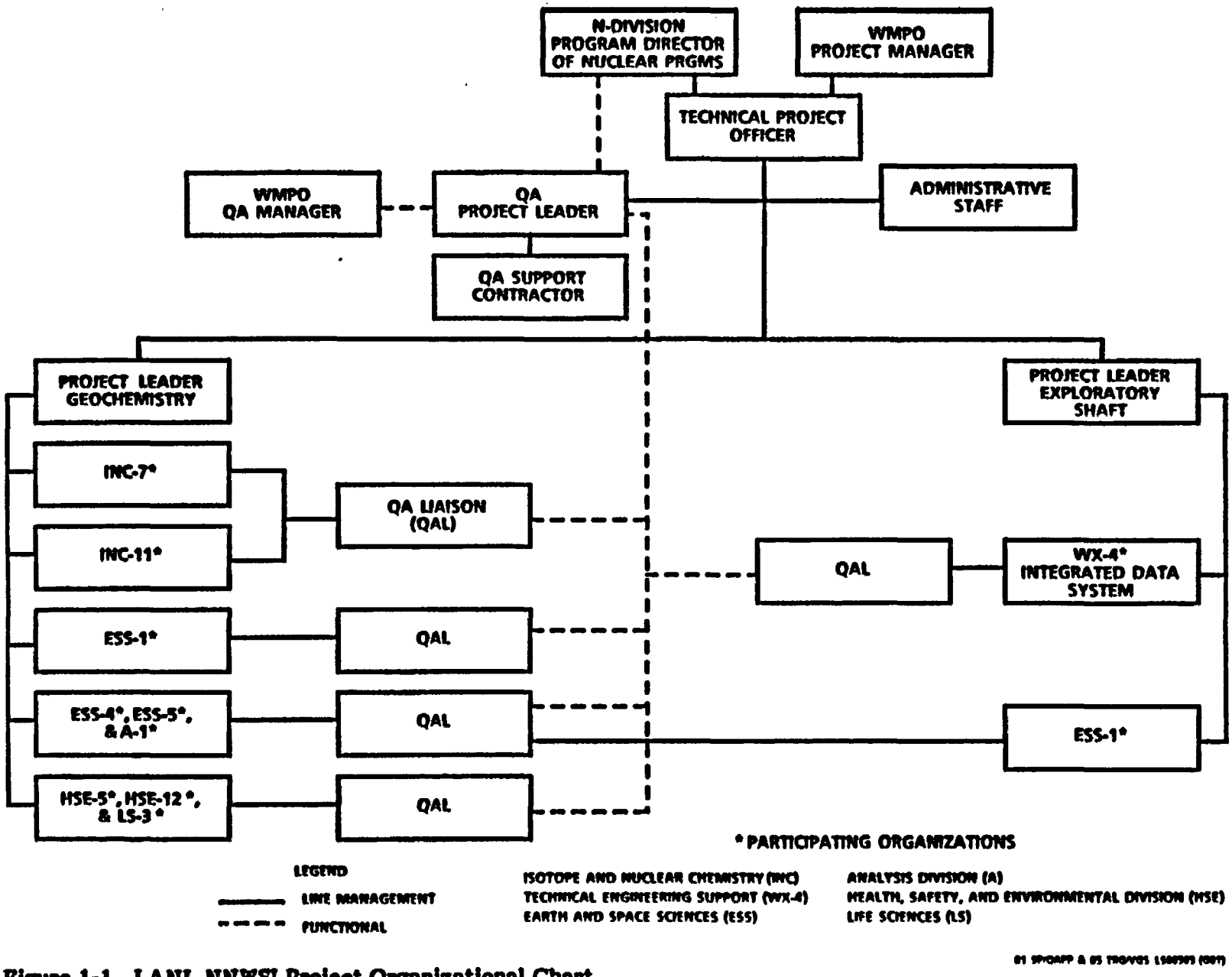

Figure 1-1. LANL NNWSI Project Organizational Chart

authority to verify the adequacy and effectiveness of QA plans, QA requirements, and QA program implementation. In addition, the QALs are not assigned duties that prevent full attention to QA responsibilities or that conflict with the reporting and resolution of QA issues and problems.

QAS responsibilities include

- issuing, revising, and controlling the distribution of the LANL Quality Assurance Manual (i.e., when changes occur in policies, practices, or the organization or when technical processes change or are added to the Project);
- ensuring that quality assurance records, which provide objective evidence of the quality of items/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, surveys, and management reviews; issuing stop-work orders, as necessary; and stopping the continuation of unsatisfactory work;
- verifying that interface requirements between the LANL organizations and LANL subcontractors have been appropriately specified and maintained; and
- training LANL QALs in appropriate administrative procedures and orienting the LANL NNWSI staff to QAPP requirements.

QAL responsibilities include

- establishing appropriate levels of quality for all NNWSI Project items/activities in accordance with LANL procedures,
- training technical personnel in appropriate administrative procedures, and
- ensuring that subtier interface requirements are appropriate for the assigned quality level.

1.2.2 QA Organizational Structure

The structure of the NNWSI Project 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 of assignments have been established to achieve, maintain, and verify quality. Organizations assigned QA functions will have the organizational freedom and authority to accomplish the assigned functions.

1.3 Achievement, Maintenance, and Verification of Quality

Quality is achieved and maintained by those performing work. Quality achievement is verified by persons or organizations not directly responsible for performing the work. Individuals or groups within the QA organization will verify conformance with established requirements (unless specifically exempted elsewhere in this QAPP).

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 subtier organization is involved in activities affecting quality, the responsibility and authority of each organization for interface are clearly established and documented, and any shared responsibilities are defined and documented. The interfaces between internal LANL organizations are documented within this QAPP. To support these interfaces, required interface documentation is defined within the implementing procedures. The NNWSI Project administrative procedures (APs) provide the implementing interface controls used by LANL. The LANL implementing procedures describe the methods of conducting and documenting interorganizational interfaces.

The interface between LANL and the WMPO is through the TPO. The SIPs are used to define interface responsibilities for scientific activities external to LANL. For NNWSI activities internal to LANL, interface responsibilities are either between the TPO and PI or specified by written directives.

TABLE 1-1

DIVISION OF LANL NNWSI QUALITY ASSURANCE RESPONSIBILITIES[a]

Function[b]	QAPL	QAS	QAL
Liaison with WMPO QA	X (lead)	X	
Coordination of program QA document review [WMPO APs, DOE orders, and NRC guidance]	X		
Project representative to QA steering committee	X		
Maintenance and distribution of DOE and NRC requirements	X (lead)	X	
Development of LANL quality procedures (QPs)		X	
Approval of QPs	X	X (lead)	X (review and comment)
Development of DPs with PIs		X	X (lead)
Approval process of DPs	X	X	X (lead)[c]
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 (NRCs) 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	X (lead)		X

TABLE 1-1

DIVISION OF LANL NNWSI QUALITY ASSURANCE RESPONSIBILITIES[a]
(continued)

Function[b]	QAPL	QAS	QAL
Selection and qualification of contractors or vendors		X	X (lead)
Response to LANL audits and surveys	X (lead)[d]		
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 WMPO approval of QALAs	X		
Design control			X
QA review and approval of procurement documents			X
Approval of sample identification, handling, storage, and control			X
Establishment of controls for measuring equipment		X	X
Approval of controls for measuring equipment	X		
Administration of measuring equipment system		X	
Inspection of new purchases related to quality activities			X
LANL NNWSI QA training	X (lead)	X	X
Conflict resolution	X[e]		

TABLE 1-1

DIVISION OF LANL NNWSI QUALITY ASSURANCE RESPONSIBILITIES[a]
(concluded)

Function[b]	QAPL	QAS	QAL
Maintenance of documents before transfer to the LANL Records Processing Center (RPC)	X	X	X
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 will play a major role in all QA functions for the LANL NNWSI Project.

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 coordinates all reviews and approvals.

d. The QAPL compiles the responses to external audits and surveys with substantial input from the QAS and QAL.

e. The QAPL is responsible for resolving quality-related conflicts that have not been resolved at lower levels. Any person involved in the NNWSI Project may appeal a dispute over QA to the LANL TPO. The QAPL may elevate unresolved conflicts to the Project Quality Manager (PQM) at the WMPO. QA personnel can elevate unresolved conflicts through the QAPL to the Program Director of Nuclear Programs at LANL and the PQM at WMPO.

2.0 QUALITY ASSURANCE PROGRAM

2.1 Basic Requirements of the Los Alamos National Laboratory Nevada Nuclear Waste Storage Investigations Quality Assurance Program

LANL's QA program is based on the contents of the LANL QAPP, which is approved by WMPO, and the LANL implementing procedures. The implementing procedures provide and implement control over activities affecting quality. The QAPP and implementing procedures will be applied in a way that is consistent with the importance of the activity. This QAPP applies to all items and activities important to repository licensing, safety, and waste isolation.

This QAPP complies with the requirements of WMPO NNWSI-NVO-196-17, Nevada Nuclear Waste Storage Investigations Project Quality Assurance Plan (QAP). The LANL NNWSI Project and subtier activities are carried out in accordance with this QAPP and LANL implementing procedures. Both WMPO and TPO signoffs of this QAPP are required before its implementation.

This QAPP applies to all LANL activities associated with the NNWSI Project, including nuclide migration studies; geochemistry; mineralogy; petrology studies; and Exploratory Shaft (ES) planning and design review for ES construction, technical direction, and the ES testing program. LANL also provides assistance in accordance with this QAPP to other project organizations in areas of specialized expertise as directed by Waste Management Project Office (WMPO).

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

- Activities affecting quality are planned and documented to ensure a systematic approach. Planning results in the documented identification of methods and organizational responsibilities. Planning is begun as early as practicable and is completed no later than the start of those activities.

- Activities affecting quality are 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 ensurance that all prerequisites for the given activity have been satisfied.

- Procedures for activities affecting quality will specify any special controls, processes, test equipment, tools, and technical skills necessary to achieve the required quality for that activity.

- Procedures for activities affecting quality will specify the means to verify quality by inspection, test, peer reviews (WMPO directed), technical review, or a combination of these.

- All LANL NNWSI Project personnel performing activities affecting quality will be trained in both technical and QA requirements of their assigned task; QA auditors are trained and qualified in accordance with NNWSI Project requirements. Project personnel will be certified, and the certification will be documented.

- LANL NNWSI Project management will assess the adequacy and implementation of this QAPP regularly and will formally report the results on an annual basis.

- LANL participants are responsible for interfaces with other NNWSI major participants as specified in the Work Breakdown Structure (WBS). These responsibilities are outlined in Section 1 (LANL NNWSI QAPP).

2.1.1 Verification of the Quality Assurance Program Plan

The QAPL or his appointee will conduct internal audits of all phases of the application of this QAPP for all LANL NNWSI activities affecting quality. These internal audits will assess the continuing implementation, effectiveness, compliance, and adequacy of the QA program.

2.1.2 Use of Data Not Generated Under Quality Assurance Controls

For use in licensing activities, the QA program for the LANL NNWSI Project provides primary data or primary data interpretations that were not generated under the NNWSI Project QA controls. Specific methods for acceptance of this information are in WMPO NNWSI APs. These methods apply to the following types of data:

- primary data or primary data interpretations and reports that were generated by LANL or LANL's subcontractors for the NNWSI Project before August 1980 (QAP, Rev 0);

- primary data from reports, books, and theses generated by non-NNWSI Project participants; and

- primary data or data interpretations from a technical journal.

2.1.3 Q-List

The Q-List is a list of geologic repository structures, systems, components, and activities that have been determined to be important to safety or waste isolation, or both, and are thereby subject to the highest QA level (QA Level I) of the NNWSI QA program.

At this time, LANL does not have prime responsibility for any Q-List items. If LANL becomes responsible for such items, a procedure will be generated to define the determination and documentation of such items.

2.1.4 Approach to Quality Assurance

The NNWSI Project uses an approach to QA, known as the graded approach, that recognizes the differences between items and activities that affect radiological health and safety and those that do not. 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 process, and operability and maintainability of the repository, including its costs and schedules. LANL or WMPO will 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 WMPO approval before work begins on the item or activity.

2.2 Application of Graded Quality Assurance

2.2.1 Extent of Application

Graded QA applies throughout the life of the NNWSI Project in accordance with the established policies, procedures, and instructions and controls activities affecting quality of the identified structures, systems, and components to an extent consistent with their importance. The QAPP applies 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.

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

2.2.2 Method of Application

Graded QA in the LANL NNWSI Project is applied according to a LANL implementing procedure, which defines the responsibility, method, and criteria for assigning and documenting QA levels to the LANL activities and items involved in the NNWSI Project. This procedure ensures that

- all NNWSI activities and items affecting quality are evaluated for QALA;
- QA levels are assigned in a manner consistent with the WMPO APs and the NNWSI Project QAP;
- the justification for the QALA is documented; and
- once a QALA has been made, it will be applied equally to the particular item or activity associated with the QALA by any participant involved therein.

The LANL QAPP applies to QA Levels I and II. Good engineering and scientific practices 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 WMPO.

QA Level I is the most stringent level and will 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 EPA. QA Level I control and documentation is applied to all activities (i.e., those activities involving near-term safety and long-term isolation) specifically concerned with the protection of the public's health and safety with respect to radiological hazards. Therefore, QA Level I will be applied to

- items or activities that affect preclosure radiological health and safety of the general public;
- items or activities that provide site-characterization data;

- items or activities that affect the retrievability of waste up to the time of repository closure;
- items or activities that provide the primary data used to support public radiological health and safety issues for a license application; and
- items or activities whose failure would cause the failure of a QA Level I item, irretrievable loss of a QA Level I item, or irretrievable loss of QA Level I data.

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.

QA Level II is the second most stringent level and will 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 will be applied to items and activities that could have a major impact on the nonradiological health and safety of the public and repository worker and items and activities whose failure would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10 CFR 20. Additionally, activities that have a major impact on Project costs or schedules, which delay the achievement of DOE/Office of Geologic Repositories (OGR) milestones, will be controlled as QA Level II.

2.3 Management Assessment

Management assessments are conducted at least annually to verify that the QA program is being effectively implemented; that the system and management control, which are 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 are performed and reported in accordance with WMPO directives, which include the minimum requirements for planning, organizing, performing, and documenting the results.

The assessment procedure will specify that results be analyzed for quality trends and that reports and recommendations be tracked. Copies of the LANL management assessment report will be transmitted to the WMPO Project Manager and WMPO PQM.

2.4 Personnel Orientation and Training Procedures

LANL has established requirements for the orientation and training of personnel performing or verifying activities that affect quality. Position descriptions will establish minimum personnel qualifications and the necessary orientation 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, inspectors, testers, and nondestructive examiners) will be certified in accordance with those codes and standards.

2.4.1 Position Description and Personnel Qualification Evaluation

For the NNWSI Project, a LANL implementing procedure requires job descriptions that specify relevant education and experience. The minimum requirements for formal education and experience are established and documented in NNWSI position descriptions for personnel performing and verifying activities that affect quality. NNWSI personnel shall have skills commensurate with NNWSI position descriptions. The education, experience, and training of personnel will be verified. The NNWSI personnel qualification evaluation will be performed by managers or supervisors responsible for the activities performed.

2.4.2 Orientation

Personnel assigned to perform activities affecting quality will first be oriented to the purpose, scope, methods of implementation, and applicability of the following documents 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.

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

2.4.3 Training

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

2.4.4 Records

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

Training or orientation records, which include the object and content of the training or orientation, dates of training or orientation, the name of the instructor, attendees, results of any NNWSI proficiency evaluations, the initial evaluation, and any other applicable information, are maintained as lifetime QA records. The evaluation documents for the proficiency of NNWSI personnel will 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 NNWSI personnel will include the verification and evaluation of employee education, experience, and training as compared to those required for the position.

3.0 SCIENTIFIC INVESTIGATION AND DESIGN CONTROL

3.1 Scientific Investigation Control

3.1.1 Preparation of the Scientific Investigation Plan

Scientific investigations affecting quality are planned and documented to ensure a systematic approach. Before the start of any scientific investigation, the responsible PI will develop for that investigation a SIP, which outlines the work to be performed and delineates the instructions for complying with the requirements of the defined scope of work.

At a minimum, the SIP will include the following:

- a description of the work to be performed, with the scope clearly defined;
- a discussion of the purpose for the work;
- identification of who is to perform the work, outlining organizational responsibilities;
- instructions on how to perform the work, written in specific procedures; and
- schedule requirements.

The description of the work to be performed in the scientific investigation includes references to any applicable regulations, requirements, performance criteria, key issues, issues, information needs, planning documents for higher-level scientific investigations, or WBS items for which the work is performed. The description identifies all of the 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 is described, including identification of the QA levels or QA controls under which that work was performed. The SIP contains a level of detail that enables an independent reviewer to determine the appropriate QA level to be applied to the investigation.

3.1.2 Quality Assurance Level Assignment

QA levels are assigned to SIPs in accordance with LANL implementing procedures. Once the SIP has been developed, the associated QALA for each of the items and activities within that plan is prepared. It may be necessary in some cases to assign QA levels to the supporting activities and items within 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 the Scientific Investigation Plan

The organization that develops the SIP conducts a technical review of it to ensure that

- fabrications, installations, modifications, inspections, experiments, and tests have been incorporated;
- the scientific investigation can be accomplished 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 is performed by any qualified individual other than those who developed the original SIP. 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. Cursory supervisory reviews do not satisfy the intent of this requirement. The results of the technical review and the resolutions of any comments by the reviewers are documented and become part of the QA records as prescribed in the implementing procedure for document review.

The SIP is signed and dated by the PI, the technical reviewers, the QAPL, the QAL, and the TPO. The TPO then forwards the SIP to the WMPO PQM for review and approval by the appropriate branch chief and the PQM. The SIP is returned to the TPO upon completion of the WMPO review and approval cycle. A peer review of the SIP may be conducted if the WMPO deems it necessary.

All technical changes in the SIP go through this same review and approval process. The PI is responsible for evaluating the effects of such changes on the associated QALAs. Minor changes to the SIP, limited to inconsequential editorial corrections, need not go through the same review and approval process as a technical change must. However, minor changes will be reviewed and approved by the appropriate project leader and concurred with by the QAPL prior to issue. The QAPL shall maintain a file of minor changes made to the SIPs.

3.1.4 Use of Computer Programs

Computer programs used for analysis are subject to the requirements of LANL implementing for software QA requirements (See Subsection 3.3).

3.1.5 The Use of Scientific Notebooks Versus the Use of Detailed Technical Implementing Procedures

There are two basic kinds of documentation that can be used for the QA documentation and control of scientific work: the scientific notebook and 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 technician performs repetitive work. Detailed procedures are required when deviation from a strict sequence of actions endangers the validity of the results. Bound notebooks, logbooks, DPs, or other appropriate forms are used to document the performance and the control over all aspects of the work.

3.1.5.1 Scientific Notebooks

Bound scientific notebooks may be used with other appropriate documents to document scientific investigations and experiments when the PI is performing or directly supervising work. Notebook documentation must be sufficiently detailed so that another qualified scientist can retrace the investigation and confirm the results or repeat the experiment and achieve the same results without recourse to the PI. Notebooks must be maintained as stipulated in LANL implementing procedures.

3.1.5.2 Detailed Technical Implementing Procedures

Detailed procedures, together with other supporting documents or notebooks, are used whenever the work is repetitive and is performed by technicians who may not be directly supervised by the PI. Such DPs are developed in accordance with the requirements given in Section 5 of this document.

Initial Entries

Before initiation of the experiment or research, the following entries, as a minimum, are made:

- the title of the experiment or research;
- the name of the qualified individual or individuals performing the experiment or research;
- a description of the experiment's objective or objectives;
- 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; and
- the dated signature of the individuals making the initial entries.

In-Process Entries

Entries made during the experiment or research must be sufficiently detailed to permit another competent experimenter or researcher to repeat the experiment or research. In-process entries include

- the date and name of the individual making the entry;
- a description of the experiment or research attempted, including the detailed step-by-step process followed, made either by reference to the implementing procedure or by actual entry into the notebook;
- 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
- final results and a summary of the outcome of the experiment or research, including a discussion of whether the experiment's objectives as outlined in

the initial entries were achieved. The final results and summary will be entered into the notebook or included in a report; if a report is written, it shall become part of the notebook.

Final Entries

The final entries in the notebooks require, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer.

3.1.5.3 Logbooks

A logbook is a bound notebook associated with a specific activity, device, location, or sample supply. Logbooks and entries thereto are controlled by LANL implementing procedures. Logbooks are also used to note any pertinent data concerning its assignment, including such entries as data runs, calibration runs and results, downtimes, sample placement, sample withdrawals, and data run results.

3.1.6 Interface Control

Internal and external scientific investigation interfaces and efforts shall be coordinated among LANL participants and other NNWSI participating organizations as specified in the work breakdown structure.

Interface controls 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 in interfaces. Interfaces between scientific investigations, or between a scientific investigation and any other Project activities, shall be coordinated among Project participants in accordance with administrative procedures established by WMPO. Interfaces between LANL and suppliers are controlled in accordance with procedures established in the procurement documents. The transmittal of information or items (including samples of natural or manmade materials) across interfaces must be documented.

3.1.7 Survey of Scientific Investigations and Experiments

The LANL QA organization will perform surveys of all scientific investigations, as deemed appropriate for the purposes and the complexity of the work. The QA survey team for a scientific investigation consists of one or more technically qualified individuals who are familiar with the SIP and one or more QA personnel. The timing and the number of surveys will be determined by the QA survey team formed for this work. Surveys are performed in accordance with the requirements specified in Section 18 of this document and in LANL implementing procedures.

3.1.8 Reports, Conclusions, and Recommendations

Technical review of the results and documentation of scientific investigations are accomplished in accordance with LANL implementing procedures, which specify that all final reports will be submitted to WMPO for review and approval.

3.1.9 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 is performed upon completion of any scientific investigation to ensure that the QA records

for that investigation are adequate and complete. Close-out verifications are performed by a team consisting of technically qualified personnel as well as QA personnel.

3.2 Design Control

LANL, at present, does have direct responsibility for design control activities. This section is included for LANL design control activities and for pass through to LANL subcontractors.

3.2.1 General

The design must 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 information and design activities refer to the data collection and analyses used in supporting design development and verification. This includes general plans and detailed implementing procedures for data collection and analyses and related information such as test results and analyses. 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 NNWSI Project 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 Project design organizations.

3.2.1.1 Quality Assurance Level Assignment

All design phases are assigned a QA level before execution in accordance with the methods specified in LANL implementing procedures.

3.2.1.2 Qualification of Personnel

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

3.2.1.3 Peer Review

A peer review will be conducted for design activities that involve, and design documents that specify, the use of untried or state-of-the-art testing and design analysis procedures and methods or that include detailed technical criteria and requirements that do not exist or are being developed. Peer reviews are a WMPO prerogative and will be conducted by it as stipulated in the QAP.

LANL will conduct any WMPO-directed peer reviews using WMPO peer review procedures.

3.2.2 Design Input

Applicable design input (such as criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards) are identified and documented, and their selection is reviewed and approved by the responsible design organization and QA organization. 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 to approved design input, including the reason for the changes, are identified, documented, approved, and controlled by the responsible design organization.

3.2.3 Design Analysis

Design analysis is 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 are produced in a form suitable for reproduction, filing, and retrieval. Calculations are identified by subject, including structure, system, or component; originator; reviewer; and date.

3.2.3.1 Documentation of Design Analysis

Documentation of design analysis includes the following:

- a definition of the objective of the analysis;
- a definition of the design input and their sources;
- a listing of applicable references;
- results of literature searches or other background data;
- identification of assumptions and 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 the QA review is to ensure that the documentation is prepared, reviewed, and approved in accordance with documented procedures and QA requirements.

3.2.3.2 Use of Computer Programs

Computer programs used for analysis must be verified and controlled as specified in LANL implementing procedures for software quality assurance requirements (see Subsection 3.3).

3.2.4 Design Verification

3.2.4.1 Identification and Documentation

The organization responsible for a design will verify the adequacy of the design according to the design control measures and identify and document the verification method used, the results of the verification, and the verifier.

3.2.4.2 Timing of Verification

Verification of the adequacy of the design is 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 will be identified and controlled. In all cases, the verification must be completed before the component, system, or structure is used.

3.2.4.3 Extent of Verification

The extent of the design verification necessary is 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. However, if new design inputs affect the application of standardized or previously proven designs, those designs that may affect other features must be verified. The original design and associated verification measures are documented and referenced in the files of subsequent applications of the design.

3.2.4.4 Changes to Verified Designs

Changes to previously verified designs require reverification, including evaluations of the effects of those changes on the overall design.

3.2.4.5 Persons Performing Verification

Design verification is performed by any certified individual(s) or certified group(s) other than those who performed the original design. Those qualified to verify design 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 is 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 is accomplished by design reviews, alternate calculations, and/or qualification testing.

Design Reviews

Design reviews are detailed critical reviews meant to ensure that the design is correct and satisfactory. At a minimum, the reviewers 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 to 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 implementing procedures?

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 will be identified in the design document. The following stipulations apply to the use of qualification tests.

- The test configuration must be clearly defined and documented.
- Testing must 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 will be considered in determining the most adverse conditions.
- Other features of the design will be verified by other means when the test is intended to verify only specific design features.

- Test results must 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 to the test are necessary to obtain adequate performance, the modification must be documented and the item must be modified and retested or otherwise verified to ensure satisfactory performance.

- When tests are being performed on models or mockups, scaling laws must be established and verified. The results of model test are subject to error analysis, where applicable, before its use in the final design work.

3.2.5 Design Change Control

Changes to approved designs, including field changes, must be justified. They will be subjected to the same control measures applied to the original design and must 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 WMPO will designate a new responsible organization, which 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 design information documents will be documented, and action will be taken to correct them. Where a significant design change is necessary, the design process and verification procedure are reviewed and the design is modified as indicated.

3.2.6 Design Interface Control

Design interfaces internal and external to LANL are identified and controlled, and the design efforts are 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 is documented and controlled. Where it is necessary to initially transmit design information informally, the design information will be confirmed promptly by a controlled document.

3.2.7 Design Output Requirements

Completed designs must be documented in sufficient detail to permit design verification. This documentation identifies 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 is represented as different from the commercial-grade item, and the difference is defined and documented.

The design document will 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 includes the participation of the technical and QA elements of both the responsible design organization and the WMPO. 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.

3.2.8 Design Documents as Quality Assurance Records

Design documentation, including design input, analyses, drawings, specifications and approved changes thereto, evidence of design verification, and records confirming interface control, are collected, controlled, stored, and maintained as QA records in accordance with procedures that meet the requirements of Section 17 of this document.

3.3 Software Quality Assurance Requirements

3.3.1 Computer Software Documentation and Control

Computer software used to support license application is documented and controlled according to LANL implementing procedures, which are consistent with guidance contained in WMPO APs. As a minimum, documentation of computer software must include the following:

- software summary,
- description of mathematical models and numerical methods,
- a user's manual,
- code assessment and support, and
- continuing documentation and code listings.

3.3.2 Software Configuration Management

LANL will institute a software configuration management program through implementing procedures and will provide documentation of this program to the Records Management System (RMS). The minimum requirements for this configuration management program shall include a unique identification, as well as software version numbers in the output; listings of the software; and a brief chronology of the software versions, including descriptions of the changes made between versions.

3.4 Technical Reviews

Technical reviews are performed by LANL per a LANL implementing procedure that defines the following:

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

Technical review records include the personnel qualifications of the reviewers, results of the review, and disposition or replies to reviewer comments. The review records are retained according to the requirements of the data or document they support.

3.5 Peer Reviews

The WMPO is responsible for establishing a peer review program and procedures. If directed by WMPO, LANL will prepare a procedure to conduct peer reviews per NVO-196-17.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Procurement Document Requirements

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

Procurement documents will 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 pass through of appropriate QA requirements),
- documentation requirements,
- nonconformance provisions, and
- provisions for spare and replacement parts.

4.1.1 Scope of Work

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

4.1.2 Technical Requirements

The procurement documents will specify the technical requirements for the work. Where necessary, these requirements 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 will identify test, inspection, and acceptance requirements for monitoring and evaluating supplier or contractor performance.

4.1.3 Quality Assurance Program Requirements

The supplier or subcontractor is required to have a documented QA program that implements either part or all of the requirements of this document as selected by the requestor. For QA Levels I and II, subcontractors' QAPPs and related purchasing documents are reviewed and approved by the QAL and the PI. Those programs that do not adequately define QA requirements, as judged by the QAL, will be corrected before initiation of activities specified by the purchase order or contract. 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 is 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

Procurement documents will provide for access to the suppliers' facilities or their subcontractors' facilities and to their records of inspection or audit by the purchaser and

appropriate WMPO personnel. Audits of suppliers or their subcontractors performed by LANL or other Project personnel will be authorized by the LANL procurement organization.

4.1.5 Documentation Requirements

Procurement documents will identify the documentation (reports, manuals, certification, etc.) required from the supplier or subcontractor and specify the time of submittal. If maintenance of specific QA records is stipulated, then the retention times and disposition requirements will be specified in accordance with Section 17 of this document.

4.1.6 Nonconformance

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

4.1.7 Spare and Replacement Parts

As appropriate, the procurement documents will identify appropriate spare and replacement parts of assemblies and delineate the appropriate technical and quality criteria required for ordering these parts or assemblies. These technical and quality criteria must specify parts equal to or better than the original. When necessary, qualified individuals will conduct engineering evaluations to determine the quality and technical requirements of the spare parts. These evaluations, which will be documented, will consider the interchangeability, function, and safety of the item.

4.2 Review of Procurement Documents

A review of the procurement documents and of changes to those documents is 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, will perform and document the review. The review is performed by, as a minimum, the responsible technical organization and the QAL. The review by the QAL will 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 to procurement documents are 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 are incorporated into the procurement documents.

Before a contract is awarded, a review of such changes and their effects is completed and documented.

Reviews of changes to procurement documents consider the following:

- inclusion of appropriate content as required by this section,
- addition or modification of criteria for design or site investigation,
- analysis of exceptions or changes requested or specified by the supplier or subcontractor, and
- determination of the effects such changes may have on the intent of the procurement documents, quality of the item, or service to be furnished.

4.4 Distribution of Procurement Documents

The QAPL will forward to WMPO a copy of all QA Level I procurement documents when issued. The procurement documents will state the vendor and the scope of work and will detail when work is to start.

5.0 INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

5.1 General

Activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, plans, or drawings, which are written according to LANL implementing procedures. Instructions, procedures, and plans include or reference quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished and include a section that identifies the QA records to be generated during implementation of the document. LANL procedures consist of QPs and DPs prepared in accordance with LANL implementing procedures. These documents, including drawings, are developed by qualified personnel and controlled as required in Section 6 of this document and distributed according to LANL implementing procedures. For drawings, the initiating organization has established procedures for the initiation, review, approval, issue, and change control necessary for their production.

5.2 Criteria

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

5.3 Reviews

Technical reviews of all instructions, procedures, plans, and drawings are performed by the originating organization per LANL implementing procedures before their implementation. Before instructions, procedures, plans, and drawings can be implemented, they must all be reviewed by the QA organization (per LANL implementing procedures) to ensure that they meet all requirements of the QAPP.

6.0 DOCUMENT CONTROL

6.1 Document Preparation, Review, Approval, and Issue

The preparation, review, approval, and issue of documents such as instructions, procedures, plans, and drawings, including changes thereto, are controlled to ensure that correct documents are available for use. Document control is implemented through procedures and applied to the following:

- documents that ensure technical adequacy,
- documents containing or specifying quality requirements, and
- documents that prescribe activities affecting quality.

The document control system is prescribed in an implementing procedure, and the QA organization provides review, resolution of comments, and approval of quality-related aspects of the documents.

6.2 Implementation of Document Control

Documents are controlled according to an implementing procedure, which

- identifies documents to be controlled;
- assigns responsibility for preparing, reviewing, approving, and issuing documents;
- defines instructions for reviewing documents for adequacy, completeness, and correctness before approval and issue;
- prescribes a method for removing or marking obsolete or superseded documents 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 to Documents

Changes to documents other than minor changes will be reviewed and approved by the same organizations that originally reviewed and approved the document, unless WMPO specifically designates other organizations to perform this function. The reviewing organizations will have access to pertinent background data or information upon which to base their approval.

Minor changes to documents, limited to inconsequential editorial corrections, do not require the same review and approval as the original documents. Before documents are issued, the TPO or his designee will verify that these editorial corrections do not substantively change the document.

6.4 Distribution of Documents

The document control system ensures that documents requiring verification are not released before verification or, if they must be released before verification, that they are uniquely identified and controlled. A master list or equivalent used to identify the correct, current, and updated versions of documents will be submitted to WMPO and WMPO QA by the records coordinator. A master document list for QA Levels I and II activities is maintained by the LANL records coordinator. The LANL will issue to the WMPO PQM and WMPO QA controlled copies of all LANL implementing procedures (i.e., DPs and QPs), plans, instructions, and the QAPP used for QA Levels I and II activities. In addition, DPs, QPs, plans, and instructions for QA Levels I and II activities are accessible for review within the area where the activity is performed.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 General Requirements

Procurement will be conducted in accordance with LANL quality procedures. Purchased material, equipment, and services will conform to the requirements of procurement documents. Source evaluation and selection are done according to LANL implementing procedures and include 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. Where required by code, regulation, or contract stipulations, documentary evidence showing that material and equipment conform to the procurement requirements will be available at the location where the material or equipment is to be used before their installation or use. Organizational responsibilities will be stated in the quality procedure. This documentary evidence will be sent to the WMPO RMS. Specific requirements for the purchase of items and services are listed below.

7.1.1 Procurement Planning

Procurement activities are planned and documented to ensure a systematic approach to procurement. The QA organization participates in the evaluation and selection of suppliers, verification of suppliers activities, and receiving inspections. Planning is accomplished as early as practicable and no later than the start of NNWSI procurement activities. Planning determines 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 item or service; and
- preparation of QA records.

7.1.2 Evaluation and Selection of Suppliers

Before a contract is awarded, suppliers are selected based on an evaluation of their ability to provide items or services in accordance with the requirements of the procurement documents. A LANL implementing procedure will detail the evaluation and selection measures to be employed and will assign the organizational responsibilities for the assessment of vendors' capabilities.

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

- an evaluation of the suppliers' histories of providing identical or similar products that performs 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 QA 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 determines the extent of conformance to the procurement documents. The evaluation considers 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 will resolve unacceptable QA conditions, which have been ascertained during the bid evaluation.

7.1.4 Interface Measures

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

- documentation of the understanding between LANL and the supplier of the provisions and specifications of the procurement documents,

- identification by the supplier of planning techniques and processes to be used in fulfilling requirements for procurement documents,

- review of supplier documents that are generated or processed during activities fulfilling requirements for procurement documents,

- methods of exchanging document information, and

- a method of identifying and processing necessary change information. (Measures to control changes in procurement documents are established, implemented, and documented in accordance with the requirements of Subsection 4.3 this QAPP.)

7.1.5 Evaluation of Supplier Performance

7.1.5.1 Verification Measures

Procurement documents establish measures to verify the supplier's performance and 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 are accomplished by qualified personnel assigned to check, inspect, audit, or witness the supplier's activities. These verification activities

will 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 WMPO to conduct a survey to determine that the item or activity is being produced or performed in accordance with the LANL requirements.

7.1.5.2 Record of Evaluation and Verification

Activities performed to verify conformance to requirements of procurement documents and their results are recorded. Source surveys and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions are documented. These completed documents are considered QA records and are 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 are submitted in accordance with requirements for procurement documents and handled, approved, and controlled according to LANL procedures for document control. The documents shall be evaluated against the criteria for procurement acceptance.

7.1.7 Acceptance of Item or Service

Methods have been established for the acceptance of an item or service being furnished by the supplier. The supplier or contractor will verify that an item or service complies with the procurement requirements before its submission for acceptance.

Methods of acceptance include

- a supplier certificate of conformance,
- a source verification,
- a receiving inspection, or
- a post-installation test at the facility site.

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 is accomplished by including a list of the specific requirements or by providing, at the point of receipt, a copy of the purchase order and the procurement specifications or drawings and a suitable certificate. The procurement requirements identified 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, explain the nonconformance, and propose a means of resolving the nonconformance.

- The certificate shall be validated by a person responsible for this QA function.

- 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 will be verified during the performance of audits of the supplier, 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 is implemented to monitor, witness, or observe activities. It is implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Once the source verification is accepted, the receiving destination of the item, LANL, and the supplier will be furnished with documented evidence of acceptance of the item.

7.1.7.3 Receiving Inspection

Purchased items are inspected as necessary to verify their conformance to specified requirements. Inspections take into account source verification, audit documentation, and the demonstrated quality performance of the supplier. Receiving inspection is performed in accordance with LANL implementing procedures. Receiving inspection is coordinated with the review of the supplier's documentation when procurement documents require such documentation. Receiving inspections will be based on objective evidence criteria, such as physical, dimensional, damage, or other measureable characteristics.

7.1.7.4 Post-Installation Testing

Post-installation testing requirements and acceptance documentation are 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 is made according to the following methods:

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

7.1.9 Control of Supplier Nonconformances

Requirements involving the control of supplier nonconformances for the item or service being procured will be stipulated in the purchasing document. Supplier nonconforming items will be reported and dispositioned as stated in Section 15, Control of Nonconforming Items. Supplier nonconforming activities and services will be reported and dispositioned as stated in Section 16, Corrective Action.

The nonconformance report for the supplier will contain the following minimum information:

- the technical or material requirement violated, with reference to the procurement document;
- the process correction proposed, when applicable; and
- the recommended disposition (i.e., use-as-is, repair).

The submittal of a nonconformance notice shall include a disposition recommendation (e.g., use as-is or repair) and technical justification. Dispositions are approved, and implementation is verified in accordance with documented procedures by the purchaser. Supplier nonconformance reports will be maintained as QA records.

Disposition of nonconformances includes

- an evaluation of nonconforming items,
- a submittal of a nonconformance notice to LANL,
- an evaluation of supplier recommendation,
- verification of the disposition, and
- maintenance of records submitted by the supplier of a nonconformance.

For activities and services, nonconforming conditions will be resolved by CARs. The CARs for the supplier will contain the following minimum information:

- the procedural requirement, including the reference to the procurement document, that has been violated;
- a request for identifying the cause of the nonconforming condition;
- the corrective action proposed; and
- the recommended disposition (i.e., re-analyze, accept as-is).

The submittal of a CAR shall include a disposition recommendation (i.e., re-analyze, accept as-is) and justification (technical when appropriate). Dispositions are approved, and implementation is verified in accordance with documented procedures by the purchaser. Supplier CARs will be maintained as QA records.

Disposition of CARs for nonconforming activities and services includes:

- an evaluation of the nonconforming aspect of the activity or service,
- a submittal of a CAR to LANL,
- an evaluation of the supplier's recommendation for corrective action taken to preclude a recurrence of the nonconformance,
- verification that the corrective action has been implemented, and
- maintenance of records submitted by the supplier.

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 will be used to accept the items.

7.2.1 Identification of Commercial-Grade Items

Where the commercial-grade item is to be used as an integral part of the designed facility, it will be identified in an approved design or design output document. 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 are done 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 are identified in the purchase order by the manufacturer's published product description (e.g., the catalog number).

7.2.4 Receipt of Commercial-Grade Item

Upon receipt of a commercial-grade item, as applicable, it will be determined that

- damage was not sustained during shipment;
- the item received was the item ordered;
- required inspection or testing is accomplished in accordance with written procedures to ensure conformance with the manufacturer's published requirements; and
- documentation, as applicable to the item, has been received and is acceptable.

8.0 IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA

8.1 Identification and Control of Items

Requirements that stipulate the identification and control of items apply to activities related to engineered items and do not apply to scientific investigations. Because LANL's scope of work is for scientific investigations and not engineered items, these requirements are included here for pass through on a LANL subcontract (and for possible future use in the event that LANL becomes responsible for engineered items).

Items, including the fabrication of items, are identified to ensure that only correct and accepted items are installed and used for activities affecting quality. Identification is maintained either on the item, on its container, or in documents traceable to the item from the initial receipt until installation and use. This identification relates an item to an applicable design or other pertinent, specifying document.

Physical identification is used to the maximum extent possible. Where physical identification on the item is either impracticable or insufficient, physical separation, procedural control, or other effective means are employed. Identification markings, when used, are applied using materials and methods that provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings are transferred to each part of an identified item when subdivided and must not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.

When required by codes, standards, or specifications to afford traceability of the item to the applicable specification and grade of the material (i.e., heat, batch, lot, part, or serial number or inspection, test, or other records), identification is designed to provide such traceability control.

Items having a limited calendar or operating life or cycles are identified and controlled to preclude use of items whose shelf or operating life has expired.

Item identification is controlled according to implementing procedures and is consistent with the planned duration and condition of storage, including provisions for maintenance or replacement of markings and identification records because of damage from handling or aging; protection of identification on items subject to excessive deterioration from environmental exposure; and provisions for updating existing facility records.

8.2 Identification and Control of Samples

These requirements apply to samples used in or resulting from scientific investigations and do not apply to the handling and control of engineered items.

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

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

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

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

Physical identification is used to the maximum extent possible. Where physical identification cannot be placed on the sample, appropriate alternative identification methods are 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 are stored and maintained in predetermined physical conditions commensurate with their intended purpose. Samples intended for long-term storage receive treatment to ensure that they do not degrade during storage. "Long term" is defined by the SIP for each sample collection case.

Measures are 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 is used to the maximum degree practical.

LANL procedures will be based upon the WMPO's AP describing the ultimate storage of all types of samples, including liquids, gases, and solids. The procedures will, 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 will be handled in accordance with Section 17 of this document.

8.3 Identification and Control of Data

The requirements included here apply to data generated from an NNWSI scientific investigation. Data generated from an NNWSI scientific investigation are identified to assist in the determination of their correct use. Identification of such data is provided in all documents and information systems in which such data appear. The identification of NNWSI Project data includes 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, which produced the data.

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

Where data are the results of the efforts of more than one organization, procedures describing the organizational responsibilities for that 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

9.1 General Requirements

The requirements for process control apply to engineered items and scientific investigations; the requirements for special process control apply to engineered items only. Processes that affect the quality of items or services are controlled either by instructions, procedures, or plans. Special processes that affect quality, such as those used in welding, heat treating, and nondestructive testing shall be accomplished by qualified personnel using qualified procedures. LANL is not presently at work on engineered items to which these requirements apply; requirements for special processes are included here for possible future use in the event that LANL does adopt any special processes and for pass through to a LANL subcontractor.

9.2 Process Control

All processes are controlled by instructions, procedures, plans, drawings, checklists, travelers, or other appropriate means to ensure that process parameters are controlled and that specified environmental conditions are maintained.

9.3 Special Process Control

9.3.1 Identification of Special Processes

A special process is one in which the results are highly dependent on either the control of the process or the operator's skill, or both, and in which the specified quality cannot be readily determined by inspection or by testing the item. It is the responsibility of the organization performing the work to identify which of its activities involve the use of special processes.

9.3.2 Special Process Procedure

A special process procedure will be written for processes not covered by existing codes and standards and for processes where the quality requirements for an item or test exceed those of existing codes or standards. The procedure for a special process must include the following:

- the necessary qualifications of procedures, personnel, and equipment;
- the necessary conditions, which include proper equipment, controlled parameters of the special process, and calibration requirements; and
- the requirements of applicable codes and standards, including acceptance criteria, for the special process.

9.3.2.1 Qualification of Special Process Procedures

Procedures will be qualified in accordance with applicable codes, standards, or other specifications. The program for the qualification of procedures will be specified in documents prepared by the responsible technical organization. The responsible QA organization will review the procedure and conduct overviews of the activities as stipulated in Section 18.0, Audits, to ensure compliance with these requirements.

9.3.2.2 Qualification of Personnel Performing Special Processes

In the event that LANL adopts the use of a special process, personnel will be trained, qualified, and certified in accordance with written procedures. The training, qualification, and certification will be the responsibility of the organization performing the work. These procedures will be reviewed by the responsible QA organization for compliance with requirements. Qualification of personnel will use the actual working procedure to the extent possible and will incorporate the personnel qualification requirements of the applicable codes, standards, or specifications.

9.3.2.3 Qualification of Special Process Equipment

Special process equipment will be checked out, qualified, and certified in accordance with specified criteria that implement the requirements of applicable codes, standards, and specifications. Equipment check-out, qualification, and certification are the responsibility of the organization performing the work. The responsible QA organization will review the procedures for qualification of equipment for compliance with requirements.

9.3.3 Special Process Records

Records will be maintained for the qualified personnel, procedures, and equipment of each special process, and the requirements for maintenance of these records will be specified in the procedure for special processes. Special process verification methods and criteria will be documented and retained.

10.0 INSPECTION

10.1 General

This section provides guidance for inspections needed to verify conformance of an item or activity to specifications in related documents. This section is included for pass through to LANL subcontractors as deemed necessary by the requester. The requirements of this section apply to engineered items and do not apply to scientific investigation activities, except for those requirements that deal with the receipt inspection of engineered items developed for LANL scientific investigations.

10.2 General Requirements for Inspections

Inspections are planned; planning results in documented, approved procedures for inspection. Inspections are performed in accordance with the approved written procedures by qualified personnel who did not perform the work being evaluated. These procedures must specify

- the criteria for determining what inspections are needed,
- how and when inspections are to be performed,
- methods for sampling,
- any mandatory hold points,
- identification and qualification of personnel,
- any special expertise required,
- criteria for acceptance,
- equipment and its accuracy necessary to perform inspection, and
- necessary documentation of results.

The results of all inspection activities must be documented by the inspecting organization.

10.3 Personnel

Inspections are performed by personnel who do not report directly to the immediate supervisor responsible for the activity being inspected. The independence of all persons performing inspections or tests will be maintained; the QA organization will verify this independence and any need for special expertise. Personnel selected to perform inspections and material testing must have the experience or training commensurate with the scope, complexity, or special nature of the activities and must be qualified to perform the assigned inspections or tests. This qualification is certified in writing. Personnel are oriented as to the technical objectives and requirements of the applicable codes and standards and the QA program elements appropriate to the inspection. Records of personnel qualification are established and maintained. The actual examinations used to qualify personnel are also retained as part of the record files. Personnel outside the QA organization may be used for inspections, provided they meet the requirements stated herein.

Requirements for qualification of personnel conducting inspections are stated in Appendix C and those for personnel conducting nondestructive examinations (NDE) are stated in Appendix D.

10.4 Inspection Hold Points

When mandatory inspection or witness hold points are established, work may not proceed beyond that point without the specific consent of the responsible representative. These witness points are indicated in documents controlling the activity. Consent to waive any specified hold or witness point is documented before work is authorized to proceed beyond the designated hold or witness point.

10.5 In-Process Inspection and Monitoring

Items are inspected in-process or under construction where necessary to verify quality. If direct inspection of items in-process is impossible or disadvantageous, indirect control is maintained by monitoring processing methods, equipment, and personnel.

Where a combination of direct inspection and process monitoring is used, it is performed systematically and documented to ensure that the specified requirements for control of the process and quality of the item are achieved for the duration of the process. The combination of inspection and process monitoring is used when other techniques cannot provide adequate control.

If sampling is used to verify acceptability of items, the sampling procedures will be based on recognized standard practices.

Where required, controls are established and documented for the coordination and sequencing of activities at established inspection points during successive stages of the conducted process or construction.

10.6 Final Inspection

A final inspection is conducted to confirm that items conform to design document specifications, including markings, calibration, adjustments, protection from damage, or other characteristics. Quality records are examined for adequacy and completeness. Final inspection includes a review of documented results and resolution of any nonconformances identified by prior inspections. The item's acceptance is documented and approved by identified authorized personnel. Modifications, repairs, or replacements of items performed subsequent to final inspection require reinspection or retests, as appropriate, to verify acceptability.

10.7 In-Service Inspection

In-service inspection specified by design documents of structures, systems, or components is planned and executed by or for the organization responsible for operation. In-service inspection verifies that the characteristics of an item remain within specified limits.

Inspection activities include evaluations of the performance capabilities of essential emergency and safety systems and equipment, verification of the calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

10.8 Inspection Records

Inspection records are retained in accordance with Section 17 of this QAPP. As a minimum, inspection records must identify the following:

- the item or activity being inspected,
- the date of the inspection,
- the name of individual performing the inspection,
- the personnel contacted during the inspection,
- a description of the observation,
- the inspection criteria for that particular item or activity,
- the equipment used during the inspection,
- the evidence as to the acceptability of the results,
- a statement of acceptance or rejection, and
- the documentation regarding any action taken in connection with conditions adverse to quality or nonconformances.

11.0 TESTING

11.1 General

Design control documents specify tests necessary to verify conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in service. Characteristics to be tested and test methods to be employed are specified in procedures. Tests are performed by trained and qualified personnel. LANL does not currently conduct any activities to which the following requirements apply. This section is included for possible future use in the event that LANL does conduct tests as defined in the NNWSI QAP, Section 11, and for pass through to LANL subcontractors.

11.2 Test Requirements

Acceptance or rejection criteria of the test, including required levels of precision and accuracy, are provided or approved by the organization responsible for the design of the item to be tested. Required tests, which may include prototype qualification tests, production tests, proof tests before installation, construction tests, pre-operational tests, and operational tests, shall be controlled. Test procedures will state the objectives and any prerequisites that must be satisfied before test commencement. These procedures include criteria for determining when a test is required and how it is performed.

11.3 Test Procedures

Instructions, procedures, and drawings for tests are prepared in accordance with the requirements of Section 5 of this document and LANL implementing procedures. Any potential sources of uncertainty and error in test procedures that must be controlled and measured to ensure that tests are well controlled must be identified. The procedures will describe, as necessary,

- calibrated instrumentation,
- appropriate equipment,
- completeness of the item to be tested,
- personnel training or qualification,
- condition of test equipment and the item to be tested,
- suitable and controlled environmental conditions,
- provisions for data acquisition and storage, and
- requirements that include acceptance/rejection criteria based on design or other technical documents.

Test plans and procedures will be reviewed in accordance with the verification requirements defined in Subsection 3.2.4 of this document and LANL implementing procedures. They prescribe mandatory hold points, methods of documenting test data and results, and methods of data analysis.

11.4 Test Results and Records

Test results are documented and evaluated by qualified personnel to ensure that test requirements have been satisfied.

As a minimum, test records will contain

- identification of the item tested,
- the date of the test,

- identification of the tester or data recorder,
- a description of the observation,
- the results and acceptability,
- action taken in connection with any deviations noted, and
- identification of the person evaluating the results.

Records are maintained in accordance with Section 17 of this program plan and the LANL implementing procedure.

11.5 Test Alternatives

In lieu of written test procedures that have been specifically prepared, appropriate sections of related documents, including American Society of Testing and Materials (ASTM) methods, supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to ensure the required quality of work.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Scope of Control Program

Tools, gages, instruments, and other measuring and test equipment used in activities affecting quality are controlled. They will 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 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.

12.2 Description of Responsibilities

All organizations using and calibrating measuring and test equipment will establish and implement a calibration program through written procedures. The QAPL is responsible for evaluating each program and ensuring that it is effective and that it complies with the LANL implementing procedure.

12.3 Program Requirements

Calibration programs will 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 ensure that such equipment meets specified requirements. The measuring device shall be specified in test and inspection documents. 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 are calibrated against certified equipment having known valid relationships to the National Bureau of Standards (NBS) or other nationally recognized standards and are adjusted and maintained at prescribed intervals. If no nationally recognized standards exist, the basis for calibration must be specified and documented in a LANL implementing procedure.

12.3.3 Capability

The method and interval of calibration for each item is defined, based on the type of equipment, stability, characteristics, required accuracy, intended use, and other conditions that affect measurement control. Measuring and test equipment must 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, which includes the validity of previously obtained results and the acceptability of previous inspections, tests, or data gathering activities of these items since the last calibration, is made and documented. Devices that are out of calibration are tagged or segregated and are not used until they have been recalibrated. If any measuring or test equipment is found to be consistently out of calibration, then it will be repaired or replaced. A calibration is performed whenever the accuracy of equipment is suspect.

12.3.4 Handling and Storage

Measuring and test equipment is 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 will be maintained as specified in the LANL implementing procedures.

13.0 HANDLING, SHIPPING, AND STORAGE

13.1 General

Work and inspection instructions, drawings, specifications, shipment instructions, or other procedures, are 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 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) are specified in the pertinent instructions provided by the responsible organization, and their existence will be verified by the QA organization.

13.3 Specific Procedures

When required for critical, sensitive, perishable, or exceptionally expensive articles, specific procedures are written for handling, storage, packaging, shipping, and preservation. Procedures are 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 are used and controlled as necessary to ensure safe and adequate handling. Special-handling tools and equipment will 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 will be experienced or trained to use the equipment. Verification and documentation of this training are maintained as QA records in accordance with LANL implementing procedures.

13.6 Marking and Labeling

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

14.0 INSPECTION, TEST, AND OPERATING STATUS OF ENGINEERED ITEMS

14.1 General

The requirements of inspection, test, and operating status (as delineated in this section) apply to engineered items and do not apply to scientific investigations. These requirements are included here for pass through to LANL subcontractors and for use in the future if LANL becomes directly responsible for engineered items.

14.2 Indication of Status

The status of inspection and test activities for engineered items will be identified either on the items or in documents traceable to the items. This identification is necessary to ensure that required inspections and tests have been performed and to ensure items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status indicators will also exhibit the operating status of systems and components of the facility (e.g., by tagging valves and switches).

14.3 Methods of Indicating Status

Status indicators include tags, markings, travelers, stamps, inspection records, or other suitable means. Approved procedures describing status indicators and their use will contain current actual examples of each type of indicator.

14.4 Application and Removal of Status Indicators

The authority for application and removal of tags, markings, labels, and stamps that indicate status will be specified in approved procedures governing inspection, test, and operating status.

15.0 CONTROL OF NONCONFORMING ITEMS

15.1 General

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

15.2 Identification

Identification of nonconforming items is made by marking, tagging, or other methods that do not adversely affect the use of the item. The identification must be legible, easily recognizable, and contain the NCR number. The method for tracking the NCR status and QA organizational responsibilities will be clearly stated in the implementing procedure. LANL implementing procedures will establish the interorganizational interfaces and NNWSI Project participant interfaces.

15.3 Nonconformance Control Log

Nonconforming items are tracked in a nonconformance control log, which 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 are 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 are employed to preclude inadvertent use of nonconforming items. Tags are permitted if they are securely attached to the items, or a unique storage area within which the items may be placed can be designated.

15.5 Disposition

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

15.5.1 Responsibility and Authority

The organization using or producing the nonconforming item is responsible for its evaluation and disposition. Those persons who are assigned signature approval of the disposition shall be identified in the NCR. The QA responsibilities include verifying and documenting the disposition of nonconformances.

15.5.2 Personnel

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

15.5.3 Disposition of the NCR

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

- Nonconformance documentation must adequately identify and describe the nonconformance.
- Appropriate justification for the NCR must be documented. In the case of use-as-is or repair dispositions of the item, technical justification is required. The as-built records, if such records are required, will reflect the accepted deviation.
- The NCR must 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 must be adequate for the recommended disposition of the item.
- If continuance has been requested, justification for the activity to continue must be documented and approved by the appropriate WMPO Branch Chief and the WMPO PQM.
- The disposition must comply with existing design documents, test plans or procedures, reports, and regulatory requirements.
- If a change is appropriate to reflect the as-built condition, then the disposition must address the action needed to change the existing design documents, test plans or procedures, reports, etc. Any documents changed will have a cross reference on the NCR.
- The disposition must identify and document the correction as repair, rework, use-as-is, or reject/scrap.
- The disposition must identify the personnel responsible for implementing the disposition.
- The disposition must describe the cause of the nonconforming condition.
- The disposition must document action needed to preclude recurrence of the nonconforming condition.

15.5.4 WMPO Approval

Dispositions of repair are subject to WMPO approval before their implementation. The original NCR for a use-as-is or repair disposition will be forwarded to WMPO for approval after technical justification of the disposition has been completed. Conditional release recommendations are also subject to WMPO approval. Copies of NCRs will be sent to the WMPO PQM and the SAIC/T&MSS Project QA Department Implementation Division Manager upon issuance and closure.

15.5.5 Corrective Action

Action taken to correct the nonconforming item will be verified and documented. Repaired or reworked items are 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 nonconforming item will be stopped until the NCR disposition is complete. If only a specific portion of an item is in nonconformance, then that specific area is identified and work may proceed on the remaining areas. Work on a nonconforming item that continues (conditional release) before implementation of the disposition is subject to approval by WMPO. Requests for conditional releases on nonconforming items must document that the following conditions are met:

- the nonconforming item can be removed or corrected at a later date without damage to, or contamination of, the associated permanent facility equipment or structures;
- the nonconforming item remains accessible for inspection;
- the nonconforming item has been evaluated and limitations for use of the equipment or system are established; and
- traceability and identification of the nonconforming item are maintained.

15.7 Nonconformances and Trending

The NCRs are periodically analyzed by the QA organization to establish quality trends and to help identify root causes of nonconformances. Results are reported to the TPO and QAPL for review and assessment. When repetitive or recurring nonconforming conditions are identified (as a trend), an evaluation is made as to whether or not further programmatic corrective action is warranted to preclude repetition. This corrective action is beyond the scope of the action taken for the disposition on the existing NCRs and is processed in accordance with LANL corrective action procedures.

15.8 Unusual Occurrences

Unusual occurrences are reported according to a LANL implementing procedure, which meets the requirements of DOE Order 5000.3 as supplemented by LANL internal policy. NCRs are evaluated to determine if further processing as unusual occurrences is required per DOE Order 5000.3 as supplemented or modified by the responsible DOE field office. Reports of unusual occurrences will be submitted to the responsible DOE field office for further processing. Copies are also provided to WMPO.

16.0 CORRECTIVE ACTION

16.1 General

The corrective action system shall ensure that conditions adverse or potentially adverse to quality, including supplier nonconforming activities and services, are identified promptly and corrected as soon as practical.

16.2 Significant Adverse Conditions

Significant conditions adverse or potentially adverse to quality will be identified promptly and corrected as soon as practical. A significant condition adverse to quality is one that, if not corrected, could have a serious effect on safety or operability or could affect the site characterization data used for licensing. Significant conditions include, but are not limited to, violations of LANL implementing procedures, activities, breakdown in the QA Program, repetitive nonconformances, and if not corrected could have a serious effect on safety or operability.

The identification, cause, and corrective action taken to preclude recurrence for significant conditions adverse to quality will be documented by the responsible organization and reported to immediate management, the TPO, and QAPL for review and assessment in accordance with LANL implementing procedures. The QA organization will verify proper implementation of corrective actions and close out corrective actions in a timely manner.

16.3 QA Follow-up Action

The QA organization shall document concurrence of 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 and document its acceptance. The organization responsible for implementing the corrective action shall assure that the corrective action is completed in a timely manner.

16.4 Corrective Action Reports

The QA organization periodically analyzes CARs to establish quality trends. Results are reported to the TPO and QAPL for review and assessment. The LANL QAPL is responsible for evaluating CARs to determine if they require further processing as unusual occurrences per DOE Order 5000.3, as supplemented by the LANL internal policy and the responsible DOE field office.

16.5 Distribution of Corrective Action Reports

Copies of CARs are sent to the SAIC/T&MSS Project QA Department Implementation Division Manager by the QAPL upon issue and closure.

17.0 DOCUMENTS AND RECORDS

17.1 General

Documents and records that furnish evidence of quality shall be specified, prepared, and maintained in accordance with LANL implementing procedures, which meet the requirements of this section. A records procedure will be issued at the earliest practical time consistent with the schedule and work activities.

17.2 Management, Control, and Preservation of Records

QA records are managed and controlled according to LANL implementing procedures, which are consistent with the NNWSI Project Administrative Procedures Manual. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, retrievability, and disposition of QA records are specified in implementing procedures.

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

For purposes of record retention, all NNWSI Project records are classified as lifetime records and are required to be retained for the life of the Project.

17.3 Minimum Records

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

17.4 Generation of Records

Records to be generated, supplied, or maintained by or for LANL are specified in design documents, procurement documents, implementing procedures, or other documents. Documents designated to become records must be legible, identifiable, accurate, complete, reproducible on microfilm and other media, and appropriate to the work accomplished. These documents are completed in accordance with LANL implementing procedures.

A LANL records management procedure will be prepared that complies with the WMPO AP 1.7Q, NNWSI Project QA Records Management. A list of typical QA records is contained in the LANL records management procedure.

17.5 Validation of Records

Documents are considered valid records only if stamped, initialed, or signed and dated by authorized persons or otherwise authenticated in accordance with approved procedures. Record authorization may be a statement by the responsible individual or

organization. These records may be originals or reproduced copies. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. Each organization must maintain a list that contains the signature and initials of the persons authorized to authenticate records.

17.6 Receipt of Records

Each organization that is responsible for the receipt of records will designate a person or organization to be responsible for receiving the records. The designee is responsible for organizing and implementing a system for receipt control of records for permanent and temporary storage in accordance with approved procedures. Each receipt control system will be structured to permit a current and accurate assessment of the status of records during the receiving process. The receipt control system includes the following:

- a method for designating the required records,
- a method for identifying the records received, and
- procedures for receipt and inspection of incoming records.

The individual or organization responsible for receiving records must provide protection from damage, deterioration, or loss during the time that the records are in their possession. Each LANL group will process its records and transfer them to the LANL RPC for further processing and transfer to WMPO. These records will be accessible to WMPO.

17.7 Records Identification

The indexing system identifies the connection between the record and the item or activity to which it applies. Records are identified by a unique number or other designation, which 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 is not repeated anywhere in the NNWSI Project. The indexing system includes the location of the record within the records system or systems.

17.8 Storage of Records

Records are controlled from the time they are completed until the time they are stored in a permanent storage facility. Temporary storage, preservation, safekeeping, and retrievability of completed records are done in accordance with the implementing procedure for the permanent storage of records. The procedure includes 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,

- the method for maintaining control of and accountability for records removed from the storage facility, and

- a method for filing supplemental information and disposing of superseded records.

17.8.1 Responsibilities

The records coordinator is responsible for ensuring that the requirements of LANL implementing procedures for the storage of records are met.

17.8.2 Storage Facilities

Requirements for the permanent and temporary storage of records and documents will be stated in LANL implementing procedures. Records and documents are 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 facilities that meet the requirements of the NNWSI Records Management Plan are at pre-determined locations sufficiently remote from each other to reduce the chance of simultaneous exposure to a hazard.

17.8.3 Preservation

Records are stored in a manner approved by the QAPL. Deterioration of the records is precluded by the following.

- Provisions are made in the storage arrangement to prevent damage from moisture, temperature, and pressure.

- Records are firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or are placed in containers and stored on shelves.

- Special processed records (e.g., radiographs, photographs, negatives, microfilm, magnetic material, etc.) are protected from damage caused by excessive light, stacking, electromagnetic fields, temperatures, and humidity.

17.8.4 Safekeeping

The procedure for storage of records includes measures to preclude the entry of unauthorized personnel into the storage area. These measures guard against larceny and vandalism.

17.8.5 Replacement, Restoration, or Substitution

Lost or damaged records will be replaced, restored, or substituted within 90 days once it is discovered that a record has been either lost or damaged to a degree that makes the record incomplete or illegible.

17.9 Corrected Information in Records

Records may be corrected in accordance with LANL implementing procedures that stipulate appropriate review or approval by the originating organization. The correction

must include the date and the identification of the person authorized to issue such correction and must not obliterate the corrected data.

17.10 Access to QA Records

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

17.11 Transfer of QA Records

The LANL RPC coordinator will review each group's records turnover, acknowledge receipt, inventory, and transfer the records to the WMPO as directed by the WMPO AP 1.7Q, NNWSI Project QA Records Management.

18.0 AUDITS

18.1 General Requirements

All LANL NNWSI Project 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 are performed using checklists in accordance with LANL implementing procedures. Qualified personnel, who do not have direct responsibility for performing the activities being audited, will conduct the audits. Audit results are documented, reviewed by the QAPL, and reported to the TPO. On the form supplied by the audit organization, the audited organization will describe the corrective action to be taken to address findings and will submit the completed form to the QAPL and the audited organization's own management. The audit organization will track audit findings to ensure that all findings are properly closed and to identify quality trends.

Audits will be performed by the QAS and will include followup action, verification of corrective action, or re-audit of specific areas.

18.2 Audits

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

18.2.1 Evaluating Audit Findings

The QAS is responsible for evaluating audit findings to determine if further processing as an unusual occurrence is required per DOE Order 5000.3 as supplemented by LANL internal policies and as supplemented or modified by the cognizant DOE field office.

18.2.2 Scheduling

Internal and external QA audits are scheduled (date, activity, and requirements) to provide complete coverage of QA program activities. Audits will be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule is evaluated periodically and revised as necessary to ensure that coverage is maintained current. Revisions of the audit schedule will be documented. The evaluation of the audit schedule includes an assessment of the effectiveness of the program based on previous audit results and corrective actions, NCRs, and information from other sources such as the American Society of Mechanical Engineers, the NRC, etc. Regularly scheduled audits are supplemented by additional audits of specific subjects when necessary to provide adequate coverage. The audit schedule, including dates and any revisions thereto, will be sent to WMPO QA and the WMPO audit and surveillance group. The audit schedule will include activities to be audited and requirements to which the activities will be audited.

18.2.3 Internal Audits

All elements of LANL's QA program are internally audited at least annually. 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.

18.2.4 External Audits

Elements of an external organization's QA program are audited at least annually or once during the life of the activity, whichever is the shorter period, with the following 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 is documented and approved by the QAPL.

18.2.5 Audit Plan

An audit plan is 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 written procedures or checklists.

18.2.6 Audit Personnel

Auditors will 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 will not be involved in the selection of the audit team. Auditors must have sufficient authority and organizational freedom to make the audit process meaningful and effective. Appendix E defines the requirements for the qualification of QA auditors.

An audit team is identified before the beginning of each audit. This team contains one or more auditors and an individual qualified as a lead auditor who organizes and directs the audit, coordinates the preparation and issue of the audit report, and evaluates the responses. The audit team leader ensures that the audit team is prepared before the audit begins.

18.2.7 Performance

Audits are performed in accordance with written procedures using checklists as early in the life of the activity as practicable and are continued at intervals consistent with the schedule for accomplishing the activity. The elements selected for an audit are 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 will be evaluated to determine if the selected elements are effective and are being implemented properly. The audit results are documented by auditors and reviewed by the management responsible for the area audited. Conditions that require prompt corrective action are reported immediately to the management of the audited organization. Audit findings are reviewed with the audited organizations at the closing meeting.

18.2.8 Reporting

The audit report is signed by the audit team leader and issued within 30 calendar days of the audit, in accordance with LANL implementing procedures. The audit report includes 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.

18.2.9 Response

Line management of the audited organization or activity will investigate any audit findings, schedule corrective action that will include measures to prevent recurrence, and 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.

18.2.10 Follow-Up Action

Follow-up action, including reaudits of specific areas, is taken to determine whether or not corrective action has been accomplished as scheduled and is verified by the auditing organization. An analysis of audit results is performed to identify quality trends.

18.2.11 Records

Audit records must include the following:

- identification of the organizations, activities, or items audited and the individuals contacted during the audit,

- a description of any deficiencies, nonconformances, or other quality problems; and

- audit plans, audit reports, written replies, and the record of completed corrective action and close-out of the audit.

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

18.3 Surveys

The audit program is supplemented by survey activities. The purpose of a survey is to monitor or observe items or activities to verify conformance to specified requirements. These surveys are conducted by LANL QAS and QAL on a scheduled and random basis.

Site investigation activities are surveyed in accordance with LANL implementing procedures. Surveys are scheduled and conducted based on the activity's relative effect on or importance to the NNWSI Project. All deficiencies, nonconformances, and quality problems identified during surveys are to be documented and monitored to ensure and verify that effective corrective action is made.

18.3.1 Planning

Surveys are performed according to written checklists or plans whenever practicable. The documentation identifies characteristics; defines methods and acceptance criteria; and provides for the recording of objective evidence of results, the

identification and qualification of personnel, and the accuracy of the equipment necessary to perform the survey.

18.3.2 Reporting Independence

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

18.3.3 Records

Survey reports will include the following:

- 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;
- the survey results; and
- a statement of acceptance or rejection.

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 AFFECTING QUALITY: Activities that affect the validity of information or data reported to NNWSI Project participants or to agencies designated to receive Project output on the functions of structures, systems, or components that are important to operator safety and that could cause undue risk to health or safety of the public. These activities may include planning, researching, developing, demonstrating, investigating, characterizing, designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, decontaminating, decommissioning, dismantling, etc.

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

AP- NNWSI Administrative Procedure: An implementing procedure which identifies the interface control methods which govern Project-wide systems and are implemented by all Project participants. Administrative procedures 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.

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

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.

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.

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.

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

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.

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

DOCUMENT: Any record not considered to be a Quality Assurance Record. The term records will be construed to be Quality Assurance Records. 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.

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.

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.

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

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

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

INTERNAL AUDIT: An audit performed by an organization on its own program to see if the program meets its QA plan.

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 NNWSI Project QA records are classified as lifetime records.

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 NNWSI Project. 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.

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

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

NNWSI PROJECT PERSONNEL: All DOE participating organizations and Nevada Test Site (NTS) support contractor personnel involved in NNWSI Project activities.

NNWSI PROJECT QUALITY ASSURANCE PLAN (QAP): The document that describes the planned, systematic QA requirements that are applicable to the NNWSI Project. The QAPPs of the WMPO, participating organizations, and NTS support contractors shall be consistent with this document.

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

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

NTS SUPPORT CONTRACTOR: Organizations that are directly under contract to DOE/NV for activities at the NTS 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.

OVERVIEW: An analysis and assessment by management of the scope, status, adequacy, and effectiveness of the quality achievement and assurance activities for the Project. 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: The government agencies external to the DOE, national laboratories, and organizations participating directly in NNWSI Project activities.

PEER REVIEW: A documented critical review performed by 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. 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. (Peer reviews are conducted at the direction of WMPO.)

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

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.

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 NNWSI Project participant.

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

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. This includes information that has been qualified and accepted in accordance with NNWSI Project AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the NNWSI Project QA Program."

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, waste isolation, or both, and a list of activities that will provide site characterization data, which will be used to assess the performance of natural barriers. The items and activities on this list are subject to the highest quality assurance level (QA Level I) of the formal QA Plan.

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.

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

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. QA includes quality control, which comprises those QA actions related to the physical characteristics of a material, structure, component, or system that provide a means by which to control the quality of the material, structure, component, or system to predetermined requirements.

QUALITY ASSURANCE RECORD: An individual document or other item that has been executed, completed, and approved and that furnishes evidence of the quality and completeness of data (including raw data), items, and activities affecting quality; documents prepared and maintained to demonstrate implementation of programs (e.g., audit, surveillance, and inspection reports); procurement documents; other documents such as plans, correspondence, documentation of telecons, specification, technical data, books, maps, papers, photographs, and data sheets; items such as magnetic media; and other materials that provide data and document quality regardless of the physical form or characteristic.

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. QA Level I applies to items and activities important to safety, which include 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 that 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 that require a level of QA 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 WMPO concerns, and the environment. Activities that have a major impact on project costs or schedules that could delay the achievement of DOE Office of Geologic Repository milestones must be controlled as QA Level II.

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 LANL's QA program, the applicable QA requirements, and the instructions to implement and apply the QA requirements to activities.

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

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

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 of completion or correction that uses existing approved procedures by which a nonconforming item or activity is made to conform to the original requirements.

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.

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, geomechanical, 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 that may be used to substantiate the performance of scientific investigations and experiments when the work involves a high degree of professional judgement, trial-and-error methods, or both.

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 or 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.

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 NTS support contractor for NNWSI Project 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 NNWSI Project 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, which require technical verification 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.

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.

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.

WASTE MANAGEMENT PROJECT OFFICE (WMPO): The organization to which the DOE, Nevada Operations Office (DOE/NV) has assigned the responsibility of administering and coordinating the activities of various participating organizations and NTS support contractors associated with the NNWSI Project.

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 QAPP, R2, 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 to 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 (NPSH), 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 startup, 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 an indication of 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 pre-operational 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 QUALIFICATIONS OF INSPECTION AND TEST PERSONNEL

C.1 Introduction

The following are the requirements for the qualification of personnel who inspect and test to verify conformance to specified requirements for the purpose of acceptability. The requirements for the qualification of personnel performing nondestructive examination are specified in Appendix D. LANL or its subcontractor does not currently conduct any inspections or tests to which the following requirements apply. However, Appendix C, Requirements for the Qualification of Inspection and Test Personnel, has been included in the event that LANL or its subcontractor does conduct inspections and tests in the future. For a detailed discussion on inspection guidance and test requirements, see QAPP, R2, Sections 10 and 11.

C.2 Functional Qualifications

Three levels of qualification will be used depending on the complexity of the functions involved. The recommendations for each level are not limiting with regard to organizational position or professional status. However, such recommendations are limiting with regard to functional activities.

C.2.1 Level I Personnel Capabilities

A Level I person shall be capable of performing and documenting the results of inspections or tests that are required to be performed in accordance with documented procedures, acceptance standards, and/or industry practices as defined in users' written procedures.

C.2.2 Level II Personnel Capabilities

A Level II person shall have all of the capabilities of a Level I person for the inspection, test category, or class in question. Additionally, a Level II person shall have demonstrated capabilities in planning inspections and tests; in setting up tests, including the preparation and set-up of related equipment; in supervising and certifying lower-level personnel; and in evaluating the validity and acceptability of inspection and test results.

C.2.3 Level III Personnel Capabilities

A Level III person shall have all of the capabilities of a Level II person for the inspection, test category, or class in question. In addition, the individual shall also be capable of evaluating the adequacy of specific programs used to train and certify inspection and test personnel whose qualifications are covered by this section.

C.3 Education and Experience Qualifications

The following education and experience recommendations will be considered. Other factors, such as previous performance or satisfactory completion of capability testing that is recognized as commensurate with the scope, complexity, or special nature of the activity, may provide reasonable assurance that a person can competently perform a particular task. These factors and the basis for their equivalency will be documented.

C.3.1 Level I Education and Experience Requirements

Level I education and experience requirements include

- two years of related experience in equivalent inspection or testing activities,
- high school graduation and six months of related experience in equivalent inspection or testing activities, or
- completion of college-level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspection or testing activities.

C.3.2 Level II Education and Experience Requirements

Level II education and experience requirements include

- one year of satisfactory performance at Level I education and experience requirements in the corresponding inspection or test category or class,
- high school graduation plus three years of related experience in equivalent inspection or testing activities,
- completion of college-level work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspection or testing activities, or
- graduation from a four-year college plus six months of related experience in equivalent inspection activities or testing activities.

C.3.3 Level III Education and Experience Requirements

Level III education and experience requirements include

- six years of satisfactory performance at Level II education and experience requirements in the corresponding inspection or test category or class;
- high school graduation plus ten years of related experience in equivalent inspection or testing activities, high school graduation plus eight years of experience in equivalent inspection of testing activities with at least two years associated with nuclear facilities or sufficient training to be acquainted with relevant QA aspects of a nuclear facility;
- completion of college-level work leading to an associate degree and seven years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities or at least sufficient training to be acquainted with the relevant QA aspects of a nuclear facility; or
- graduation from a four-year college plus five years related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities or at least sufficient training to be acquainted with the relevant QA aspects of a nuclear facility.

C.4 Certification

C.4.1 Qualification Requirements

In the event that LANL or its subcontractor becomes more responsible for inspection and testing activities in the future, LANL shall designate those activities that require qualified inspection and test personnel and the minimum qualification requirements for such personnel. Further, LANL shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the established requirements are permitted to perform inspection and test activities. If a single inspection or test requires implementation by a team or a group, then personnel who do not meet the requirements of this section will be used in data-taking assignments or in repository or equipment operation and will be supervised or overseen by a qualified individual.

C.4.2 Personnel Selection

Personnel selected to perform inspection and test activities will have the experience or training commensurate with the scope, complexity, or special nature of the activities.

C.4.3 Indoctrination

Provisions will be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are to be employed.

C.4.4 Training

The need for a formal training program will be determined, and such training activities will be conducted as required to qualify personnel who perform inspection and tests. On-the-job training will be included in the program and will emphasize first-hand experience gained through actual performance of inspections and tests. Instructions will also be provided for those changes to the QAPP and implementing procedures that affect previous training.

C.4.5 Determination of Initial Capability

The capabilities of a candidate for certification will be initially determined by a suitable evaluation of the candidate's education, experience, training, and test results of demonstrated capability in accordance with the organization's procedure for personnel qualification.

C.4.6 Evaluation of Performance

The job performance of inspection and test personnel will be re-evaluated at periodic intervals not to exceed three years. Re-evaluation will include evidence of continued satisfactory performance or redetermination of capability. If, during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in his qualified area for a period of one year shall be re-evaluated, and the organization shall, according to its procedures, redetermine the person's capability.

C.4.7 Certification of Qualification

The qualification of personnel shall be certified in writing in an appropriate form and will include the following information:

- the employer's name;
- the identification of the person being certified;
- activities for which the person is certified to perform;
- the basis used for certification, including such factors as education, experience, and training (when necessary), test results (where applicable), and results of capability demonstration;
- results of periodic evaluations;
- results of physical examinations (when required);
- the signature of LANL's designated representative who is responsible for such certification; and
- dates of certification and certification expiration.

C.4.8 Physical

LANL or its subcontractors will identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examinations.

APPENDIX D

D.0 REQUIREMENTS FOR THE QUALIFICATIONS OF NONDESTRUCTIVE EXAMINATION PERSONNEL

D.1 Introduction

Appendix D provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), and leak-testing (LT), hereinafter referred to as nondestructive examination (NDE), to verify conformance to specified requirements.

D.2 Certification

D.2.1 Applicable Documents

The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 edition, and its applicable supplements shall apply as requirements to NDE personnel covered by this section.

D.2.2 Program

LANL or its subcontractor will establish written procedures for the control and administration of NDE personnel training, examination, and certification.

D.2.3 Certificate of Qualification

The qualification of personnel will be certified in writing in an appropriate form, including the following information:

- the employer's name;
- the identification of the person being certified;
- activities that the person is certified to perform;
- the basis used for certification, including such factors as education, experience, and training (when necessary), test results (where applicable); and results of capability demonstration;
- results of periodic evaluations;
- results of physical examinations (when required);
- the signature of LANL's designated representative who is responsible for such certification; and
- dates of certification and certification expiration.

D.2.4 Physical

LANL or its subcontractors shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examinations.

APPENDIX E

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

E.1 Introduction

All LANL NNWSI Project 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. Appendix E provides requirements for the qualification of lead auditors. A lead auditor organizes and directs audits, reports audit findings, and evaluates corrective actions. Appendix E also provides amplified requirements for the qualifications of individuals, hereinafter referred to as auditors, who participate in an audit, including specialists, management representatives, and auditors-in-training.

E.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.

E.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.

E.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 closing audit findings.

E.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.

E.1.2 Qualification of Lead Auditors

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

E.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.

E.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 NNWSI Project;
- 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: 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; and
- on-the-job training, including applicable elements of the audit program.

E.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.

E.1.2.4 Examination

Prospective lead auditors must pass an examination that will evaluate their comprehension of and ability to apply the body of knowledge identified in Subsection E.1.2.2 of this Appendix. The test may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section E.3 of this Appendix.

E.2 Maintenance of Qualification

E.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.

E.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 E.1.2.2 of this Appendix, re-examination in accordance with Subsection E.3.2 of this Appendix, and participation as an auditor in at least one nuclear facility QA audit.

E.3 Administration

E.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.

E.3.2 Qualification Examination

The development and administration of the examination for a lead auditor required by Subsection E.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 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.

E.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.

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME I

CONTENTS

QUALITY ASSURANCE PROCEDURES (QP)

NOTE: Please note that the table of contents now reflects new procedural alpha numeric designators. As each procedure is revised, the new designator will be used and ultimately the old designator will be completely removed.

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME I

QUALITY ASSURANCE PROCEDURES (QP) - Concluded

Present Designations	Title	New Designations
TWS-QAS-QP-12.1, R1	NNWSI Instrument Calibrations	
TWS-QAS-QP-13.1, R0	Handling, Storage, and Shipping Procedure	
TWS-MSTQA-QP-14, R1	Research and Development (Experimental) Procedure	TWS-QAS-QP-03.X, R0
TWS-MSTQA-QP-16, R0	NNWSI Control of Nonconformances	TWS-QAS-QP-15.X, R0
TWS-QAS-QP-17, R0	NNWSI QA Audits	TWS-QAS-QP-18.1, R0
TWS-QAS-QP-17.1, R0	Records Management Procedure (Draft QAL Manuals)	
TWS-MSTQA-QP-18, R1	Assignment of Quality Levels for Los Alamos NNWSI Activities and Items	TWS-QAS-QP-02.X, R0
TWS-MSTQA-QP-19, R0	NNWSI Change Requests	TWS-QAS-QP-06.X, R0
TWS-QAS-QP-21, R0	Corrective Action	TWS-QAS-QP-16.X, R0
TWS-QAS-QP-22, R0	NNWSI Supplier Qualification	TWS-QAS-QP-07.X, R0

CHANGE REQUESTS (CR)

CR No. 007	Modifies QP-12,R0 (CR in front of QP)
CR No. 008	Modifies QP-06,R2 (CR in front of QP)
CR No. 009	Modifies QP-18,R1 (CR in front of QP)
CR No. 011	Modifies QP-12,R0 (CR in front of QP)
CR No. 012	Modifies QP alpha numeric code (CR in front of Volume I Table of Contents)
CR No. 013	Modifies QP-16,R0
CR No. 019	Modifies QP-14, R1 (CR in front of QP)
CR No. 024	Modifies QP-16, R1 (CR in front of QP-16, R1)
CR No. 026	Modifies QP-19,R0 (CR in front of QP)

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME II

CONTENTS

DETAILED PROCEDURES (DP)

Isotopic Nuclear Chemistry DPs

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME II

DETAILED PROCEDURES (DP) - Continued

TWS-INC-DP-62, R1	Bulk NTS Well Water Samples
TWS-INC-DP-63, R0	Preparation of NTS Core Samples for NNWSI Crushed Rock Experiments
TWS-INC-DP-65, R0	Procedure for Volcanism Field Studies

Health, Safety, and Environmental Division DPs

TWS-HSE5-DP-201, R0	Air Particulate Sample Preparation Procedure for SEM Evaluation
TWS-HSE5-DP-202, R0	Operating Instructions for Amray Model 1000 Scanning Electron Microscope and Kevex Model 7000 Energy Dispersive X-Ray Analyzer for Evaluation of Air Samples Collected on Nuclepore Filters
TWS-HSE5-DP-206	Fiber Counting Procedure
TWS-HSE5-DP-211, R0	Preparation and use of Air Particulate Filter Sampling Devices
TWS-HSE5-DP-212, R0	Preparation, Calibration, and use of Cascade Impactors
TWS-HSE5-DP-213, R0	Procedure For The Calibration and Use of SKC Personal Sampling Pumps
TWS-HSE5-DP-214, R0	Procedures For The Calibration and Use of Alpha-1 Personal Sampling Pumps
TWS-HSE5-DP-215, R0	Procedures For The Calibration of The Singer Dry Gas Meter

WX-Design Engineering Division DPs

TWS-WX-DP-59, R0	NNWSI Exploratory Shaft Facility Design Control Procedure

CHANGE REQUESTS (CR)

CR No. 006	Modifies DP-35,R0 (CR in front of DP)
CR No. 025	Modifies TWS-INC-DP-35, R0 (CR in front of DP-35, R0)

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME III

CONTENTS

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME III

EARTH AND SPACE SCIENCES DPs - Concluded

ENVIRONMENTAL SCIENCE

CHANGE REQUESTS (CR)

QUALITY ASSURANCE PROGRAM INDEX OF PROCEDURES FOR LOS ALAMOS NNWSI PROJECT

This index is prepared and maintained in accordance with TWS-MSTQA-QP-02.

Section No.	Title	NNWSI Procedure Reference
1.	Organization	
2.	Quality Assurance Program	LANL-NNWSI-QAPP Sections 1 and 2. TWS-MSTQA-QP-02 TWS-QAS-QP-02.1 TWS-MSTQA-QP-18
3.	Design Control	LANL-NNWSI-QAPP Section 3. TWS-WX-DP-59
4.	Procurement Document Control	LANL-NNWSI-QAPP Section 4. TWS-QAS-QP-04.1 TWS-QAS-QP-22
5.	Instructions, Procedures, and Drawings	LANL-NNWSI-QAPP Section 5. TWS-QAS-QP-03 TWS-QAS-QP-05.1 TWS-QAS-QP-05.2 TWS-MSTQA-QP-07 TWS-MSTQA-QP-09 TWS-MSTQA-QP-11 TWS-QAS-QP-12.1 TWS-QAS-QP-13.1 TWS-MSTQA-QP-14 TWS-MSTQA-QP-15 TWS-INC-WP-12 TWS-ESS-DP-01 TWS-INC-DP-02 TWS-ESS-DP-03 TWS-ESS-DP-04 TWS-CNC-DP-05

* Procedures affected by this issue have been underscored.

Section No.	Title	NNWSI Procedure Reference
5.	Instruction, Procedures, and Drawings (continued)	TWS-ESS-DP-06
		TWS-ESS-DP-07
		TWS-ESS-DP-09
		TWS-ESS-DP-10
		TWS-ESS-DP-11
		TWS-CNC-DP-14
		TWS-CNC-DP-15
		TWS-ESS-DP-16
		TWS-CNC-DP-17
		TWS-CNC-DP-18
		TWS-ESS-DP-20
		TWS-CNC-DP-22
		TWS-CNC-DP-23
		TWS-ESS-DP-24
		TWS-ESS-DP-25
		TWS-INC-DP-26
		TWS-INC-DP-27
		TWS-ESS-DP-28
		TWS-INC-DP-30
		TWS-INC-DP-34
		TWS-INC-DP-35
		TWS-INC-DP-36
		TWS-INC-DP-37
		TWS-INC-DP-38
		TWS-INC-DP-39
		TWS-INC-DP-40
		TWS-INC-DP-41
		TWS-INC-DP-42
		TWS-INC-DP-43
		TWS-INC-DP-44
		TWS-INC-DP-45
		TWS-ESS-DP-50
		TWS-ESS-DP-51
		TWS-ESS-DP-52
		TWS-ESS-DP-53
		TWS-ESS-DP-54
		TWS-ESS-DP-55
		TWS-ESS-DP-56
		TWS-WX-DP-59
		TWS-INC-DP-60
		TWS-INC-DP-61
		TWS-INC-DP-62
		TWS-INC-DP-63
		TWS-INC-DP-65
		TWS-INC-DP-101
		TWS-ESS-DP-102
		TWS-ESS-DP-103
		TWS-ESS-DP-105
		TWS-ESS-DP-106

* Procedures affected by this issue have been underscored.

Section No.	Title	NNWSI Procedure Reference
5.	Instruction, Procedures, and Drawings (concluded)	TWS-ESS-DP-107 TWS-ESS-DP-110 TWS-ESS-DP-111 TWS-ESS-DP-112 TWS-ESS-DP-113 TWS-INC-DP-114 TWS-ESS-DP-115 TWS-HSE5-DP-201 TWS-HSE5-DP-202 TWS-HSE-5-DP-206 TWS-HSE5-DP-211 TWS-HSE5-DP-212 TWS-HSE5-DP-213 TWS-HSE5-DP-214 TWS-HSE5-DP-215 TWS-HSE12-DP-301
6.	Document Control	LANL-NNWSI-QAPP Section 6. TWS-MSTQA-QP-03 TWS-QAS-QP-07 TWS-MSTQA-QP-10 TWS-MSTQA-QP-19
7.	Control of Purchased Items and Services	LANL-NNWSI-QAPP Section 7. TWS-QAS-QP-04.1
8.	Identification and Control of Items	LANL-NNWSI-QAPP Section 8.
9.	Control of Processes	LANL-NNWSI-QAPP Section 9. TWS-MSTQA-QP-14
10. & 11.	Inspection and Test and Control	LANL-NNWSI-QAPP Sections 10 & 11. TWS-MSTQA-QP-11 TWS-MSTQA-QP-14
12.	Control of Measuring and Test Equipment	LANL-NNWSI-QAPP Section 12. TWS-QAS-QP-12.1, R1

* Procedures affected by this issue have been underscored.

Section No.	Title	NNWSI Procedure Reference
13.	Handling, Storage, and Shipping	LANL-NNWSI-QAPP Section 13. TWS-QAS-QP-13.1
14.	Inspection, Test, and Operating Status	LANL-NNWSI-QAPP Section 14.
15.	Control of Nonconforming Items	LANL-NNWSI-QAPP Section 15. TWS-MSTQA-QP-16
16.	Corrective Action	LANL-NNWSI-QAPP Section 16. TWS-QAS-QP-21
17.	Quality Assurance Records	LANL-NNWSI-QAPP Section 17. TWS-MSTQA-QP-03 TWS-QAS-QP-17.1
18.	Audits	LANL-NNWSI-QAPP Section 18. TWS-QAS-QP-17

* Procedures affected by this issue have been underscored.

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME I

CONTENTS

QUALITY ASSURANCE PROCEDURES (QP)

NOTE: Please note that the table of contents now reflects new procedural alpha numeric designators. As each procedure is revised, the new designator will be used and ultimately the old designator will be completely removed.

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME I

QUALITY ASSURANCE PROCEDURES (QP) - Concluded

Present Designations	Title	New Designations
TWS-QAS-QP-12.1, R1	NNWSI Instrument Calibrations	
TWS-QAS-QP-13.1, R0	Handling, Storage, and Shipping Procedure	
TWS-MSTQA-QP-14, R1	Research and Development (Experimental) Procedure	TWS-QAS-QP-03.X, R0
TWS-MSTQA-QP-16, R0	NNWSI Control of Nonconformances	TWS-QAS-QP-15.X, R0
TWS-QAS-QP-17, R0	NNWSI QA Audits	TWS-QAS-QP-18.1, R0
TWS-QAS-QP-17.1, R0	Records Management Procedure (Draft QAL Manuals)	
TWS-MSTQA-QP-18, R1	Assignment of Quality Levels for Los Alamos NNWSI Activities and Items	TWS-QAS-QP-02.X, R0
TWS-MSTQA-QP-19, R0	NNWSI Change Requests	TWS-QAS-QP-06.X, R0
TWS-QAS-QP-21, R0	Corrective Action	TWS-QAS-QP-16.X, R0
TWS-QAS-QP-22, R0	NNWSI Supplier Qualification	TWS-QAS-QP-07.X, R0

CHANGE REQUESTS (CR)

CR No. 007	Modifies QP-12,R0 (CR in front of QP)
CR No. 008	Modifies QP-06,R2 (CR in front of QP)
CR No. 009	Modifies QP-18,R1 (CR in front of QP)
CR No. 011	Modifies QP-12,R0 (CR in front of QP)
CR No. 012	Modifies QP alpha numeric code (CR in front of Volume I Table of Contents)
CR No. 013	Modifies QP-16,R0
CR No. 019	Modifies QP-14, R1 (CR in front of QP)
CR No. 024	Modifies QP-16, R1 (CR in front of QP-16, R1)
CR No. 026	Modifies QP-19,R0 (CR in front of QP)

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME II

CONTENTS

DETAILED PROCEDURES (DP)

Isotopic Nuclear Chemistry DPs

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME II

DETAILED PROCEDURES (DP) - Continued

TWS-INC-DP-62, R1	Bulk NTS Well Water Samples
TWS-INC-DP-63, R0	Preparation of NTS Core Samples for NNWSI Crushed Rock Experiments
TWS-INC-DP-65, R0	Procedure for Volcanism Field Studies

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TWS-HSE5-DP-206	Fiber Counting Procedure
TWS-HSE5-DP-211, R0	Preparation and use of Air Particulate Filter Sampling Devices
TWS-HSE5-DP-212, R0	Preparation, Calibration, and use of Cascade Impactors
TWS-HSE5-DP-213, R0	Procedure For The Calibration and Use of SKC Personal Sampling Pumps
TWS-HSE5-DP-214, R0	Procedures For The Calibration and Use of Alpha-1 Personal Sampling Pumps
TWS-HSE5-DP-215, R0	Procedures For The Calibration of The Singer Dry Gas Meter

WX-Design Engineering Division DPs

TWS-WX-DP-59, R0	NNWSI Exploratory Shaft Facility Design Control Procedure

CHANGE REQUESTS (CR)

CR No. 006	Modifies DP-35,R0 (CR in front of DP)
CR No. 025	Modifies TWS-INC-DP-35, R0 (CR in front of DP-35, R0)

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME III

CONTENTS

EARTH AND SPACE SCIENCES DPS

Los Alamos National Laboratory
Quality Assurance Documents
for the
Nevada Nuclear Waste Storage Investigations

VOLUME III

EARTH AND SPACE SCIENCES DPs - Concluded

ENVIRONMENTAL SCIENCE

CHANGE REQUESTS (CR)

QUALITY ASSURANCE PROGRAM INDEX OF PROCEDURES FOR LOS ALAMOS NNWSI PROJECT

This index is prepared and maintained in accordance with TWS-MSTQA-QP-02.

Section No.	Title	NNWSI Procedure Reference
1.	Organization	
2.	Quality Assurance Program	LANL-NNWSI-QAPP Sections 1 and 2. TWS-MSTQA-QP-02 TWS-QAS-QP-02.1 TWS-MSTQA-QP-18
3.	Design Control	LANL-NNWSI-QAPP Section 3. TWS-WX-DP-59
4.	Procurement Document Control	LANL-NNWSI-QAPP Section 4. TWS-QAS-QP-04.1 TWS-QAS-QP-22
5.	Instructions, Procedures, and Drawings	LANL-NNWSI-QAPP Section 5. TWS-QAS-QP-03 TWS-QAS-QP-05.1 TWS-QAS-QP-05.2 TWS-MSTQA-QP-07 TWS-MSTQA-QP-09 TWS-MSTQA-QP-11 TWS-QAS-QP-12.1 TWS-QAS-QP-13.1 TWS-MSTQA-QP-14 TWS-MSTQA-QP-15 TWS-INC-WP-12 TWS-ESS-DP-01 TWS-INC-DP-02 TWS-ESS-DP-03 TWS-ESS-DP-04 TWS-CNC-DP-05

* Procedures affected by this issue have been underscored.

Section No.	Title	NNWSI Procedure Reference
5.	Instruction, Procedures, and Drawings (continued)	TWS-ESS-DP-06
		TWS-ESS-DP-07
		TWS-ESS-DP-09
		TWS-ESS-DP-10
		TWS-ESS-DP-11
		TWS-CNC-DP-14
		TWS-CNC-DP-15
		TWS-ESS-DP-16
		TWS-CNC-DP-17
		TWS-CNC-DP-18
		TWS-ESS-DP-20
		TWS-CNC-DP-22
		TWS-CNC-DP-23
		TWS-ESS-DP-24
		TWS-ESS-DP-25
		TWS-INC-DP-26
		TWS-INC-DP-27
		TWS-ESS-DP-28
		TWS-INC-DP-30
		TWS-INC-DP-34
		TWS-INC-DP-35
		TWS-INC-DP-36
		TWS-INC-DP-37
		TWS-INC-DP-38
		TWS-INC-DP-39
		TWS-INC-DP-40
		TWS-INC-DP-41
		TWS-INC-DP-42
		TWS-INC-DP-43
		TWS-INC-DP-44
		TWS-INC-DP-45
		TWS-ESS-DP-50
		TWS-ESS-DP-51
		TWS-ESS-DP-52
		TWS-ESS-DP-53
		TWS-ESS-DP-54
		TWS-ESS-DP-55
		TWS-ESS-DP-56
		TWS-WK-DP-59
		TWS-INC-DP-60
		TWS-INC-DP-61
		TWS-INC-DP-62
		TWS-INC-DP-63
		TWS-INC-DP-65
		TWS-INC-DP-101
		TWS-ESS-DP-102
		TWS-ESS-DP-103
		TWS-ESS-DP-105
		TWS-ESS-DP-106

* Procedures affected by this issue have been underscored.

Section No.	Title	NNWSI Procedure Reference
5.	Instruction, Procedures, and Drawings (concluded)	TWS-ESS-DP-107 TWS-ESS-DP-110 TWS-ESS-DP-111 TWS-ESS-DP-112 TWS-ESS-DP-113 TWS-INC-DP-114 TWS-ESS-DP-115 TWS-HSE5-DP-201 TWS-HSE5-DP-202 TWS-HSE-5-DP-206 TWS-HSE5-DP-211 TWS-HSE5-DP-212 TWS-HSE5-DP-213 TWS-HSE5-DP-214 TWS-HSE5-DP-215 TWS-HSE12-DP-301
6.	Document Control	LANL-NNWSI-QAPP Section 6. TWS-MSTQA-QP-03 TWS-QAS-QP-07 TWS-MSTQA-QP-10 TWS-MSTQA-QP-19
7.	Control of Purchased Items and Services	LANL-NNWSI-QAPP Section 7. TWS-QAS-QP-04.1
8.	Identification and Control of Items	LANL-NNWSI-QAPP Section 8.
9.	Control of Processes	LANL-NNWSI-QAPP Section 9. TWS-MSTQA-QP-14
10. & 11.	Inspection and Test and Control	LANL-NNWSI-QAPP Sections 10 & 11. TWS-MSTQA-QP-11 TWS-MSTQA-QP-14
12.	Control of Measuring and Test Equipment	LANL-NNWSI-QAPP Section 12. TWS-QAS-QP-12.1, R1

* Procedures affected by this issue have been underscored.

Section No.	Title	NNWSI Procedure Reference
13.	Handling, Storage, and Shipping	LANL-NNWSI-QAPP Section 13. TWS-QAS-QP-13.1
14.	Inspection, Test, and Operating Status	LANL-NNWSI-QAPP Section 14.
15.	Control of Nonconforming Items	LANL-NNWSI-QAPP Section 15. TWS-MSTQA-QP-16
16.	Corrective Action	LANL-NNWSI-QAPP Section 16. TWS-QAS-QP-21
17.	Quality Assurance Records	LANL-NNWSI-QAPP Section 17. TWS-MSTQA-QP-03 TWS-QAS-QP-17.1
18.	Audits	LANL-NNWSI-QAPP Section 18. TWS-QAS-QP-17

* Procedures affected by this issue have been underscored.

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 28
Rev 0
Date 4/27/88

Procedure No. TWS-ESS-DP-04, R4 THIN SECTION PREPARATION PROCEDURE

Change Requested: Start typing text here

Replace Section 4.3 'Documentation' with Section 4.3 'Records', to state:

Thin section request forms and sample log forms will be sent to the LANL Records Processing Center on a semiannual basis.

Reason for Change: Start typing text here

LATA Audit No. LANL-NNWSI-88-03 found that these records were not getting into the formal records management system.

Change Requested By Larry W Maassen **Date** 4/27/88

Reviewed By Dave Vaniman **Date** 4/27/88

QAPL Approval Karen A. West **Date** 5/3/88

TPO Approval K. J. Hurtado **Date** 5/3/88

Effective Date May 3, 1988 **Date** 5/3/88

LOS ALAMOS NATIONAL LABORATORY
NNWSI
CHANGE REQUEST

Change Request No. 29
Rev 0
Date 4/27/88

Procedure No. TWS-ESS-DP-114, RO SAMPLE COLLECTION PROCEDURE FOR ROCK VARNISH STUDIES

Change Requested: Start typing text here

Insert the following as the first paragraph in Section 4.3:

Rock varnish samples shall be packed for shipment to Los Alamos in a manner so as to preclude destruction of the varnished rock surface during transport. Each varnished clast will be individually wrapped in paper or other protective material and placed in a cloth sample bag on which sample identification numbers will be marked by a permanent marking pen. Sample bags containing rock varnish samples will be hand carried to Los Alamos whenever possible. If sample bags containing rock varnish samples are shipped to Los Alamos, they shall be packed in heavy cardboard shipping containers sturdy enough to preclude crushing of samples during transport.

Reason for Change: Start typing text here

LATA Audit No. LANL-NNWSI-88-03, Finding No. 3 found that the above indicated procedure did not adequately address handling requirements for the collected samples.

Change Requested By Charles D Harrington **Date** April 28, 1988

Reviewed By Wayne L Wilkins **Date** April 28, 1988

QAPL Approval Kenneth Wolfe **Date** 5/3/88

TPO Approval L. Hunter **Date** 5/3/88

Effective Date May 3, 1988 **Date** 5/3/88

11 FR/M LS06503 (G01)

Los Alamos
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

May 6, 1988

TWS-N5/05-88-11

J. Blaylock, WMPO, Las Vegas, NV
H. Kalia, LANL-NNWSI, Las Vegas, NV
S. Klein, Sr., SAIC, Las Vegas, NV
R. Loux, Jr., NANP, Carson City, NV
H. Nitsche, LBNL, Berkeley, CA
K. Sommer, DOE, Washington, DC
J. Kennedy, NRC, Washington, DC
L. Ibe, Weston, Washington, DC
A. Pendergrass, LATA, Los Alamos, NM
W. Roper, Jr., EG&G, Las Vegas, NV
H. Fuentes, UofT, El Paso, TX
SAIC, Records Center, Las Vegas, NV

SUBJECT: LANL NNWSI QA MANUAL REVISIONS

Enclosed are revisions for inclusion into the QA Manual. Also included is a receipt acknowledgement form, which gives instructions for revising the manual.

If you have any questions, please call Karen Foster at LATA, 662-1763.

Sincerely yours,

H. P. Nunes
LATA, QAS

HPN/lpg

Enclosure: a/s

cy: K. A. West, N-5, MS J521
CRM-4 (2), w/o att., MS A150
RPC, (3) w/o att., MS J521

NH03.102.7
~~NHCC~~ wm-11 1/1

TO: Henry Paul Nunes
Los Alamos National Laboratory
LATA QAS, MS-M321
Los Alamos, NM 87545

FROM: _____ Book Number: _____
(Please Print)

SUBJECT: ACKNOWLEDGEMENT OF RECEIPT TO THE LANL NNWSI QA MANUAL ADDITIONS AND/OR REVISIONS.

Enclosures: Table of Contents (May 6, 1988)
Program Index (May 6, 1988)
CR No. 026
CR No. 028
CR No. 029
QAPP, R2

I have received and made the revisions/additions to my assigned copy of the LANL NNWSI QA Manual as outlined below.

VOLUME I

Replace	Procedure No.	With	Procedure No.
	Table of Contents (April 8, 1988)		Table of Contents (May 6, 1988)
	QA Program Index (April 8, 1988)		QA Program Index (May 6, 1988)
	LANL-NNWSI-QAPP, R1		LANL-NNWSI-QAPP, R2

Remove	Procedure No.	
	TWS-MSTQA-QP-12, R0	(Note: Replaced by QP-04.1, R0 which was distributed 4-8-88)

Add	Procedure No.	Before	Procedure No.
	CR No. 026		TWS-MSTQA-QP-19, R0

VOLUME II

Replace	Procedure No.	With	Procedure No.
	Table of Contents (April 8, 1988)		Table of Contents (May 6, 1988)
	QA Program Index (April 8, 1988)		QA Program Index (May 6, 1988)

WM-11
NH03/1

VOLUME III

Replace	Procedure No.	With	Procedure No.
	Table of Contents (April 8, 1988)		Table of Contents (May 6, 1988)
	QA Program Index (April 8, 1988)		QA Program Index (May 6, 1988)

Add	Procedure No.	Before	Procedure No.
	CR No. 028		TWS-ESS-DP-04, R4
	CR No. 029		TWS-ESS-DP-114, R0

Signature

Date