

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

Effective Date _____

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POLICY

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

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

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LIST OF ACRONYMS

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

1.0 ORGANIZATION

1.1 Los Alamos National Laboratory Yucca Mountain Project

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

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

1.1.1 Responsibilities of the Technical Project Officer

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

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

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

1.1.2 Responsibilities of the Project Leader for the Exploratory Shaft

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

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

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

1.1.3 Responsibilities of the Project Leader for Geochemistry

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

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

1.1.4 Responsibilities of the Principal Investigators and Other Contributing Investigators

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

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

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

1.2 Quality Assurance Functions

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

1.2.1 Dedicated Quality Assurance Positions

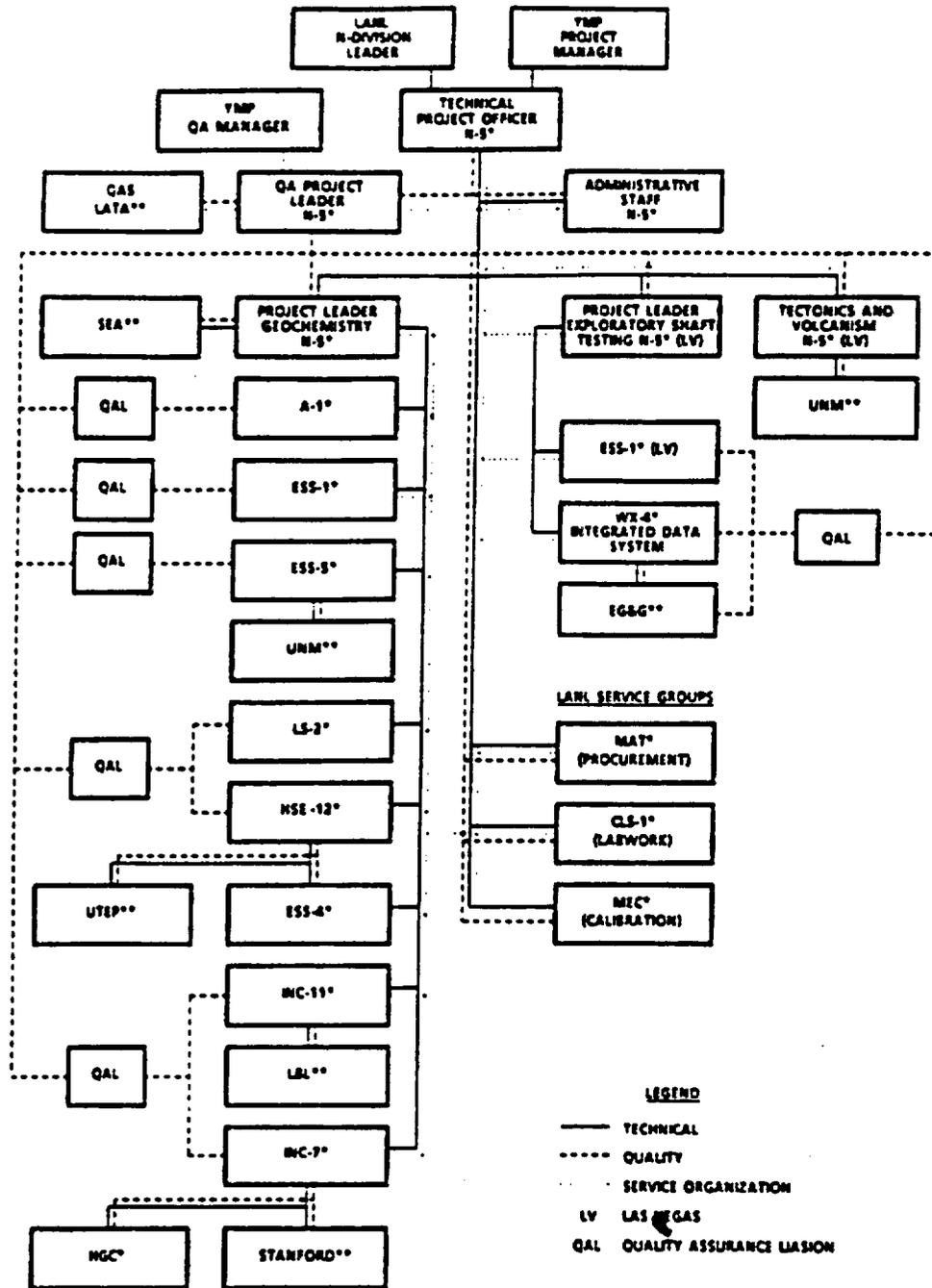
1.2.1.1 Quality Assurance Project Leader

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

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

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

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



* LANL PARTICIPATING GROUPS

- A ANALYSIS
- CLS-1 CHEMISTRY AND LASER SCIENCES
- ESS EARTH AND SPACE SCIENCES
- NSF HEALTH, SAFETY AND ENVIRONMENTAL

** SUBCONTRACTORS

- EGSG EGSG
- HGC HYDROGEOCHEM
- LATA LOS ALAMOS TECHNICAL ASSOCIATES
- LBL LAWRENCE BERKELEY LABORATORY

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

1.2.1.2 Other Dedicated Quality Assurance Positions

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

QAS responsibilities include, but are not limited to,

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

QAL responsibilities include, but are not limited to,

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

1.2.2 QA Organizational Structure

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

1.3 Achievement, Maintenance, and Verification of Quality

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

TABLE 1-1

DIVISION OF LANL YMP QA RESPONSIBILITIES^a

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

TABLE 1-1

DIVISION OF LANL YMP QA RESPONSIBILITIES^a
 (continued)

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

TABLE 1-1

DIVISION OF LANL YMP QA RESPONSIBILITIES^a
 (concluded)

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

conformance with established requirements (unless specifically exempted elsewhere in this QAPP).

1.4 Interface Between Organizations

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

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

2.0 QUALITY ASSURANCE PROGRAM

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

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

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

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

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

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

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

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

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

2.1.1 Verification of the Quality Assurance Program Plan

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

2.1.2 Use of Data Not Generated under Quality Assurance Controls

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

2.1.3 Approach to Quality Assurance

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

2.2 Application of Graded Quality Assurance

2.2.1 Extent of Application

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

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

2.2.2 Method of Application

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

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

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

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

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

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

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

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

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

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

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

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

2.3 Quality Assurance Activities

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

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

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

2.4 Management Assessment

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

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

2.5 Personnel Indoctrination and Training Procedures

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

2.5.1 Position Descriptions and Evaluation of Personnel Qualifications

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

2.5.2 Indoctrination

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

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

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

2.5.3 Training

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

2.5.4 Training and Certification for Auditor

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

2.5.5 Records

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

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

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

3.0 SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL

3.1 Scientific Investigation Control

3.1.1 Preparation of Scientific Investigation Planning Documents

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

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

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

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

3.1.2 Quality Assurance Level Assignment

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

3.1.3 Review and Approval of Scientific Investigation Planning Documents

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

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

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

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

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

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

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

3.1.4 Scientific Investigation Data Interpretation and Analysis Documents

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

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

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

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

3.1.5 Use of Computer Programs

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

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

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

3.1.6.1 Detailed Technical Procedures

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

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

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

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

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

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

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

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

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

Any procedural deviation encountered during activities shall be documented, reported, and evaluated for significance.

3.1.6.2 Scientific Notebooks

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

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

Initial Entries

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

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

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

In-Process Entries

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

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

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

Final Entries

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

3.1.6.3 Logbooks

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

3.1.7 Interface Control

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

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

3.1.8 Verification of Scientific Investigation

3.1.8.1 Verification Planning

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

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

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

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

3.1.8.2 Verification Hold Points

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

3.1.8.3 Reporting Independence of Personnel

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

3.1.9 Reports, Conclusions, and Recommendations

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

3.1.10 Close-Out Verification

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

3.2 Design Control

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

3.2.1 General

The design shall be defined, controlled, and verified. The term design refers to specifications, drawings, design criteria, and performance requirements for the natural and engineered components of the repository system. Design information and design activities refer to the data collection and analyses used in supporting design development and verification. This includes general plans and technical procedures for data collection and analyses and related information such as test results and analyses. Data collection activities resulting from scientific investigations can produce design input. Data analysis includes the initial step of data reduction as well as broad systems analyses (such as performance assessments), which integrate many other data and analyses of individual parameters.

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

3.2.1.1 Quality Assurance Level Assignment

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

3.2.1.2 Qualification of Personnel

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

3.2.1.3 Peer Review

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

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

3.2.2 Design Input

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

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

3.2.3 Design Analysis

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

3.2.3.1 Documentation of Design Analysis

Documentation of design analysis shall include the following:

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

3.2.3.2 Use of Computer Programs

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

3.2.4 Design Verification

3.2.4.1 Identification and Documentation

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

3.2.4.2 Timing of Verification

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

3.2.4.3 Extent of Verification

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

3.2.4.4 Changes in Verified Designs

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

3.2.4.5 Persons Performing Verification

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

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

3.2.4.6 Methods of Design Verification

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

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

Design Reviews

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

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

Alternate Calculations

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

Qualification Tests

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

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

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

3.2.5 Design Change Control

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

3.2.6 Design Interface Control

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

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

3.2.7 Design Output Requirements

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

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

3.2.8 Design Documents as Quality Assurance Records

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

3.3 Software Quality Assurance Requirements

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

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

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

3.3.1 Computer Software Documentation and Control

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

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

3.3.2 Software Description

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

3.3.2.1 Baseline Elements

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

3.3.2.2 Software Changes

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

3.3.2.3 Software Testing

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

3.3.2.4 Qualification of Existing Software

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

3.3.2.5 Interface Management

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

3.3.2.6 Software Configuration Management

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

3.4 Technical Reviews

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

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

3.5 Peer Reviews

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

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Procurement Document Requirements

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

Procurement documents shall contain the following information as appropriate:

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

4.1.1 Scope of Work

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

4.1.2 Technical Requirements

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

4.1.3 Quality Assurance Program Requirements

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

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

4.1.4 Right of Access

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

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

4.1.5 Documentation Requirements

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

4.1.6 Nonconformance

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

4.2 Review of Procurement Documents

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

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

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

4.3 Procurement Document Changes

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

The review of changes shall include

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

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

4.4 Distribution of Procurement Documents

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

5.0 INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

5.1 General

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

5.2 Criteria

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

5.3 Reviews

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

5.4 Distribution

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

6.0 DOCUMENT CONTROL

6.1 Document Preparation, Review, Approval, and Issue

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

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

6.2 Implementation of Document Control

Documents shall be controlled according to a QP that

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

6.3 Changes in Documents

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

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

6.4 Distribution of Documents

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

7.0 CONTROL OF PURCHASED ITEMS AND SERVICE

7.1 General Requirements

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

7.1.1 Procurement Planning

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

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

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

7.1.2 Evaluation and Selection of Suppliers

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

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

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

7.1.3 Bid Evaluation

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

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

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

7.1.4 Interface Measures

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

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

7.1.5 Evaluation of Supplier Performance

7.1.5.1 Verification Measures

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

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

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

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

7.1.5.2 Record of Evaluation and Verification

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

7.1.6 Control of Documents Generated by Suppliers

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

7.1.7 Acceptance of Item or Service

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

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

Methods of acceptance for items include

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

7.1.7.1 Certificate of Conformance

The following minimum criteria apply to a certificate of conformance.

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

7.1.7.2 Source Verification

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

7.1.7.3 Receiving Inspection

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

7.1.7.4 Postinstallation Testing

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

7.1.8 Procurement of Services

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

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

7.1.9 Control of Supplier Issued Nonconformances

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

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

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

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

Disposition of nonconformances by the requester includes

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

7.2 Commercial-Grade Items

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

7.2.1 Identification of Commercial-Grade Items

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

7.2.2 Source Evaluation and Selection

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

7.2.3 Purchase Order

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

7.2.4 Receipt of Commercial-Grade Items

Receipt of a commercial-grade item shall determine that

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

8.0 IDENTIFICATION AND CONTROL OF SAMPLES AND DATA

8.1 Identification and Control of Samples

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

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

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

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

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

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

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

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

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

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

8.2 Identification and Control of Data

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

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

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

9.0 CONTROL OF PROCESSES

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

10.0 INSPECTION

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

11.0 TESTING

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

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Scope of Control Program

Tools, gages, instruments, and other measuring and test equipment used in activities affecting quality shall be controlled. They shall be calibrated and adjusted at specified periods to maintain measurement accuracy within specified limits. The scope and methodology of the control program includes all equipment or systems used to calibrate, measure, gage, test or inspect, either to control or to acquire data, to verify conformance to a specified requirement, or to establish characteristics or values not previously known. Calibration and control measures are not required for rulers, tape measures, levels, and other such devices if normal commercial equipment provides adequate accuracy.

12.2 Description of Responsibilities

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

12.3 Program Requirements

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

12.3.1 Selection

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

12.3.2 Calibration

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

12.3.3 Capability

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

12.3.4 Handling and Storage

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

12.4 Records

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

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

13.0 HANDLING, SHIPPING, AND STORAGE

13.1 General

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

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

13.2 Special Equipment and Protective Environments

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

13.3 Specific Procedures

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

13.4 Inspection and Testing of Special Tools and Equipment

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

13.5 Training of Special Equipment Operators

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

13.6 Marking and Labeling

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

14.0 INSPECTION, TEST, AND OPERATING STATUS OF ENGINEERED ITEMS

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

15.0 CONTROL OF NONCONFORMANCES

15.1 General

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

15.2 Identification

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

15.3 Nonconformance Control Log

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

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

15.4 Segregation

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

15.5 Disposition

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

15.5.1 Responsibility and Authority

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

15.5.2 Personnel

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

15.5.3 Disposition of the NCR

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

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

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

15.5.4 Project Office Notification

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

15.5.5 Corrective Action

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

15.6 Conditional Release

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

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

15.7 Nonconformances and Trending

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

16.0 CORRECTIVE ACTION

16.1 General

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

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

16.2 Significant Adverse Conditions

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

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

16.3 QA Follow-Up Action

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

16.4 Corrective Action Reports

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

17.0 RECORDS

17.1 General

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

17.2 Management, Control, and Preservation of Records

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

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

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

17.3 Minimum Records

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

17.4 Generation of Records

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

17.5 Validation and Authentication of Records

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

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

17.6 Receipt of Records

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

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

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

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

17.7 Records Identification

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

17.8 Storage of Records

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

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

17.8.1 Responsibilities

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

17.8.2 Storage Facilities

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

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

17.8.3 Preservation

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

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

17.8.4 Safekeeping

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

17.8.5 Replacement, Restoration, or Substitution

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

17.9 Corrected Information in Records

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

17.10 Access to QA Records

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

17.11 Transfer of QA Records

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

18.0 AUDITS

18.1 General Requirements

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

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

18.2 Audits

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

18.2.1 Scheduling

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

18.2.2 Internal Audits

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

18.2.3 External Audits

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

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

18.2.4 Audit Plan

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

18.2.5 Audit Personnel

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

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

18.2.6 Performance

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

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

18.2.7 Reporting

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

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

18.2.8 Response

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

18.2.9 Follow-Up Action

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

18.2.10 Records

Audit records shall include

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

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

18.3 Surveys

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

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

18.3.1 Planning

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

18.3.2 Reporting Independence

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

18.3.3 Records

Survey reports shall include the following:

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

APPENDIX A

TERMS AND DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DEVIATION: A departure from specified requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

QUALIFICATION TESTING: Demonstration that an item meets design requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

REPOSITORY: See Geologic Repository Operations Area.

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

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

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

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

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

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

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

SITE: Location of the controlled area.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

WAIVER: Documented authorization to depart from specified requirements.

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

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

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

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

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

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

APPENDIX B

B.0 DESIGN INPUTS

B.1 Introduction

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

B.2 Applicable Design Inputs

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

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

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

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

APPENDIX C

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

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

APPENDIX D

D.0 REQUIREMENTS FOR THE QUALIFICATION OF NONDESTRUCTIVE
EXAMINATION PERSONNEL

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

APPENDIX E

E.0 LIST OF TYPICAL QA RECORDS

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

E.1 Site Characterization

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

E.2 Design Records

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

E.3 Procurement Records

- **Procurement specifications.**
- **Purchase order including amendments.**

E.4 Manufacturing Records for Procured Equipment

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

E.5 Installation and Construction Records

E.5.1 Receiving and Storage - Nonconformance Reports

E.5.2 General

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

APPENDIX F

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

F.1 Introduction

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

F.1.1 Qualification of Auditors

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

F.1.1.1 Orientation

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

F.1.1.2 Training Programs

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

F.1.1.3 On-the-Job Training

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

F.1.2 Qualification of Lead Auditors

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

F.1.2.1 Communication Skills

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

F.1.2.2 Training

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

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

F.1.2.3 Audit Participation

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

F.1.2.4 Examination

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

F.2 Maintenance of Qualification

F.2.1 Maintenance of Proficiency

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

F.2.2 Requalification

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

F.3 Administration

F.3.1 Organizational Responsibility

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

F.3.2 Qualification Examination

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

F.4 Certification of Qualification

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

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

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

APPENDIX G

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

G.1 General

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

G.2 Methods for Qualification of Existing Data

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

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

G.3 Selection and Documentation of Qualification Methodology

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

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

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

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

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

APPENDIX H

H.0 REQUIREMENTS FOR COMPUTER SOFTWARE

H.1 Objectives and Scope

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

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

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

H.2 Verification and Validation

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

H.2.1 Software Verification

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

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

H.2.2 Model Validation

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

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

H.3 Software Configuration Management

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

H.3.1 Configuration Identification

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

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

H.3.2 Configuration Change Control

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

H.3.3 Configuration Status Accounting

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

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

H.4 Discrepancy Reporting and Corrective Action

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

Software discrepancy procedures shall ensure that, as a minimum,

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

H.5 Media Control and Security

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

H.6 Software Acquisition, Procurement, and Transfer

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

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

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

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

H.7 Software Quality Assurance Plan

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

The LANL SQAP shall identify the:

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

H.8 Software Life Cycle

Each LANL group shall use the life cycle controls below.

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

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

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

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

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

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

H.8.1 Life Cycle Requirements Phase

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

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

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

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

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

H.8.2 Life Cycle Design Phase

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

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

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

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

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

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

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

H.8.3 Life Cycle Coding Phase

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

Verification activities during this phase shall consist of

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

Software coding documentation shall address the following, as applicable:

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

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

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

H.8.4 Life Cycle Testing Phase

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

- execution of the test cases and evaluation of the results,
- evaluation of the completed software to ensure adherence to the requirements, and
- preparation of a report describing the results of software verification.

Life cycle testing activities shall be documented. Software testing documentation includes a plan that describes the tasks and criteria for accomplishing the verification of the software in this phase. The documentation also specifies the hardware and system

software configuration(s) for which the software is designed. In those cases where testing is used to ensure that requirements have been met in the software design, test documentation shall provide traceability from requirements to design as implemented in the code. This documentation also includes a report on the results of the execution of the life cycle verification activities. The report includes the results of all previous reviews, audits, and tests, and a summary of the status of the software.

Model validation will be conducted in accordance with Section H.2.2 of this appendix. Because model validation is dependent on application, model validation may not be completed at this stage.

The software testing review is an evaluation of the adequacy of completed software life cycle verification activities and model validation plans. The review results in an approval of verification and validation documentation.

H.8.5 Life Cycle Installation and Checkout Phase

During this phase, the software may become part of a system that incorporates other software components, hardware, and production data. The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating data bases, and verifying that all components have been included.

Testing activities during this phase shall consist of the execution of test cases for installation and integration. Test cases from earlier phases may be used for installation testing.

H.8.6 Life Cycle Application and Maintenance Phase

During the application and maintenance phase, the software is approved for operational use. Further activities may consist of maintenance of the software to identify and remove latent errors (corrective maintenance), response to new or revised requirements (perfective maintenance), or adaptation of the software to changes in the software environment (adaptive maintenance). Software modifications shall be approved, documented, tested, and controlled in accordance with software configuration management requirements. User notification of changes and corrections is a vital aspect of the maintenance phase.

LANL shall establish procedures for controlling the application of software that performs technical calculations in support of site characterization and performance assessment analyses and for the design, analysis, and operation of repository structures, systems, and components. These software applications shall be reviewed and approved to ensure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.

LANL shall include in QPs, methods for documenting software applications that perform technical calculations to ensure that these applications and the results of these applications may be independently reproduced.

Procedures shall be established for reviewing these applications to provide reasonable assurance that the software used is appropriate for the intended application and that the results produced are accurate. Documentation appropriate for a given application or analysis shall include the computer code, the input data, the assumptions

or approximations used to develop the input data, and appropriate user documentation for performing the application or analysis.

H.9 Mandatory Documentation

The following documentation is mandatory as applicable to the particular software and is maintained as a QA record (reference Section 3.3.1):

- . software summary form,
- . software requirements,
- . software design and change,
- . software verification and validation,
- . continuing documentation and code listings,
- . mathematic and numerical models,
- . user's manual,
- . code assessment and support, and
- . configuration management support.

Mandatory documents shall be reviewed in accordance with LANL review procedures. These documents shall comply with the documentation requirements of NUREG-0856.

APPENDIX I

I.0 REQUIREMENTS FOR THE IDENTIFICATION OF ITEMS AND ACTIVITIES TO BE INCLUDED ON THE Q-LIST

I.1 Introduction

This appendix provides requirements for the identification of items important to safety and the identification of items and activities important to waste isolation. These items and activities are subject to the highest quality assurance level (QA Level I) of this QAPP, and shall be listed on a "Q-List."

The Project Office will prepare the appropriate AP or APs for determining the items and activities to be placed on the "Q-List." This procedure will describe the Probabilistic Risk Assessment (PRA) techniques and performance allocation methods used for identifying Q-listed items and activities.

I.2 Quality Assurance Criteria for Licensing

The purpose of the geologic repository program is to permanently dispose of high-level nuclear waste. In order to obtain a license for receipt and possession of radioactive material at the geologic repository, it must be demonstrated that the repository system will function as required to protect health and safety of the public and the environment. Requirements for licensing a repository to meet this goal are specified in 10 CFR Part 60. These requirements describe the performance objectives and other technical criteria to assure safe operation during waste emplacement and retrieval (if necessary), as well as effective containment and long-term isolation of waste following permanent closure of the geologic repository. The QA Level I requirements of this QA Plan specify the QA program for those items and related activities important to safety and/or waste isolation to assure that their characterization, design, construction, and operation comply with the requirements of 10 CFR Part 60.

I.2.1 Criteria for the Q-List and Quality Activities List

The QA Level I requirements of this QA Plan apply to items and activities important to safety and/or waste isolation. As derived from 10 CFR Part 60 (60.152), this QA program is based on the 18 criteria of 10 CFR Part 50 Appendix B. These criteria address, in general terms, the basic elements of a QA program, such as organization, design control, test control, inspection, and records management. As noted in 10 CFR 60.152, these criteria are supplemented as necessary to meet the specific requirements of the repository program. In addition to the QA Level I requirements of this QAPP, items important to safety and the waste package are subject to the design criteria of 10 CFR 60.131(b) and 60.135, respectively.

I.2.2 Criteria for Non-Q-List Items

Certain items that are not important to safety and/or waste isolation shall also be addressed in the license application to demonstrate compliance with 10 CFR Part 60 requirements such as those associated with meeting the design criteria in 10 CFR 131 (a) for protection of worker health safety. While these items are not subject to the QA Level I requirements of this QA Plan, QA Level II requirements shall be applied. Additional guidance related to this subject can be found in NUREG-1318, (April, 1988), paragraph 5.1(b).

1.2.3 Data Not Collected Under a 10 CFR 60 Subpart G QA Program

All data collection, interpretations, analyses, and other work to be used to support findings related to "important to safety" and/or "waste isolation" in the licensing process shall be technically and procedurally defensible. "Existing data" shall be qualified in accordance with the requirements of Appendix G of this QAPP. In addition to existing data, some materials that may be important to safety and/or waste isolation may already have been purchased prior to implementation of a 10 CFR 60 Subpart G QA Program. Supporting documentation on these materials (e.g., the technical specifications and QA records) shall be reviewed to determine whether they meet the technical and QA requirements for their designated function. If not, they shall be "qualified" for use to assure they will perform their intended function.

1.3 Identification of Items Important to Safety

Items important to safety are those items essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of unrestricted area at any time until the completion of permanent closure (10 CFR 60.2). The 0.5 rem value is, therefore, the threshold for determining what structures, systems, and components shall be on the Q-list as items important to safety. The rationale for placing a system, structure, or component on the Q-list is to provide added assurance, via application of rigorous QA/QC and design requirements, that they should perform their designated function.

Probabilistic Risk Analysis (PRA) shall be used to the extent practicable, to support the identification of structures, systems, and components important to safety in the license application. Use of this approach for the operations phase of the high-level waste program is consistent with the approach prescribed by the Environmental Protection Agency standard (40 CFR Part 191) for the overall system containment following emplacement of waste in a geologic repository. In cases where data are limited, engineering judgment and conservative bounding assumptions shall be used. Conservative assumptions shall include non-mechanistic failures where information and/or experience are not adequate to reliably determine failure modes and accident scenarios. However, non-mechanistic failures need not be considered where failure modes and mechanisms are understood and failure rates can be determined.

Operator actions or errors which could initiate accidents shall be identified in PRAs or other analysis. These shall be controlled to minimize the probability of occurrence. Other activities which are subject to QA Level I requirements, such as designing, inspecting, and purchasing, will not be identified in PRAs but shall be controlled in accordance with QA Level I requirements.

PRAs shall utilize the following techniques:

System modeling to depict the combination of safety function and system successes or failures which constitute accident scenarios. Two modeling techniques which may be used are event tree analysis, which identifies the sequence of events that may result in an accident, and fault tree analysis, which determines how failures in safety systems may occur. Both techniques are analytical tools which organize and characterize potential accidents in a methodical manner.

An event tree defines a comprehensive set of accident sequences that encompasses the effects of all realistic and physically possible potential accidents. By definition, an initiating event is the beginning point in the sequence. Hence, a comprehensive list of accident-initiating events shall be compiled to ensure that the event trees properly depict all important sequences.

The fault tree examines the various ways in which a system designed to perform a safety function can fail. Each safety system identified in the event tree as involved in an accident shall be examined to determine how failures of components within that system could cause the failure of the entire system.

If failure of a mitigating system should contribute to an offsite dose, individual components within the mitigating system shall be reviewed, using fault tree analysis, to determine the effect of their failure on performance of the overall system. For example, individual components in the ventilation system which may need to be analyzed include dampers, motors, and filters.

Consequence analysis of accident scenarios identified in event/fault tree analyses to determine the amount and kind of radionuclides which may reach the unrestricted area and contribute to an off-site dose. Consequence analysis includes identification of a source term for radioactive releases and evaluation of mechanisms for movement and deposition of radioactive materials released from the high-level waste facility. The energy, magnitude, and timing of radiological releases resulting from various accidents shall be considered in this analysis.

Analysis to assess the effect of uncertainties in the data base and uncertainties arising from modeling assumptions on the PRA findings. The insights gained in the analysis about features that are significant contributors to risk can provide qualitative understanding into system performance.

Additional guidance related to the assessment of pre-closure accidents can be found in NUREG 1318, (April, 1988), paragraph 5.2(a).

1.3.1 Redundancy

The use of redundant structures, systems, and components is a method of providing additional assurance that necessary safety functions will be performed if an accident occurs and that the accident dose limit will not be exceeded. In a redundant system, the failure of one train of the system shall not comprise or prevent the associated safety function from being performed. For the high-level waste repository, 10 CFR 60 [60.131(b) (5) (ii)] addresses requirements for redundancy. The items needed to provide redundancy of items important to safety shall also be on the "Q-list."

1.3.2 Use of Previously Established Guidelines and Standards

Many guidelines and standards have been developed in the nuclear power reactor program and other nuclear programs which may be applicable for the geologic repository program. For example, there are regulatory guides covering design basis earthquakes, floods, and tornado wind velocities which may be used in the design of the HLW facility and developing the Q-list. While some of these guidelines and standards may not be directly applicable to a geologic repository, they shall be considered to the extent practicable, to eliminate the need to develop new approaches.

I.3.3 Retrieval

The option for retrieval of waste is addressed as a performance objective in 10 CFR 60.111(b). If retrieval is found to be necessary, analyses of retrieval operations shall be conducted at that time, to identify Q-list items.

I.4 Identification of Items and Activities Important to Waste Isolation

The term "important to waste isolation" refers to engineered and natural barriers that will be relied on to meet the containment and isolation performance objectives of 10 CFR 60 Subpart E. Four of the performance objectives for waste isolation after permanent closure are stated in 10 CFR 60.112 and 60.113 and include:

- ground water travel time
- waste package containment period
- maximum yearly release rate from the engineered barrier system
- the overall system performance objective in 10 CFR 60.112 for release of radioactive materials to the accessible environment (the Environmental Protection Agency standard in 40 CFR Part 191).

The items and activities important to waste isolation shall include:

- Components of the engineered barrier system relied on to meet the performance objectives.
- Elements of the natural barrier system (e.g., host rock, and geochemical retardation characteristics) relied on to meet the performance objectives.
- Activities necessary to demonstrate that the performance objectives will be met, including collection of data to characterize the site or performance of engineered barriers.
- Activities in the preclosure phase that could affect post-closure performance.

The broad performance objectives for waste isolation provide some flexibility in allocating credit among the various components of the natural and engineered barrier systems to meet each objective. For example, a 300 to 1,000 year lifetime for the waste package might be achieved by a combination of performance from each of the components in the waste package or by a single component, such as the canister. The allocation of performance among the various components of the natural and engineered barrier system for each performance objective will provide the basis for determining which barriers are important to waste isolation. Performance assessments shall be conducted on these barriers to ascertain that those relied on will meet the waste isolation and containment performance objectives of 10 CFR Part 60. The initial allocations of performance will provide a basis for determining what site characterization testing will be needed. The initial allocations of performance among the barriers is likely to change based on the results of performance assessments using data collected during site characterization.

It is expected that most of the data collected during the site characterization phase can potentially be used in the license application performance assessments. During the early phase of characterization in particular, when little is known about the site and the importance of data characterizing it, data collection activities shall be controlled in accordance with the QA Level I requirements of this QAPP. However, there may be cases where it is known that data are not needed for performance assessments, or will be duplicated later in accordance with QA Level I requirements of this QAPP and therefore would not have to be performed in accordance with QA Level I requirements at this time. For example, scoping tests or tests to examine the feasibility and appropriateness of a data collection technique may not need to be performed in accordance with the QA Level I requirements of this QAPP.

Note: Additional guidance related to this subject can be found in NUREG-1318, "TECHNICAL POSITION ON ITEMS AND ACTIVITIES IN THE HIGH-LEVEL WASTE GEOLOGIC REPOSITORY PROGRAM SUBJECT TO QUALITY ASSURANCE REQUIREMENTS" (APRIL 1988).

APPENDIX J

J.0 REQUIREMENTS FOR PEER REVIEW

J.1 Introduction

This appendix provides the requirements regarding the applicability of peer reviews, the structure of peer review groups, acceptability of peers, and the conduct and documentation of peer reviews.

J.2 Applicability of Peer Review

A peer review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and waste isolation cannot otherwise be established through testing, alternate calculations or reference to previously established standards and practices.

In general, the following conditions are indicative of situations in which a peer review shall be considered.

- Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.
- Decisions or interpretations having significant impact on performance assessment conclusions will be made.
- Novel or untried testing, plan, procedure, and/or analyses are or will be utilized.
- Detailed technical criteria or standard industry procedures do not exist or are being developed.
- Results of tests are not reproducible or repeatable.
- Data or interpretations are ambiguous.
- Data adequacy is questionable—such as, data may not have been collected in conformance with an established QA program.

A peer review shall be used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means.

J.3 Structure of Peer Review Group

The number of peers comprising a peer review group shall vary commensurate with the following:

- the complexity of the work to be reviewed,

- its importance to establishing that safety or waste isolation performance goals are met,
- the number of technical disciplines involved,
- the degree to which uncertainties in the data or technical approach exist, and
- the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.

The collective technical expertise and qualifications of peer review group members shall span the technical issues and areas involved in the work to be reviewed, including any differing bodies of scientific thought. The potential for technical or organizational partiality shall be minimized by selecting peers to provide a balanced peer review group. Technical areas more central to the work to be reviewed shall receive proportionally more representation in the peer review group.

J.4 Acceptability of Peers

The technical qualification of the peer reviewers in their review areas, shall be at least equivalent to that needed for the original work under review and shall be the primary consideration in the selection process. Each peer shall have recognized and verifiable technical credentials in the technical area that the peer has been selected to review.

Members of the peer review group shall be independent of the original work to be reviewed. Independence in this case means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed. In some cases (i.e., funding considerations) it may be difficult to meet the independence criteria without reducing the technical quality of the peer review. When the independence criteria cannot be met, a documented rationale shall be included in the peer review report.

J.5 Peer Review Process

Since the peer review process may vary from case to case, a peer review plan shall be prepared prior to initiating a peer review. The peer review plan shall describe the work to be reviewed, the size and spectrum of the peer review group, and the suggested method and schedule necessary to produce a peer review report.

The peer review group shall evaluate and report on:

- validity of assumptions,
- alternate interpretations,
- uncertainty of results and consequences if incorrect,
- appropriateness and limitations of methodology and procedures,
- adequacy of application,
- accuracy of calculations,
- adequacy of requirements and criteria, and
- validity of conclusions.

Documentation shall be prepared to indicate the results of meetings, deliberations, and activities of the peer review process.

J.6 Peer Review Report

A report documenting the results of the peer review shall be prepared and issued under the direction of the peer review group chairperson. The report shall be signed by each peer review group member. The peer review report shall include the following:

- a clear description of the the work or issue that was peer reviewed;
- conclusions reached by the peer review process;
- individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate; and
- listing of the peers and the technical qualification and evidence of independence for each peer, including potential technical and/or organizational partiality.

Note: Additional guidance related to this subject can be found in NUREG-1297, "PEER REVIEW FOR HIGH LEVEL NUCLEAR WASTE REPOSITORIES" (FEBRUARY 1988).

APPENDIX K

K.0 FORMAT AND CONTENT REQUIREMENTS FOR SITE CHARACTERIZATION PLAN STUDY PLANS

K.1 Purpose and Objectives of Studies

- Describe the information that will be obtained in this study. Briefly discuss how this information will be used.
- Provide the rationale and justification for the information to be obtained by the study. The study plan can be justified by (1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the Site Characterization Plan); (2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); and (3) direct Federal, State, and other regulatory requirements for specific studies. Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and that higher level goal.

K.2 Rationale for Selected Study

- Provide the rationale and justification for the selected tests and analyses (including standard tests). Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitations of the various options; and
- Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). This rationale should also identify reasonable alternatives; summarize reasons for not selecting these alternatives, and reference, if available, reports which evaluate alternatives considered.
- Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. Factors to be considered include:
 - potential impacts on the site from testing;
 - whether the study needs to simulate repository conditions;
 - required accuracy and precision of parameters to be measured with test instrumentation;
 - limits of analytical methods that will use the information from the tests;
 - capability of analytical methods to support the study;

- time required versus time available to complete the study;
- the scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field;
- interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and
- interrelationships involving significant interference among tests and exploratory shaft facility design and construction, as appropriate (refer to Section 8.4 of the Site Characterization Plan or its references for specific exploratory shaft facility design information).

K.3 Description of Tests and Analyses

- Because studies comprise tests and analyses, provide the following for each type of test:
 - Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g., spatial location relative to the site, exploratory shaft facility elements, repository layout, stratigraphic units, depth, and test location).
 - Summarize the test methods. Reference any standard procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA Level I. Reference the applicable specific QA requirements that will be applied to the test.
 - Specify the tolerance, accuracy, and precision required in the test, where appropriate.
 - Indicate the range of expected results of the test and the basis for those expected results.
 - List the equipment required for the test and describe briefly any such equipment that is special.
 - Describe techniques to be used for data reduction and analysis of the results.
 - Discuss the representativeness of the test including why the test results are considered representative of future conditions or the spatial

variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results.

- Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests
- Show the relationship of the test to the set performance goals and confidence levels.
- For each type of analysis, do the following:
 - State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels.
 - Describe the methods of analysis including any analytical expressions and numerical models that will be employed.
 - Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA Level I. Reference the applicable QA requirements.
 - Identify the data input requirements of the analysis.
 - Describe the expected output and accuracy of the analysis.
 - Describe the representativeness of the analytical approach (e.g., with respect to spatial variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.

K.4 Application of Results

- Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies).
- For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the Site Characterization Plan) that will use the information produced from the studies described above, and refer to any use of the results for model validation.
- For design uses, refer to, or describe, where the information from the study described above will be used in construction equipment design and development, and engineering system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals).

- For characterization uses, refer to, or describe, where the information from the study described above will be used in planning other characterization activities.

K.5 Schedule and Milestones

- Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing, data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities.
- Describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study.
- Dates for activities or milestones including durations and interrelationships, for the study plans will be provided. These should reference the master schedules provided in Section 8.5 of the Site Characterization Plan.

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Organization LANL QA Document's Title, No., Revision _____

Date Received _____ Reviewed By Carl Higby, Hector and Mike McGovern LANL/QAS Date Review Completed _____

Review Comments: Yes No Date Comments Returned to Org. _____ Comments Resolved By _____

Review Requirements per NWS/88-9 Rev. 2	Review Results			Organization's Resolution		Review Dispo.	
	Sat - Para. No.	Unsat - Para. No. -	Comments	Acc. Rej.	Reason	Acc.	Rej.
SECTION I ORGANIZATION							
1.0 QUALITY ASSURANCE RESPONSIBILITIES OF PROJECT PARTICIPANTS							
(1)The Nevada Nuclear Waste Storage Investigations (NNWSI) Project Participants shall be responsible for the establishment and execution of a Quality Assurance Program Plan (QAPP). (2)The participants may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the Quality Assurance (QA) program, or any part thereof, but shall retain the responsibility therefore. (3)The delegation of execution of the QA Program Plan requirements shall be documented. (4)The organizational structure, lines of communication, authority and duties of personnel and organizations performing activities affecting quality shall be clearly established and delineated in writing. (5)These activities affecting quality include both the performing functions of attaining quality objectives and the QA functions. (6)While the line organization is responsible for performing these activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.	1.2, 2.1 1.1 1.1 1.1	OK OK OK	Could the preparer of this document under the paper add the column "SAT" to facilitate the process?				
2.0 QA FUNCTIONS							
(7)The QA functions are those of assuring that an appropriate QA program is established and executed effectively and of verifying, such as by checking, testing, surveillance and inspection, that activities that affect the quality have been performed correctly. (8)The persons and organizations performing these functions shall have sufficient authority, access to work areas, and freedom to identify quality problems; to initiate, and to propose solutions through designated channels; to verify	Section I 1.1, 1.3 1.2, 2.1.1 1.2	OK OK OK					

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implementation of the solutions; and to assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. (9) This includes the ability to stop (or cause to be stopped) unsatisfactory work through established channels. (10) Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected and shall report to a management level at which this required authority and organizational freedom are provided, including sufficient independence from cost and schedule.

2.1 DEDICATED QA POSITIONS

(11) The person responsible for directing and managing the overall NNWSI Project Participant QA program shall be identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. (12) This person shall have appropriate management and QA knowledge and experience and shall be at the same or higher organization level as the highest line manager responsible for performing activities affecting quality and sufficiently independent from cost and schedule.

(13) Personnel in this position shall have responsibility for approval of (1) CAPPs, changes thereto, and interpretations thereof and (2) implementing procedures and all changes thereto. (14) This position shall have effective communication channels with other senior management positions. (15) Personnel in this position shall have the responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA program implementation by that organization and its subordinate organizations. (16) Full-time dedicated QA positions are to be established by the Waste Management Project Office (WMPO), Participating Organizations, and the Nevada Test Site (NTS)

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	<p>Support Contractors. (17)The management position that retains overall authority and responsibility for the QA Programs as well as personnel considered to be "full-time dedicated" shall not be assigned duties that would prevent full attention to NWSI Project QA responsibilities or that would conflict with the reporting and resolution of QA issues and problems related to the NWSI Project.</p> <p style="text-align: center;">2.2 AUTHORITY</p> <p>(18)Authority for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and others shall be identified. (19)This authority shall include the ability of QA personnel to elevate the resolution of disputes to progressively higher organization levels through established channels including the MPO PCM, if the dispute cannot be resolved within the organization.</p> <p style="text-align: center;">2.3 ORGANIZATIONAL STRUCTURE</p> <p>(20)Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations at which the activities are to be performed, the organizational structure for executing the QA program may take various forms provided that the persons and organizations assigned the QA functions have the required authority and organizational freedom. (21)The QA responsibilities of all organizational elements depicted on organization charts shall be described.</p>	1.2.1.1	OK					
	1.2.1.1	OK	note "c" on table in section 1					
		OK	1.0 Figure					

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<p align="center">3.0 QUALITY ASSURANCE PROGRAM PLAN</p> <p>(22) A Quality Assurance Program Plan (QAPP) shall apply to all items and activities of an organization affecting quality. (23) The organizational structure and the responsibility of assignments shall be clearly established such that certain results, as described below, are obtained.</p>	2.1	OK	Figure 1-1				
<p align="center">3.1 ACHIEVEMENT AND MAINTENANCE OF QUALITY</p> <p>(24) Quality is achieved and maintained by those who have been assigned responsibility for performing work.</p>	1.1, 1.3	OK					
<p align="center">3.2 VERIFICATION</p> <p>(25) Quality achievement is verified by persons or organizations not directly responsible for performing the work. (26) Verification of conformance to established requirements (acceptance) is accomplished by individuals or groups within the QA organization unless specifically exempted elsewhere in this document.</p>	1.1, 1.3 1.3	OK					
<p align="center">4.0 MULTIPLE ORGANIZATIONS</p> <p>(27) If more than one organization is involved in the execution of activities affecting quality, then the responsibility and authority of each organization shall be established clearly and documented.</p>	Figure 1-1	REX OK					

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	<p>4.1 DOCUMENTATION OF INTERFACES</p> <p>(28)The external interfaces between organizations and the internal interfaces between organizational units and changes thereto shall be documented. (29)All interface responsibilities shall be defined and documented. (30)Interfaces between the WFO, the Participating Organizations, and the NTS Support Contractors shall be described in the QAPPs of the respective organizations. (31)From an overall NNWSI Project standpoint, these interfaces are exchanges of technical requirements of work to be performed and until completion of work. (32)The NNWSI Project Administrative Procedures (APs) provide the implementing interface controls utilized by all of the NNWSI Project participants while Participating Organization and NTS Support Contractors plan procedures describe the methods of conducting inter-organizational interfaces.</p> <p>(33)The organizational structure conducting the QA programs varies from organization to organization, and each one shall be described in the individual organization's QAPP. (34)The Technical Project Officer of the respective Participating Organizations and the respective NTS Support Contractors are responsible to the WFO Project Manager to ensure that the Project activities for which they are responsible are performed to a QAPP and implementing procedures that are consistent with this QAPP.</p>	<p>Figure 1-1</p> <p>-</p> <p>N/A</p> <p>N/A</p> <p>Section 5 and 2.1</p> <p>Figure 1-1 and text 1.1</p>	<p>UNSAT 1.4</p> <p>29) 1.4 + F161.1</p> <p>30) UNSAT ORDER</p> <p>31) OK</p> <p>OK</p>	<p>✓</p> <p>OK</p>	<p>Rej.</p>	<p>Reason</p>	<p>✓</p> <p>PKR</p>	<p>Rej.</p>

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	SECTION II QUALITY ASSURANCE PROGRAM							
1.0 EXTENT OF THE QUALITY ASSURANCE PROGRAM								
<p>(1)The Quality Assurance (QA) Program for the NWSI Project consists of the NWSI Quality Assurance Plan (QAP), the QA Program Plans of the Waste Management Project Office (NWPO), the Participating Organizations, and the Nevada Test Site (NTS) Support Contractors, and the QA and technical procedures required to implement these documents. (2)The NWSI Project Office will submit this QAP and the NWPO QAPP to the OCRM Director, Office of Quality Assurance for approval. (3)Pending receipt of this approval, QA plans may be issued by NWPO for interim use. (4)When any QA plan is issued for interim use, the transmittal record shall be appropriately marked to indicate that it is for interim use. (5)Final QA plans will include a signature block for approval by the Director, Office of Quality Assurance.</p> <p>(6)Each NWSI Project Participant shall develop a Quality Assurance Program Plan which shall provide the description of the organization's QA program and indicate the commitment to the applicable NWSI Project QA requirements given herein. (7)Each Quality Assurance Program Plan (QAPP) shall include consideration of the technical aspects of the activities affecting quality and shall be generated by the respective QA organization with assistance from the technical staff. (8)The QAPP shall provide instruction to implement and apply the QA requirements to the technical activities of the NWSI Project. (9)It shall be planned, implemented, and maintained in accordance with this document and be consistent with and address all of the applicable requirements of this NWSI QA Plan. (10)Management above or outside of the QA organization</p>	N/A		APPROX LTR SPECIFIC					
	N/A		OK					
	N/A		OK					
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	<p>shall regularly receive information as to the scope, status, adequacy, compliance, etc. of the QA Program. (11) Management shall perform readiness reviews, as deemed appropriate. (12) Readiness reviews shall apply to major scheduled/planned activities which could affect quality. (13) Readiness reviews shall be used in verifying that specified prerequisites and programmatic requirements have been identified prior to starting a major activity.</p> <p>(14) The hierarchy of criteria applicable to the Project are shown in Figure 1 of the Introduction of this document. (15) With the exception of the CFR, where deviations between requirements of the higher-tier documents referenced in that Figure and this QAP exist, the requirements of this document shall prevail.</p> <p style="text-align: center;">1.1 QA CRITERIA</p> <p>(16) The QA Criteria and specific requirements associated with these criteria have been adopted to the NWSI Project activities through this QA plan and shall be addressed in the QAPs of the WFO, the Participating Organizations, and NTS Support Contractors. (17) When a specific criteria is not applicable to an organization's activities, it shall be noted in the QAP and recorded on the checklist required in paragraph 1.2 below with justification of its exception.</p> <p style="text-align: center;">1.2 CONTENTS OF THE QAP</p> <p>(18) The Quality Assurance Program of each organization shall consist of the QAP plus appropriate implementing procedures required to provide and implement control over activities affecting quality. (19) The control shall be consistent with the importance of the activity. (20) These procedures shall be developed by qualified personnel and be reviewed and approved by the cognizant QA organization prior to implementation to assure that they meet all the requirements of their QAP.</p>	<p>2.1</p> <p>2.1</p> <p>2.1</p> <p>N/A</p> <p>N/A</p> <p>N/A</p> <p>Satisfactory</p> <p>2.1</p> <p>2.1</p> <p>5.1, 5.4, 5.5</p>	<p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p>					

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<p>(21) The QAPP of each Participating Organization and NTS Support Contractor shall be submitted to the WFO for review prior to implementation and shall include a checklist based on this NWSI QAP which identifies how and where each requirement of this document is addressed. (22) The WFO is also required to complete a checklist based on NWSI/88-9 (formerly WFO-196-17) for the preparation of the WFO QAPP. (23) The QAPP of each Project Participating Organization and NTS Support Contractor shall be reviewed, comments resolved, and the document approved by the WFO within a timely manner.</p> <p align="center">1.3 QAPP VERIFICATION</p> <p>(24) Assurance that the QA requirements have been adequately addressed and effectively implemented will be provided by the WFO with support from the SAIC/TMMS Project QA Department during the review and approval of each organization's QAPP, monitoring and surveillance operations, and audits of activities. (25) The Participating Organizations' and NTS Support Contractors' management shall also monitor their respective QAPPs through internal audits to assess the adequacy of their program and assure its effective implementation.</p> <p align="center">1.4 USE OF DATA NOT GENERATED UNDER QA CONTROLS</p> <p>(26) The QA program for the NWSI Project provides for the acceptance of existing data for use in licensing activities that were not generated under the controls of a QA Program which meets the requirements of 10 CFR 60, Subpart G. (27) Specific methods for acceptance of this information are contained in NWSI Project Administrative Procedure 5.90. (28) This procedure shall meet the requirements of NUREG - 1298 "Qualification of Existing Data for High-Level Nuclear Waste Repositories" (February, 1988). (29) These requirements are contained in Appendix G to this QA Plan. (30) Once accepted, this existing data is classified as "primary data" for licensing purposes.</p>	2.1	OK	<p align="center"><i>REST 21 "CHARGE APPROVAL" TO REVIEW</i></p>	<p align="center"><i>DATA</i></p>				<p align="center"><i>AP</i></p>
	N/A	OK						
	2.1	OK						
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	2.1.1	OK						
<p align="center"><i>2.1.2</i></p>	<p align="center"><i>OK</i></p>							

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<p align="center">1.5 METHODOLOGY FOR FORMULATING THE "Q" LIST AND QUALITY ACTIVITIES LIST</p> <p>(31)The WFO shall prepare the appropriate NWSI AP or APs for determining the items and activities to be placed on the Project Q-List and Quality Activities List. (32)Procedure(s) shall meet the requirements of NWSI - 1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements" (April, 1988). These requirements are contained in Appendix I to this QA Plan.</p>	N/A	OK					
	N/A	OK					
<p align="center">1.6 APPROACH TO QA</p> <p>(33)The NWSI Project uses an approach to QA that recognizes the differences between items and activities that affect radiological health and safety and waste isolation and those that do not. (34)The approach is designed to ensure that each item or activity is assigned a QA level that is consistent with its potential impact or importance, or both, in terms of radiological health and safety, waste isolation, nonradiological health and safety, the U.S. Nuclear Regulatory Commission (NRC) licensing requirements, the operability and maintainability of the repository, costs, and schedules. (35)The Participating Organizations or WFO shall identify the appropriate quality assurance levels for all items and activities that affect quality associated with site characterization, facility and equipment construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. (36)Once assigned, the QA level for a particular item or activity shall be applied by all NWSI Project participants involved in the activity.</p>	N/A						
	N/A						
	2.2.1	2.2.2 OK					
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	<p>1.7 APPLICATION OF QA</p> <p>(37)A QAPP that complies with the requirements of this document, NWSI/88-9 (formerly NVO-196-17), shall be established by each NWSI Participant at the earliest practicable time consistent with the schedule for accomplishing the activities. (38) QAPP shall assure that procedures required to implement the requirements in this document are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official. (39)The QAPP shall be applied throughout the life of the NWSI Project in accordance with the established policies, procedures, and instructions. (40)The QAPP shall apply to all items and activities affecting quality. It also shall identify the major organizations participating in the project and the designated functions of these organizations. (41)The QAPP shall provide control over activities that affect the quality of the identified structures, systems, and components to an extent consistent with their importance. (42)The activities that affect quality shall be accomplished under suitably controlled conditions. (43)Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that all prerequisites for the given activity have been satisfied. (44)The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection, test, peer review, or a combination of these. (45)The program shall provide for indoctrination and, as necessary, training of personnel performing activities that affect quality to assure that suitable proficiency is achieved.</p> <p>(46)The WFO shall regularly assess the status and adequacy of the QA Programs of the Participating Organizations and WFS Support Contractors by means of overview, surveillance, and audit activities.</p>							
N/A	OK							
Policy	OK							
2.2.1	OK							
2.1	OK							
2.1	OK							
2.1	OK							
2.1	OK							
2.1	OK							
N/A	OK							

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	<p align="center">2.0 APPLICATION OF GRADED QUALITY ASSURANCE</p> <p align="center">2.1 SCOPE</p> <p>2.1.1 EXTENT OF APPLICATION</p> <p>(47)The requirements of this section are applicable (as defined herein) to all items and activities that affect quality during geologic repository site characterization, facility and equipment design, procurement and construction, facility operation, performance confirmation, permanent closure, decommissioning, and dismantling of surface facilities. (48)The preparation of administrative and management planning documents shall not require QA level assignments, except for project level documents which are specifically required by the Nuclear Waste Policy Act of 1982 (as amended), or are required for licensing. In addition, procurement of administrative items (i.e., office supplies) do not require QA level assignments. (49)The WFO shall develop a Project administrative procedure for the application of graded QA. (50)The procedure shall be in consonance with the QA requirements specified herein. (51)It may be necessary to exempt certain NWSI items and activities from QA Level assignment. (52)Requests for exemptions shall be documented and shall contain sufficient justification to support the exemption request. Such exemptions shall be approved by the WFO PCM.</p> <p>2.1.2 PURPOSE OF A GRADED QA PROGRAM</p> <p>(53)The purpose of a graded QA program is to select the QA requirements and measures to be applied to items and activities in the Repository Program consistent with their importance to safety, waste isolation, and the achievement of U.S. Department of Energy (DOE) mission objectives. (54)This will be accomplished by deliberate quality planning and selective application of QA requirements on the item or activity to be performed, with varying degrees of QA applied depending on item function, complexity, consequence of failure, reliability, replicability of results, and similar considerations.</p>							
2.2.1	2.1	OK						
2.2.1		OK						
N/A		OK						
N/A		OK						
2.2.1		OK						
2.2.1		OK						
2.1.3		53 INCOMPLETE						✓ RRR
2.2.1		54 INCOMPLETE						✓ RRR

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<p>2.1.3 DETERMINATION OF THE DEGREE OF WHICH APPLICATION IS NECESSARY</p> <p>(55) This approach involves (1) identifying those items and activities whose failure could cause undue risks to the public and facility personnel or extended interruption of facility operation with critical economic losses, or both, and (2) ensuring that these items and activities are covered by a commensurate QA program. (56) Alternatively, an item whose failure or malfunction could result only in operational inconvenience or negligible economic loss may deserve only a quality inspection by the purchaser upon the delivery of the item. (57) Between these two extremes, there are varying degrees of QA to achieve the desired confidence in the quality of the completed line of activity.</p>	N/A N/A N/A	OK OK OK		
<p>2.1.4 FLEXIBILITY OF QA REQUIREMENT SELECTION</p> <p>(58) The graded approach set forth here provides flexibility in the selection of the quality assurance requirements to be applied to an item or activity that is commensurate with the relative importance of the role or function assigned to the item or activity.</p>	N/A	OK		
<p style="text-align: center;">2.2 REQUIREMENTS</p> <p>(59) The requirements specified in this section are to be used to apply the graded quality philosophy to all NWSI Project items and activities.</p>	N/A	OK		
<p>2.2.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QA REQUIREMENTS</p> <p>(60) The appropriate Quality Assurance Level for any item or activity shall be determined by the application of decision criteria as provided by the NWSI Administrative Procedures. (61) The basis for the selection of the Quality</p>	2.2.2 2.2.2	OK	<p>UNSAT ADD REF TO APQ SATIS. 2ND BULLET RR</p>	

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	<p>Assurance Level and assigned QA requirements shall be documented. (62)The assigned Quality Assurance Levels and QA requirements must be submitted to the WFO for review, resolution of comments, and approval prior to implementation or use. This review and approval shall be performed by the WFO FGI and appropriate WFO Branch Chiefs.</p> <p>2.2.2 SELECTION OF SPECIFIC QA LEVELS</p> <p>(63)This approach incorporates three quality assurance levels (QA level) of which one will be assigned to each technical task that affects the quality of the NWSI Project. (64)The definition, application, and assignment to each of the three QA levels are described in the following discussion.</p> <p>2.2.2.1 (65)QA Level I - are 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.</p> <p>(66)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. (67)Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. (68)The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.</p>	<p>2.2.2 6th bullet</p> <p>2.2.2 3rd bullet</p> <p>N/A</p> <p>2.2.2</p> <p>2.2.2</p> <p>2.2.2</p> <p>2.2.2</p> <p>N/A</p>	<p>OK</p> <p>OK</p> <p>OK SEE NOTE</p> <p>OK APPA</p> <p>OK APPA</p> <p>OK APPA</p> <p>OK APPA</p> <p>OK APPA</p>					

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	<p>2.2.2.2 QA Level II -(69)are those activities and items related to the systems, structures, and components which require a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE and NRC concerns, and the environment.</p> <p>2.2.2.3 QA Level III -(70)are those activities and items not classified as QA Levels I or II.</p> <p>2.2.3 APPLICATION OF LEVELS</p> <p>2.2.3.1 QA LEVEL I</p> <p>QA Level I is the most stringent level of quality assurance. (72)It is to 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 U.S. Environmental Protection Agency (EPA) for protecting public health and safety from radiological hazards. (73)QA Level I activities which are on the Q-List will provide the primary data input to the basis for the NRC to authorize construction and to issue a license for the DOE to receive and possess source, special nuclear, and byproduct material (waste) at the geologic repository. (74)QA Level I control and documentation must be applied to activities, including site characterization, scientific investigation, facility and equipment design, procurement, and construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities when they are specifically concerned with the protection of the public's health and safety with respect to a radiological hazard.</p>	2.2.2		OK APPR				
	2.2.2		OK APPR					
	2.2.2		OK					
	2.2.2		OK					
	2.2.2		OK MADE SPECIFIC					

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<p>(75) To keep radionuclides out of man's environment, a high level radioactive waste repository will utilize engineered systems, structures, and components to contain the waste and ensure the short-term safety. (76) The repository also will utilize the natural barriers to afford long-term isolation. In this context, QA Level I must be applied for near-term safety as well as long-term isolation as per the following:</p> <ul style="list-style-type: none"> Where items and activities could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, or result in, an incident 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, until the permanent closure of the repository. Where items and activities provide primary data which will be relied on for performance assessment of the repository system. This data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research which have a significant impact to site-characterization or are an essential part of the data base that directly support the final design of the repository and waste package performance. Where activities could adversely impact the waste isolation capabilities of the engineered and natural barriers. Where items are relied on to meet the postclosure performance objectives of the engineered barriers of the repository. 	N/A	OK					
	N/A	OK					
	2.2.2	OK					

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<ul style="list-style-type: none"> Where items and activities that, having failed, could cause a failure of a QA level I item, or irretrievable loss of QA level I data. The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) will be assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationships. As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities shall be governed by the QA level assigned to the item. 								
<p>2.2.3.2 QA LEVEL II</p> <p>(79) QA Level II is the second highest level of quality assurance. (79) QA Level II controls and documentation shall be applied to the NWSI Project activities, and items that are specifically concerned with nonradiological operation of the exploratory shaft facilities and repository, and the radiological safety of the repository worker. (80) The high-level waste (HLW) repository will utilize engineered systems, structures, and components which must be designed, constructed, fabricated, tested, and operated to meet the performance objectives during the operational phase and to minimize the nonradiological hazard to the public and repository worker and the radiological hazard to the repository worker. (81) Additionally, activities that have a major impact on project costs or schedules that could delay the achievement of DOE/Office of Civilian Radioactive Waste Management (OCRWM) milestones must be appropriately controlled.</p>	2.2.2 2.2.2 N/A 2.2.2	OK OK OK						

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	<p>(82) Therefore, Quality Assurance Level II must be applied to activities and items as follows:</p> <ul style="list-style-type: none"> Where items and activities that are essential to the design, construction, and operation of the repository or of the exploratory shaft, and could have a major impact on the non-radiological and safety of the public and repository worker. Where items and activities which having failed or which are performed inadequately would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10CFR20. Where items and activities could affect the retrievability of waste up to the time of repository closure. Where items and activities that involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components. The design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/method/equipment is preferred, shall be assigned a QA level of II prior to execution. A particular item can be identified and defined as a separate QA Level assignment may be made for that item. Once the QA Level for such an item is identified and approved, design procurement and construction activities shall be governed by the QA Level assigned to the item. 							

2.2.2



~~INCOMPLETE~~
OK RKR 1/26/89

INCOMPLETE ADD RELIABILITY

OMITTED

~~CDM~~
~~CDM~~

✓
RKR
✓
RKR

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<p>(89) In some cases, data or data interpretations generated as a result of activities controlled in accordance with QA Level II or III programs, or activities performed prior to the complete implementation of the NNWSI Project Quality Assurance Plan may be used in the licensing process as background or corroborative information.</p> <p>2.2.4 GENERAL</p> <p>(90) The requirements contained in this document apply to Quality Assurance Levels I and II items and activities unless otherwise noted herein. (91) The requirements imposed for QA Level III items and activities are those commercial, administrative, scientific, engineering, commercial, and laboratory practices that are commonly used by the organizations participating in the NNWSI Project.</p> <p align="center">3.0 QA ACTIVITIES</p> <p align="center">3.1 OVERVIEW</p> <p>(92) Each NNWSI Project Participant shall perform overview of the QA activities of all organizations (including subcontractors doing supportive work) under their purview. (93) Overview is to include the following as appropriate:</p> <ul style="list-style-type: none"> o The review and approval of QAPPs. o Surveillance of activities affecting quality to verify compliance with requirements. o Performance of quality audits to verify the adequacy and compliance of QA programs. 	<p>2.2.2</p> <p>2.2.2</p> <p>2.2.2</p> <p>2.3</p>	<p>OK</p> <p>OK SEE P 11 NER 1/26/89</p> <p>OK</p>	<p>0</p>	

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<p>and the tracking of recommendations. (101)Copies of all management assessments are to be provided to the Project Manager, WFO and the WFO PCM. (102)The Project Manager, WFO will make appropriate submittals of management assessment reports to OCRM. (103)Management above or outside the QA organization shall be responsible for the management assessment activity.</p>	2.4 N/A 2.4	OK OK	
<p>5.0 PERSONNEL SELECTION, INDOCTRINATION, AND TRAINING PROCEDURES</p> <p>5.1 ESTABLISHMENT OF REQUIREMENTS</p> <p>(104)All NAWSI Project participants shall establish requirements for the selection, indoctrination, and training of personnel performing or verifying activities that affect quality. (105)The requirements shall establish position descriptions that set forth minimum personnel qualifications and provide for appropriate indoctrination or training or both, prior to initiation of activities that affect quality. (106)In addition to the following requirements for indoctrination and training, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, nondestructive examiners, etc.) shall be certified in accordance with the detailed requirements specified in Appendix C, D, or F, as applicable.</p>	2.5 2.5 2.5	UNSAT OK OK	UNSAT ADD 'SELECTION' DEFINE 'ORIENTATION' OK
<p>5.1.1 POSITION DESCRIPTION</p> <p>(107)Minimum education and experience requirements shall be established and documented in position descriptions for each position involved in the performance of activities that affect quality.</p>	2.5.1	OK	

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	<p>5.1.2 PERSONNEL QUALIFICATION EVALUATION</p> <p>(109) Personnel selected shall have education and experience commensurate with the minimum requirements specified in the position description. (109) Relevant education and experience shall be verified. (110) This verification shall be documented. (111) The initial capabilities of an individual shall be based upon an evaluation of their education, experience, and training and compared to those established for the position. (112) Evaluations shall be documented by managers or supervisors responsible for the activities to be performed.</p> <p>5.1.3 INDOCTRINATION</p> <p>(113) Prior to assigning personnel to perform activities affecting quality, they shall be indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the work to be accomplished. (114) Indoctrination may be accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or other instructional methods.</p> <ul style="list-style-type: none"> o QAPP's o Implementing Procedures and Instructions (applicable to the individual's responsibilities). o Regulations o Project level Documents 							
	2.5.1	OK						
	2.5.1	OK						
	2.5.1	OK						
	2.5.1	OK						
	2.5.2	OK						
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<p>5.1.4 TRAINING</p> <p>(115)Prior to assigning personnel to perform quality affecting activities training, if needed, shall be conducted to gain the required proficiency. (116)The training (in-depth instruction) shall include the principles, techniques, and requirements of the activity. (117)Such in-depth instruction may be internal or external classroom sessions, classroom sessions supplemented by hands-on workshops, on-the-job training, other instructional methods, or combinations thereof.</p>	2.5.3		OK	
	2.5.3		OK	
	2.5.3		OK	
<p>5.1.5 PROFICIENCY EVALUATION</p> <p>(118)After the initial personnel qualification evaluation, the job proficiency of personnel who perform activities affecting quality shall be evaluated and documented at least annually. (119)Proficiency evaluations may be performed in conjunction with periodic or day-to-day employee performance evaluations. (120)Proficiency evaluations shall be performed by managers or supervisors who have responsibility for the activities being performed or verified.</p>	2.5.2		OK	
	2.5.2		OK	
	2.5.2		OK	
<p>5.1.6 RECORDS</p> <p>(121)Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations shall be retained as lifetime QA records. (122)These records shall include, as a minimum, the items listed below.</p>	2.5.5		OK	
	2.5.5		OK	

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<p>5.1.6.1 Personnel Qualification Evaluation Records</p> <p>(123)Records of the verification and evaluation of a candidate's education, experience, and training, compared to those required for the position.</p>	2.5.5	OK	
<p>5.1.6.2 Indoctrination Records</p> <p>(124)Records of indoctrination which include the objective and content of the indoctrination, date or dates of indoctrination, and other applicable information.</p>		OK	
<p>5.1.6.3 Training Records</p> <p>(125)Records of training which include the objective(s) and content of the training, name of the instructor, attendees, dates of attendance, and result of proficiency evaluations (where applicable), and other applicable information.</p>		OK	
<p>5.1.6.4 Proficiency Evaluation Records</p> <p>(126)Records of proficiency evaluation shall include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.</p>		OK	

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<p>ACTION III</p> <p>SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL</p> <p>1.0 SCIENTIFIC INVESTIGATION CONTROL</p> <p>1.1 PREPARATION</p> <p>1.1.1 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR</p> <p>(1) Prior to the start of scientific investigation, the responsible Principal Investigator (PI) shall develop a scientific investigation planning document for that investigation. (2) Scientific investigations categorized as site characterization activities, as defined in the Nuclear Waste Policy Act (as amended) shall utilize study plans as the scientific investigation planning document. (3) The WFO shall conduct a technical, QA, and management review of scientific investigation planning documents and approve the document prior to implementation. (4) Study plans shall also be reviewed and approved by OCRM prior to implementation. (5) Such planning documents shall contain or shall reference the following:</p> <p>1.1.1.1 Description of Work to be Performed</p> <p>(6) A description of the work to be performed in the scientific investigation and the proposed methodology for accomplishing the work including a discussion of the overall purpose for the work shall be provided in the scientific investigation planning document. (7) References to any applicable regulations, requirements, performance criteria, key issues, issues, information needs, higher level scientific investigation planning documents, or Work Breakdown Structure (WBS) items, for which the work is to be</p>	<p>3.1.1</p> <p>3.1.1</p> <p>N/A</p> <p>N/A</p> <p>3.1.1</p> <p>3.1.1</p> <p>3.1.1</p>	<p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p></p> <p>UNSAT ADD "PURPOSE"</p> <p>OK RNR 1/27/01</p> <p>OK</p>			

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<p>performed shall also be provided. (8) This discussion shall identify all of the factors and concerns that are important for the planning or the performance of the scientific investigation including identification, explanation, and justification for areas where scientific notebooks are to be used.</p>	3.1.1	OK		
<p>1.1.1.2 Description of previous work</p> <p>(9) A description of any previous work which will be used in support of the scientific investigation, including the identification of the Quality Assurance Levels, or Quality Assurance (QA) controls, under which that previous work was performed. (10) Note: This requirement does not apply to study plans.</p>	2.1.1	OK		
<p>1.1.2 PLANNING DOCUMENTS</p> <p>(11) The scientific investigation planning document shall contain a level of detail which would enable an independent reviewer to determine the appropriate QA Level to be applied to the investigation. (12) For Site Characterization activities, the purpose and key milestones of study plans is described in the SCP. (13) The format and content of study plans shall meet the requirements of Appendix R of this QA Plan.</p>	3.1.1	OK		
<p>1.2 ASSIGNMENT OF QUALITY ASSURANCE LEVELS</p> <p>1.2.1 ASSIGNMENT</p> <p>(14) Once a scientific investigation planning document, as specified in Paragraph 1.1.1 of this section has been developed, the Quality Assurance Levels for all of the items and activities which are associated with that work, may be assigned. (15) It may be necessary in some cases to assign Quality Assurance Levels to the items and activities within a plan that was prepared earlier.</p>	3.1.1	OK		
	N/A	OK		
	3.1.1	OK		
	3.1.2	OK		
	3.1.2	OK		

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<p>(16) Therefore, the Quality Assurance Level assignments are not a part of the planning documents themselves, even though they would normally accompany those planning documents and go through the same review and approval process.</p> <p>1.2.2 CONFORMANCE</p> <p>(17) Scientific investigation planning documents shall be prepared and Quality Assurance Levels shall be assigned in accordance with the methods specified in the Nevada Nuclear Waste Storage Investigations (NWSI) Project Administrative Procedures Manual.</p> <p align="center">1.3 REVIEW AND APPROVAL PROCESS</p> <p>1.3.1 RESPONSIBILITY</p> <p>(18) The responsible Participating Organization shall conduct a technical review of the scientific investigation planning document. (19) This review shall be performed by any qualified individual(s) other than those who developed the original planning document. (20) In exceptional cases, the originator's immediate supervisor can perform the review if the supervisor is the only technically qualified individual, and if the need is individually documented and approved in advance with the concurrence of the QA manager of the originating organization. (21) The results of this technical review, and the resolution of any comments by the reviewer or reviewers, shall be documented, and shall become a part of the records.</p>	<p>3.1.2</p> <p>3.1.1</p> <p>3.1.3</p>	<p>OK</p> <p>UNSAT COMPLETED</p> <p>OK</p>	<p>✓</p>

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<p>1.3.2 WASTE MANAGEMENT PROJECT OFFICE REVIEW</p> <p>(22)The WPO Project Quality Manager and the appropriate WPO Branch Chief shall review and approve the scientific investigation planning document prior to implementation. (23)The WPO PCM shall return the planning document to the responsible organization's TPO upon completion of the WPO review and approval cycle. (24)Study plans shall also be reviewed and approved by OUMS prior to implementation.</p> <p>1.3.3 PEER REVIEW</p> <p>(25)A peer review of the scientific investigation planning document will be conducted when deemed necessary by the WPO.</p> <p align="center">1.4 SCIENTIFIC INVESTIGATION DATA INTERPRETATION AND ANALYSIS</p> <p>1.4.1 INTERPRETATION/ANALYSIS DOCUMENTS</p> <p>(26)Interpretation/analysis shall be performed in a planned, controlled, and documented manner. (27)Interpretation/analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. (28)These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer and date.</p>	<p>3.1.3</p> <p>↓</p>	<p>22 & 24 UNSAT</p> <p>23 OK</p> <p>OK</p>	<p>ADD PRIOR TO IMPLEMENTATION</p>	
	<p>3.1.4</p> <p>↓</p>	<p>OK</p>		

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	<p>1.4.2 DOCUMENTATION OF INTERPRETATION/ANALYSIS</p> <p>(29) Documentation of interpretation/analysis shall include the following:</p> <ul style="list-style-type: none"> • Definition of the objective of the interpretation/analysis. • Definition of input and their sources. • A listing of applicable references. • Results of literature searches or other background data • Identification of assumptions • Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the basis of application to the specific problem. • Signatures and dates of review and approval by appropriate personnel. <p align="center">1.5 USE OF COMPUTER PROGRAMS</p> <p>(30) Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subsection 3.0 and Appendix N of this QA Plan. (31) The documentation and control measures shall be consistent with the guidance contained in NRCRG-0056, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."</p>	3.1.4	OK					
	3.1.5	OK						
	3.1.5							

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1.6 THE USE OF SCIENTIFIC METHODS VERSUS THE USE OF TECHNICAL IMPLEMENTING PROCEDURES	Review Results			Organization's Resolution			Review Dispo.	
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<p>1.6.1 DOCUMENTATION</p> <p>(32) There are two methods which can be used for the quality assurance, documentation and control of scientific work. (33) These are the scientific notebook system and the technical implementing procedure system. (34) The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgment, trial and error methods, or developing the methodology by which an activity will be accomplished. (35) When the scientific notebook system is used, the study plan or scientific investigation planning document shall be the controlling document used to perform the activity since it describes the proposed approach or general procedure for accomplishing the work. (36) Alternatively, the technical implementing procedure system will generally be used when qualified personnel are performing repetitive work which does not include the use of a high-degree of professional judgment or trial and error methods in the performance of the work. (37) Detailed technical implementing procedures are required when it is not possible to deviate from a prescribed sequence of actions, without endangering the validity of the results that will be obtained from the work. (38) Modifications made to these procedures as detailed in Para. 1.6.2. (39) Logbooks or appropriate forms or both are used, particularly in repetitive work, to document the performance of the work according to the technical implementing procedure, and to maintain absolute control over all other aspects of the work.</p>	<p>3.1.6 OK</p> <p>3.1.6 OK</p> <p>3.1.6 OK</p>	<p>exception - (36) UNSAT INCOMPLETE</p> <p>3.1.6.1 (36) UNSAT INCOMPLETE</p> <p>3.1.6 (37) UNSAT CHANGE "STRICT TO PRESCRIBED"</p> <p>3.1.6.1 (37) UNSAT OMITTED REF OK RFR SEE 3.1.6.1</p> <p>3.1.6 (37) CONFORM</p>	<p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p>	<p>3) ADDED 3.1.1</p>	<p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p>			

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<p>1.6.2 TECHNICAL IMPLEMENTING PROCEDURES</p> <p>(40) Detailed technical implementing procedures together with appropriate logbooks and other supporting documents, shall be used whenever the work is repetitive. (41) Each technical implementing procedure shall be developed in accordance with the requirements given in Section V of this document and reviewed for compliance with the requirements of this section of the QA Plan. (42) Modifications may be made to the technical aspects of technical implementing procedures by the individual utilizing the procedure. (43) If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer.</p> <p>(44) Requirements and acceptance or rejection criteria, including required levels of precision and accuracy, shall be provided or approved by the organization responsible for the scientific investigation, unless otherwise designated.</p> <p>(45) Technical procedures utilized for scientific investigations shall provide for the following as appropriate:</p> <ul style="list-style-type: none"> o Requirements, objectives, methods and characteristics to be tested or observed. o Acceptance limits, if applicable, contained in applicable documents, including precision and accuracy. 	3.1.6.1		<p>4-42 OK</p> <p>43 UNSAT THE PE DOES NOT NECESSARILY HAVE THIS EXPERTISE</p> <p>00</p> <p>UNSAT ADD REQUIREMENTS OR PROCEDURES PROVIDED FOR IMPLEMENTATION OF REVISED UNSAT LIMITED RISK 1/25/89 OK IN 5th BULLET</p>	

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	<ul style="list-style-type: none"> Prerequisites such as calibrated instrumentation, adequate an appropriate equipment and instrumentation, suitable and controlled environmental conditions, and provisions for data collection and storage. For activities of long duration, specific provisions shall be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions to be designed to ensure validity of data throughout the scientific investigation. Mandatory verification points. Acceptance and rejection criteria, including required levels of precision and accuracy (NOTE: "accept/reject criteria" means those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output that, in itself, cannot be characterized as acceptable or unacceptable. A task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject criteria" apply the conditions and methods stated in the procedure.) Methods of documentation of recording data and results, including precision and accuracy. Methods of data reduction. Provision for ensuring that prerequisites have been 	3.1.6.1						

3.1.6.1

OK

OK

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	<p>1.6.3 SCIENTIFIC NOTEBOOKS</p> <p>(52) Scientific notebooks along with other appropriate documents may be used to document scientific investigations and experiments. (53) In such cases, this documentation shall be sufficient such that another qualified scientist can use the notebook to retrace the investigation and confirm the results, or repeat the experiment and achieve the same results without recourse to the PI.</p> <p>1.6.4 FORMAT FOR DOCUMENTATION</p> <p>(54) Documentation of scientific work i.e. experiments and research shall be performed using bound logbooks or notebooks to provide written record of the experiment or research.</p> <p>1.6.4.1 Initial Entries</p> <p>(55) Where appropriate, and prior to initiation of the experiment or research, the following entries, as a minimum, shall be made</p> <ul style="list-style-type: none"> • Title of the experiment or research. • Name of the qualified individual or individuals performing the experiment or research. • Description of the experiment's objective or objectives and the proposed approach or procedure for achieving these objectives. This may be accomplished by reference to the appropriate study plan or other scientific investigation planning document which controls the work. 							

3.1.6.2
3.1.6.2

OK

OK

OK

OK

~~UNSAT - INCOMPLETE~~ OK FOR THIS
THIS IS CONTAINED IN STUDY PLAN

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<ul style="list-style-type: none"> • Equipment and materials to be employed during the experiment or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material. • Calibration requirements. • Dated signature of the individual or individuals making the initial entries. • Special training or qualification requirements. • Documentation of suitable and controlled environmental conditions, if applicable. • Required levels of precision and accuracy shall be identified. • The potential sources of uncertainty and error in scientific investigations which must be controlled and measured to assure the investigations are well controlled shall be identified. <p>(56) The initial entries described above are considered to be a "general" procedure and shall be entered into the scientific notebook prior to beginning an investigation. (57) Modifications may be made by the individual performing the investigation. (58) If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site, or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer.</p>	<ul style="list-style-type: none"> ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ 	<ul style="list-style-type: none"> OK OK OK OK OK OK OK OK <p style="font-size: 1.2em; margin-top: 20px;">56 57 58</p>	<p style="font-size: 1.2em; margin-top: 20px;">56 57 58</p> <p style="font-size: 1.2em; margin-top: 20px;">56 57 58</p>
		<p style="font-size: 1.2em; margin-top: 20px;">56 57 58</p> <p style="font-size: 1.2em; margin-top: 20px;">56 57 58</p>	<p style="font-size: 1.2em; margin-top: 20px;">56 57 58</p> <p style="font-size: 1.2em; margin-top: 20px;">56 57 58</p>

56 OK in 3.1.1.2
* Not true
see Initial, pg. 13
57-58 UNSAT
CONFORM TEST

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<p>1.6.4.3 Final Entries</p> <p>(60)The final entries in the record shall have, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer.</p>	3.1.6.2	<p>OK RKR IN 2ND SENTENCE</p> <p>60 UNSAT OMITTED</p> <p>PART OF REC'D</p>	✓
<p>1.6.4.4 Final Results</p> <p>(61)Final results and a summary of the results of the experiment or research shall be documented (e.g. in a technical report). (62)This shall include a discussion of whether the experiment's objectives as outlined in the initial entries (Paragraph 1.6.4.1) were achieved. (63)This documentation shall become part of the QA records of the activity.</p>	↓	<p>61 UNSAT CHANGE "MAY" TO "SHALL"</p> <p>62 OK</p> <p>63 OMITTED</p>	✓ ✓
<p style="text-align: center;">1.7 CHANGE CONTROL</p> <p>(64)All changes in scientific investigation planning documents shall go through the same review and approval process as specified in Paragraph 1.3 of this section. (65)The Participating Organization shall be responsible for evaluating the impacts of such changes on the associated Quality Assurance level assignments.</p>	3.1.3	OK	
<p style="text-align: center;">1.8 INTERFACE CONTROL</p> <p>1.8.1 COORDINATION</p> <p>(66)Internal and external scientific investigation interfaces shall be identified and scientific investigation efforts shall be coordinated among and within Participating Organizations. (67)Interface controls shall include the assignment of responsibility and the establishment of procedures among and</p>	3.1.7	<p>67 OK</p> <p>OK SEE 67</p>	✓
<p style="text-align: center;">1.8.2</p>	3.1.7	OK	✓

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	<p>within Participating Organizations for the review, approval, release, distribution and revision of documents involving scientific investigation interfaces. (68)Interfaces within a participating organization shall be coordinated according to procedures developed by that participating organization. (69)Interfaces between scientific investigations, or between a scientific investigation and any other Project activity including design activities, shall be coordinated among Project participants in accordance with administrative procedures established by the WFO. (70)Interfaces between Participating Organizations and their suppliers shall be controlled in accordance with procedures established by the Participating Organization. (71)Ongoing field or laboratory scientific investigations shall be identified to preclude inadvertent interruption and to ensure operational compatibility. (72)Such identification shall be clearly evident at the location at which the scientific investigation is being performed. (73)Field investigations shall identify the location of the investigation.</p> <p>1.8.2 TRANSMITTAL</p> <p>(74)The method of transmittal of information or items, including samples of natural or man-made materials, across interfaces shall be documented.</p> <p>1.9 VERIFICATION OF SCIENTIFIC INVESTIGATIONS</p> <p>1.9.1 VERIFICATION PLANNING</p> <p>(75)Planning for verification activities shall be accomplished and documented via verification procedures, instructions, or checklists. (76)Verification procedures, instructions, or checklists shall provide for following:</p> <ul style="list-style-type: none"> o Identification of characteristics and activities to be verified. 	3.1.1	OK					
	3.1.8.1	OK						
	3.1.8.1	OK						
	3.1.8.1	OK						

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<ul style="list-style-type: none"> • A description of the method of verification. • Identification of the individuals or groups responsible for performing the verification. • Acceptance and rejection criteria. • Identification of required procedures, drawings, and specifications (including revisions). • Recording identification of the verifier and the results of the verification. 	3.18.1	✓						
<p>1.9.2 VERIFICATION HOLD POINTS</p> <p>(77)Mandatory verification hold-points shall be established as necessary. (78)When such hold points are established, work may not proceed without the specific consent of the responsible representative. (79)These hold points shall be indicated in appropriate documents controlling the activity. (80)Consent to waive any specified hold point shall be documented before work can be continued beyond the designated hold point.</p>	3.18.2	OK						
<p>1.9.3 REPORTING INDEPENDENCE OF PERSONNEL</p> <p>(81)Verification shall be performed by personnel who do not report directly to the immediate supervisor(s) who is/are responsible for performing the activity being verified. (82)If these personnel are not part of the formal QA organization, they shall have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further</p>	3.18.3	OK						

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<p>processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. (83)When these persons or organizations who perform the verification activities are not part of the formal QA organization (i.e., part of line management), then the quality assurance organization shall overview and monitor the verification activity.</p> <p style="text-align: center;">1.10 SURVEILLANCE OF SCIENTIFIC INVESTIGATIONS AND EXPERIMENTS</p> <p>1.10.1 LOGISTICS OF SURVEILLANCE</p> <p>(84)The QA organization within the Participating Organization shall perform surveillances of all scientific investigations, as may be deemed appropriate for the purpose and the complexity of the work. (85)The QA surveillance team for a scientific investigation shall consist of one or more qualified technical individuals and one or more QA personnel. (86)The timing and the number of surveillances shall be determined by the QA surveillance team that is formed for this work. (87)Surveillances will be performed in accordance with the requirements specified in Section XVIII of this document.</p> <p>1.10.2 SURVEILLANCE TEAM</p> <p>(88)The technical member or members of the QA surveillance team shall be familiar with the plan for the scientific investigation.</p> <p style="text-align: center;">1.11 REPORTS, CONCLUSIONS, AND RECOMMENDATIONS</p> <p>(89)The Participating Organization shall have implementing procedures for the technical review and approval of the results of scientific investigations. (90)These procedures shall include the NFPD in the review and approval cycle of the final report.</p>	<p>3.18.3 ↓</p> <p>3.18.1</p> <p>3.1.8.1</p> <p>3.1.10</p> <p>3.1.8.1</p> <p>3.1.8.1</p> <p>3.1.9</p> <p>3.1.9</p>	<p>OK</p> <p>OK</p> <p>OK</p> <p>UNSAT OMITTED</p> <p>OMITTED</p> <p>OK</p> <p>OK</p> <p>OK</p>	<p>Acc.</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p>

OK ADD INTERFERENCES
REQ REQUIREMENTS OK
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<p align="center">1.12 CLOSE-OUT VERIFICATION</p> <p>(91)The Participating Organization shall perform a close-out verification upon the completion of any scientific investigation to assure that the QA records for that investigation are adequate and complete. (92)This will be done because it may be a considerable period of time after the work is completed and before the investigation is used in the licensing process. (93)Close-out verifications shall be performed by a team consisting of qualified technical personnel as well as QA personnel.</p>	3.1.10 ↓		OK				
<p align="center">2.0 DESIGN CONTROL</p> <p align="center">2.1 GENERAL</p> <p>2.1.1 DEFINITION</p> <p>(94)The design shall be defined, controlled, and verified. (95)The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. (96)Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. (97)This includes general plans and detailed implementing procedures for data collection and analyses and related information such as test results and analysis. (98)The data collection activities result from scientific investigations and produce design input. (99)Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters.</p>	3.2.1 ↓		OK				

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					Reason		
<p>(100) It is the policy of the NWWSI Project that a 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. (101) It is recognized that the number and length of design phases required to produce a completed or final design of any particular item or facility may vary, among organizations responsible for design, according to the timeliness and availability of pertinent information and the complexity of the item or facility. (102) It is also recognized that all Project design activities, although undertaken by different organizations, which may progress at different rates, are dependent on and require an interface with each other to produce a unified facility design.</p> <p>2.1.2 QUALITY ASSURANCE LEVEL ASSIGNMENT</p> <p>(103) All design phases shall be assigned a Quality Assurance Level prior to execution in accordance with the methods specified in the NWWSI Project Administrative Procedures Manual.</p> <p>2.1.3 QUALIFICATION OF PERSONNEL</p> <p>(104) Personnel performing design work shall be instructed, trained, and qualified in accordance with the requirements of Section II of this document. (105) Instructions, procedures and drawings for design work shall be in accordance with the requirements of Section V of this document.</p>	3.2.1 ↓	OK					
	3.2.11	OK					
	3.2.12 ↓	OK					

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<p>2.1.4 PEER REVIEW</p> <p>(106)For design activities including design output documents which involve use of untried or beyond state-of-the-art testing and analysis procedures and methods, or where detailed technical criteria and requirements do not exist or are being developed, a peer review shall be conducted. (107)The peer review shall meet the requirements of Paragraph 4.0 of this section of the NQWSI Project Quality Assurance Plan (QAP).</p>	3.2.1.3		DB UN SAT ADD BEYOND STATE OF THE ART	✓			✓ AR
<p>2.2 DESIGN INPUT</p> <p>2.2.1 IDENTIFICATION, REVIEW AND APPROVAL OF INPUT</p> <p>(108)Applicable design input, such as site characterization data, criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards, shall be identified, documented, and their selection reviewed and approved by the responsible design organization and the responsible QA organization. (109)The purpose of the QA review is to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements. (110)The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.</p>	3.2.2		OK				

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<p>2.2.2 CHANGES TO DESIGN INPUT</p> <p>(111) Changes to approved design input, including the reason for the changes, shall be identified, documented, approved, and controlled by the responsible design organization.</p>	3.2.4		OK					
<p>2.2.3 CONSIDERATIONS FOR DESIGN INPUT</p> <p>(112) Considerations for inputs as they apply to specific items or systems are contained in Appendix B.</p>	App B		OK					
<p align="center">2.3 DES.</p> <p>2.3.1 DESIGN ANALYSIS DOCUMENTS</p> <p>(113) Design analyses shall be performed in a planned, controlled, and documented manner. (114) Design analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, design input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. (115) These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject (including structure, system, or component) originator, reviewer, and date.</p>	3.2.3		OK					
<p>2.3.2 DOCUMENTATION OF DESIGN ANALYSES</p> <p>(116) Documentation of design analysis shall include the following:</p> <ul style="list-style-type: none"> o Definition of the objective of the analysis. o Definition of design input and their sources. 	3.2.3.1		OK					

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<ul style="list-style-type: none"> • A listing of applicable references. • Results of literature searches or other background data. • Identification of assumptions and identification of those which require verification as the design proceeds. • Identification of any computer calculation, including computer type, program name, version, input, output, and type of program verification, and type of application to the specific problem. • Signatures and dates of review and approval by appropriate personnel including QA Personnel. The purpose of the QA review is to assure that the documentation is prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements. 	3.2.3.1						
<p>2.3.3 USE OF COMPUTER PROGRAMS</p> <p>(117) Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subparagraph 3.0 and Appendix B of this QA Plan.</p>	3.2.3.2		UNSAT LAST SENTENCE OMITTED	OK			OK
<p>2.4 DESIGN VERIFICATION</p> <p>2.4.1 IDENTIFICATION OF DOCUMENTATION</p> <p>(118) Control measures shall be applied to verify the adequacy of design documentation shall be performed in a timely manner. (119) The responsible person shall identify, document the verification method used, the results of verification, and the date.</p>	3.2.4.1		OK				

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	<p>2.4.5 PERSONNEL PERFORMING VERIFICATION</p> <p>(129) Design verification shall be performed in accordance with the requirements of Paragraph 2.4.6 of this Section by any competent, certified individual or individuals or certified group or groups other than those who performed the original design. (130) This includes the following:</p> <p>2.4.5.1 (131) Individuals or groups from the originator's same organization.</p> <p>2.4.5.2 (132) Individuals or groups from other organizations contracted for this purpose.</p> <p>2.4.5.3 (133) The originator's supervisor providing all of the following requirements are met:</p> <ul style="list-style-type: none"> o The supervisor is the only individual in the organization competent to perform verification. o The supervisor did not establish the design input used, specify a singular design approach, or rule out certain design considerations. o The rationale for satisfying the two requirements above is documented and approved by management superior to the supervisor. The QA manager shall also concur with this rationale. <p>2.4.6 METHODS OF DESIGN VERIFICATION</p> <p>(134) Design verification shall be accomplished by any one or a combination of the following: design reviews, alternate calculations, qualification testing, or peer review.</p>							

3.2.45 OK



3.2.46 OK

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<p>2.4.6.1 Design Reviews</p> <p>(175) Design reviews are detailed critical reviews to provide assurance that the design is correct and satisfactory. (176) At a minimum, the items below shall be considered during the review and the results of such deliberations shall be documented.</p> <ul style="list-style-type: none"> • Were the design inputs correctly selected? • Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed? • Was an appropriate design method used? • Were the design inputs correctly incorporated into the design? • Is the design output reasonable compared to design inputs? • Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions? • Are computer programs used for analysis identified and verified in accordance with the methods specified in paragraph 3.0 of this Section. 	<p>3.2.4.6</p> 	<p>OK</p>	<p></p>

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<p>2.4.6.2 Alternate Calculations</p> <p>(137)Alternate calculations are a form of analysis which may be used to determine the adequacy of the original analyses. (138)The use of alternate calculations shall include a review of the appropriateness of assumptions, inputs and computer programs or other calculation method used.</p> <p>2.4.6.3 Qualification Tests</p> <p>(139)Qualification tests that involve actual physical testing of systems, structures, or components may be used to verify the adequacy of design. (140)Where design adequacy is to be verified by qualification tests, the tests shall be identified. (141)The test configuration shall be clearly defined and documented.</p> <p>(142)Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. (143)Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. (144)Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. (145)Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met. (146)If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. (147)When tests are being performed on models or mockups, scaling laws shall be established and verified. (148)The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design work.</p>	<p>3.2.4.6</p> <p>↓</p>	<p>OK</p> <p>OK</p> <p>OK</p>	

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	<p>2.4.6.4 Peer Review</p> <p>(149) Peer review is an acceptable method of design verification when the design is beyond state-of-the-art and other methods of design verification are not feasible.</p> <p>2.5 DESIGN CHANGE CONTROL</p> <p>2.5.1 CHANGES TO APPROVED DESIGNS</p> <p>(150) Changes to approved designs, including field changes, shall be justified and subjected to design control measures commensurate with those applied to the original design and approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the WFO shall designate a new responsible organization. (151) The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design. (152) Errors and deficiencies in approved design and design information documents shall be documented, and action taken to assure that all errors and deficiencies are corrected. (153) Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.</p>	<p>3.2.13</p> <p>3.2.5</p>	<p>UNSAT INCOMPLETE (SEE COMMENT 106)</p> <p>UNSAT DELETE "THE DESIGN"</p>	<p>✓</p> <p>✓</p>	<p>✓</p> <p>✓</p>	<p>✓</p> <p>✓</p>	<p>✓</p> <p>✓</p>

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	<p style="text-align: center;">2.6 DESIGN INTERFACE CONTROL</p> <p>2.6.1 IDENTIFICATION AND RESPONSIBILITY</p> <p>(154) Internal and external design interfaces shall be identified and controlled and design efforts shall be coordinated among and within responsible design organizations. (155) Interface controls shall include the assignment of responsibility and the establishment of procedures among and within responsible design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.</p> <p>2.6.2 INFORMATION TRANSMITTED ACROSS INTERFACES</p> <p>(156) Design information transmitted across interfaces shall be documented and controlled. (157) Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. (158) Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.</p> <p style="text-align: center;">2.7 DESIGN OUTPUT REQUIREMENTS</p> <p>2.7.1 DESIGN OUTPUT DOCUMENTS</p> <p>Design output documents shall:</p> <p>2.7.1.1 (160) Relate to the design input by documentation in sufficient detail to permit design verification.</p>							
	3.2.6	OK						
	3.2.6	OK						
	3.2.7	UNSAT INCORPORATE						✓ RPL

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<p>2.7.1.1 (61)Identify assemblies or components or both that are part of the assembly designed. (62)When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection or testing or both, to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented different from the commercial grade item in a manner traceable to a documented definition of the difference.</p> <p>2.7.1.3 (63)Show evidence that the required review and approval cycle has been achieved prior to release for procurement, construction, or release to another organization for use in other design activities. (64)As a minimum, the review and approval cycle shall include the participation of the technical and QA elements of both the responsible design organization and the WFO. (65)The purpose of the QA review is to assure that the documents are prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.</p> <p>2.8 DESIGN DOCUMENTS AS QA RECORDS</p> <p>(66)Design documentation, including design inputs, analyses, drawings, specifications, approved changes thereto, evidence of design verification and records confirming interface control shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section XVII of this document.</p>	3.2.7	OK					
	↓	OK					
	3.2.8	OK					

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<ul style="list-style-type: none"> • Relate the types of documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use. • Identify the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software. • Specify the process to be used for verification and validation of the software developed or applied to geologic repository design analysis. • Identify the procedure for reporting and documenting software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action. <p>3.1.2 (174) Software shall be placed under configuration management as each baseline element is approved. (175) Software baseline elements shall be uniquely identified to assure positive control of all revisions; the identification of each code version shall be directly related to the associated documentation.</p> <p>3.1.3 (176) Changes to software shall be systematically evaluated, coordinated, and approved to assure that the impact of a change is carefully assessed prior to updating the baseline, required action is documented, and the information concerning approved changes is transmitted to all affected organizations. (177) Changes to computer software shall be subject to the same level of approval, verification, and validation as the original software.</p>	App H						
	App H						
	App H						
	App H						
	3.3.2.1	OK					
	3.3.2.1	OK					
	3.3.2.2	OK					

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<p>3.1.4 (178) Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NWSI-0056, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. (179) This requirement may be met in part by existing documentation if properly referenced as to the NWSI-0056 requirements.</p>	App H				
<p>3.1.5 (179) Testing of software, including new or modified software, shall be performed under these inputs and conditions necessary to exercise the software, including boundary conditions and to provide a suitable benchmark or sample problem for installation. (181) The goal of testing is to develop a set of test cases that have highest probability of detecting the most errors in order to identify under what conditions the software does not perform properly.</p>	3.3.2.3 ↓	OK			
<p>3.1.6 (182) Verification and validation of computer software shall be performed prior to the use of such software to perform technical calculations in support of site-characterization, performance assessment analysis and the design, analysis, and operation of repository structures, systems and components. (183) In those cases where this requirement cannot be met, the portion or portions of software which have not been verified and validated shall be identified and controlled. (184) In all cases, the verification and validation of software shall be completed prior to relying on the software to support the licensee application.</p>	App H ↓				
<p>3.1.7 (185) Verification and validation procedures shall assure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.</p>	App H ↓				

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<p>3.1.8 (186) Existing software shall be qualified for use. (187) This qualification shall be based on the ability of the software to provide acceptable results for specific applications and compliance with the requirements of this section. (188) Software that has not been developed in accordance with this QA Plan may be qualified for use provided the software is verified and validated, a software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this section.</p> <p>3.1.9 (189) Methods for determining the applicability of requirements and managing interfaces involving the documentation, configuration management, change, qualification, verification, and validation of software, shall be described in each organization's software QA Plan and procedures.</p> <p align="center">3.2 DOCUMENTATION OF COMPUTER SOFTWARE</p> <p>(190) Documentation of scientific and engineering software shall include the following, as a minimum:</p> <ul style="list-style-type: none"> o Software requirements specification; o Software design and change documentation; o Description of mathematical models and numerical methods; o Software verification and validation documentation; o User documentation; o Code assessment and support; 	<p>3.3.2.4</p> <p>↓</p> <p>3.3.2.5</p> <p>App Hand 3.3.1</p> <p>↓</p>	<p>188) UNSAT ADD "IN REQUIREMENTS ... SECTION"</p> <p>UNSAT ADD "SOFTWARE PLAN"</p>						

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<p>5.0 TECHNICAL REVIEWS</p> <p>(197) When technical reviews are required, they shall be conducted in accordance with procedures that contain specific criteria for the performance of the technical review.</p>	3.4	OK					

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	<p align="center">SECTION IV</p> <p align="center">PROCUREMENT DOCUMENT CONTROL</p> <p align="center">1.0 REQUIREMENTS</p> <p align="center">1.1 MEASURES TO ASSURE ADEQUATE QUALITY</p> <p>(1) Measures shall be established to ensure that applicable regulatory requirements, design or site investigation bases, and other requirements that are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services utilized on the Nevada Nuclear Waste Storage Investigations (NNWSI) Project. (2) To the extent necessary, procurement documents of Participating Organizations and Nevada Test Site (NTS) Support Contractors, shall require sub-tier contractors to provide a Quality Assurance (QA) program that is consistent with the pertinent provisions of this NNWSI Quality Assurance Plan as required for the specified Quality Assurance Level.</p> <p align="center">1.2 WFO PROCURED SERVICES</p> <p>(3) Waste Management Project Office (WFO) initiated procurements for services shall be controlled through the use of the Federal Acquisition Regulations (FAR) and Department of Energy Acquisition Regulations (DEAR).</p> <p>(4) When the WFO procures services from contractors or requests services from national laboratories and supporting Federal agencies, the WFO shall prepare work agreements, memos of understanding, interagency agreements, management agreements, or other suitable documents.</p>							
	4.1	OK						
	4.1.3	UNSAT	REVISE WORDING TO MEET INTENT OF REQUIREMENT	✓				✓
	N/A	OK						
	N/A	OK						

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<p>2.0 ADDITIONAL REQUIREMENTS FOR QA LEVEL I ACTIVITIES</p> <p>2.1 CONTENT OF PROCUREMENT DOCUMENTS</p> <p>(5) Procurement documents issued at all tiers of procurement shall include provisions for items listed below, as deemed necessary by the purchaser:</p> <p>2.1.1 SCOPE</p> <p>(6) A statement of the scope of the work to be performed by the supplier shall be in the procurement documents.</p> <p>2.1.2 TECHNICAL REQUIREMENTS</p> <p>(7) Technical requirements shall be specified in the procurement documents. (8) Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. (9) The procurement documents shall provide for identification of test, inspection, and acceptance requirements of the purchaser for monitoring and evaluating the supplier's performance.</p> <p>2.1.3 QA REQUIREMENTS</p> <p>2.1.3.1 (10) Procurement documents shall require that the supplier have a documented QA program that implements either portions or all of the requirements of this document. (11) Quality Assurance Program Plans (QAPs) and documents of subcontractors for Quality Assurance Level I purchases shall be reviewed and approved by the procuring Project participant. (12) Those which do not adequately define QA requirements, as judged by the QA representative of the Project participant, shall be corrected prior to initiation of activities</p>	4.1	OK						
	4.1.1	OK						
	4.1.2	OK						
	4.1.3	10, 11, 13, 14 OK 12 UNSAT AS FAR AS MIGHT CONFORM WORDING						

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<p>specified by the purchase order or contract. (13)The extent of the program required shall depend upon the type and use of the item or service being procured. (14)The procurement documents shall require the supplier to incorporate appropriate QA program requirements in subtier procurement documents.</p> <p>2.1.3.2 (15)In developing QA requirements for test and other equipment, consideration should be given to whether proper performance of that equipment can be determined during or after its use (i.e., whether failure or malfunction of the equipment can be detected).</p> <p>2.1.4 RIGHTS OF ACCESS</p> <p>(16)At each tier of procurement, the procurement documents shall provide for access to the suppliers' facilities and records for inspection or audit by the purchaser, appropriate WFO personnel, or other WFO authorized representatives. (17)WFO access to subtier contractor facilities shall be arranged by the contracting organization.</p> <p>2.1.5 DOCUMENTATION REQUIREMENTS</p> <p>(18)The procurement documents at all tiers shall identify the documentation required to be submitted to the purchaser. (19)The time of submittal shall also be established. (20)If the purchaser requires the supplier to maintain specific QA records, then the retention times and disposition requirements shall be specified in accordance with Section XVII of this QA Plan.</p> <p>2.1.6 NONCONFORMANCE</p> <p>(21)The procurement documents shall prescribe the purchaser's requirements for reporting and approving disposition of nonconformances.</p>	4.1.3	OK						
	4.1	OK INTENT						
	4.1.3	OK						
	4.1.4	16 DEFICIENT CONFORM		✓			✓	
	↓	17 UNSAT CONFORM DURING		✓			✓	
	4.1.5	(Exception - All records will be maintained w/ the Project) UNSAT 5/11/89 18 UNSAT 19 & 20 OK		✓			✓	
	↓							
	4.1.6	OK						

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<p>2.1.7 SPARE AND REPLACEMENT PARTS</p> <p>(22)The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate designation of the technical and quality related data that are required for ordering these parts or assemblies. (23)The technical and quality requirements shall be equal to or better than the original. (24)If QA or technical requirements of the original item cannot be determined, then an engineering evaluation shall be conducted by qualified individuals to establish the requirements. (25)The evaluation shall consider the interchangeability, function and safety of the item. (26)The evaluation shall be documented.</p>		<p>OK N/A to LANL at the present time</p>	
<p>2.2 PROCUREMENT DOCUMENT REVIEW</p> <p>(27)A review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective supplier or suppliers include appropriate provisions to assure that items or services will meet the specified requirements. (28)The review shall be performed and documented prior to contract award. (29)Procurement document reviews shall be performed by personnel who have access to pertinent information and who have adequate understanding of the requirements and intent of the procurement documents. (30)The review shall include, as a minimum, the cognizant technical organization and QA organization. (31)The review by the QA organization shall assure that the following requirements are met:</p> <ul style="list-style-type: none"> o QA requirements are correctly stated, inspectable, and controllable. o There are adequate acceptance and rejection criteria. o Procurement documents have been prepared, reviewed, and approved in accordance with this QA Requirements Manual. 	<p>4.2</p> <p>↓</p>	<p>27-29 OK</p> <p>30 UNSAT ADD COGNIZANT TECHNICAL ORGANIZATION</p> <p>31 OK</p>	<p>✓</p>

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<p>2.3 PROCUREMENT DOCUMENT CHANGES</p> <p>(32) Procurement document changes shall be subject to the same degree of control as utilized in the preservation of the original documents. (33) Changes that are made as a result of evaluation or precontract negotiations shall be incorporated into the procurement documents. (34) The review of such changes and their effects shall be completed and documented prior to contract award. (35) Review of changes shall include the following considerations:</p> <ul style="list-style-type: none"> Appropriate content shall be included in procurement documents as required by Paragraph 2.1 of this Section. Additional or modified design or site investigation criteria shall be determined. Analysis of exceptions or changes requested or specified by the supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished. 	4.3		32 + 33 OK					
	↓		34 UNSAT ADD DOCUMENTED	✓			✓	
	4.1		35 UNSAT INCORPORATED INTO 4.3	✓			✓	
	—		unclear requirement				✓	
	4.3		PROGRAM OK	✓			✓	
<p>2.4 DISTRIBUTION OF PROCUREMENT DOCUMENTS</p> <p>(36) Participating Organizations and NWS Support Contractors shall forward to the SAIC/TMSS Project QA Department (QA Verification Division Manager), a copy of purchase documents, and changes thereto, as issued, when purchases involve Quality Assurance Level I items or services. (37) Only those purchase documents which identify the vendor, describe the scope of work, and detail when work is to start are required to be submitted to the SAIC/TMSS Project QA Department.</p>	4.4		} UNSAT ADD SAIC/TMSS QA DEPT					
	4.4						NOT REQD NO CONTRACTUAL ARRANGEMENT WITH TMSS	✓

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<p>SECTION V</p> <p>INSTRUCTIONS, PROCEDURES, PLANS AND DRAWINGS</p> <p>1.0 GENERAL</p> <p>(1) Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings, of a type appropriate to the circumstances except as noted in paragraph 1.0 of this Section. (2) These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. (3) Instructions and procedures shall include a section which identifies the QA records which are generated during implementation of the document. (4) If plans are used in lieu of procedures, then these plans shall also include or reference appropriate acceptance criteria and identify the QA records which are generated. (5) These documents, including drawings, shall be controlled as required in Section VI of this document.</p> <p>2.0 REVIEWS</p> <p>(6) An independent review of all instructions, procedures, plans and drawings shall be performed by the originating organization to assure technical adequacy and inclusion of appropriate quality requirements. (7) If applicable, this review shall consider whether the activities are not repeatable, have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities.</p>	<p>5.1</p> <p>↓</p>	<p>1) UNSAT INCORPORATE EXCEPTION OK PER 1/27/89 NOTED IN SECS 3 & PAR 6.3 REF 5.2</p> <p>2) OK</p> <p>4) REF 5.2</p>	<p>Acc.</p>	<p>Rej.</p> <p style="text-align: center;">X REF</p>	<p>Acc.</p>	<p>Rej.</p>
	<p>5.3</p> <p>↓</p>	<p>OK</p>	<p>Acc.</p>	<p>Rej.</p>	<p>Acc.</p>	<p>Rej.</p>

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3.0 INSTRUCTIONS FOR SCIENTIFIC NOTEBOOKS

(9) The Participating Organizations shall prepare instructions for the control of scientific notebooks, plans and the other documentation that will be used in scientific investigations. (7) Scientific notebooks are used in scientific investigations, the requirements of Section III, paragraph 3.1.6.2 shall prevail over the requirements of this Section. (10) Scientific records shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section XVII of this document.

See Section 3

OK IN SECTION 3.1.6.2

4.0 DISTRIBUTION

(11) Each Participating Organization and Nevada Test Site (NTS) Support Contractor shall maintain and provide the NTSO PSM and the SAIC/TMSS Project Quality Assurance Department Manager with controlled distribution of all implementing procedures, plans and instructions used for QA Level I and II activities.

5.4

UNSAT DELETE IF APPLICABLE, ADD SAIC/TMSS PSM, PQA, NOT REQD.

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<p>SECTION VI</p> <p>DOCUMENT CONTROL</p> <p>1.0 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE</p> <p>1.1 METHODS</p> <p>(1) The preparation, review, approval, and issuance of documents such as instructions, procedures, plans and drawings, including changes thereto, shall be controlled through the implementation of methods that assure that only correct documents are used. (2) Document control shall be applied to the following:</p> <ul style="list-style-type: none"> o Documents containing or specifying quality requirements. o Documents that prescribe activities affecting quality. <p>(3) The document control system shall be documented, and the QA organization shall provide the appropriate review, resolution of comments, and concurrence with respect to quality-related aspects of the documents.</p> <p>1.2 IMPLEMENTATION</p> <p>(4) Implementation of document control shall provide for the following:</p> <ul style="list-style-type: none"> o Identification of documents to be controlled. 	6.1	OK					
	6.1	OK					
	↓						
	6.2	OK					
	6.2	OK					

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	<p>2.2 MINOR CHANGES</p> <p>(7) Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. (8) To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.</p> <p>3.0 DISTRIBUTION OF DOCUMENTS</p> <p>3.1 DOCUMENT CONTROL SYSTEM</p> <p>(9) The document control system shall assure that documents requiring verification are not released prior to verification or, if they must be released before verification, they are uniquely identified as such and controlled in accordance with Paragraph 1.2 of this section. A master list or equivalent used to identify the correct, current and updated versions of documents shall be submitted to the WFO PCM and the SAIC/TMSS Project Quality Assurance Department Manager.</p>	<p>6.3</p> <p>↓</p>	<p>OK BY SAME ORGANIZATION</p>					
	<p>6.4</p> <p>↓</p>	<p>9) ADD IN ACCORDANCE WITH 6.2</p> <p>10) ADD SAIC/TMSS</p>	<p>ACC</p>		<p>NO CONTRACTOR ARRANGEMENT</p>		<p>✓ RIR</p> <p>✓</p>	

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	<p style="text-align: center;">SECTION VII CONTROL OF PURCHASED ITEMS AND SERVICES</p> <p style="text-align: center;">1.0 GENERAL REQUIREMENTS</p> <p>(1) Measures shall be established to ensure that purchased material, equipment, and services conform to the procurement documents. (2) These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, audit, and examination of products upon delivery. (3) Where required by code, regulation, or contract requirement, documentary evidence that material and equipment conform to the procurement requirements shall be available at the location where the material or equipment is to be used prior to installation or use of such material and equipment. (4) This documentary evidence shall be retained under the control of the Waste Management Project Office (WMPO) QA Records Management System (QRMS) and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, that are to be met by the purchased material and equipment. Specific requirements for the control of purchased items and services are listed below.</p> <p style="text-align: center;">1.1 PROCUREMENT PLANNING</p> <p>1.1.1 GENERAL</p> <p>(5) Procurement activities shall be planned and documented to ensure a systematic approach to the procurement process. (6) Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities. (7) Appropriate Quality Assurance (QA)</p>							
	7.1	OK						
	7.1	UNSAT	CONFORM WORDING					
	7.1.7	UNSAT	ADD "ANY SHALL BE AVAILABLE EQUIPMENT"			SEE 7.1.7.3		
	7.1.7	UNSAT	ADD FOOT OR PKR					
	7.1.1	OK						
	↓	OK						
		UNSAT	REQT INCOMPLETE					

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	<ul style="list-style-type: none"> • Verification (surveillance, inspection, or audit) activities by purchaser, including notification for hold-and-witness points. • Control of nonconformances. • Corrective action. • Acceptance of item or service. • QA records. <p align="center">1.2 SOURCE EVALUATION AND SELECTION</p> <p>1.2.1 SELECTION OF SUPPLIERS</p> <p>(12) The selection of suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents before the award of contract.</p> <p>1.2.2 SOURCE EVALUATION AND SELECTION MEASURES</p> <p>(13) Procurement source evaluation and selection measures shall be implemented by the purchaser and shall provide for identification of the purchaser's organizational responsibilities for determining supplier capability.</p>	7.1.1						
	7.1.2	OK						
	7.1.2		UNSAT. ADD ORGANIZATIONAL RESPONSIBILITIES OK IN 7.1 RKR 11/29/07					

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<p>1.2.3 MEASURES FOR EVALUATION AND SELECTION OF PROCUREMENT SOURCES</p> <p>(14) Measures for evaluation and selection of procurement sources, and the results thereof, shall be documented and shall include one or more of the following items:</p> <ul style="list-style-type: none"> • Evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history shall reflect current capability. • Supplier's current quality assurance system supported by documented qualitative and quantitative information that can be objectively evaluated. • Supplier's technical and quality capability as determined by a direct evaluation of their facilities and personnel and the implementation of his QA program. 								
<p>1.3 BID EVALUATION</p> <p>1.3.1 EXTENT OF CONFORMANCE</p> <p>(15) Bid evaluation shall determine the extent of conformance to the procurement documents. (16) This evaluation shall be performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:</p> <ul style="list-style-type: none"> • Technical considerations. • QA requirements. 	<p>7.1.2</p> <p>↓</p>	<p>OR</p>						
	<p>7.1.3</p> <p>↓</p>	<p>15 OK</p> <p>16 ADD "ORGANIZATIONS..."</p>						

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<ul style="list-style-type: none"> • Supplier's personnel. • Supplier's production capabilities. • Supplier's past performance. • Alternates. • Exceptions. <p>1.3.2 RESOLUTION OF UNACCEPTABLE QUALITY ASSURANCE CONDITIONS</p> <p>(17) Before the award of the contract, the purchaser shall receive or obtain commitments to resolve unacceptable quality assurance conditions resulting from the bid evaluation.</p> <p style="text-align: center;">1.4 SUPPLIER PERFORMANCE EVALUATION</p> <p>1.4.1 INTERFACE MEASURES</p> <p>(18) The purchaser of items and services shall establish measures to interface with the supplier. (19) The measures shall include the following:</p> <ul style="list-style-type: none"> • Documentation of the understanding between purchaser and supplier of the provisions and specifications of the procurement documents. • Requiring the supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements. 	<p>7.1.3</p> <div style="text-align: center;">↓</div>	<p>UNSAT CHARGE "SUPPLIER QUALIFICATION" TO "BID EVALUATION"</p>	<p style="text-align: right;">BDM</p>
	<p>7.1.4</p> <div style="text-align: center;">↓</div>	<p>OK SEE 7.1.3</p> <p>Exception - covered under laboratory procurement policies as part of letting contracts</p> <p>Exception - not relevant to lab procurements</p> <p>DISAGREE POSSIBLY FOR COMMERCIAL GRADE ITEMS BUT NOT TRUE FOR ALL MATERIAL</p>	<p style="text-align: right;">BDM</p>

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	Sat - Para. No.	Unsat - Para. No. -	Comments	Acc.	Rej.	Acc.	Rej.
<ul style="list-style-type: none"> Reviewing supplier documents that are generated or processed during activities fulfilling procurement document requirements. Identifying and processing necessary change information. Measures to control changes in procurement documents shall be established, implemented and documented in accordance with the requirements of this QA Plan. Establishing methods of document information exchange between purchaser and supplier. 							
<p>1.4.2 VERIFICATION MEASURES</p> <p>1.4.2.1 EXTENT OF VERIFICATION</p> <p>(20) The purchaser of items and services shall establish measures to verify supplier's performance, as deemed necessary by the purchaser. The measures shall establish the extent of source surveillance and inspection activities.</p> <p>NOTE: (21) When a Participating Organization, or Nevada Test Site (NTS) Support Contractor, utilizes another Participating Organization or NTS Support Contractor for NWSI activities for which they are responsible, the user organization shall initiate a request to WFO to conduct a WFO surveillance of the organization performing the work. The surveillance shall be conducted to determine that the item or activity is being produced or performed in accordance with the user organization's requirements. These surveillances may utilize NTS Support Contractor or Participating Organization personnel as technical advisors.</p>	<p>7.1.4</p> <p>↓</p>	<p>OK</p> <p>↓</p>					

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	<p>(22)The extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance. (23)Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the suppliers' activities. (24)These verification activities shall be conducted as early as practicable. (25)However, the purchaser's verification activities shall not relieve the supplier of their responsibility for verification of quality achievement.</p> <p>1.4.2.2 Record of Verification Activities</p> <p>(26)Activities performed to verify conformance to requirements of procurement documents shall be recorded. (27)Source surveillances and inspections, audits, receiving inspections, non-conformances, dispositions, waivers, and corrective actions shall be documented. (28)These completed documents shall be considered QA records and shall be controlled in accordance with Section XVII of this Quality Assurance Plan (QAP). (29)The purchaser shall ensure that this documentation is evaluated to determine the supplier's QA program effectiveness.</p> <p>1.5 CONTROL OF DOCUMENTS GENERATED BY SUPPLIERS</p> <p>(30)Documents that are generated by suppliers shall be controlled, handled, and approved in accordance with documented procedures. (31)Means shall be implemented to ensure that the submittal of these documents is accomplished in accordance with the procurement document requirements. (32)These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.</p>	7.1.5.1 ↓	OK					
	7.1.5.2 ↓	OK						
	7.1.6 ↓	OK						

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<p>1.6 ACCEPTANCE OF ITEM OR SERVICE</p> <p>1.6.1 METHODS FOR ACCEPTANCE</p> <p>(33)Methods shall be established for the acceptance of an item or service being furnished by the supplier. (34)Prior to offering the item or service for acceptance, the supplier shall verify that the item or service being furnished complies with the procurement requirements. (35)Purchaser methods used to accept an item or related service from a supplier shall be either a supplier certificate of conformance, a source verification, a receiving inspection or post-installation test at the facility site, or a combination thereof. Requirements applicable to these methods of acceptance are listed below.</p> <p>1.6.1.1 Certificate of Conformance</p> <p>(36)When a certificate of conformance is used, the following minimum criteria shall be met:</p> <ul style="list-style-type: none"> • The certificate shall identify the purchased material or equipment, such as by the purchase order number. • The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, or other specifications. This may be 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, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment. 	<p>7.1.7</p> <p style="text-align: center;">↓</p>	<p>OK</p>	
	<p>7.1.7.1</p> <p style="text-align: center;">↓</p>	<p>OK</p>	

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- The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means by which to resolve the nonconformances.
- The certificate shall be attested to by a person who is responsible for this QA function and whose function and position are described in the purchaser's or supplier's QA program.
- The certificate system, including the procedures to be followed in filling out a certificate and the administrative procedures for the review and approval of the certificate, shall be described in the purchaser's or supplier's QA program.
- Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification shall be conducted by the purchaser at intervals commensurate with the supplier's past quality performance.

1.6.1.2 Source verification

(37) If source verification is used, then it shall be performed at intervals that are consistent with the importance and complexity of the item or service, and it shall be implemented to monitor, witness, or observe activities. (38) Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. (39) Upon purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the purchaser to the seller.

Review Results			Organization's Resolution			Review Dispo.	
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7.1.7.1		UNSAT INCOMPLETE					
7.1.7.2		OK					

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<p>1.6.1.3 Receiving inspection</p> <p>(40)When receiving inspection is used, purchased items shall be inspected as necessary to verify their conformance to specified requirements, by taking into account source verification and audit documentation and the demonstrated quality performance of the supplier. (41)Receiving inspection shall be performed in accordance with established procedures and inspection instructions to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. (42)Receiving inspection shall be coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection. (43)Receiving inspections associated with engineered items shall be planned, performed, and documented in accordance with the requirements specified in Section X, Para. 2.1, 4.0, 4.1, 6.1, 9.0 and 9.1 of this document. (44)Personnel selected to receipt inspection activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities. (45)When required, personnel shall also be indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are applicable.</p>	7.1.73	OK						
	7.1.72	OK						
	7.1.73	UNSAT INCOMPLETE						
	N/A	OK						
	7.1.73	UNSAT OMITTED						
	7.1.73	UNSAT OMITTED						
<p>1.6.1.4 Post-Installation testing</p> <p>(46)When post-installation testing is used, post-installation test requirements and acceptance documentation shall be established mutually by both the purchaser and the supplier.</p>	7.1.74	OK						

OK

OK

OK

OK

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	<p align="center">1.7 ACCEPTANCE OF SERVICES ONLY</p> <p>1.7.1 PROCUREMENT OF SERVICES ONLY</p> <p>(47) In certain cases involving procurement of services only, such as third party inspections, engineering, and consulting; and installation, repair, overhaul, or maintenance work, the purchaser shall accept the service by any or any combination of the following methods:</p> <ul style="list-style-type: none"> o Technical verification of data produced. o Surveillance, audit, or both, with regard to the activity. o Review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc. <p align="center">1.8 CONTROL OF SUPPLIER NONCONFORMANCES</p> <p>1.8.1 METHODS</p> <p>(48) The purchaser and supplier shall establish and document methods for disposition of items and services that do not meet procurement document requirements. These methods shall include the following provisions:</p> <p>1.8.1.1 Evaluation</p> <p>(49) Provisions for evaluation of nonconforming items.</p>							
	7.1.8		OK					
	7.1.9		OK					

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<p>1.0.1.2 Submittal</p> <p>(50) Provisions for submittal of nonconformance notice to purchaser by supplier as directed by the purchaser. (51) These submittals shall include supplier recommended disposition (e.g., use as-is or repair) and technical justification. (52) Nonconformances to the procurement requirements or purchaser approved documents, which consist of one or more of the items listed below shall be submitted to the purchaser. (53) Approval of the recommended disposition shall be in accordance with documented procedures:</p> <ul style="list-style-type: none"> o Technical or material requirement is violated. o Requirement in supplier documents, which has been approved by the purchaser, is violated. o Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework. o The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired. 	<p>7.1.9</p> <p>↓</p>	<p><i>UNSAT REGARDING IT BEING TOO VAGUE TO REVIEW AGAINST REQUIREMENTS & EXCEPTIONS</i></p> <p><i>Exception - nonconformance notice drafted by purchaser and sent to supplier IN ALL CASES?</i></p> <p><i>Exception - disposition recommended by purchaser NOT ACCORDING TO 7.1.9</i></p>
<p>1.0.1.3 Disposition</p> <p>(54) Provisions for purchaser disposition of supplier recommendation.</p>	<p>n/a</p>	<p><i>Relevant to engineered items DISCREPANCY IS INCORPORATED</i></p>
<p>1.0.1.4 Verification</p> <p>(55) Provisions for verification of the implementation of the disposition.</p>	<p>7.1.9</p> <p>↓</p>	<p>OK</p>

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<p>1.0.1.5 Records maintenance</p> <p>(56)Provisions for maintenance of records of nonconformances that are submitted by the Supplier.</p>	7.19	OK			
<p>2.0 COMMERCIAL-GRADE ITEMS</p> <p>2.1 ALTERNATIVES</p> <p>(57)If a design requires commercial-grade items, then the following requirements are an acceptable alternative to other requirements of this section, except as noted in Paragraph 2.1.2 below and the requirements of Section IV of this QAP. (58)If a scientific investigation requires commercial-grade items they may be controlled by the use of the following requirements (except Paragraph 2.1.1) and Section IV of this QAP.</p>	7.2	OK			
<p>2.1.1 IDENTIFICATION OF COMMERCIAL-GRADE ITEMS</p> <p>(59)Where the commercial-grade item is to be used as an integral part of the designed facility, it shall be identified in an approved design or design out-put document. (60)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.</p>	7.2	OK			
<p>2.1.1 IDENTIFICATION OF COMMERCIAL-GRADE ITEMS</p> <p>(59)Where the commercial-grade item is to be used as an integral part of the designed facility, it shall be identified in an approved design or design out-put document. (60)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.</p>	7.2.1	UNSAT	<p>INCOMPLETE REP DESIGN (SMT PLAN, SPECIFICATION etc) DOCUMENT</p>		
<p>2.1.2 SOURCE EVALUATION AND SELECTION</p> <p>(61)Source evaluation and selection shall be in accordance with Paragraph 1.2. If it is determined necessary by the purchaser based on the complexity of the item and importance to safety.</p>	7.2.1	OK			
<p>2.1.2 SOURCE EVALUATION AND SELECTION</p> <p>(61)Source evaluation and selection shall be in accordance with Paragraph 1.2. If it is determined necessary by the purchaser based on the complexity of the item and importance to safety.</p>	7.2.2	OK			

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	<p>2.1.3 PURCHASE ORDER</p> <p>(62) Commercial-grade items shall be identified in the purchase order by the manufacturer's published product description (e.g., the catalog number).</p> <p>2.1.4 RECEIPT OF COMMERCIAL-GRADE ITEM</p> <p>(63) After receipt of a commercial-grade item, the purchaser shall determine that the following conditions have been met:</p> <ul style="list-style-type: none"> • Damage was not sustained during shipment. • The item received was the item ordered. • Inspection, testing, or both, is accomplished by the purchaser, in accordance with written procedures, to ensure conformance with the manufacturer's published requirements. If applicable, acceptance of the item may be accomplished via the calibration program in accordance with the requirements of Section XII of this QA Plan. • Documentation, as applicable to the item, was received and is acceptable. 	7.2.3	OK					
	7.2.4	UNSAT DELETE "AS APPLICABLE"						

~~OK~~

~~OK~~



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<p>1.1.1 (9) Physical identification shall be used to the maximum extent possible. (10) Where physical identification on the item is either impracticable or insufficient, physical separation, procedural control, or other appropriate means shall be employed.</p>	8.1		OK				
<p>1.1.2 (11) Identification markings, when used, shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. (12) Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.</p>			OK				
<p>1.1.3 (13) When specified by codes, standards or specification that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part or serial number; or specified inspection, test or other records) the program shall be designed to provide such identification and traceability control.</p>			OK				
<p>1.1.4 (14) Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.</p>			OK				
<p>2.0 CONTROL</p> <p>(15) Provisions shall be made for the control of item identification consistent with the planned duration and condition of storage, such as: (1) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; (2) protection of identification on items subject to excessive deterioration due to environmental exposure; (3) provisions for updating existing facility records.</p>			OK				

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<p align="center">PART B - IDENTIFICATION AND CONTROL OF SAMPLES</p> <p>(16) Procedures shall be developed and implemented to assure that samples are identified and controlled in a manner consistent with their intended use. (17) Such procedures shall define the responsibilities (including interface between organizations) for collection, identification, handling, storage, transportation and the generation of records.</p> <p align="center">1.0 IDENTIFICATION</p> <p>(18) Physical identification shall be used to the maximum extent possible. (19) Where physical identification cannot be placed on the sample, appropriate alternative identification methods shall be described and used. (20) All identification methods shall provide methods whereby identification of samples can be traced to the appropriate documentation such as drawings, specifications, drilling logs, test records, inspection documents, and nonconformance reports.</p> <p align="center">1.1 GENERAL</p> <p>(21) Samples shall be identified by placing the identification directly on the sample, on their container or on records traceable thereto. (22) If it is impractical to place the identification on the sample, methods shall be described and implemented to assure that samples are not mixed with like samples and that the correct identification of samples is verified and documented prior to release for use.</p>	8.2 ↓	OK	
		OK	
		OK	

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<p>1.1.1 (23) Procedures shall be developed and implemented to assure that sample collection methods, techniques and related equipment produce the intended sample. (24) Sample handling methods shall be developed, documented and utilized to assure that all samples meet the technical objectives dictated by the scientific investigation, for which the samples are collected.</p> <p>1.1.2 (25) Storage methodology shall be developed and implemented to assure that samples are maintained in predetermined physical conditions commensurate with their intended purpose. (26) Samples intended for long term storage shall receive appropriate treatment to assure that they do not degrade during storage. (27) <u>Long term</u> is not defined herein and shall be defined by the responsible organization depending on the sensitivity of the sample to storage conditions.</p> <p>1.1.3 (28) Transportation methods shall be described and effected by procedures prescribing appropriate containers, handling and any other environmental or safety considerations for the sample(s). (29) Where multiple organizations are involved, appropriate procedures shall define responsibilities and documentation methods to be used.</p> <p>1.1.4 (30) Controls shall be developed and implemented to assure that sample identification is verified and maintained when handled, transported or transferred from one organization's responsibility to another.</p> <p>1.1.5 (31) Measures shall be taken to maintain sample identification while in storage. (32) These measures shall be consistent with the planned duration and conditions of storage and shall describe actions to be taken where samples may have a maximum life expectancy while in storage. (33) Physical segregation of samples to preclude mixing with like samples shall be used to the maximum degree practical.</p>	8.2 ↓	OK		
		OK		

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	<p>1.1.6 (34) Where samples are controlled by more than one organization, procedures describing the organizational responsibilities shall be developed and implemented.</p> <p>1.1.7 (35) The WFO will develop and implement an Administrative Procedure (AP) describing the ultimate curation of all types of samples including liquids, gases and solids. (36) The AP will, as a minimum, address the transportation, handling, storage, retrievability of samples and the generation and retention of records. (37) All records generated as a result of testing of samples shall be handled in accordance with Section XVII.</p> <p align="center">PART C - IDENTIFICATION AND CONTROL OF DATA</p> <p align="center">1.0 IDENTIFICATION</p> <p>(38) Data generated from a Nevada Nuclear Waste Storage Investigation (NNWSI) scientific investigation shall be identified to assist in the determination of its correct use. (39) Identification of such data shall be provided in all documents, information systems, or both, in which such data appear.</p> <p align="center">1.1 GENERAL</p> <p>(40) The identification of NNWSI Project data shall include a reference to the origin of the data (task, test, experiment, report, publication, etc.) and an indication of the Quality Assurance Level assigned to the activity which produced the data.</p> <p>1.1.1 (41) Control measures shall be established and implemented to assure that NNWSI Project data are properly justified. (42) These measures shall include verification of the identification of such data prior to release for use.</p>	8.2						
	↓	OK						
	8.3							
	↓	OK						
	↓	OK						
	↓	OK						

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	<p>1.1.2 (43) 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. (44) 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.</p>	9.3		OK				

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<p>SECTION IX</p> <p>CONTROL OF PROCESSES</p> <p>1.0 GENERAL REQUIREMENTS</p> <p>(1)The requirements of this section apply to engineered items and scientific investigations for <u>process control</u>. (2)The requirements for <u>special processes</u> apply to engineered items only. (3)Measures shall be established to ensure that processes that affect quality of items or services are controlled either by instruction, procedure, or other appropriate means. (4)Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination shall be accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.</p> <p>2.0 PROCESS CONTROL</p> <p>2.1 METHOD</p> <p>(5)All processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. (6)These means shall ensure that process parameters are controlled and that specified environmental conditions are maintained.</p>	<p>9.1</p> <p>↓</p>	<p>1-3 OK</p> <p>4th DEZITE TRO REQ</p>		
	<p>9.2</p> <p>↓</p>	<p>OK</p>		

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<p align="center">2.2 IDENTIFICATION OF SPECIAL PROCESSES</p> <p>2.2.1 RESPONSIBILITY</p> <p>(7) It is the responsibility of the Participating Organization and Nevada Test Site (NTS) Support Contractor that is performing the work to identify which portions of its activities involve the use of special processes. (8) A special process is a process 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 testing of the item.</p> <p>2.2.2 QUALIFICATION REQUIREMENTS</p> <p>(9) The necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in the procedures or instructions either for processes that are not covered by existing codes and standards or for processes where the quality requirements for an item or test exceed those of existing codes or standards.</p> <p>2.2.3 CONDITIONS</p> <p>(10) Conditions necessary for accomplishment of the special process shall be included in procedures or instructions. (11) These conditions shall include proper equipment, controlled parameters of the special process and calibration requirements.</p>			<p align="center"><i>Remainder of this section is N/A to LANL Scope OK</i></p>		

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<p align="center">2.5 SPECIAL PROCESS EQUIPMENT</p> <p>(21)Special process equipment shall be checked out, qualified, and certified in accordance with specified requirements. (22)These requirements shall implement the requirements of applicable codes, standards, and specifications. (23)Equipment checkout, qualification, and certification shall be the responsibility of the organization performing the work. (24)The responsible QA organization shall review the procedures for qualification of equipment for compliance with requirements.</p> <p align="center">2.6 SPECIAL PROCESS RECORDS</p> <p>(25)Records shall be maintained for the currently qualified personnel, procedures, and equipment of each special process and the requirements for maintenance of these records shall be specified. (26)Special process verification methods and criteria shall also be documented and retained.</p>			<i>See above</i>	

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<p align="center">2.3 QUALIFICATION OF SPECIAL PROCESS PROCEDURES</p> <p>2.3.1 PROGRAM FOR QUALIFICATION</p> <p>(13) Procedures shall be qualified in accordance with applicable codes, standards or other specifications. (14) The program for qualification of procedures shall be specified in documents prepared by the cognizant technical organization. (15) The responsible QA organization shall provide appropriate reviews to assure compliance with these requirements.</p> <p align="center">2.4 QUALIFICATION OF PERSONNEL PERFORMING SPECIAL PROCESSES</p> <p>2.4.1 TRAINING, QUALIFICATION, AND CERTIFICATION</p> <p>(16) Personnel shall be trained, qualified, and certified in accordance with written procedures. (17) The training and qualification, and certification shall be the responsibility of the organization that is performing the work. (18) These procedures shall be reviewed by the responsible Quality Assurance (QA) organization for compliance with requirements.</p> <p>2.4.2 PROCEDURE</p> <p>(19) Qualification shall utilize the actual working procedure, to the extent possible.</p> <p>2.4.3 PERSONNEL QUALIFICATION REQUIREMENTS</p> <p>(20) Qualification of personnel shall incorporate the personnel qualification requirements of the applicable codes, standards, or specifications.</p>			<i>See above</i>					

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	<p>2.2.4 APPLICABLE CODES AND STANDARDS</p> <p>(12) The requirements of applicable codes and standards, including acceptance criteria for the special process, shall be specified or referenced in the procedure of instructions.</p>			See above				

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<p style="text-align: center;">SECTION X</p> <p style="text-align: center;">INSPECTION</p> <p style="text-align: center;">1.0 GENERAL REQUIREMENTS</p> <p>(1) Measures shall be established by or for the Participating Organizations and Nevada Test Site (NTS) Support Contractors to provide inspections required to verify conformance of an item or activity to specified requirements. (2) These measures shall provide for: (1) inspections to be performed in accordance with written procedures by qualified personnel who did not perform the work being evaluated; (2) criteria for determining when inspections are required or how and when inspections are to be performed; (3) sampling methodology, if used; (4) the identification of mandatory hold points; and (5) identification of inspections requiring special expertise. (3) The results of all inspection activities shall be documented by the inspecting organization. (4) The requirements of this section apply to engineered items and do not apply to scientific investigation activities.</p> <p style="text-align: center;">2.0 PERSONNEL</p> <p style="text-align: center;">2.1 REPORTING INDEPENDENCE OF PERSONNEL</p> <p>(5) Inspections shall be performed by personnel who do not report directly to the immediate supervisor(s) who is/are responsible for performing the activity being inspected. (6) If these personnel are not part of the formal QA organization, they shall have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further</p>			<p style="text-align: center;"><i>This section is not applicable to LANL scope OK?</i></p>				

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<p>processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. (7)When these persons or organizations who perform the inspection activities are not part of the formal QA organization (i.e., part of line management), then the quality assurance organization shall oversee and monitor the inspection activity.</p> <p align="center">2.2 QUALIFICATION</p> <p>(8)Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspections or tests. (9)The qualification of personnel performing inspection and test activities shall be certified in writing. (10)Personnel selected to perform inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities. (11)Personnel shall also be indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are to be employed.</p> <p align="center">3.0 INSPECTION HOLD POINTS</p> <p>(12)Mandatory inspection or witness hold-points shall be established as necessary. (13)When such hold or witness points are established, work may not proceed without the specific consent of the responsible representative. (14)These hold or witness points shall be indicated in appropriate documents controlling the activity. (15)Consent to waive any specified hold or witness point shall be documented before work can be continued beyond the designated hold or witness point.</p>				

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<p style="text-align: center;">4.0 INSPECTION PLANNING</p> <p>(16) Planning for inspection activities shall be accomplished and documented via inspection procedures, instructions, or checklists.</p> <p>(17) Inspection procedures, instructions, or checklists shall provide for the following:</p> <ul style="list-style-type: none"> • Identification of characteristics and activities to be inspected. • A description of the method of inspection. • Identification of the individuals or groups responsible for performing the inspection operation. • Acceptance and rejection criteria. • Identification of required procedures, drawings, and specifications and revisions. • Recording inspector or data recorder and the results of the inspection operation. • Specifying necessary measuring and test equipment including accuracy requirements. <p style="text-align: center;">4.1 SAMPLING</p> <p>(18) When sampling is used to verify acceptability of a group of items, the sampling procedures shall be based on recognized standard practices.</p>					

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<p style="text-align: center;">5.0 IN-PROCESS INSPECTION</p> <p>(19) Inspection of items in-process or under construction shall be performed for work activities where necessary to verify quality. (20) If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.</p> <p style="text-align: center;">5.1 COMBINED INSPECTION AND MONITORING</p> <p>(21) Where a combination of inspection and process monitoring methods is used, it shall be performed in a systematic manner to ensure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process. (22) Both inspection and process monitoring shall be provided when other techniques cannot provide adequate control.</p> <p style="text-align: center;">5.2 CONTROLS</p> <p>(23) Where required, controls shall be established and documented for the coordination and sequencing of activities at established inspection points during successive stages of the conducted process or construction.</p> <p style="text-align: center;">6.0 FINAL INSPECTION</p> <p>(24) Final inspection shall include a records review of the results and resolution of nonconformances identified by prior inspections. (25) The final inspection shall be planned to reach a conclusion regarding conformance of the item to specified requirements.</p>					

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<p style="text-align: center;">6.1 INSPECTION REQUIREMENTS</p> <p>(26) Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the item's quality and conformance to specified requirements. (27) If not previously examined, then quality records shall be examined for adequacy and completeness.</p> <p style="text-align: center;">6.2 ACCEPTANCE</p> <p>(28) The item's acceptance shall be documented and approved by identified authorized personnel.</p> <p style="text-align: center;">6.3 MODIFICATIONS, REPAIRS, OR REPLACEMENTS</p> <p>(29) Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retests, as appropriate, to verify acceptability.</p> <p style="text-align: center;">7.0 IN-SERVICE INSPECTION</p> <p>(30) Required in-service inspection of structures, systems, or components shall be planned and executed by or for the organization responsible for operation.</p> <p style="text-align: center;">7.1 METHODS</p> <p>(31) Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specific limits. (32) Inspection methods shall include evaluation of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.</p>				

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	<p align="center">8.0 QUALIFICATION REQUIREMENTS</p> <p>Appendix C of this document defines the requirements for the qualification of inspection and test personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptance. Appendix D defines the requirements for qualification of nondestructive examination personnel.</p> <p align="center">9.0 RECORDS</p> <p>(33) The following are the requirements for inspection records which shall be retained in accordance with Section XVII of this QSP.</p> <p align="center">9.1 INSPECTION RECORDS</p> <p>(34) As a minimum, inspection records shall identify the following:</p> <ul style="list-style-type: none"> • Item or activity. • The date of the inspection. • Name of individual performing the inspection. • Name or names of personnel contacted during the inspection. • A description of the type of observation (method of inspection). 							

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<ul style="list-style-type: none"> • Inspection criteria including identification of drawing, specification, etc. (and applicable revision). • Equipment used during the inspection. • Evidence as to the acceptability of the results. • Acceptance statement. • References to information on action taken in connection with conditions adverse to quality, nonconformances and/or actions taken to resolve any discrepancies. <p style="text-align: center; margin: 10px 0;">9.2 PERSONNEL QUALIFICATION RECORDS</p> <p>(35)Records of personnel qualification shall be established and maintained by the employer. (36)The actual examinations used to qualify personnel shall also be retained as part of the record files.</p>				

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<p align="center">SECTION XI</p> <p align="center">TEST CONTROL</p> <p align="center">1.0 GENERAL DISCUSSION</p> <p>(1)Tests required to verify conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in service shall be planned and executed. (2)Characteristics to be tested and test methods to be employed shall be specified. (3)The test procedures shall be implemented by trained and appropriately qualified personnel. (4)The requirements of this section apply to engineered items and do not apply to scientific investigation activities.</p> <p align="center">2.0 TEST REQUIREMENTS</p> <p>(5)Test requirements and acceptance or rejection criteria, including required levels of precision and accuracy, shall be provided or approved by the organization responsible for the design of the item to be tested, unless otherwise designated. (6)Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests shall be controlled. (7)Test requirements and acceptance or rejection criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents.</p>			<p><i>This section is not applicable to the LANL scope OK</i></p>	

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<p>3.0 TEST PROCEDURES</p> <p>3.1 TEST INSTRUCTIONS, PROCEDURES AND DRAWINGS</p> <p>(8) Instructions, procedures, and drawings for tests shall be prepared in accordance with the requirements of Section V of this document. (9) Test procedures or instructions shall contain criteria for determining when a test is required and how the test is performed.</p> <p>3.2 TEST PREREQUISITES</p> <p>(10) Test procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. (11) Prerequisites shall include the following, as applicable: (1) calibrated instrumentation, (2) appropriate equipment, (3) completeness of item to be tested, (4) trained or appropriately qualified personnel, (5) condition of test equipment and the item to be tested, (6) suitable and controlled environmental conditions, and (7) provisions for data acquisition and storage.</p> <p>3.3 REVIEW OF PROCEDURES</p> <p>(12) Test plans and procedures shall be reviewed in accordance with the verification requirements defined in Paragraph 2.4 of Section III of this document. (13) They shall prescribe mandatory inspection hold points (as required), methods of documenting test data and results, and methods of data analysis.</p>				

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<p style="text-align: center;">3.4 POTENTIAL SOURCES OF ERROR</p> <p>(14) The potential sources of uncertainty and error in test procedures which must be controlled and monitored to assure that tests are well controlled shall be identified.</p> <p style="text-align: center;">3.5 ALTERNATIVES</p> <p>(15) In lieu of specifically prepared written test procedures, appropriate sections of related documents, such as American Society for Testing and Materials (ASTM) methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. (16) Such documents shall include adequate instructions to assure the required quality of work.</p> <p style="text-align: center;">4.0 TEST RESULTS</p> <p>(17) Test results shall be documented and their conformance with acceptance criteria evaluated by a responsible authority to assure that test requirements have been satisfied.</p> <p style="text-align: center;">5.0 TEST RECORDS</p> <p>(18) Test records shall, as a minimum, identify the following:</p> <ul style="list-style-type: none"> o Item tested. o Date of test. 			

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<ul style="list-style-type: none"> • Tester or data recorder identification. • Type of observation. • Results and acceptability. • Action taken in connection with any deviations noted. • Person evaluating results. 							

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<p>SECTION XII</p> <p>CONTROL OF MEASURING AND TEST EQUIPMENT</p> <p>1.0 GENERAL</p> <p>1.1 MAINTAINING ACCURACY OF EQUIPMENT</p> <p>(1) Measures shall be established to ensure that tools, gages, instruments, and other measuring and test equipment used in activities that affect quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.</p> <p>1.2 SCOPE OF CONTROL PROGRAM</p> <p>(2) The Quality Assurance Program Plans (QAPPs) of the Participating Organizations and Nevada Test Site (NTS) Support Contractors shall define the scope and methodology of their program for the control of measuring and test equipment. (3) This shall include all measuring and test equipment or systems used to calibrate, measure, gage, test, or inspect either to control or to acquire data to verify conformance to a specified requirement, or to establish characteristic or values not previously known.</p> <p>1.3 DESCRIPTION OF RESPONSIBILITIES</p> <p>(4) The responsibilities of all organizations shall be described for the establishment, implementation and assurance that the calibration program is effective.</p>	<p>12.1</p> <p>↓</p> <p>12.2</p>	<p>OK</p> <p>OK</p> <p>OK</p>		

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<p>2.0 PURPOSE OF EQUIPMENT</p> <p>(5) Measuring and test equipment are devices or systems used to calibrate, measure, gage, test, or inspect either to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known.</p> <p>(6) Specific requirements for control of measuring and test equipment are listed below:</p> <p>2.1 SELECTION</p> <p>(7) Selection of measuring and test equipment shall be controlled to assure that such equipment is of proper type, range, and accuracy, to accomplish the function of determining conformance to specified tolerance requirements. The type, range, and accuracy of a measuring device shall be documented in test and inspection documents. (8) Each device shall have a unique identification number. (9) This number shall be recorded on the data sheet, log, etc., along with the measurement taken, to ensure traceability to the measurement of the device that was used to take the measurement.</p> <p>2.2 CALIBRATION</p> <p>(10) Measuring and test equipment shall be calibrated against certified equipment having known valid relationships to the National Bureau of Standards or other nationally recognized standards and shall be calibrated, adjusted, and maintained at prescribed intervals. (11) If no nationally recognized standards exist, the basis for calibration shall be documented. (12) Calibrating standards shall have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. (13) The management authorized to perform this function shall be identified.</p>	N/A	CR IN 12.1						
	N/A	CR STATEMENT						
	12.3.1	OK						
	12.3.2	REQ 10 "CALIBRATED" OML 12-77 11-13 OK						

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<p>2.3 CONTROL</p> <p>(14) The method and interval of calibration for each item shall be defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. (15) Measuring and test equipment must be labeled, tagged, or otherwise documented in a fashion which indicates the due date of the next calibration and to provide traceability to calibration data. (16) If measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous results obtained and of the acceptability of items previously inspected, tested or data gathered since the last calibration. (17) Devices that are out of calibration shall be tagged or segregated and shall not be used until they have been recalibrated. (18) If any measuring or test equipment is found to be out of calibration consistently, then it shall be repaired or replaced. (19) A calibration shall be performed when the accuracy of equipment is suspect.</p>	12.3.3		14-18 OK 19 "BROUGHT INTO SERIOUS QUESTION & SUBSTITUTED FOR 'SUSPECT' UN'SAT"					
<p>2.4 COMMERCIAL DEVICES</p> <p>(20) Calibration and control measures are not required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.</p>			12.1 OK					
<p>2.5 HANDLING AND STORAGE</p> <p>(21) Measuring and test equipment shall be handled properly and stored to maintain accuracy.</p>	12.3.4		OK					

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	<p>2.6 RECORDS</p> <p>(22) Records shall be maintained and equipment shall be marked suitably to indicate calibration status. (23) Calibration records shall identify the calibration procedure (including revision) utilized to perform the calibration.</p>	<p>12.4 ↓</p>	<p>22</p>	<p>UNSAT "TO INDICATE STATUS" OMITTED</p> <p>23 OK</p>	<p>✓</p>	<p>✓</p>	<p>✓</p>	<p>✓</p>

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<p align="center">1.3 INSPECTION AND TESTING OF SPECIAL TOOLS AND EQUIPMENT</p> <p>(3) Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling. (4) Special handling tools and equipment shall be inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are maintained adequately.</p>	<p align="center">13.4</p> <p align="center">13.4</p>	<p align="center">OR</p>	
<p align="center">1.4 OPERATORS OF SPECIAL EQUIPMENT</p> <p>(7) Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.</p>	<p align="center">13.5</p>	<p align="center">OR</p>	
<p align="center">1.5 MARKING AND LABELING</p> <p>(8) Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.</p>	<p align="center">13.6</p>	<p align="center">OR</p>	

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<p style="text-align: center;">SECTION XIV</p> <p style="text-align: center;">INSPECTION, TEST, AND OPERATING STATUS</p> <p style="text-align: center;">1.0 INDICATION OF STATUS</p> <p>(1)The requirements of this section apply to engineered items and do not apply to scientific investigations. (2)The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. (3)Status indicators shall also provide for indicating the operating status of systems and components of the facility, such as by tagging valves and switches, to prevent inadvertent operation.</p> <p style="text-align: center;">2.0 METHODS OF INDICATING STATUS</p> <p>(4)Status shall be maintained through indicators, such as physical location and tags, markings, travelers, stamps, inspections records, or other suitable means. (5)Procedures describing status indicators and their use shall contain current actual examples of each type indicator.</p> <p style="text-align: center;">3.0 APPLICATION AND REMOVAL OF STATUS INDICATORS</p> <p>(6)The authority for application and removal of status indicating tags, markings, labels, and stamps shall be specified in procedures governing inspection, test, and operating status.</p>			<p><i>This section is not applicable to the LANL scope. OK</i></p>				

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<p style="text-align: center;">SECTION XV</p> <p style="text-align: center;">CONTROL OF NONCONFORMING ITEMS</p> <p style="text-align: center;">1.0 GENERAL REQUIREMENTS</p> <p>(1) Measures shall be established to control items that do not conform to requirements to prevent their inadvertent installation or use. (2) These measures shall include documented procedures for identification, documentation, evaluation, segregation (when practical), disposition, and notification to affected organizations. (3) All personnel involved in Nevada Nuclear Waste Storage Investigations (NNWSI) Project activities are responsible for reporting nonconformances in accordance with their established nonconformance control procedures. (4) These procedures shall be consistent with the minimum requirements listed below.</p> <p style="text-align: center;">1.1 IDENTIFICATION</p> <p>1.1.1 METHOD OF IDENTIFICATION</p> <p>(5) Identification of nonconforming items shall be made by marking, tagging, or other methods that shall not adversely affect the end use of the item. (6) The identification shall be legible, easily recognizable, and shall contain the nonconformance report number. (7) The nonconformance report number shall be a sequential number preceded by an organizational acronym (e.g. LLNL-1, USGS-6, etc). (8) If tags are used, they shall be securely attached to avoid loss during handling.</p>	<p>15.1</p> <p>↓</p>	<p>OK</p>					
	<p>15.2</p> <p>↓</p> <p>15.4</p>	<p>5, 6 & 8 OK</p> <p>7 NOT INCORPORATED</p> <p>OK IN 15.3 1st BULLET</p>					

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	<p>1.1.2 EXCEPTIONS</p> <p>(9) If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.</p> <p>1.1.3 CONDITIONAL RELEASE</p> <p>(10) Work on the nonconforming item shall be stopped until completion of the action specified in the Nonconformance Report (NCR) disposition. (11) If only a specific portion of the item is in nonconformance, then that specific area shall be identified and work may proceed on the remaining areas. (12) If work on a nonconforming item must be continued (conditional release) prior to implementation of the disposition, the Waste Management Project Office (WMPO) shall approve such continuance. (13) Requests for conditional release on nonconforming items shall include documented justification that the following conditions are met:</p> <ul style="list-style-type: none"> 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 is evaluated and limitation(s) for use of the equipment or system is established. Traceability and identification of the nonconforming item are maintained. 	15.4		UNSAT INCOMPLETE OR RRR 1/21/89				
	15.6		15.6 NOT SATISFACTORIAL OR CONTINUED DELETE "AT RISK"			ON 1/30/89 CONTRACTOR RESUMED HIS REVISION OF THIS COMMENT. INCORPORATED 1/31/89 RRR		

RRR

RRR

RRR
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	<p>1.2 LOGGING</p> <p>1.2.1 NONCONFORMANCE CONTROL LOG</p> <p>(14) Each NWSI Project participant shall maintain a nonconformance control log to track nonconforming items. (15) This log shall contain the following information:</p> <ul style="list-style-type: none"> • The nonconformance report number. • A brief description of the nonconforming condition. • Identification of the person or organization responsible for determining and carrying out the nonconformance disposition. • The status of each nonconformance report (open or closed). <p>1.3 SEGREGATION</p> <p>1.3.1 HOLD AREA</p> <p>(16) When practical, nonconforming items shall be segregated by placing them in a clearly identified and designated hold area until they are dispositioned properly.</p> <p>1.3.2 ALTERNATIVE</p> <p>(17) When segregation is impractical or impossible because of physical conditions, such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.</p>	<p>15.3</p> <p>↓</p>	<p>OK</p>					
	<p>15.4</p> <p>↓</p>	<p>OK</p>						
	<p>↓</p>	<p>OK</p>						

1.4 DISPOSITION

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<p>1.4 DISPOSITION</p> <p>1.4.1 NONCONFORMANCE CHARACTERISTICS</p> <p>(18) Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. (19) Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel. (20) Distribution of nonconformance documentation shall be to all affected organizations.</p> <p>1.4.2 RESPONSIBILITY AND AUTHORITY</p> <p>(21) The responsibility and authority for the evaluation, disposition, and close-out of nonconforming items shall be defined and documented. (22) Those personnel assigned signature approval of the disposition shall be identified. Quality Assurance (QA) responsibilities relating to nonconformances shall be described.</p> <p>1.4.3 PERSONNEL</p> <p>(23) Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area that they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.</p>	<p>15.5</p> <p>↓</p> <p>15.5.1</p> <p>15.5.1</p> <p>15.5.2</p>	<p>OK</p> <p>15.1 (RTR 19)</p> <p>OK</p> <p>2) UNSAT IDENTIFY IN PROCEDURE</p> <p>LAST SIGNATURE OF 15.5.1 DOES NOT MAKE SENSE, CHECK</p> <p>OK</p>	<p>OK</p>

OK

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	<p>1.4.4 DISPOSITIONING OF NCR</p> <p>(24) The person or organization assigned the responsibility of dispositioning the NCR shall ensure the following:</p> <ul style="list-style-type: none"> • Nonconformance documentation adequately identifies and describes the nonconformance. • Appropriate justification for the disposition has been documented. In the case of use-as-is or repair dispositions, technical justification is required. The as-built records, if such records are required, shall reflect the accepted deviation. • The disposition has referenced any approved design documents, procedures, plans, work orders, etc., that are to be used for the correction of the nonconforming condition. • The technical details for correction of the nonconforming condition are adequate for the recommended disposition. • If continuance has been requested, justification for the activity to continue has been documented and approved by the appropriate WFO Branch Chief and the WFO PGM. • The disposition complies with existing design documents, test plans or procedures, reports, and regulatory requirements. • If a change to reflect the as-built condition is appropriate, then the disposition addresses action to change the existing design documents, test plans or procedures, reports, etc. Any documents changed shall also be cross referenced on the NCR. 	15.5.3	UNSAT 5 TH BULLET (LIMITED)	ACC		<p>APPROVAL WILL BE BY LAST TPO QA PL</p> <p>NOTE ON 1/30/89 CONTRACTOR REBUNDLED HIS REJECTION OF THIS COMMENT INCORPORATION VERIFIED PRR</p>	

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	<p>Disposition has identified and documented the correction as repair, rework, use-as-is, or reject/scrap.</p> <p>Disposition has identified the people or organization responsible to implement the disposition.</p> <p>1.4.3 WFO APPROVAL</p> <p>(25) In those cases where the responsible organization proposes a disposition of "repair", WFO shall approve the proposed disposition prior to implementation. (26) In the case of a proposed disposition of "use-as-is", the NCR shall be forwarded to WFO for approval after all actions necessary to support technical justification of the disposition have been completed. (27) The appropriate WFO Branch Chief and the WFO PM shall approve NCR dispositions involving "repair" or "use-as-is" determinations and conditional release recommendations.</p> <p>1.4.6 CORRECTIVE ACTION</p> <p>(28) The action taken to correct the nonconforming item shall be verified and documented. (29) Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria, unless the nonconforming item disposition has established alternate acceptance criteria.</p> <p>1.4.7 INTERFACES</p> <p>(30) Internal interfaces between organizational units and external interfaces between NWSI Project participants shall be clearly described.</p>	<p>15.53</p> <p>↓</p> <p>15.54</p> <p>15.54</p> <p>N/A</p> <p>15.55</p> <p>15.55</p> <p>15.7</p>	<p>UNSAT OMITTED</p> <p>OK</p> <p>OK</p>	<p>Acc.</p> <p>Rej.</p> <p>Acc.</p> <p>Rej.</p>	<p>Reason</p> <p>ON 1/30/89 CONTRACTOR RESCINDED THE REJECTION OF THIS COMMENT. (INCORPORATION IN TEST VERIFIED ON 1/31/89 IN 15.5.3) RRR</p>	<p>Acc.</p> <p>Rej.</p>		

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	<p>2.0 REPETITIVE NONCONFORMANCES</p> <p>(31) When repetitive or recurring nonconforming conditions are identified, an evaluation shall be made as to whether or not further programmatic corrective action is warranted to preclude repetition. (32) This corrective action shall be beyond the scope of the action taken for the disposition on the existing NCRs and shall be processed in accordance with corrective action procedures developed by each NWSI Project participant.</p> <p>3.0 TRENDS</p> <p>(33) Nonconformance reports shall be periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances. (34) Results shall be reported to upper management for review and assessment.</p> <p>4.0 DISTRIBUTION OF DOCUMENTS</p> <p>(35) Copies of nonconformance reports for items shall be sent to the WFO PM and the SAIC/TWES Project QA Department (QA Engineering Division Manager) by the originating organization upon issuance and upon closure. (36) The original nonconformance reports shall be sent to the WFO for approval as required by Paragraph 1.4.5 of this section.</p>							
15.7	OK							
15.7	OK							
	OK							
15.5.4	35 UNSAT	ADD SAIC/TWES						
15.5.4	36 UNSAT	"APPROVAL" REQUIRED						

✓
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 CONTRACTOR RESOLUTIONS OBJECTIVE INCORPORATED THIS BEPT IN PARA 15.5.3 VERIFIED EXR 1/31/89
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<p align="center">SECTION XVI</p> <p align="center">CORRECTIVE ACTION</p> <p align="center">1.0 GENERAL</p> <p>(1)A corrective action system is to be defined in the Quality Assurance Program Plan (QAPP) of each Nevada Nuclear Waste Storage Investigations (NWSI) Project Participant and NWS Support Contractor. (2)This system shall ensure that conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as practical.</p> <p align="center">1.1 SIGNIFICANT ADVERSE CONDITIONS</p> <p>(3)For significant conditions adverse to quality the identification, cause, and corrective action taken to preclude recurrence shall be documented and reported to immediate management and upper levels of management for review and assessment. (4)A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability. (5)Significant conditions include, but are not limited to breakdowns in the Quality Assurance program and repetitive nonconformances. (6)Upon discovering or receiving notification that a significant condition adverse to quality or unusual occurrence exists, each NWSI Project Participant shall ensure that:</p> <ul style="list-style-type: none"> o Immediate actions have been taken to remedy the specific condition(s). o Causative factors have been determined. 	16.1 ↓ 16.2 ↓	OK OK		

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	<ul style="list-style-type: none"> Controls have been reviewed, implemented, monitored and revised, if necessary. Affected managers at all levels have been notified of adverse condition(s) and of lessons to be learned to improve conditions or avoid similar occurrences. <p>1.2 FOLLOW-UP ACTION</p> <p>(7)The QA organization shall document concurrence of the adequacy of proposed corrective actions to assure that QA requirements will be satisfied. (8)Follow-up action shall be taken by the QA organization to verify proper implementation of this corrective action and to close out the corrective action. (9)The organization responsible for implementing the corrective action shall assure that the corrective action is completed in a timely manner.</p> <p>1.3 CORRECTIVE ACTION</p> <p>(10)Corrective action reports shall be periodically analyzed by the QA organization to show quality trends. (11)Results shall be reported to upper management for review and assessment.</p> <p>2.0 DISTRIBUTION OF DOCUMENTS</p> <p>(12)Copies of corrective action reports shall be sent to the SAIC/TMSS Project QA Department (QA Engineering Division Manager) by the originating organization upon issuance and closure. (13)Those that document significant conditions adverse to quality shall be reported to the appropriate OCRM Associate Director.</p>	<p>16.2</p> <p>↓</p> <p>16.3</p> <p>↓</p> <p>16.4</p> <p>↓</p>	<p>OK</p> <p>OK</p>	<p>17 UNSAT ADD SAN/TMSS</p> <p>13 OR WPAO RERT</p>				

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<p>SECTION XVII</p> <p>QUALITY ASSURANCE RECORDS</p> <p>1.0 GENERAL REQUIREMENTS</p> <p>(1) Records that furnish documentary evidence of quality shall be specified, prepared, and maintained in accordance with NWSI Administrative Procedures which shall meet the requirements of this Section. (2) This shall include the requirements that all documents be legible, identifiable, and retrievable.</p> <p>1.1 DEFINITION</p> <p>(3) A document or other item is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined below. (4) The term records, used throughout this Section is to be interpreted as Quality Assurance Records. (5) Quality Assurance Records include (1) individual documents that have been executed, completed, and approved and that furnish evidence of the quality and completeness of data (including raw data), and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents, such as plans, correspondence, documentation of telecons, specifications, technical data, books, maps, papers, photographs, and data sheets; (5) magnetic media; and (6) other materials that provide data and document quality, regardless of the physical form or characteristic. (6) A completed record is a document that will either receive no more entries or</p>	17.1	OK					
	17.2	OK	17.4 & 17.2				
	17.3						
	17.4	OK					
	N/A	DISAGREE	APPROVING TO STATE ALL DOC. ARE RECORDS				
	App A	OK					
	17.4	OK					

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<p>whose revision would normally consist of the release of the document; and is signed and dated by the originator and, as applicable, by personnel authorized to approve the document. (7)Records shall be distributed, handled and controlled in accordance with written procedures. (8)All records (including superseded records) shall be retained for the NWSI Project.</p> <p>1.2 ESTABLISHING A RECORD SYSTEM</p> <p>(9)A record system or systems shall be established by each NWSI Project participant at the earliest practicable time consistent with the schedule for accomplishing work activities.</p> <p>1.2.1 RECORDS MANAGEMENT</p> <p>(10)The record system shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation prepared in accordance with section V of this document. (11)The records management activities to be performed by the NWSI Project Participating Organizations, Nevada Test Site (NTS) Support Contractors, and the Waste Management Project Office (WFO) when processing QA records are detailed in the NWSI Project Administrative Procedures Manual.</p> <p>(12)The WFO shall prepare a NWSI Project Information Management System Plan and shall submit the plan to OCRM for review and approval. (13)The records management plan shall:</p> <ul style="list-style-type: none"> Identify the types of records to be generated, purchased, or maintained, including all records referenced in pertinent final reports and other documents. 	17.2 ↓	OK + 17.1					
	17.1	OK					
	17.2 ↓	OK					
	N/A N/A	OK					

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<ul style="list-style-type: none"> Identify the methods to be used to comply with all applicable records requirements, including those to be used to control in-process records. Identify and define the responsibilities of pertinent organizations, including the QA organization. <p>(14) Consistent with applicable regulatory requirements, the WFO shall establish requirements concerning record types and retention that shall include duration, location, and assigned responsibility.</p> <p>1.2.2 MAINTENANCE RECORDS</p> <p>(15) Sufficient records shall be specified, prepared, and maintained to furnish documented evidence of activities that affect quality. (16) The records shall include at least the following: operating logs, the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. (17) Also, the records shall include closely related data such as qualifications of personnel, procedures, and equipment. A list of typical QA records is contained in Appendix E.</p> <p>1.2.3 CONTROL OF RECORDS</p> <p>(18) Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition of QA records shall be established and documented.</p>	<p>N/A</p> <p>17.3</p> <p>17.3</p> <p>17.3</p> <p>17.2</p>	<p>OK</p> <p>15) UNSAT ADD SPECIFIED & PREPARED</p> <p>OK</p> <p>OK</p> <p>OK</p>	<p>OK</p>

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	<p>1.3 PRESERVATION OF RECORDS</p> <p>(19) The procedure that defines the implementation of the record system for each organization shall identify measures to be implemented for the preservation and safe-keeping of the records before storage and for the prevention of delays between record completion and storage at the Project Record Center.</p> <p>1.4 RETENTION CLASSIFICATION</p> <p>(20) For purposes of record retention, all NWSI Project records are classified as lifetime records and are required to be retained for the life of the Project.</p> <p>2.0 GENERATION OF RECORDS</p> <p>2.1 RECORDS SPECIFICATION</p> <p>(21) The applicable design specifications, procurement documents, implementing procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for the WFO.</p> <p>2.1.1 QUALITY OF RECORDS</p> <p>(22) Documents that are designated to become records shall be legible, identifiable, accurate, complete, reproducible, microfilmable, and appropriate to the work accomplished.</p>	<p>17.2</p> <p>↓</p> <p>17.7</p> <p>↓</p>	<p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p>					

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17.4 17.2	OK						
17.5 ↓	OK						
17.5	OK						

2.1.2 COMPLETION OF RECORDS

(23) Documents that are designated to become records shall be completed in accordance with the methods specified in the NWSI Project Administrative Procedures Manual.

3.0 VALIDATION OF RECORDS

3.1 METHODS OF VALIDATION

(24) Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated in accordance with approved procedures. (25) These records may be originals or reproduced copies. (26) Authentication may take the form of a statement by the responsible individual or organization. (27) Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization.

3.2 AUTHENTICATION LIST

(28) Each organization shall maintain a list which contains the signature and initials of the personnel authorized to authenticate records.

4.0 RECEIPT OF RECORDS

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<p align="center">4.1 RECEIPT CONTROL</p> <p>(29) Each organization that is responsible for the receipt of records shall designate a person or organization to be responsible for receiving the records. (30) The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage in accordance with approved procedures. (31) Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process. (32) As a minimum, the receipt control system shall include the following:</p> <ul style="list-style-type: none"> • A method for designating the required records. • A method for identifying the records received. • Procedures for receipt and inspection of incoming records. • A method for submittal of completed records to the storage facility without unnecessary delay. <p align="center">4.2 PROTECTION OF RECORDS</p> <p>(33) The individual or organization responsible for receiving records shall provide protection from damage, deterioration, or loss during the time that the records are in their possession.</p>	17.6		OK
			OK

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	<p>5.0 RECORDS IDENTIFICATION</p> <p>5.1 IDENTIFICATION DESIGNATION</p> <p>(34)Records or indexing systems, or both, shall provide sufficient information to permit identification between the record and the items or activities to which it applies. (35)Records shall be clearly identified by a unique number or other designation which is directly traceable to controlling programmatic information (e.g., project, contract number, task number, preparing organization, author, date, title, subject, etc.). (36)This unique identification number or other designation shall not be repeated anywhere in the Nevada Nuclear Waste Storage Investigations (NNWSI) Project. (37)The Waste Management Project Office (WMPO) or its designee shall review and approve the records identification system of all its contractors and subcontractors to ensure consistency.</p> <p>5.2 INDEXING SYSTEM</p> <p>(38)The records shall be indexed and the indexing system or systems shall include, as a minimum, the location of the record within the records system or systems.</p> <p>6.0 PERMANENT STORAGE FACILITY</p> <p>(39)Records shall be controlled from the time they are complete until the time they are stored in a permanent storage facility. (40)Temporary storage, preservation, safe keeping, and retrievability of completed records shall be in accordance with the requirements applicable to the permanent storage of records. (41)The use of dual storage facilities is an acceptable alternative to a single fire-rated, environmentally controlled facility.</p>							
17.7	61K							
17.7	6K							
17.7	OK							
N/A	W/DATE NOT INCORPORATED							
17.7	OK							
17.8	OK							
17.8								
17.8.2								

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<p align="center">6.1 STORAGE LOCATION</p> <p>(42)The records shall be stored in a predetermined location or locations that meets the requirements of applicable standards, codes, and regulatory agencies.</p>	17.8.2		ok
<p align="center">6.2 STORAGE PROCEDURE</p> <p>(43)Before the records are stored, a written storage procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure. (44)As a minimum, this procedure shall include the following:</p> <ul style="list-style-type: none"> • 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 (see Paragraph 4.1 of this section). • 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. • A method for filing supplemental information (see Paragraph 9.0 of this section). 	17.8.		ok

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<p align="center">7.0 PRESERVATION</p> <p>(45) Records shall be stored in a manner approved by the organization or organizations responsible for storage. (46) In order to preclude deterioration of the records, the following requirements shall apply:</p> <ul style="list-style-type: none"> • Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure. • Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. • Provisions shall be made for special processed records (e.g. radiographs, photographs, negatives, microfilm, magnetic material, etc.) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity. 	17.B.3	OK	
<p align="center">8.0 SAFEGUARDING</p> <p align="center">8.1 MEASURES TO PRECLUDE ENTRY</p> <p>(47) Measures shall be established to preclude the entry of unauthorized personnel in the storage area. (48) These measures shall guard against larceny and vandalism.</p>	17.B.4	OK	

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<p align="center">10.1 CONSTRUCTION AND MAINTENANCE OF FACILITY</p> <p>(53) Records shall be stored in 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; and infestation of insects, mold, or rodents.</p>	17.8.2	OK	
<p align="center">10.2 METHODS</p> <p>(54) The two satisfactory methods of providing storage facilities are (1) single and (2) dual; these are detailed in the following sections.</p>	17.8.2	OK	
<p>10.2.1 SINGLE FACILITY</p> <p>(55) Design and construction of a single record storage facility shall meet the following criteria:</p> <ul style="list-style-type: none"> o It shall have reinforced concrete, concrete block, masonry, or equal construction. o It shall have a floor and roof with drainage control and if a floor drain is provided, then a check valve (or equivalent device) shall be included. o It shall have doors, structures and frames, and hardware that shall be designed to comply with the requirements of a minimum two hour fire rating. 	N/A	OK	

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<ul style="list-style-type: none"> • Sealant shall be applied over walls as a moisture or condensation barrier. • Surface sealant shall be placed on the floor to provide a hard wearing surface to minimize concrete dusting. • It shall have foundation sealant and provisions for drainage. • It shall have forced-air circulation with a filtration system. • It shall have a fire protection system. • Only those penetrations used exclusively for fire protection, communication, lighting, or temperature and humidity control are allowed. All such penetrations shall be sealed or dampened to comply with the minimum two-hour fire protection rating. • The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing. • If the facility is located within a building or structure, then the environment and construction of that building can provide a portion or all of these criteria. 	N/A	OK					

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	<p>10.2.2 ALTERNATE SINGLE FACILITIES</p> <p>(56) The following are acceptable alternatives to the criteria for a single facility:</p> <ul style="list-style-type: none"> • Two-hour fire rated vault that meets National Fire Protection Association (NFPA) 232-1975. • Two-hour fire rated Class B fire containers that meet the requirements of NFPA 23.-1975. • Two-hour fire rated file room that meets the requirements of NFPA 232-1975 with the following additional provisions. <ul style="list-style-type: none"> - An early-warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended control station. - Records storage in fully enclosed metal cabinets. - Adequate access and aisle ways. - Work that is not associated directly with record storage or retrieval shall be prohibited in the file room. - Smoking, eating, or drinking shall be prohibited in the file room. - Two-hour fire rated dampers or doors in all boundary penetrations. 							

N/A OK



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<p>10.2.3 DUAL FACILITIES</p> <p>(57) If storage at dual facilities for each record is provided, then the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. (58) Neither facility is required to satisfy the requirements of Paragraphs 10.2.1 or 10.2.2 but shall meet the other requirements of this document.</p>	17.8.2	CK		
<p align="center">11.0 RETRIEVAL</p> <p align="center">11.1 PROVISIONS</p> <p>(59) Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type. (60) Final reports shall contain a listing, by unique number or other designation, that enables prompt retrieval of all documents used to compile or evaluate the report. (61) This listing shall include, as a minimum, all referenced documents, peer review or other review documents, computer codes, data sheets, procedures, and test plans. (62) All documents referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineers handbook, etc., shall be retrievable from the Records Management System (RMS).</p> <p align="center">11.2 PERSONNEL</p> <p>(63) A list shall be maintained that designates those personnel who shall have access to the files.</p>	N/A	OK OTHER REFS INCORPORATED IN TEXT		
	17.8	NOT INCORPORATED		
	17.3	OK		
	17.3	OK		
	17.3	OK		
	17.10	OK		

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	<p>11.3 ACCESSIBILITY</p> <p>(64) Records maintained by a Participating Organization or Nevada Test Site (NTS) Support Contractor at their facility or other location (on an interim or other basis) shall be accessible to the WFO or its designated alternate.</p> <p>11.6 DISPOSITION</p> <p>12.1 ACCESSIBILITY AT VARIOUS LOCATIONS</p> <p>(65) Records that are accumulated at various locations, prior to transfer, shall be made accessible to the WFO either directly or through the procuring organization.</p> <p>12.2 CUSTODIAN</p> <p>(66) The custodian shall inventory the submittals, acknowledge receipt, and process these records in accordance with this document or the procedures implementing this document.</p> <p>12.3 REQUIREMENTS OF REGULATORY AGENCIES</p> <p>(67) Various regulatory agencies have requirements concerning records that are within the scope of this document. (68) The most stringent requirements shall be used to determine final dispositions.</p>							
	17.10	OK						
	↓	OK						
	17.6	UNSAT	ARCHIVAL RECIPIENT OMITTED					
	N/A	OK	LIFETIME STORAGE					
	N/A							

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<p align="center">1.1 NWSI PROJECT AUDITS</p> <p>(9)The NWSI Project audit program will be executed at the Project level by the Waste Management Project Office (WPO) and at the activity level by individual Participating Organizations and WTS Support Contractors.</p> <p>1.1.1 WPO AUDITS</p> <p>(10)The SAIC/TMSS Project QA Department shall develop a schedule defining the WPO audits planned for each fiscal year. (11)This schedule shall be approved and issued by the WPO as an annual planning document. (12)As a minimum, WPO shall audit all NWSI Project participants annually. (13)The audits shall cover the entire scope of the participants' O&M. (14)Additional audits may be conducted when a unique need arises or when an audit is requested by a Participating Organization or WTS Support Contractor. (15)Participating Organizations and WTS Support Contractors shall be audited to verify the effectiveness and adequacy of implementation of all elements of their respective O&Ms and this QA Plan. (16)These audits will eliminate the need for Participating Organizations or WTS Support Contractors to conduct audits of each other. (17)Representatives of the Participating Organizations, or WTS Support Contractors, or both may be invited to participate in a WPO audit when the audited organization's activities are of mutual interest. (18)Copies of audit documents for the WPO audits shall be sent to the audited organization. (19)The WPO shall also conduct internal audits, which cover the complete WPO O&M and this O&M, on an annual basis.</p>	13.2	OR	<p align="center">DISAGREE COVERED IN B. 2.1, 18.22 LANGUAGE IN THE SPECIFIC TO LPAAL</p>
	N/A		

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	<p>1.1.2 PARTICIPATING ORGANIZATION AND NTS SUPPORT CONTRACTOR AUDITS</p> <p>(20) Each Participating Organization and NTS Support Contractor shall conduct internal (covering their entire OAPP, on an annual basis) and external (direct subcontractor) audits of activities under its direct control, but they will not conduct audits of each other. (21) These audits will be scheduled, planned, conducted, and reported as described in their respective OAPPs and this Quality Assurance Plan (QAP). (22) External and internal audit schedules, dates, and changes thereto, shall be sent to the SRJC/TMSS Project QA Department (QA Verification Division Manager). (23) Audit schedules shall identify the date of the audit, the activities to be audited, and the requirements to which the activities are to be audited.</p> <p>1.2 SCHEDULING</p> <p>(24) Internal and external QA audits, shall be scheduled in a manner that shall provide coverage and coordination with ongoing QA program activities. (25) Audits shall be scheduled at a frequency commensurate with the status and importance of the activity and shall be initiated early enough to assure effective QA. (26) Each NWSI Project Participant shall perform or arrange for annual evaluations of suppliers. (27) This evaluation shall be documented and shall take into account, where applicable, (1) review of supplier furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions, (2) results of previous source verifications; audits, and receiving inspections; (3) operating experience of identical or similar products furnished by the same supplier; and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.</p>							
	18.2.1, 23		OK					
	exception		REQ 22 NOT ACCURATE					
	18.2.1		REQ 23 UNSAT - CORRECTLY INTERPRETED OK RRTZ			NOT CONTRADICTORY RELATING TO RTR TMO 55. SENT TO PPM		PPM
	18.2.1		OK					

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<p>1.2.1 INTERNAL AUDITS</p> <p>(28) Applicable elements of an organization's QAPP shall be audited at least annually or at least once during the life of the activity, whichever is shorter. (29) The scope of the audit shall be established by: considering the results of any previous audits, the nature and frequency of identified deficiencies, and any significant changes in personnel, organization, or in the QA program.</p>	18.2.2	OK						
<p>1.2.2 EXTERNAL AUDITS</p> <p>(30) Elements of an external organization's QA program shall be audited at least annually or once during the life of the activity, whichever is the shorter period, with the following exception: (31) If the activity is less than four months in duration, an audit is not required to be performed unless an audit is necessary due to the complexity or importance of the activity being performed.</p> <p>(32) The justification for not performing audits of vendors whose activities are less than four months in duration shall be documented and approved by the responsible QA Manager prior to implementation of the activity. (33) A copy of the documented justification shall be provided to the Yucca Mountain Project Office PPM.</p>	18.2.3	OK						
<p>1.2.3 JOINT AUDITS</p> <p>(34) If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. (35) The scope of this audit shall satisfy the needs of all of the purchasers.</p>		OK						

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<p>and the audit report shall be distributed to all the purchasers for whom the audit was conducted. (36)Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.</p> <p align="center">1.3 PREPARATION</p> <p>Preparation for an audit shall include the items listed below.</p> <p>1.3.1 AUDIT PLAN</p> <p>(37)The auditing organization shall develop and document an audit plan for each audit. (38)This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.</p> <p>1.3.2 PERSONNEL</p> <p>(39)The auditing organization shall select and assign auditors who are independent of any direct responsibility for the performance of the activities that they are to audit. (40)If the audit is to be an internal one, then the personnel who have direct responsibility for performing the activities to be audited shall not be involved in the selection of the audit team. (41)Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. Appendix F defines the requirements for the qualification of QA audit personnel.</p>	18.2.3	OK		
	18.2.4	OK		
	↓			
	18.2.5	OK		
	↓			

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	<p>1.3.3 SELECTION OF AUDIT TEAM</p> <p>(42)An audit team shall be identified before the beginning of each audit. (43)This team shall contain one or more auditors and shall have an individual qualified as a lead auditor who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates the responses. (44)The audit team leader shall identify the technical specialists, if any, who will participate in the audit and include this information in the audit plan. (45)Audit team members selected to participate in audits for technical consideration purposes shall have appropriate technical expertise or experience in the work being audited. (46)Multidisciplinary audit teams shall be employed when activities to be audited involve more than a single technical area. (47)The audit team leader shall ensure that the audit team is prepared before the audit begins.</p> <p style="text-align: center;">1.4 PERFORMANCE</p> <p>(48)Audits shall be performed in accordance with written procedures using checklists as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity. (49)Elements that have been selected for audit shall be evaluated against specified requirements including a review of corrective actions taken on deficiencies in the area being audited that were identified during previous audits. (50)Objective evidence shall be examined to the depth necessary to determine if these elements are adequate for effective control and to determine whether or not they are being implemented effectively. (51)The audit results shall be documented by audit personnel and shall be reviewed by management having responsibility for the area audited. (52)Conditions that require prompt corrective action shall be reported immediately to the management of the audited organization. (53)Audit findings will be reviewed with the audited organization at a closing meeting.</p>							

18.2.5 OK

18.2.6 OK

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<p>1.3 REPORTING</p> <p>(54)The audit report shall be signed by the audit team leader and should be issued within 30 calendar days. (55)This report shall include the following information, as appropriate:</p> <ul style="list-style-type: none"> • Description of the audit scope. • Identification of the auditors. • Identification of persons contacted during audit activities. • Summary of audit results, including a statement of the effectiveness of the QA program elements that were audited. • Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization. 	18.2.7		OK					
<p>1.4 RESPONSE</p> <p>(56)Management of the audited organization or activity shall investigate adverse audit findings; determine root cause; schedule corrective action, including measures to prevent recurrence; and, within thirty calendar days of receipt of the audit report, notify the appropriate organizations in writing of action taken or planned. (57)The adequacy of audit responses shall be evaluated by or for the auditing organization.</p>	18.2.8		OK					

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<p>1.7 FOLLOW-UP ACTION</p> <p>(58) Follow-up action shall be taken to determine whether or not corrective action has been accomplished as scheduled and shall be verified by the auditing organization. (59) An analysis of audit results shall be performed by the QA organization to identify quality trends. (60) The results of the analysis shall be reported to responsible management for review, assessment, and appropriate action.</p>	18.2.9 ↓	OK
<p>1.8 RECORDS</p> <p>1.8.1 AUDITS</p> <p>(61) As a minimum, audit records shall include the following:</p> <ul style="list-style-type: none"> • Identification of the organization(s), activities, or items audited and the individual(s) contacted during the audit(s). • Description of any efficiencies, nonconformances, and potential quality problems identified. • Audit plans, audit reports, written replies, and the record of completion of corrective action, and close-out of the audit. 	18.2.10 ↓	OK
<p>1.8.2 PERSONNEL RECORDS</p> <p>(62) Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer. Records for each Lead Auditor shall be maintained and updated annually.</p>	↓	OK

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<p align="center">2.0 SURVEILLANCES</p> <p>(63)The NWSI Project audit program shall be supplemented by independent surveillance activities. (64)The purpose of a surveillance is to monitor or observe items or activities to verify conformance to specified requirements. (65)These surveillances shall be conducted by the NWC, the Participating Organizations and the WTS Support Contractors, and shall be either scheduled or implemented on a random basis.</p> <p>(66)Procedures for the surveillance of site investigation activities shall be established and executed in accordance with procedures prepared by the organization performing the activity. (67)Surveillances shall be scheduled and conducted based on the activity's relative impact or importance, or both, to the NWSI Project. (68)All deficiencies, nonconformances, and potential quality problems identified during surveillances are to be documented and monitored until verification of effective corrective action is made. Specific requirements applicable to surveillance activities are as follows:</p>	18.3		63-67OK
<p align="center">2.1 PLANNING</p> <p>(69)Surveillances are to be performed to written checklists or surveillance plans whenever practical. (70)The documentation shall identify characteristics, methods, and acceptance criteria, shall provide for recording objective evidence of results, and accuracy of the equipment necessary to perform surveillance. (71)The specification of acceptance criteria related to surveillances may be as simple as "to verify proper implementation of procedures" or "to verify conformance to requirements".</p>	18.31		OK

REQ 68 UNSAT, ADD:
"POTENTIAL QUALITY PROBLEMS".

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<p align="center">2.2 REPORTING DEFICIENCIES</p> <p>(72) Surveillance personnel shall not report directly to the immediate supervisors who are responsible for the work being surveilled.</p>	18.3.2	OK	
<p align="center">2.3 RECORDS</p> <p>(73) As a minimum, surveillance records shall identify the following:</p> <ul style="list-style-type: none"> • Item or activity. • Date of surveillance. • Name of individual performing the surveillance. • Identification of the organization(s), activities, or items surveilled, including the name or name of personnel contacted. • Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance. Nonconformances shall be handled in accordance with the requirements of Section XV of KVI, as applicable. • Surveillance criteria. • Equipment used during the surveillance. • Results. • Acceptance statement. 	18.3.3		<p align="center">UNSAT LAST SEATPAKE OF 5TH BULLET QUITE</p>

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	<p>APPENDIX A</p> <p>TERMS AND DEFINITIONS</p> <p>ACCEPTANCE CRITERIA: Specified limits defined in codes, standards, or other requirement documents placed on characteristics of an item, process, or service.</p> <p>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 areas.</p> <p>ACTIVITIES THAT AFFECT QUALITY: Deeds, actions, work, or performance of a specific function or task. The NWWS QA Program applies to activities affecting the quality of all systems, structures, and components important to safety, and to the design and characteristics of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation. The QA Level I requirements of this QA Program apply to all activities affecting the quality of structures, systems, and components important to safety and engineered barriers important to waste isolation. These activities include: designing (including such activities as safety analyses, laboratory testing of waste package materials to characterize their performance, and performance assessments), purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying. These types of activities do not need to be identified as part of the Q-list nor do they require QA</p>							
	App A ✓	011						
	✓	05						
	✓	06						

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<p>level assignment. However, activities related to natural barriers important to waste isolation shall be identified and listed on a Q-list. These activities include: performance assessments, site characterization testing, and activities that may impact the waste isolation capability of the natural barrier. Examples are site characterization activities such as exploratory shaft construction, borehole drilling, and other activities that could physically or chemically alter properties of the natural barriers in an adverse way.</p> <p>ACTIVITY: Any time consuming effort (operation, task, function, or service) which influences or affects the achievement or verification of the objectives of the NWSI Project as depicted in the WBS Dictionary.</p> <p>AP - NWSI 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).</p> <p>AUDIT: A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, codes, standards, instructions, drawings, and other applicable requirements, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.</p>	✓	OK	
	✓	OK	
	✓	OK	

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<p>AUTHENTICATION (QA RECORDS): Authentication is the act of attesting that the information contained within a document is accurate, complete, and appropriate to the work accomplished. Authentication is accomplished by one of the following methods: (1) a stamped, initialed, or signed, and dated document; (2) a statement by the responsible individual or organization; or (3) issuing a document which is clearly identified as a statement by the reporting individual or organization. A document cannot become a Quality Assurance (QA) record until it has been authenticated.</p>			OMITTED	
<p>AUXILIARY SOFTWARE: (1) Software that may be easily and exactly verified, and that performs a simple function such as conversion of units, change in data format, or plotting of data in support of primary analysis software. (2) A stream of commands or sequence of streams of commands executed to utilize system maintained software in which the system maintained software generates reportable results. Auxiliary software does not generate primary data.</p>	✓		OK	
<p>BARRIER: Any material or structure that prevents or substantially delays the movements of water or radionuclides.</p>	✓		OK	
<p>BASELINE: As used for computer software: (1) The stage of computer software at a completed and reviewed phase of the software lifecycle; (2) Approved documentation generated within or as a result of completing a phase of the software life cycle.</p>	✓		OK	
<p>CERTIFICATE OF CONFORMANCE: A document signed by an authorized individual that certifies the degree to which items or services meet specified requirements.</p>	✓		OK	

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<p>COMPUTER CODE VERIFICATION: Assurance that a computer code correctly performs the operations specified in a numerical model (NOREG-0034). Usually accomplished by comparing code results to (1) a hand calculation, (2) an analytical solution or approximation, or (3) a verified code designed to perform the same type of analysis (benchmarking).</p>	✓	UNSAT REF TO AUREG CDSG OMITTED	✓
<p>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 which, if not corrected, could have a serious effect on safety or operability.</p>	✓	OK	
<p>CONFIGURATION MANAGEMENT: As used for computer software; (1) A system for orderly control of software, including methods used for labeling, changing, and storing software and its associated documentation. (2) The systematic evaluation, coordination, approval or disapproval, and implementation of all approved changes in an item of software after establishment of its configuration.</p>	✓	OK	
<p>CONSEQUENCE ANALYSIS: A method by which the consequence of an event are calculated and expressed in some quantitative way, e.g., money loss, deaths, or quantities of radionuclides released to the accessible environment.</p>	✓	OK	
<p>CONTAINMENT: The confinement of radioactive waste within a designated boundary.</p>	✓	OK	
<p>CONTAINMENT, PERIOD OF: Known as 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.</p>	✓	OK	

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<p>CERTIFICATION: The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.</p> <p>CHARACTERISTIC: Any property or attribute of an item, process, or service that is distinct, describable, and measurable.</p> <p>COMMERCIAL GRADE ITEM: An item satisfying all of the following requirements:</p> <ol style="list-style-type: none"> 1) The item is not subject to design or specification requirements that are unique to Mined Geologic Disposal Systems; 2) 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. 3) The item is used in applications other than Mined Geologic Disposal Systems. <p>COMPUTER MODEL VALIDATION: Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (NWREG-0856). Usually accomplished by comparing code results to (1) physical data, or (2) a verified or validated code designed to perform the same type of analysis (e.g., benchmarking with a validated code). Peer review may be used for code validation if it is the only available means for validating a code.</p>	✓		OK					
	✓		OK					
	✓		OK					
	✓		Change to "CODE" MODELS are not validated but verified delete UNSAT REF TO NWREG 0856 OMITTED					

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	<p>CONTRACTOR: An organization under contract to provide supplies, construction, or services.</p> <p>CONTROLLED AREA: The surface location, which is to be marked by suitable monuments, that extend 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.</p> <p>CONVERSION REPORT: A written description of all modifications made to the original code or an externally available existing code after it is acquired.</p> <p>CORRECTIVE ACTION: Measures taken to rectify conditions that are adverse to quality and, where necessary, to preclude repetition.</p> <p>CORROBORATIVE DATA: Existing data used to support or substantiate other existing data.</p> <p>CREDIBLE EVENT OR CREDIBLE ACCIDENT: An event or accident scenario which needs to be considered in the design of a geologic repository.</p> <p>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.</p>	<p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p>	<p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>UNSAT</p> <p>OK</p> <p>OK</p>	<p></p> <p></p> <p></p> <p></p> <p></p> <p></p> <p></p>	<p></p> <p></p> <p></p> <p></p> <p>CRP</p> <p></p> <p></p>	<p></p> <p></p> <p></p> <p></p> <p></p> <p></p>	<p></p> <p></p> <p></p> <p></p> <p></p> <p></p>

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<p>DESIGN INPUT: Those criteria, parameters, bases, or other design requirements upon which the detailed final design is based.</p> <p>DESIGN OUTPUT: Documents, such as drawings, specifications, and others that define technical requirements of structures, systems, and components.</p> <p>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.</p> <p>DEVIATION: A departure from specified requirements.</p> <p>DISPOSITION: The action taken to resolve a nonconforming condition and to restore acceptable conditions.</p> <p>DOCUMENT: Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this Appendix.</p> <p>DOE: The U.S. Department of Energy or its duly authorized representatives.</p> <p>ENGINEERED BARRIER SYSTEM: The waste package and the underground facility.</p> <p>ENGINEERED ITEM: Any structure, system, or component identified in design documents as being a functional part of the completed facility.</p>	✓	OK					
	✓	OK					
	✓	OK					
	✓	OK					
	✓	OK					
	✓	UNSAT					
	✓	OK					
	✓	OK					
	✓	OK					

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<p>EXISTING DATA: Data developed prior to the implementation of a 10 CFR 60, Subpart G QA program by DOE and its contractors, or data developed outside the DOE repository program, such as by oil companies, national laboratories, universities, or data published in technical or scientific publications. Existing data does not include information which is accepted by the scientific and engineering community as established facts (e.g., engineering handbooks, density tables, gravitational laws, etc.).</p>	✓	OK					
<p>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.</p>	✓	OK					
<p>FINAL DESIGN: Approved design output documents and approved changes thereto.</p>	✓	OK					
<p>FUNCTIONAL CHARACTERISTICS: Those attributes of a repository or its structures, systems, and components that determine its performance with respect to safety, reliability, operability, and other design criteria established in the OGR Program or other Federal regulatory documents.</p>	✓	OK					
<p>GEOLOGIC REPOSITORY: A system that is either intended to be used for 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.</p>	✓	OK					
<p>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.</p>	✓	OK					

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	<p>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.</p> <p>IMPORTANT TO WASTE ISOLATION: The barriers that must meet the criteria that address long-term performance of the engineered and natural barriers to prevent the release of radionuclides from the site to the accessible environment (i.e. for achieving the postclosure performance objectives in 10CFR60, Subpart E).</p> <p>INDOCTRINATION: Instruction provided to personnel for familiarization with programmatic and work-oriented documents applicable to the assigned activity.</p> <p>INSPECTOR: A person who performs inspection activities to verify whether or not an item or activity conforms to specified requirements.</p> <p>INSPECTION: Examination or measurement to verify whether an item or activity conforms to specified requirements.</p> <p>INTERNAL AUDIT: An audit of those portions of an organization's QA program that is retained under its direct control and within its organizational structure.</p> <p>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.</p>	✓	OK					
	✓	OK						
	✓	OK						
	✓	OK						
	✓	UNSAT						
	✓	OK						

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	<p>ITEM: An all-inclusive term that is used in place of any of the following: apparatus, 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.</p> <p>LIFETIME RECORDS: Quality Assurance Records that furnish evidence of the quality and completeness of data, items, and activities affecting quality. All NWSI Project QA Records are classified as Lifetime Records.</p> <p>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 NWSI 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.</p> <p>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.</p> <p>NWSI PROJECT PARTICIPANTS: An all inclusive term used to describe (generically) the various organizations involved in the NWSI Project. This term includes the WFO, Participating Organizations, and NTS Support Contractors. These organizations are required to have a WFO approved Quality Assurance Program Plan (QAPP) for the conduct of their activities.</p> <p>NWSI PROJECT PERSONNEL: All U.S. Department of Energy Participating Organizations, and NTS Support Contractor personnel involved in NWSI Project activities.</p>	✓	OK				
	✓	UNSAT					
	✓	OK					
	✓	OK					
	WFA ✓	YM - participating org	OK				
	WFA ✓	YM - project personnel					

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	Sat - Para. No.	Unsat - Para. No. -	Comments	Acc.	Fej.	Reason	Acc.	Rej.
	<p>NWSI PROJECT QUALITY ASSURANCE PLAN (QAP): The document that describes the planned, systematic quality assurance requirements that are applicable to the NWSI Project.</p> <p>NWSI PROJECT WORK BREAKDOWN STRUCTURE (WBS) DICTIONARY: A controlled document which establishes a product oriented framework for organizing and defining work to be accomplished.</p> <p>NONCONFORMANCE: A deficiency in characteristics, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.</p> <p>NON-MECHANISTIC FAILURES: Postulated failures which are not based on previously observed models or mechanisms but which are assumed to provide conservatism in safety assessments.</p> <p>NTS: Nevada Test Site</p> <p>NTS SUPPORT CONTRACTOR: Organizations that are directly under contract to DOE/NV for activities at the NTS and other locations.</p> <p>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.</p> <p>OPERATIONS, PERIOD OF: Includes the time during which emplacement of wastes occurs; any subsequent period before permanent closure during which the emplaced wastes are retrievable; and permanent closure, which includes sealing of shafts.</p>	1.0	OK ²					
	✓	OMITTED WBS Dictionary	OK					
	✓	OK						
	✓	OK						
	Acronyms	OMITTED	OK					
	✓	OK						
	✓	OK						
	✓	OK						

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<p>OVERVIEW: An analysis and assessment by management of the scope, status, adequacy and effectiveness of Program, quality achievement and assurance activities. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate.</p>	✓	OK	
<p>OWNER: The person, group, company, agency, or corporation that has or will have title to the repository.</p>	✓	OK	
<p>PARTICIPATING ORGANIZATION: This term applies to the following: (1) the government agencies external to the DOE, (2) national laboratories, and (3) organizations participating directly in NWSI Project activities.</p>	✓	OK	
<p>PEER: A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work.</p>	✓	OK	
<p>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 judgment 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.</p>	✓	UNSAT	CADA
<p>A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work. In contrast to peer review, the term "technical review" refers to a review to verify compliance to predetermined requirements; industry standards; or common scientific, engineering, and industry practices.</p>	✓		

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	<p>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 NWSI Project Participant.</p> <p>PROCEDURE: A document that specifies or describes the way in which an activity is to be performed.</p> <p>PRIMARY DATA: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable Quality Assurance Level I requirements and is necessary for the resolution of the NRC performance objectives of 10CFR60 in accordance with the NWSI Project Issues Resolution Strategy. This includes information that has been qualified and accepted in accordance with NWSI Project AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the NWSI Project QA Program."</p> <p>PROCUREMENT DOCUMENT: Purchase requisitions, purchase orders, letters of intent, work authorization letters, drawings, contracts, specifications, instructions, or any document that provides a means by which to acquire possession or ownership of items, or right to the use of services by payment.</p> <p>PURCHASER: The organization responsible for the establishment of procurement requirements and for the issuance or administration, or both, of procurement documents.</p> <p>Q-LIST: A list of geologic repository engineered structures, systems, and components that have been determined to be important to safety, and engineered barriers important to waste isolation that must be covered under the QA requirements of 10 CFR 60, Subpart G.</p>	✓	OK				
	✓	OK					
	✓	OK					
	✓	OK					
	✓	UNSAT		✓			✓

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<p>1.2.2 TRAINING</p> <p>(13) Prospective Lead Auditors shall have training to the extent necessary to ensure their competence in auditing skills. (14) Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor:</p> <ul style="list-style-type: none"> o Knowledge and understanding of this document, 10 CFR Part 60, and other nuclear and/or DOE related codes, standards, regulations, and regulatory guides, as applicable to the NWSI Project. o General structure of Quality Assurance programs and applicable elements as defined in this document. o Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings. o Audit planning in the functions related to quality for the following activities: site characterization (scientific investigations), design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility. o On-the-job training to include applicable elements of the audit program. 	F.1.2.2		OK				

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<p>QUALIFICATION (OF DATA): A formal process intended to provide a desired level of confidence that data are suitable for their intended use.</p>	✓		OK					
<p>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.</p>	✓		OK					
<p>QUALIFICATION TESTING: Demonstration that an item meets design requirements.</p>	✓		OK					
<p>QUALIFIED DATA: Data initially collected under a 10 CFR 80, Subpart G quality assurance program or existing data qualified in accordance with Appendix G of this QA Plan.</p>	✓		OK					
<p>QUALIFIED PROCEDURE: An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.</p>	✓		OK					
<p>QUALITY ACTIVITIES LIST: A list of those major activities conducted during site characterization, construction, operation, or closure that relate to natural barriers important to waste isolation. These activities, which must be covered under the 10 CFR 80, Subpart G Quality Assurance program, include data gathering, performance assessments, and those activities that could affect a natural barrier's ability to isolate waste.</p>	✓		OK					
<p>QUALITY ASSURANCE: 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.</p>	✓		OK					
			MATRIX OFFICERS ?					

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

QUALITY ASSURANCE LEVEL I: those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public. Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 60CFR191.

✓

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✓
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<p>QUALITY ASSURANCE LEVEL II: those activities and items related to the systems, structures, and components which require a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE and NRC concerns, and the environment.</p>	✓	UNSAT		0
<p>QUALITY ASSURANCE LEVEL III: those activities and items not classified as QA Levels I or II.</p>	✓	OK		
<p>QUALITY ASSURANCE PROGRAM PLAN (QAPP): The document that describes the organization's Quality Assurance Program, the applicable QA requirements, and defines how compliance with the QA criteria will be accomplished.</p>	✓	OK		
<p>RADIOACTIVE WASTE: High-Level Waste (HLW) and other radioactive materials that are received for emplacement in a geologic repository.</p>	✓	OK		
<p>READINESS REVIEW: An independent, systematic documented review to determine and inform management of the readiness to advance from one phase, process, or activity into another. Readiness Reviews are used to coordinate many elements and provide attention to detail, to assure that the project is ready to proceed to the comprehensive review of a total project or a particular segment of the project.</p>	✓	OK		
<p>RECEIVING: Taking delivery of an item at a designated location.</p>	✓	OK		
<p>RELIABILITY ANALYSIS: An analysis that estimates the reliability of a system or component.</p>	✓	OK		

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	<p>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.</p> <p>REPOSITORY: See Geologic Repository Operations Area.</p> <p>RETRIEVAL: The act of intentionally removing radioactive waste from the underground location at which the waste had been emplaced previously for disposal.</p> <p>REWORK: The process by which a nonconforming item or activity is made to conform to the original requirements by completion or correction utilizing existing approved procedures.</p> <p>RIGHT OF ACCESS: The right of a purchaser or designated representative to enter the premises of a supplier for the purpose of inspection, surveillance, or Quality Assurance audit.</p> <p>SCENARIO: An account or sequence of a projected course of action or event.</p> <p>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 which are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation and/or closure of the geologic repository.</p>	✓	OK					
	✓	OK						
	✓	OK						
	✓	UNSAT		✓				✓
	✓	OK						
	✓	OK						

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<p>SCIENTIFIC NOTEBOOK: A document which may be used to provide a written record of the results of scientific investigations and experiments when the work involves a high degree of professional judgment or trial and error methods, or both. These notebooks may be used in lieu of a technical procedure.</p>	✓	OK	
<p>SERVICE: The performance of activities that include but are not limited to site characterization, design, fabrication, investigation, inspection, nondestructive examination, repair, or installation.</p>	✓	OK	
<p>SITE: Location of the controlled area.</p>	✓	OK	
<p>SITE CHARACTERIZATION: The program of exploration and research both in the laboratory and in the field that is undertaken to establish the geologic conditions and the ranges of parameters of a particular site that are relevant to the procedures under 10 CFR Part 60. Site characterization includes borings, surface excavations, excavation or exploratory shafts, limited subsurface lateral excavations and borings, and in site 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.</p>	✓	OK	
<p>SPECIAL PROCESS: A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.</p>	✓	OK	
<p>SURVEILLANCE: The act of monitoring or observing to verify whether or not an item or activity conforms to specified requirements.</p>	✓	Modified to survey	

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	<p>TECHNICAL REVIEW: A documented traceable review performed by qualified personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Technical reviews are in-depth, critical reviews, analyses and evaluation of documents, material or data that require technical verification and/or validation for applicability, correctness, adequacy and completeness.</p> <p>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.</p> <p>TRACEABILITY: The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.</p> <p>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.</p> <p>UNDERGROUND FACILITY: The underground structure, including openings and backfill materials, but excluding shafts, boreholes, and their seals.</p> <p>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.</p> <p>VERIFICATION: The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether or not items, processes, services, or documents conform to specified requirements.</p> <p>WAIVER: Documented authorization to depart from specified requirements.</p>	✓	UNSAT		✓			✓
	✓							
	✓	OK						
	✓	OK						
	✓	OK						
	✓	OK						

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<p>WASTE MANAGEMENT PROJECT OFFICE (WMPO): The organization to which the U.S. Department of Energy, Nevada Operations Office (DOE/NVO), has assigned the responsibility of administering and coordinating the activities of various Participating Organizations and NTS Support Contractors associated with the NWSI Project.</p> <p>WASTE PACKAGE: The waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.</p> <p>VALIDATION (QA RECORDS): Validation is the act of reviewing a document or document package to ensure it is complete, authenticated, reproducible, and microfilmable.</p>	✓	OE					
	✓	CR					
		OMITTED					

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<p>APPENDIX B</p> <p>DESIGN INPUTS</p> <p>Design inputs include many characteristics and functions of an item or system. These inputs vary depending on the application; however, it is desirable to consider at least the following listed inputs as they apply to specific items or systems of the repository:</p> <ol style="list-style-type: none"> 1. Basic functions of each structure, system, and component. 2. Performance requirements such as capacity rating and system output. 3. Codes, standards, and regulatory requirements including the applicable laws, agenda, or both. 4. Design conditions such as pressure, temperature, fluid chemistry, and voltage. 5. Loads such as seismic, wind, thermal, and dynamic. 6. Environmental conditions anticipated during storage, construction, and operation such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, nuclear radiation, electromagnetic radiation, and duration of exposure. 7. Interface requirements including definition of the functional and physical interfaces involving structures, systems, and components. 	<p>App B</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p>	<p>OK</p> <p>-</p> <p>-</p> <p>-</p> <p>-</p> <p>-</p> <p>-</p>					

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8. Material requirements including such items as compatibility, electrical insulation properties, protective coating, and corrosion resistance.	✓							
9. Mechanical requirements such as vibration, stress, shock, and reaction forces.	✓							
10. Structural requirements covering such items as equipment foundations and pipe supports.	✓							
11. Hydraulic requirements such as pump set positive suction heads (NPSH), allowable pressure drops, and allowable fluid velocities.	✓							
12. Chemistry requirements such as provisions for sampling and limitations on water chemistry.	✓							
13. Electrical requirements such as source of power, voltage, raceway requirements, electrical insulation, and motor requirements.	✓							
14. Layout and arrangement requirements.	✓							
15. Operational requirements under various conditions such as repository startup, normal repository operation, repository emergency operation, special or infrequent operation, system abnormal or emergency operation, repository decontamination, decommissioning, and dismantling.	✓							

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	16. Instrumentation and control requirements including indicating instruments, controls, and alarms required for operation, testing, and maintenance. Other requirements such as the type of instrument, installed spares, range of measurement, and location of indication are included.	✓	/					
17. Access and administrative control requirements for repository security.	✓	/						
18. Redundancy, diversity, and separation requirements of structures, systems, and components.	✓	/						
19. Failure effects requirements of structures, systems, and components including a definition of those events and accidents that they must be designed to withstand.	✓	/						
20. Test requirements including pre-operational and subsequent periodic in-service tests and the conditions under which they will be performed.	✓	/						
21. Accessibility, maintenance, repair, and in-service inspection requirements for the repository including the conditions under which these will be performed.	✓	/						
22. 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.	✓	/						
23. Transportability requirements such as size and shipping weight, limitation, and Interstate Commerce Commission regulations.	✓	/						

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24. Fire protection or resistance requirements.	✓							
25. Handling, storage, cleaning, and shipping requirements.	✓							
26. Other requirements to prevent undue risk to the health and safety of the public.	✓							
27. Materials, processes, parts, and equipment suitable for application.	✓							
28. Safety requirements for preventing injury to personnel including such items as radiation safety that restrict the use of dangerous materials, escape provisions from enclosures, and grounding of electrical systems.	✓							
29. Quality control and Quality Assurance requirements.	✓							
30. Reliability requirements of structures, systems, and components, including their interactions, which may impair functions that are important to safety.	✓							
31. Interface requirements between repository equipment and operation and maintenance personnel.	✓							
32. Requirements for criticality control and accountability of nuclear materials.	✓							

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<p align="center">APPENDIX C</p> <p align="center">REQUIREMENTS FOR THE QUALIFICATION OF INSPECTION AND TEST PERSONNEL</p> <p align="center">1.0 GENERAL</p> <p>The following are the requirements for the qualification of personnel who perform inspection and testing 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.</p> <p align="center">2.0 FUNCTIONAL QUALIFICATIONS</p> <p>(1) Three levels of qualification shall be utilized depending on the complexity of the functions involved. (2) The requirements for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional activities.</p> <p align="center">2.1 LEVEL I PERSONNEL CAPABILITIES</p> <p>(3) 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 user's written procedures.</p>	OK		Not applicable to ANL scope				

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<p align="center">2.2 LEVEL II PERSONNEL CAPABILITIES</p> <p>(4) A Level II person shall have all of the capabilities of a Level I person for the inspection or test category or class in question. (5) Additionally, a Level II person shall have demonstrated capabilities in planning inspections and tests; in setting up tests, including preparation and setup of related equipment, as appropriate; in supervising and certifying lower level personnel; and in evaluating the validity and acceptability of inspection and test results.</p> <p align="center">2.3 LEVEL III PERSONNEL CAPABILITIES</p> <p>(6) A Level III person shall have all of the capabilities of a Level II person for the inspection, test category or class in question. (7) 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.</p> <p align="center">3.0 EDUCATION AND EXPERIENCE QUALIFICATIONS</p> <p>(8) These education and experience requirements shall be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the inspection or test activity may provide reasonable assurance that a person can competently perform a particular task. (9) Other factors which may demonstrate capability in a given job are previous performance or satisfactory completion of capability testing. (10) These factors and the basis for their equivalence shall be documented.</p>							

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						Reason	
<p>(11) 3.1 LEVEL I EDUCATION AND EXPERIENCE REQUIREMENTS</p> <ul style="list-style-type: none"> o Two years of related experience in equivalent inspection or testing activities; or o High school graduation and six months of related experience in equivalent inspection or testing activities; or o 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. <p>(12) 3.2 LEVEL II EDUCATION AND EXPERIENCE REQUIREMENTS</p> <ul style="list-style-type: none"> o One year of satisfactory performance as a Level I in the corresponding inspection or test category or class; or o High school graduation plus three years of related experience in equivalent inspection or testing activities; or o Completion of college work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspection or testing activities; or o Graduation from a four-year college plus six months of related experience in equivalent inspection activities or testing activities. 							

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	Sat. - Para. No.	Unsat. - Para. No. -	Comments	Acc.
<p>(13) 3.3 LEVEL III EDUCATION AND EXPERIENCE REQUIREMENTS</p> <ul style="list-style-type: none"> o Six years satisfactory performance as a Level II in the corresponding inspection or test category or class; or o High school graduation plus ten years of related experience in equivalent inspection or testing activities; or high school graduation plus eight years of experience in equivalent inspection or testing activities with at least two years associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with relevant Quality Assurance aspects of a nuclear facility; or o 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, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or o Graduation from a four-year college plus five years related experience in equivalent inspection or testing activities with a least two years of this experience associated with nuclear facilities or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility. 				

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<p align="center">4.0 CERTIFICATION</p> <p align="center">4.1 QUALIFICATION REQUIREMENTS</p> <p>(14)The responsible organization shall designate those inspection and test activities that require qualified inspection and test personnel and the minimum qualification requirements for such personnel. (15)Further, the responsible organization 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. (16)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 may be used in data-taking assignments or in repository or equipment operation, provided they are supervised or overseen by a qualified individual.</p> <p align="center">4.2 PERSONNEL SELECTION</p> <p>(17)Personnel selected to perform inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.</p> <p align="center">4.3 INDOCTRINATION</p> <p>(18)Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards, elements of the Quality Assurance Program Plan, and procedures that are to be employed.</p>			

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Review Requirements per NNWSI/86-9 Rev. 2	Review Results			Oy
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<p style="text-align: center;">4.4 TRAINING</p> <p>(19)The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspection and tests. (20)On-the-job training shall be included also in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests. (21)Training shall also be provided with regard to those changes to the QAPP and implementing procedures that affect previous training.</p> <p style="text-align: center;">4.5 DETERMINATION OF INITIAL CAPABILITY</p> <p>(22)The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration in accordance with the organization's personnel qualification procedure.</p> <p style="text-align: center;">4.6 EVALUATION OF PERFORMANCE</p> <p>(23)The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed three years. (24)Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability. (25)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, then that person shall be removed from that activity until such time as the required capability has been demonstrated. (26)Any person who has not performed inspection or testing activities in his qualified area for a period of one year shall be reevaluated and a redetermination of their capability made in accordance with the organization qualification procedure.</p>				

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	Sat - Para. No.	Unsat - Para. No. - Comments	
<p align="center">4.7 CERTIFICATION OF QUALIFICATION</p> <p>(27) The qualification of personnel shall be certified in writing in an appropriate form, including the following information:</p> <ul style="list-style-type: none"> o Employer's name. o Identification of person being certified. o Activities certified to perform. o Basis used for certification that includes such factors as: <ul style="list-style-type: none"> - Education, experience, and training (when necessary). - Test results (where applicable). - Results of capability demonstration. o Results of periodic evaluation. o Results of physical examinations (when required). o Signature of employer's designated representative who is responsible for such certification. o Dates of certification and certification expiration. 			

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<p align="center">4.0 PHYSICAL</p> <p>(20) The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examinations.</p>							

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<p align="center">APPENDIX D</p> <p align="center">REQUIREMENTS FOR THE QUALIFICATIONS OF NON-DESTRUCTIVE EXAMINATION PERSONNEL</p> <p>(1) This Appendix 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), which is hereinafter referred to as nondestructive examination (NDE), to verify conformance to specified requirements.</p> <p align="center">1.0 CERTIFICATION</p> <p align="center">1.1 APPLICABLE DOCUMENTS</p> <p>(2) 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.</p> <p align="center">1.2 PROGRAM</p> <p>(3) The responsible organization shall establish written procedures for the control and administration of NDE personnel training, examination, and certification.</p>			<p align="center">OK</p> <p align="center"><i>Not applicable to LANL scope</i></p>				

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	<p align="center">1.3 CERTIFICATE OF QUALIFICATION</p> <p>The qualification of personnel shall be certified in writing in an appropriate form, including the following information:</p> <ul style="list-style-type: none"> o Employer's name. o Identification of person being certified. o Activities certified to perform. o Basis used for certification that includes such factors as; <ul style="list-style-type: none"> - Education, experience, and training (when necessary). - Test results (where applicable). - Results of capability demonstration. o Results of periodic evaluation. o Results of physical examinations (when required). o Signature of employer's designated representative who is responsible for such certification. o Dates of certification and certification expiration. 							

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	<p align="center">1.4 PHYSICAL</p> <p>(4)The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examinations.</p>							

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Review Requirements per NWSI/88-9 Rev. 2	Review Results			O
	Sat - Para. No.	Unsat - Para. No. -	Comments	
<ul style="list-style-type: none"> ○ As-built drawings and records (Note: As-built drawings and records shall correctly identify the installed condition of the item. The type of as-built drawings and records to be maintained shall be specified). ○ Certificate of compliance. ○ Eddy-current examination final results. ○ Electrical control verification tests results. ○ Ferrite test results. ○ Heat treatment records. ○ Liquid penetrant examination final results. ○ Location of weld filler material. ○ Magnetic particle examination final results. ○ Major defect repair records. ○ Material properties records. ○ Nonconformance reports. ○ Performance test procedures and results records. ○ Pipe and fitting location report. 	✓ ✓ N/A to LAR			

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Review Requirements per NWWSI/88-9 Rev. 2	Review Results			Or
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<ul style="list-style-type: none"> o Pressure test (hydrostatic or pneumatic). o Radiographs (for in-service inspection applications). o Radiograph review records. o Ultrasonic examination final results. o Welding procedures. <p style="text-align: center;">5.0 INSTALLATION AND CONSTRUCTION RECORDS</p> <p style="text-align: center;">5.1 RECEIVING AND STORAGE - NONCONFORMANCE REPORTS</p> <p style="text-align: center;">5.2 CIVIL</p> <ul style="list-style-type: none"> o Concrete cylinder test reports and charts. o Concrete design mix reports. o Concrete placement records. o Inspection reports for channel pressure tests. o Material property reports on containment liner and accessories. o Material property reports on metal containment shell and accessories. o Material property reports on reinforcing steel. 	<p>N/A to LANL</p> <p>↓</p> <p>✓</p>			
	<p>Specific N/A to LANL</p> <p>↓</p>			

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<ul style="list-style-type: none"> o Material property reports on reinforcing steel splice sleeve material. o Procedure for waste package vessel pressure proof test and leak rate tests and results. o Reports of high strength bolt torque testing. o Soil compaction test reports. o Location and description of structural support systems. o Details, methods of emplacement, and location of seals used. <p style="text-align: center;">5.3 WELDING</p> <ul style="list-style-type: none"> o Ferrite test results. o Heat treatment records. o Liquid penetrant test final results. o Material property records. o Magnetic particle test final results. o Major weld repair procedures and results. o Radiographs (for in-service inspection application). o Radiograph review records. 								

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<ul style="list-style-type: none"> o Weld location diagrams. o Weld procedures. <p style="text-align: center;">3.4 MECHANICAL</p> <ul style="list-style-type: none"> o Cleaning procedures and results. o Code data reports. o Installed lifting and handling equipment procedures, inspection, and test data. o Lubrication procedures. o Material properties records. o Pipe and fitting location reports. o Pipe hanger and restraint data. o Pressure test results (hydrostatic or pneumatic). o Safety valve response test procedures. 	<p style="font-size: 2em; margin: 0;">n/a</p> <hr style="border: 1px solid black; width: 100%;"/>			

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Review Requirements per NWWS/88-9 Rev. 2	Review Results		Or Acc. f
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<p style="text-align: center;">5.5 ELECTRICAL AND INSTRUMENTATION AND CONTROL</p> <ul style="list-style-type: none"> o Cable pulling tension data. o Cable separation data. o Cable splicing procedures. o Cable terminating procedures. o Certified cable test reports. o Relay test procedures. o Voltage breakdown test results on liquid insulation. <p style="text-align: center;">5.6 GENERAL</p> <ul style="list-style-type: none"> o As-built drawings and records. o Final inspection reports and releases. o Nonconformance reports. o Specifications and drawings. o Details of equipment, methods, progress, and sequence of work. o Construction problems. 	<p style="font-size: 2em;">N/A</p> <p style="font-size: 2em;">↓</p> <p style="font-size: 1.5em;">N/A</p> <p style="font-size: 1.5em;">N/A</p> <p style="font-size: 1.5em;">✓</p> <p style="font-size: 1.5em;">✓</p> <p style="font-size: 1.5em;">N/A</p> <p style="font-size: 1.5em;">N/A</p>		

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Review Requirements per NRC 10 CFR 171.24	Review Results		Or Acc.
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<ul style="list-style-type: none"> o Anomalous conditions encountered. <p style="text-align: center;">6.0 PRE-OPERATIONAL AND START-UP TEST RECORDS</p> <ul style="list-style-type: none"> o Automatic emergency power source transfer procedures and results. o Final system adjustment data. o Pressure test results (hydrostatic or pneumatic). o Instrument alternating current (AC) systems and inverters test procedures and reports. o Offsite power source energizing procedures and test reports. o Onsite emergency power source energizing procedure and test reports. o Pre-operational test procedures and results. <p style="text-align: center;">7.0 OPERATION RECORDS</p> <ul style="list-style-type: none"> o Records and drawing changes that identify repository design modifications made to systems and equipment described in the Final Safety Analysis Report. o Radioactive waste inventory, emplacement location, and transfer records. 	<div style="text-align: center;">✓</div> <div style="text-align: center;">N/A</div> <div style="text-align: center;">↓</div> <div style="text-align: center;">N/A</div> <div style="text-align: center;">↓</div>		

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<ul style="list-style-type: none"> o Offsite environmental monitoring survey records. o Waste shipment records. o Repository radiation and contamination survey results. o Radiation exposure records for individuals entering radiation control areas. o Records of gaseous and liquid radioactive material released to the environment. o Records of transient or operational cycles for those repository components designed for a limited number of transients or cycles. o Training and qualification records for members of the repository operating staff. o In-service inspection records. o Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments. o Meeting minutes of the Repository Nuclear Safety Committee and licensee nuclear review board. o Surveillance activities, inspections, and calibrations required by the technical documents. o Records of repository tests and experiments. 	N/A						

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	<ul style="list-style-type: none"> o Changes made to Operating Procedures. o Sealed source leak-test results. o Records of annual physical inventory of all sealed source material. o Logs of repository operation. o Records and logs of maintenance activities, inspection, repair, and replacement of principal items of structures, systems, and components o Operational, shift supervisor, and control-room logs. o Licensee event reports. o Fire protection records. o Nonconformance reports. o Repository equipment operations instructions. o Security plan and procedures. o Emergency plan and procedures. o Quality Assurance and Quality Control Manuals. o Records of activities required by the security plan and procedures. 							

N/A



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	<p align="center">APPENDIX F</p> <p align="center">REQUIREMENTS FOR THE QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL</p> <p align="center">1.0 GENERAL</p> <p>This Appendix provide requirements for the qualification of Lead Auditors. A Lead Auditor organizes and directs audits, reports audit findings, and evaluates corrective action. This Appendix also provides simplified requirements for the qualifications of individuals, henceforth referred to as Auditors, who participate in an audit, such as technical specialists, management representatives, and auditors-in-training.</p> <p align="center">1.1 QUALIFICATION OF AUDITORS</p> <p>(1)The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of Quality Assurance programs. (2)Personnel selected for Quality Assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. (3)Auditors either shall have or shall be given appropriate training or orientation to develop their competence to perform required audits. The competence of personnel to perform the various auditing functions shall be developed by one or more of the methods listed below.</p>							
	F.1	OK						
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<p>1.1.1 ORIENTATION</p> <p>(4)Orientation to provide a working knowledge and understanding of this document and the auditing organization's procedures for implementing audits and reporting results.</p>	F.1.1.1	OK					
<p>1.1.2 TRAINING PROGRAMS</p> <p>(5)Training programs to provide general and specialized training in audit performance. (6)General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. (7)Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing audit findings.</p>	F.1.1.2						
<p>1.1.3 ON-THE-JOB-TRAINING</p> <p>(8)On-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. (9)Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.</p>	F.1.1.3	OK					
<p align="center">1.2 QUALIFICATION OF LEAD AUDITORS</p> <p>(10)An individual shall meet the requirements listed below before being designated a Lead Auditor:</p>	E.1.2	OK					
<p>1.2.1 COMMUNICATION SKILLS</p> <p>(11)The prospective Lead Auditor shall have the capability to communicate effectively, both orally and in writing. (12)These skills shall be attested to in writing by the Lead Auditor's employer.</p>	E.1.2.1	OK					

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<p>1.2.3 AUDIT PARTICIPATION</p> <p>(15)The prospective Lead Auditor shall have participated in a minimum of five Quality Assurance audits within a period of time not to exceed three years prior to the date of qualification. (16)One of the audits shall be a nuclear Quality Assurance audit that shall be made within the year prior to qualification.</p>	F.1.2.3 ↓		OK				
<p>1.2.4 EXAMINATION</p> <p>(17)The prospective Lead Auditor shall pass an examination that shall evaluate his comprehension of and ability to apply the body of knowledge identified in Paragraph 1.2.2 above. (18)The test may be oral, written, practical, or any combination of the three types. (19)If any portion of the examination is oral, written documentation of the oral examination questions/content shall be maintained. (20)The development and administration of the examination shall be in accordance with Paragraph 1.4 of this section.</p>	F.1.2.4 ↓		OK				
<p>1.3 MAINTENANCE OF QUALIFICATION</p> <p>1.3.1 MAINTENANCE OF PROFICIENCY</p> <p>(21)Lead Auditors shall 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 quality assurance program and program auditing; and participation in training programs. Based on annual assessment, management may extend the qualification, require retraining, or require requalification. (22)These evaluations shall be documented.</p>			OK				

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<p>1.3.2 REQUALIFICATION</p> <p>(23)Lead Auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. (24)Requalification shall include retraining in accordance with the requirements of Paragraph 1.2.2 of this section, reexamination in accordance with Paragraph 1.4.2, and participation as an Auditor in at least one nuclear Quality Assurance audit.</p>	F.2.2							
	↓	OK						
<p>1.4 ADMINISTRATION</p> <p>1.4.1 ORGANIZATIONAL RESPONSIBILITY</p> <p>(25)Training of auditors shall be the responsibility of the employer. (26)The responsible auditing organization shall select and assign personnel who are independent of any direct responsibility for the performance of the activities that they will audit. (27)The Lead Auditor shall, prior to commencing the audit, ensure that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.</p>	F.3							
	F.3.1							
	↓	OK						
<p>1.4.2 QUALIFICATION EXAMINATION</p> <p>(28)The development and administration of the examination for a Lead Auditor required by Paragraph 1.2.4 is the responsibility of the employer. (29)The employer may delegate this activity to an independent certifying agency, but shall retain responsibility for conformance to this document of the examination and its administration. (30)Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. (31)Copies of the objective evidence regarding the type or types and content of the examination or examinations shall be retained by the employer.</p>	F.3.2							
	↓	OK						

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<p align="center">1.5 CERTIFICATION OF QUALIFICATION</p> <p>(32) Each Lead Auditor shall be certified by his employer as being qualified to lead audits. As a minimum, this certification shall document the following:</p> <ul style="list-style-type: none"> o Employer's name. o Lead Auditor's name. o Date of certification or recertification. o Basis of qualification (i.e., education, experience, communication skills, training, examination, etc.). o Signature of employer's designated representative who is responsible for such certification. 	FH ↓	OK					

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	<p style="text-align: center;">APPENDIX G</p> <p style="text-align: center;">REQUIREMENTS FOR QUALIFICATION OF EXISTING DATA NOT GENERATED UNDER A QA PROGRAM MEETING THE REQUIREMENTS OF 10 CFR 60, SUBPART G</p> <p style="text-align: center;">1.0 GENERAL .</p> <p>This Appendix provides the requirements for the qualification of existing data, that will be needed to support a license application, which have not been initially generated under a QA Program meeting the requirements of 10CFR60, Subpart G.</p> <p style="text-align: center;">2.0 METHODS FOR QUALIFICATION OF EXISTING DATA</p> <p>2.1 (1)Four methods or combinations of methods are acceptable for the process of qualifying existing data:</p> <p>a. (2)The execution of the peer review process in accordance with the requirements of Appendix J of this QA Plan.</p> <p>b. (3)The use of corroborating data which is defined as existing data used to support or substantiate other existing data. Inferences drawn to corroborate the existing data shall be clearly identified, justified, and documented. (4)The level of confidence associated with corroborating data is related to the quality of the program under which it was developed and the number of independent data sets. (5)The amount of corroborating data needed shall be dealt with on a case-by-case basis in the documented reviews for qualification.</p>							
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	<p>c. (6)The use of confirmatory testing which is defined as testing conducted under a 10CFR60, Subpart G QA program which investigates the properties of interest (e.g., physical, chemical, geologic mechanical) of an existing data base. (7)One example of confirmatory testing is testing conducted under the same environmental conditions and with similar or the same procedures, test material, and equipment as the original test which generated the existing data. (8)Another type of confirmatory testing is testing conducted by different test methods and equipment but which still investigates the same parameter of interest. (9)The amount of confirmatory testing required shall be dealt with on a case-by-case basis in the documented reviews for qualification.</p> <p>d. (10)Demonstrating that the existing data was collected under a QA program which is equivalent to a 10 CFR 60, Subpart G QA program.</p> <p>3.0 SELECTION AND DOCUMENTATION OF QUALIFICATION METHODOLOGY</p> <p>3.1(11)When the methods indicated in Sections 2.1b, 2.1c, and 2.1d are utilized to qualify existing data, a technical review shall be conducted to support the quality of the data. (12)Additional confidence/credibility can be achieved when a combination of methods is used.</p> <p>3.2 (13)Documentation of the decision process shall provide an auditable trail of all factors used in arriving at the choice of the qualification method(s), and the decision as to the qualification of the existing data. (14)The level of confidence in the existing data shall be commensurate with the intended use of the data. (15)Attributes which shall be considered in the qualification process are:</p>	G.2						
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	<p>a. Qualifications of personnel or organizations generating the data are comparable to qualification requirements of personnel generating similar data under the approved 30 CFR 60, Subpart G program.</p> <p>b. The technical adequacy of equipment and procedures used to collect and analyze the data.</p> <p>c. The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).</p> <p>d. The environmental conditions under which the data were obtained if germane to the quality of data.</p> <p>e. The quality and reliability of the measurement control program under which the data were generated.</p> <p>f. The extent to which conditions under which the data were generated may partially meet Subpart G.</p> <p>g. Prior uses of the data and associated verification processes.</p> <p>h. Prior peer or other professional reviews of the data and their results.</p> <p>i. Extent and reliability of the documentation associated with the data.</p> <p>j. Extent and quality of corroborating data or confirmatory testing results.</p> <p>k. The degree to which independent audits of the process that generated the data were conducted.</p>						

G.3



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<p>l. The importance of the data to showing that the proposed repository design meets the performance objectives of 10 CFR 60, Subpart E.</p> <p>m. Replication of test results.</p> <p>Note: Additional guidance related to this subject can be found in NUREG-1298 "QUALIFICATION OF EXISTING DATA FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES" (February, 1988).</p>	G.3 ↓ ✓		OK	

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APPENDIX H

REQUIREMENTS FOR COMPUTER SOFTWARE USED TO SUPPORT A HIGH-LEVEL NUCLEAR WASTE REPOSITORY LICENSE APPLICATION

This appendix provides detailed requirements for the development, maintenance, and security of computer software. It supplements Section III of this QA plan and shall be used in conjunction with that section.

1.0 OBJECTIVES

(1)The purpose of this appendix is to establish requirements for the development, management, control, and documentation of software used to support the Yucca Mountain Project. (2)The attainment of software quality is dependent on the control of the entire software development process, and is not assured solely by inspection and test of the end product. (3)This appendix prescribes appropriate systematic practices that shall:

- o Reduce the likelihood of defects entering executable code during development.
- o Ensure that the end product answers the requirements of its intended application.
- o Reduce the likelihood that defects will be introduced into executable code during later maintenance and modification.

App H
LANL is using revised ^{NFM} App H.

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2-3 NOT INCORPORATED

FOR COMMENTS ON THIS SECTION SEE ORS E: K SCHWARZBAUER DATED 2/2/89. LANL USED COMMITTEE DRAFT OF SECTION H THEREFORE THIS PORTION OF CHECKLIST CANNOT BE USED IN REVIEW
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	<p align="center">2.0 APPLICABILITY</p> <p>(4)The detailed requirements set forth in this appendix apply to computer software used to produce or manipulate data which is used directly in site characterization, and the design, analysis, performance assessment, and operation of repository structures, systems, and components. (5)The extent to which these requirements apply is related to the nature, complexity, and importance of the software application. (6)The application of specific requirements shall be prescribed in plan(s) for software quality assurance and in written policies and procedures.</p> <p align="center">3.0 TERMS AND DEFINITIONS</p> <p>Terms and definitions for NWSI Project software are contained in Appendix A to this QA Plan.</p> <p align="center">4.0 SOFTWARE LIFE CYCLE</p> <p>(7)Organizations implementing software development activities shall adhere to a software life cycle model that requires that software development or acquisition proceed in a traceable, planned, and orderly manner. (8)The relative emphasis placed on each phase of the software development cycle will depend on the nature and complexity of the software being developed.</p> <p>(9)Each phase of the software development cycle shall provide specific attributes that shall be incorporated into verification and validation activities. (10)The documentation for each phase of the software development cycle shall be reviewed and approved as specified in each organization's software QA Plan. (11)An example of one such model is described below:</p>							
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<p align="center"> <u>Requirements</u> <u>Design</u> <u>Implementation</u> <u>Test</u> <u>Installation and Checkout</u> <u>Operation and Maintenance</u> 4.1 SOFTWARE QA PLAN (12) The application of the software life cycle to the development and/or use of the software shall be as described in the Software Quality Assurance Plan. </p>	N/A 			
	H.7			

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<p>4.1.1 (13) A software QA plan shall be prepared for each software development/ application effort at the start of the software life cycle. (14) This plan may be prepared individually for each piece of software or may exist as a generic document to be applied to all software prepared within an organization. (15) The software QA plan shall identify:</p> <ul style="list-style-type: none"> o The software products to which it applies. o The organizations responsible for software quality and their tasks and responsibilities. o Required documentation. o The required software reviews. <p>(16) The software QA Plan should reference any standards, conventions, techniques, or methodologies which guide the software development, and describe methods to assure compliance to the same.</p> <p>4.1.2 (17) Within the software QA plan, software lifecycle management shall be described. (18) Each participant shall present the specific software lifecycle controls for their organization in their software QA Plan. (19) The following lifecycle elements shall apply, as appropriate, for the specific lifecycle model defined, interpreted, and described in each organization's software QA plan.</p> <p>4.1.2.1 Requirements Phase</p> <p>(20) During this phase requirements that pertain to functionality, performance, design constraints, attributes, and external interfaces of the</p>	<p>N/A</p> <p>H.7</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>H.7</p> <p>H.7</p> <p>H.7</p> <p>H.8.1</p>	<p>Software plan will be a ^{generic} an ^{ANSI} Project document. Several software life cycles occur for different software.</p>					

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<p>completed software shall be specified, documented, and reviewed. (21)These requirements shall possess the following characteristics:</p> <ul style="list-style-type: none"> o A format and language that is understood by the programming organization and the user. o Enough detail to allow for objective verification. o Adequate definition to provide for the response of the software to the identified input data. o The information necessary to design the software without prescribing the software design itself. <p>4.1.2.2 Design Phase</p> <p>(22)During the design phase a software design based on the requirements shall be specified, documented, and systematically reviewed. (23)The design shall specify the overall structure (control and data flow), and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). (24)The design may necessitate the modification of the requirements documentation.</p> <p>(25)Design phase verification and validation activities during this phase shall consist of:</p> <ul style="list-style-type: none"> o The generation of design-based test cases. o The review and analysis of the software design. o The verification of the software design. 	H.8.1						
	H.8.2						

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<p>4.1.2.3 Implementation Phase</p> <p>(26) During this phase the design shall be translated into a programming language and the implemented software shall be debugged. (27) Only minor, if any, design issues shall be resolved at this phase.</p> <p>(28) Verification and validation activities during this phase shall consist of:</p> <ul style="list-style-type: none"> o The possible modification of test cases necessary due to design changes made during coding. o The examination of source code listings to assure adherence to coding standards and conventions. <p>4.1.2.4 Testing Phase</p> <p>(29) During the testing phase the design as implemented in code shall be exercised by executing the test cases. (30) Failure to successfully execute the test cases <u>may</u> require the modification of the requirements, the design, the implementation, or the test plans and test cases.</p> <p>(31) Verification and validation activities during this phase shall consist of:</p> <ul style="list-style-type: none"> o The evaluation of the completed software to assure adherence to the requirements. o The preparation of a report on the results of software verification and validation. 	H.8.3		LANC calls "Coding Phase"				
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<p>4.1.2.5 Installation and Checkout Phase</p> <p>(32) During this phase the software becomes part of a system incorporating other software components, the hardware, and production data. (33) The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating databases, and verifying that all components have been included.</p> <p>(34) Testing activities during this phase shall consist of the execution of test cases for installation and integration. (35) Test cases from earlier phases shall be enhanced and used for installation testing.</p>	<p>H.8.5</p> <p>✓</p> <p>✓</p> <p>✓</p>		<p>Acc. x</p>
<p>4.1.2.6 Operations and Maintenance Phase</p> <p>(36) During the operations and maintenance phase the software has been approved for operational use. (37) Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the software environment (adaptive maintenance). (38) Software modifications shall be approved, documented, tested (including regression testing as appropriate), and controlled in accordance with Paragraph 5.0.</p>	<p>H.8.6</p> <p>✓</p> <p>✓</p>	<p><i>Applications Maintenance Phase</i></p> <p><i>Exception to controlling in accordance w/ Section 5. LANL will control using section 6.</i></p>	
<p>5.0 SOFTWARE VERIFICATION AND VALIDATION</p> <p>(39) Verification and validation plans by the responsible project organization shall employ methods such as inspection, analysis, demonstration, and test to assure that the software adequately and correctly performs all intended functions, and that the software does not perform any function that either by itself or in combination with other functions can degrade the entire system.</p>	<p>H.2.14</p> <p>H.2.2</p>		

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5.2 VALIDATION

(50) Validation activities are performed to demonstrate that the model as embodied in the computer software is a correct representation of the process or system for which it is intended. (51) This is accomplished by comparing software results against verified and traceable data obtained from laboratory experiments, field experiments or observations, or in situ testing. (52) Specific sets of data used in the validation process shall be identified and justification shall be made for their use.

(53) When data are not available from the sources mentioned above, alternative approaches used shall be documented. (54) Alternative approaches may include peer review and comparisons with the results of similar analysis performed with verified software. (55) The results of software validation shall be documented.

6.0 SOFTWARE CONFIGURATION MANAGEMENT

(55) A software configuration management system shall be established to assure positive identification of software and control of all software baseline changes.

6.1 CONFIGURATION IDENTIFICATION

(57) A configuration baseline shall be identified at the completion of each major phase of the software development cycle. (58) Approved changes to a baseline shall be added periodically to the baseline as updates. (59) A baseline plus updates shall specify the most recent software configuration. (60) Updates shall be incorporated into subsequent baselines. (61) Both

H.2.2

Section 3, 3.2, as well
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H.3.1

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<p>baselines and updates shall be defined by their composition of software configuration items.</p> <p>(62) A labeling system for configuration items shall be implemented that:</p> <ul style="list-style-type: none"> o Uniquely identifies each configuration item or version number. o Identifies changes to configuration items by revision. o Places the configuration item in a relationship with other configuration items. <p align="center">6.2 CONFIGURATION CHANGE CONTROL</p> <p>(63) Changes to baseline software configuration items shall be formally documented. (64) This documentation shall contain a description of the change, the identification of the originating organization, the rationale for the change, and the identification of affected baselines and software configuration items. (65) The change should be formally evaluated by a qualified individual or organization with the ability to approve or disapprove the proposed change. (66) Assurance shall be provided that only authorized changes are made to software baselines and software configuration items.</p> <p align="center">6.3 CONFIGURATION STATUS ACCOUNTING</p> <p>(67) The information that is needed to manage software configuration items shall be recorded and reported. (68) This information shall include a listing of the approved configuration identification, the status of proposed changes to the configuration, the implementation status of approved changes, and all information to support the functions of configuration identification, and configuration control.</p>	<p>H.3.1</p> <p>H.3.1</p> <p>↓</p> <p>H.3.2</p> <p>✓</p> <p>→</p> <p>✓</p> <p>H.3.3</p> <p>↓</p>	<p>→</p> <p><u>Covered</u> in QP.</p>				

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	<p align="center">7.0 DOCUMENTATION</p> <p>(69) Minimum acceptable lifecycle documentation of computer software developed or modified for use on the Yucca Mountain Project shall be specified in each participant's software QA plan(s). (70) The documentation provided shall describe the following, as applicable. (71) Additional documentation may also be identified in the software quality assurance plan for each Yucca Mountain Project participant's software project.</p> <p align="center">7.1 SOFTWARE REQUIREMENTS SPECIFICATION</p> <p>(72) A specific capability of software can be called a requirement only if its achievement can be verified by a prescribed method. (73) Software requirements documentation shall outline the requirements that the proposed software must fulfill. (74) The requirements shall address the following:</p> <ul style="list-style-type: none"> o Functionality - the functions the software are to perform. o Performance - The time-related issues of software operation such as speed, recovery time, response time, etc. o Design constraints imposed on implementation - any elements that will restrict design options. o Attributes - non-time-related issues of software operation such as portability, correctness, security, maintainability, etc. o External Interfaces - interactions with other participants, hardware, and other software. 							

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H.B.1



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	<p style="text-align: center;">7.2 SOFTWARE DESIGN DOCUMENTATION</p> <p>(75) Software design documentation is a document or series of documents that shall contain:</p> <ul style="list-style-type: none"> o A description of the major components of the software design as they relate to the requirements of the software requirements specification. o A technical description of the software with respect to control flow, data flow, control logic, and data structure. o A description of the allowable and tolerable ranges for inputs and outputs. o The design described in a manner that is easily traceable to the software requirements. o Code assessment and support documentation and descriptions of mathematical models and numerical methods as required by NRC publication NUREG-0836. o Continuing documentation, code listings, and software summary forms as required by NUREG-0836. <p style="text-align: center;">7.3 SOFTWARE IMPLEMENTATION DOCUMENTATION</p> <p>(76) Any design changes made to the requirement and design phase documents shall be assessed as to the impact on the design. (77) The revised requirement and design phase documents shall be reviewed to the same level of review as the original documents. (78) The results of this phase <u>should</u> be the basis for the software verification and validation plan(s).</p>							

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<p align="center">7.4 SOFTWARE VERIFICATION AND VALIDATION DOCUMENTATION (TEST)</p> <p>(79) Software verification and validation documentation shall include a plan that describes the tasks and criteria for accomplishing the verification of the software in each phase, and the validation of the software. (80) The documentation shall also specify the hardware and system software configuration pertinent to the software. (81) The documentation shall be organized in a manner that allows traceability to both the software requirements and the software design. (82) This documentation will also include a report on the results of the execution of the software verification and validation activities. (83) This report shall include the results of all reviews, audits, and tests, and a summary of the status of the software.</p>	<p>H.8.4</p> <p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p>			
<p align="center">7.5 USER DOCUMENTATION</p> <p>(84) User documentation shall be prepared in accordance with NUREG-0056 and shall include a description of:</p> <ul style="list-style-type: none"> o Program considerations, options, and initialization procedures. o Anticipated error situations and how the user can correct them. o Internal and external data files, their input sequence, structures, units, and ranges. o Input and output options, defaults, and formats. o System interface features and limitations. 	<p>H.9</p>	<p>See OP 3.1 for specifics</p>		

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<ul style="list-style-type: none"> • Information for obtaining user and maintenance support. • Sample problems. <p style="text-align: center; margin: 10px 0;">8.0 REVIEWS</p> <p>(85) Reviews of software development activity shall be performed as each life cycle phase is completed to assure the completeness and integrity of each phase of development. (86) The procedures used for reviews shall identify the participants and their specific responsibilities during the review and in the preparation and distribution of the review report.</p> <p>(87) The documentation for all reviews shall contain a record of review comments, a plan, and timetable for the resolution of the review comments, and the personnel responsible for this resolution.</p> <p>(88) After review comments are received, the approved documents shall be updated and placed under configuration management.</p> <p style="text-align: center; margin: 10px 0;">8.1 SOFTWARE REQUIREMENTS REVIEW</p> <p>(89) The review of software requirements shall be performed at the completion of the software requirements documentation. (90) This review shall assure that the requirements are complete, verifiable and consistent. (91) The review shall also assure that there is sufficient detail available to complete the software design.</p>	<p style="margin-top: 150px;">✓</p> <p style="margin-top: 10px;">Section 3.4</p> <p style="margin-top: 10px;">See QP 3.1</p> <p style="margin-top: 10px;">See QP 3.1</p> <p style="margin-top: 10px;">4.8.1</p> <p style="text-align: center; margin-top: 10px;">↓</p>			

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	<p align="center">8.2 SOFTWARE DESIGN REVIEW</p> <p>(92)The software design review will be held at the completion of the software design documentation. (93)This review shall evaluate the technical adequacy of the design approach, and assure that the design answers all the requirements in the requirements documentation. (94)The complexity of the software design may require the performance of two design reviews; one at the completion of the overall software architecture, and the second at the completion of the total design.</p> <p align="center">8.3 SOFTWARE IMPLEMENTATION REVIEW</p> <p>(95)The software implementation review is an evaluation of the completed requirements, design, and implementation process prior to independent verification and validation.</p> <p align="center">8.4 SOFTWARE VERIFICATION AND VALIDATION REVIEW</p> <p>(96)The software verification and validation review is an evaluation of the adequacy of verification and validation plans or procedures and completed software verification and validation activities. (97)The review results in an approval of verification and validation documentation.</p> <p align="center">9.0 DISCREPANCY REPORTING AND CORRECTIVE ACTION</p> <p>(98)A formal procedure of software discrepancy reporting and corrective action shall be established. (99)This discrepancy reporting system shall be integrated with the configuration management system to assure formal processing of discrepancy resolutions.</p>							
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	H.8.4							
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	H.2.1							
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	<p>(100) Software discrepancy reporting and corrective action procedures shall assure that, as a minimum:</p> <ul style="list-style-type: none"> o Defects are documented and corrected. o Defects are assessed for criticality and inspected as previous applications. o Corrections are reviewed and approved before changes to the software configuration are made. o Preventive and corrective actions provide for appropriate notification of affected organizations. <p align="center">10.0 MEDIA CONTROL AND SECURITY</p> <p>(101) Physical media containing the images of software shall be physically protected to prevent their inadvertent damage or degradation.</p> <p align="center">11.0 ACQUIRED SOFTWARE</p> <p>(102) Procedures shall be established for controlling the transfer of computer software from an outside source to a user organization and from a user organization to an outside requesting organization. (103) Software transfer requests of the organization (or purchases) from an outside source shall include appropriate criteria to enable the software received to comply, as such as possible, with the requirements of this QA Plan and the needs of</p>	H.4						
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<p>the organization's computer system. (104)Those requirements not met by the software received shall be completed by the organization in the relative phase of the software life cycle that is incomplete or, if that is not possible, the reason shall be documented and maintained with the software and distributed to the users.</p> <p>(105)Configuration management change controls shall be established for documenting the conversion of software to be used on a computer system, and/or peripheral hardware, other than that for which it was designed. (106) Conversion includes all modifications and tests made to input/output or the source code or additional software written to run the original software on the new system. (107)Software conversion shall be documented and maintained for the specific version of the software and the computer system on which it is installed. (108)Software conversion changes shall be evaluated and activities performed in accordance with the appropriate configuration management system elements.</p> <p align="center">12.0 COMPUTER SOFTWARE APPLICATIONS</p> <p>(109)Organizations shall establish procedures for controlling the application of verified and/or validated computer software to technical calculations in support of site-characterization or design, analysis, performance assessment, and operation of repository structures, systems, and components.</p> <p>(110)Organizations shall establish procedures for documenting and reviewing software application and analyses and assuring that all results are accurate and reproducible. (111)Requirements shall be established for identifying or otherwise marking record copies of all analyses and supporting documentation. Supporting documentation includes computer output (results).</p>	<p>A.6</p> <p>↓</p> <p>H.8</p> <p>↓</p>			

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<p>code input data including data bases and original sources/references of and assumptions used to obtain such data, code design, user's and/or operation manuals, verification/validation test results and/or hand calculations.</p> <p>(112) Technical calculations using software shall be performed with applicable computer codes and with software operating procedures defined sufficiently to allow independent repetition of the entire computation.</p> <p>(113) Controls shall be established for generating and documenting software used to perform technical calculations. (114) All auxiliary software used should be included in documentation of technical calculations performed and should be included in independent review as part of the calculation.</p> <p>(115) All applications of computer software shall be independently reviewed and approved to assure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.</p>	<p>A.B</p> <p>↓</p> <p>N/Requirement</p> <p>A.B</p> <p>↓</p>			

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APPENDIX I

REQUIREMENTS FOR THE IDENTIFICATION OF ITEMS
AND ACTIVITIES SUBJECT TO QUALITY ASSURANCE REQUIREMENTS

1.0 GENERAL

This Appendix provides requirements for identification of structures, systems and components important to safety in the pre-closure phase and for identification of the barriers important to waste isolation in the post closure phase which are to be listed on the "Q-List"; and for identification of those major activities conducted during site characterization, construction, operation or closure that relate to natural barriers important to waste isolation and which are to be listed on the Quality Activities List.

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2.0 QUALITY ASSURANCE CRITERIA FOR LICENSING

The purpose of the geologic repository program is to permanently dispose of high-level nuclear waste. In order to obtain a license for receipt and possession of radioactive material at the geologic repository, it must be demonstrated that the repository system will function as required to protect health and safety of the public and the environment. Requirements for licensing a repository to meet this goal are specified in 10 CFR Part 60. These requirements describe the performance objectives and other technical criteria to assure safe operation during waste emplacement and retrieval (if necessary), as well as effective containment and long-term isolation of waste following permanent closure of the geologic repository. The QA Level I requirements of this QA Plan specify the QA program for those items and related activities important to safety and/or waste isolation to assure that

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	<p>their characterization, design, construction, and operation comply with the requirements of 10 CFR Part 60.</p> <p>2.1 QUALITY ASSURANCE CRITERIA FOR THE Q-LIST AND QUALITY ACTIVITIES LIST</p> <p>The QA Level I requirements of this QA Plan apply to items and activities important to safety and/or waste isolation. As derived from 10 CFR Part 60 (60.152), this QA program is based on the 10 criteria of 10 CFR Part 50 Appendix B. These criteria address, in general terms, the basic elements of a QA program, such as organization, design control, test control, inspection, and records management. As noted in 10 CFR 60.152, these criteria are supplemented as necessary to meet the specific requirements of the repository program. In addition to the QA Level I requirements of this QA Plan, items important to safety and waste isolation are subject to the design criteria of 10 CFR 60.131(b) and 60.135 respectively.</p> <p>2.2 CRITERIA FOR NON-Q-LIST ITEMS</p> <p>Certain items that are not important to safety and/or waste isolation shall also be addressed in the license application to demonstrate compliance with 10 CFR Part 60 requirements such as those associated with meeting the design criteria contained in 10 CFR 60.131(a) for protection of worker health and safety. While these items are not subject to the QA Level I requirements of this QA Plan, QA Level II requirements shall be applied. Additional guidance related to this subject can be found in NUREG-1310, (April, 1988), paragraph 5.1(b).</p>	<p>I.2.1</p> <p>↓</p>	<p>OK</p>					
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<p>2.3 DATA NOT COLLECTED UNDER A 10 CFR 60 SUBPART G QA PROGRAM</p> <p>All data collection, interpretations, analyses, and other work to be used to support findings related to important to safety and/or waste isolation in the licensing process shall be technically and procedurally defensible. "Existing data" shall be qualified in accordance with the requirements of Appendix G of this QA Plan. In addition to existing data, some materials that may be important to safety and/or waste isolation may already have been purchased prior to implementation of a 10 CFR 60 Subpart G QA Program. Supporting documentation on these materials (e.g. the technical specifications and QA records) shall be reviewed to determine whether they meet the technical and QA requirements for their designated function. If not, they shall be "qualified" for use to assure they will perform their intended function.</p>	I.2.3						
<p>3.0 IDENTIFICATION OF ITEMS IMPORTANT TO SAFETY</p> <p>Items important to safety are those items essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of unrestricted area at any time until the completion of permanent closure (10 CFR 60.2). The 0.5 rem value is, therefore, the threshold for determining what structures, systems, and components shall be on the Q-List as items important to safety. The rationale for placing a system, structure, or component on the Q-list is to provide added assurance, via application of rigorous QA/QC and design requirements, that they should perform their designated function.</p>	I.3						

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<p>3.1 Probabilistic Risk Analysis (PRA) may be used to the extent practicable, to support the identification of structures, systems, and components important to safety in the license application. Use of this approach for the operations phase of the NRM program is consistent with the approach prescribed by the EPA standard (40 CFR Part 191) for the overall system containment following emplacement of waste in a geologic repository. In cases where data are limited, engineering judgment and conservative bounding assumptions shall be used. Conservative assumptions shall include non-mechanistic failures where information and/or experience are not adequate to reliably determine failure modes and accident scenarios. However, non-mechanistic failures need not be considered where failure modes and mechanisms are understood and failure rates can be determined.</p> <p>3.2 Operator actions or errors which could initiate accidents shall be identified in PRAs or other analyses. These shall be controlled to minimize the probability of occurrence. Other activities which are subject to QA Level I requirements, such as designing, inspecting, and purchasing will not be identified in PRAs but shall be controlled in accordance with QA Level I requirements.</p> <p>3.3 PRAs shall utilize the following techniques:</p> <p>3.3.1 System modeling to depict the combination of safety function and system successes or failures which constitute accident scenarios. Two modeling techniques which may be used are event tree analysis, which identifies the sequence of events that may result in an accident, and fault tree analysis, which determines how failures in safety systems may occur. Both techniques are analytical tools which organize and characterize potential accidents in a methodical manner.</p>	I.3		OK	
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<p>An event-tree defines a comprehensive set of accident sequences that encompasses the effects of all realistic and physically possible potential accidents. By definition, an initiating event is the beginning point in the sequence. Hence, a comprehensive list of accident-initiating events shall be compiled to ensure that the event trees properly depict all important sequences.</p> <p>A fault tree examines the various ways in which a system designed to perform a safety function can fail. Each safety system identified in the event tree as involved in an accident shall be examined to determine how failures of components within that system could cause the failure of the entire system.</p> <p>If failure of a mitigating system could contribute to an off-site dose, individual components within the mitigating system shall be reviewed, using fault tree analysis, to determine the effect of their failure on performance of the overall system. For example, individual components in the ventilation system which may need to be analyzed include dampers, motors, and filters.</p> <p>3.3.2 Consequence analysis of accident scenarios identified in event/fault tree analyses to determine the amount and kind of radionuclides which may reach the unrestricted area and contribute to an off-site dose. Consequence analysis includes identification of a source term for radioactive releases and evaluation of mechanisms for movement and deposition of radioactive materials released from the MLW facility. The energy, magnitude, and timing of radiological releases resulting from various accidents shall be considered in this analysis.</p>	I.3							
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	<p>3.3.3 Analysis to assess the effect of uncertainties in the data base and uncertainties arising from modeling assumptions on the PRA findings. The insights gained in the analysis about features that are significant contributors to risk can provide qualitative understanding into system performance.</p> <p>Additional guidance related to the assessment of pre-closure accidents can be found in NUREG 1310, (April, 1988), paragraph 3.2(a).</p> <p>3.4 REDUNDANCY</p> <p>The use of redundant structures, systems, and components is a method of providing additional assurance that necessary safety functions will be performed if an accident occurs and that the accident dose limit will not be exceeded. In a redundant system, the failure of one train of the system shall not comprise or prevent the associated safety function from being performed. For the high-level waste repository, 10 CFR 60 (60.131(b)(5)(ii)) addresses requirements for redundancy. The items needed to provide redundancy of items important to safety shall also be on the Q-List.</p> <p>3.5 USE OF PREVIOUSLY ESTABLISHED GUIDELINES AND STANDARDS</p> <p>Many guidelines and standards have been developed in the nuclear power reactor program and other nuclear programs which may be applicable for the geologic repository program. For example, there are regulatory guides covering design basis earthquakes, floods, and tornado wind velocities which may be used in the design of the HLW facility and developing the Q-List. While some of these guidelines and standards may not be directly applicable to a geologic repository, they shall be considered to the extent practicable, to eliminate the need to develop new approaches.</p>	<p>I.3</p> <p>↓</p> <p>I.4/3</p> <p>↓</p> <p>I.3</p> <p>↓</p>	<p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p>					

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	<ul style="list-style-type: none"> o Elements of the natural barrier system (e.g., host rock, and geochemical retardation characteristics) relied on to meet the performance objectives. o Activities necessary to demonstrate that the performance objectives will be met, including collection of data to characterize the site or performance of engineered barriers. o Activities in the preclosure phase that could effect post-closure performance. <p>The broad performance objectives for waste isolation provide some flexibility in allocating credit among the various components of the natural and engineered barrier systems to meet each objective. For example, a 300 to 1000 year lifetime for the waste package might be achieved by a combination of performance from each of the components in the waste package or by a single component, such as the canister. The allocation of performance among the various components of the natural and engineered barrier system for each performance objective will provide the basis for determining which barriers are important to waste isolation. Performance assessments shall be conducted on these barriers to ascertain that those relied on will meet the waste isolation and containment performance objectives of 10 CFR Part 60. The initial allocations of performance will provide a basis for determining what site characterization testing will be needed. The initial allocations of performance among the barriers is likely to change based on the results of performance assessments using data collected during site characterization.</p> <p>It is expected that most of the data collected during the site characterization phase can potentially be used in the license application performance assessments. During the early phase of characterization in particular, when little is known about the site and the importance of data characterizing it, data collection activities shall be controlled in</p>	<p>I 4</p> <p>↓</p>						

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<p>accordance with the QA Level I requirements of this QA Plan. However, there may be cases where it is known that data are not needed for performance assessments, or will be duplicated later in accordance with QA Level I requirements of this QA Plan and therefore would not have to be performed in accordance with the QA Level I requirements at this time. For example, scoping tests or tests to examine the feasibility and appropriateness of a data collection techniques may not need to be performed in accordance with the QA Level I requirements of this QA Plan.</p> <p align="center">5.0 SUBMITTAL REQUIREMENTS</p> <p>5.1 LICENSE APPLICATION</p> <p>A description of the QA program to be applied to items important to safety and/or waste isolation shall be submitted with the license application. The submittal shall identify the structures, systems, and components important to safety and describe the analyses used in this identification. It should also identify the barriers important to waste isolation falling under the QA program and describe the evaluations used to identify these barriers (10 CFR 60.21(c) (1)(ii)(C)). A Quality Activities List, as defined in Section 1.0, should also be provided listing major site characterization, isolation, operation, and performance confirmation activities under the QA program.</p> <p>5.2 SITE CHARACTERIZATION PLANS</p> <p>The following information related to the Q-List should be submitted in the Site Characterization Plan:</p> <ul style="list-style-type: none"> A description of the QA program to be applied to items and activities during the site characterization phase. 	<p align="center">I.4</p> <p align="center">↓</p> <p align="center">N/A to LANL</p> <p align="center">↓</p>	<p align="center">OK</p> <p align="center">OK</p>	

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	<ul style="list-style-type: none"> o A preliminary Q-List identifying <u>major structures, systems, and components</u> important to safety, engineered barriers important to waste isolation and the methodology used to develop the list. o A list of major site characterization <u>activities</u> (Quality Activities List) and the QA requirements which apply to them. o A general description of the process by which the preliminary Q-List will be revised as the design advances. <p>Plans for development and implementation of a QA program to demonstrate that non-Q-List licensing requirements are met should also be described in the Site Characterization Plan.</p> <p>6.0 GRADED APPLICATION OF QA MEASURES</p> <p>The 10 CFR 60 Subpart G requirements can be met using graded QA measures and should be applied to items and activities important to safety and/or waste isolation based on considerations such as the following:</p> <ul style="list-style-type: none"> o The impact of malfunction or failure of the item, or the impact of erroneous data associated with data collection activities, on safety or waste isolation. o The complexity of design or fabrication of an item, or design and implementation of a test, or the uniqueness of an item of test. o The special controls and surveillance needed over processes, tests, and equipment. 	<p>N/A to LANL</p> <p>↓</p> <p>N/A to LANL</p> <p>✓</p> <p>✓</p> <p>✓</p>	<p>OK</p> <p>NOT INCORPORATED</p>					

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<ul style="list-style-type: none"> o The degree to which functional compliance can be demonstrated by inspection or test. o The quality history and degree of standardization of the item or test. <p>Note: Additional guidance related to this subject can be found in NUREG-1318, "TECHNICAL POSITION ON ITEMS AND ACTIVITIES IN THE HIGH-LEVEL WASTE GEOLOGIC REPOSITORY PROGRAM SUBJECT TO QUALITY ASSURANCE REQUIREMENTS" (APRIL, 1988).</p>	✓			
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	<p align="center">APPENDIX J</p> <p align="center">REQUIREMENTS FOR PEER REVIEW</p> <p align="center">1.0 General</p> <p>This appendix provides the requirements regarding the applicability of peer reviews, the structure of peer review groups, acceptability of peers, and the conduct and documentation of peer reviews.</p> <p align="center">2.0 APPLICABILITY OF PEER REVIEW</p> <p>2.1 (1)A peer review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and waste isolation cannot otherwise be established through testing, alternate calculations or reference to previously established standards and practices.</p> <p>2.2 (2) In general, the following conditions are indicative of situations in which a peer review shall be considered:</p> <p>a. Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.</p> <p>b. Decisions or interpretations having significant impact on performance assessment conclusions will be made.</p>							

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<p>c. Novel or beyond the state-of-the-art testing, plans and procedures, or analyses are or will be utilized.</p> <p>d. Detailed technical criteria or standard industry procedures do not exist or are being developed.</p> <p>e. Results of tests are not reproducible or repeatable.</p> <p>f. Data or interpretations are ambiguous.</p> <p>g. Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program.</p> <p>2.3 (3) A peer review shall be used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means.</p> <p style="text-align: center;">3.0 STRUCTURE OF PEER REVIEW GROUP</p> <p>(4) The number of peers comprising a peer review group shall vary commensurate with the following:</p> <p>A. The complexity of the work to be reviewed.</p> <p>B. Its importance to establishing that safety or waste isolation performance goals are met.</p> <p>C. The number of technical disciplines involved.</p>	<p>J.2</p> <p style="font-size: 2em;">↓</p> <p>J.3</p> <p style="font-size: 2em;">↓</p>	<p>OK</p> <p>OK</p>	<p>Acc. R</p>

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<p>D. The degree to which uncertainties in the data or technical approach exist.</p> <p>E. The extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.</p> <p>3.2 (5)The collective technical expertise and qualifications of peer review group members shall span the technical issues and areas involved in the work to be reviewed, including any differing bodies of scientific thought. (6)The potential for technical or organizational partiality shall be minimized by selecting peers to provide a balanced peer review group. (7)Technical areas more central to the work to be reviewed shall receive proportionally more representation in the peer review group.</p> <p align="center">4.0 ACCEPTABILITY OF PEERS</p> <p>4.1 (8)The technical qualification of the peer reviewers, in their review areas, shall be at least equivalent to that needed for the original work under review and shall be the primary consideration in the selection of peer reviewers. (9)Each peer shall have recognized and verifiable technical credentials in the technical area that the peer has been selected to review.</p> <p>4.2 (10)Members of the peer review group shall be independent of the original work to be reviewed. (11)Independence in this case means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed. (12)In some cases (i.e. funding considerations) it may be difficult to meet the independence criteria without reducing the technical quality of the peer review. (13)When the independence criteria cannot be met, a documented rationale shall be included in the peer review report.</p>	<p>J.3</p> <p>↓</p> <p>↓</p> <p>J.4</p> <p>↓</p> <p>↓</p>	<p>OK</p> <p>OK</p> <p>OK</p>					

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<p>5.0 PEER REVIEW PROCESS</p> <p>5.1 (14) Since the peer review process may vary from case to case, a peer review plan shall be prepared prior to initiating a peer review. (15) The peer review plan shall describe the work to be reviewed, the size and spectrum of the peer review group, and the suggested method and schedule necessary to produce a peer review report.</p> <p>5.2 (16) The peer review group shall evaluate and report on:</p> <ul style="list-style-type: none"> a. Validity of assumptions. b. Alternate interpretations. c. Uncertainty of results and consequences if incorrect. d. Appropriateness and limitations of methodology and procedures. e. Adequacy of application. f. Accuracy of calculations. h. Adequacy of requirements and criteria. g. Validity of conclusions. <p>(17) Documentation shall be prepared to indicate the results of meetings, deliberations, and activities of the peer review process.</p>	J.5							

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<p>6.0 PEER REVIEW REPORT</p> <p>6.1 (18)A report documenting the results of the peer review shall be prepared and issued under the direction of the peer review group chairperson and shall be signed by each peer review group member. (19)The peer review report shall include the following:</p> <ul style="list-style-type: none"> a. A clear description of the work or issue that was peer reviewed. b. Conclusions reached by the peer review process. c. Individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate. d. Listing of the peers and the technical qualification and evidence of independence for each peer, including potential technical and/or organizational partiality. <p>Note: Additional guidance related to this subject can be found in NUREG-1297, "PEER REVIEW FOR HIGH LEVEL NUCLEAR WASTE REPOSITORIES" (FEBRUARY, 1988).</p>	<p>JK</p> <p>↓</p>	<p>OK</p>					

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	<p>APPENDIX K</p> <p>FORMAT AND CONTENT REQUIREMENTS FOR SCP STUDY PLAN</p> <p>1.0 Purpose and Objectives of Studies:</p> <p>1.1 (1) Describe the information that will be obtained in the study. Briefly discuss how this information will be used; and</p> <p>1.2 (2) Provide the rationale and justification for the information to be obtained by the study. (3) It can be justified by: 1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the SCP); 2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); 3) direct Federal, State, and other regulatory requirements for specific studies. (4) Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and that higher level goal.</p> <p>2.0 Rationale for Selected Study:</p> <p>2.1 (5) Provide the rationale and justification for the selected tests and analyses (including standard tests). (6) Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. (7) Describe the advantages and limitations of the various options; and</p>							
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	<p>2.2 (8) Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). (9) This rationale should also identify reasonable alternatives; summarize reasons for not selecting these alternatives, and reference if available, reports which evaluate alternatives considered.</p> <p>2.3 (10) Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. (11) Factors to be considered include:</p> <ul style="list-style-type: none"> a) Potential impacts on the site from testing; b) Whether the study needs to simulate repository conditions; c) Required accuracy and precision of parameters to be measured with test instrumentation; d) Limits of analytical methods that will use the information from the tests; e) Capability of analytical methods to support the study; f) Time required versus time available to complete the study; g) The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field; 	K.2					

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	<p>b) Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and.</p> <p>1) Interrelationships involving significant interference among tests and ESP design and construction, as appropriate (refer to Section 8.4 of the SCP or its references for specific ESP design information)/</p> <p>3.0 Description of Tests and Analyses:</p> <p>3.1 (12) Since studies are comprised of tests and analyses, provide for each type of test:</p> <p>a) Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g., spatial location relative to the site, ESP elements, repository layout, stratigraphic units, depth, and test location);</p> <p>b) Summarize the test methods. Reference any standard procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA level 1. Reference the applicable specific QA requirements that will be applied to the test;</p>	<p>K.2</p> <p>↓</p> <p>K.3</p> <p>↓</p>	<p>OK</p> <p>OR</p> <p>OK</p> <p>OK</p>					

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Review Requirements per NQWS/88-9 Rev. 2	Review Results			Organization's Resolution			Review Dispo.	
	Sat - Para. No.	Unsat - Para. No. -	Comments	Acc.	Rej.	Reason	Acc.	Rej.
	<p>c) Specify the tolerance, accuracy, and precision required in the test, where appropriate;</p> <p>d) Indicate the range of expected results of the test and the basis for those expected results;</p> <p>e) List the equipment required for the test and describe briefly any such equipment that is special;</p> <p>f) Describe techniques to be used for data reduction and analysis of the results;</p> <p>g) Discuss the representativeness of the including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results;</p> <p>h) Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests, and</p> <p>i) Relationship of the test to the set performance goals and confidence levels.</p> <p>3.2 (13) For each type of analysis:</p> <p>a) State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;</p>	K 3						

OK

QA COMPLIANCE REVIEW CHECKLIST

Review Requirements per NWSI/88-9 Rev. 2	Review Results			Acc.
	Sat - Para. No.	Unsat - Para. No. -	Comments	
<p>b) Describe the methods of analysis including any analytical expressions and numerical models that will be employed;</p> <p>c) Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA level 1. Reference the applicable QA requirements.</p> <p>d) Identify the data input requirements of the analysis;</p> <p>e) Describe the expected output and accuracy of this analysis; and</p> <p>f) Describe the representativeness of the analytical approach (e.g., with respect to spatial variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.</p> <p>4.0 Application of Results:</p> <p>4.1 (14) Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies)</p> <p>4.2 (15) For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) that will use the information produced from the studies described above, and refer to any use of the results for model validation;</p>	K.3			
	K.4	OK		
		OK		

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Review Requirements per NNWSI/88-9 Rev. 2	Review Results			Organization's Resolution		Review Dispo.		
	Sat. - Para. No.	Unsat. - Para. No. -	Comments	Acc.	Rej.	Reason	Acc.	Rej.
	<p>4.3 (16) For design uses, refer to , or describe, where the information from the study described above will be used in construction equipment design and development, and engineering system design and development (e.g., waste packages, repository engineered barriers, and shafts and borehole seals); and</p> <p>4.4 (17) For characterization uses, refer to, or describe, where the information from the study described above will be used in planning other characterization activities.</p> <p><u>Schedule and Milestones:</u></p> <p>5.1 (18) Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities;</p> <p>5.2 (19) Describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study; and</p> <p>5.3 (20) Dates for activities or milestones including durations and inter-relationships, for the study plans will be provided. These should reference the master schedules provided in Section 8.3 of the SCP.</p>	K.4 ↓ K.5 ↓	OK OK OK OK OK					