SANDIA NATIONAL LABORATORIES

NUCLEAR WASTE REPOSITORY TECHNOLOGY

QUALITY ASSURANCE PROGRAM PLAN

SLTR88-0001

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Approved: R. R. Richards — April 10, 1989
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T. O. Hunter, Manager
SNL NWRT Department
(Technical Project Officer)
Date

Rec'ed w/Ltr Dated 4/10/89

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SANDIA NATIONAL LABORATORIES
NUCLEAR WASTE REPOSITORY TECHNOLOGY
QUALITY ASSURANCE PROGRAM PLAN

INTRODUCTION

The Yucca Mountain Project (YMP) was established by the Department of Energy-Nevada Operations Office (DOE/NV) to evaluate planned and systematic actions to provide sufficient information to expand the public's confidence in the suitability of a geologic repository site and its subsystems and components for high-level radioactive waste isolation. The location of the potentially acceptable geologic repository site under evaluation is on and adjacent to the Nevada Test Site (NTS). This evaluation includes all systems, structures, and components important to safety for the design, construction, and characterization of barriers important to high-level waste isolation and to related activities.

It is possible that the results of these investigations will support Nuclear Regulatory Commission (NRC) licensing decisions and assessment of risks to public health and safety for the geologic repository. To ensure that important investigations are carried out properly, it is essential to specify the method of achieving the quality aspects of the work. This Quality Assurance Program Plan (QAPP) provides that required specification.

Sandia National Laboratories (SNL), as part of its contract to the Department of Energy, is a participating organization in the Yucca Mountain Project. Sandia's principal responsibility is to function as lead organization for the Systems, Repository, and Test Facilities Work Breakdown Structure (WBS) elements. SNL is responsible for repository systems development; data management and analysis; systems performance assessment of the repository; conceptual design of the repository; determining the thermal and mechanical properties of the host rock; repository sealing performance requirements, materials evaluation, design, and testing; and providing assistance to other Yucca Mountain Project participants in areas of specialized expertise. The specific WBS elements that comprise Sandia's responsibility and to which this QA Program applies are shown on Figure 2 in Section 1.

All of the SNL YMP work described above can be modeled as a <u>process</u> (design activities, analysis, data-collection, etc.) which requires some <u>input</u> (performance objectives, design bases, data, samples, measurement equipment, etc.) and produces an <u>output</u> or product (Conceptual Design Report, performance assessment predictions, parameter values, etc.). The SNL approach to achieving and assuring quality calls for exercising appropriate controls on the process and its inputs and outputs. Means will be used to determine the effectiveness of these controls and feedback will occur in order that input controls and process controls have optimum effect, such that the final product attains the required quality. The numbered sections of this QA Program Plan state the specifics of these controls and feedback mechanisms and how, when, and where they are applied. As a participant in the Yucca Mountain Project, SNL will conduct a QA Program that conforms to the Yucca Mountain QA Plan, NNWSI/88-9. This Quality Assurance Program will be carried out throughout the life of the Yucca Mountain Project.

Note on word usage: In this document certain verb forms are intended to convey the following meanings:

- "will" is used to indicate a projected future occurrence or condition, as in standard future-tense usage,
- "shall" is used to indicate a requirement,
- "may," "can," and "should" indicate optionality.

The use of the pronouns "he" or "his" in this document or in its implementing procedures is solely for grammatical simplicity and is not to be construed as implying any gender bias or preference.

PURPOSE AND SCOPE

This Quality Assurance Program Plan describes the manner in which the overall quality assurance requirements for the Yucca Mountain Project will be fulfilled within the Sandia National Laboratories Nuclear Waste Repository Technology Department (Dept. 6310). The Quality Assurance (QA) requirements addressed in this plan arise from:

- YMP Quality Assurance Plan (QAP), YMP/88-9
- YMP Project Administrative Procedures (APs)
- Sandia National Laboratories Quality Plan

It is the purpose of this QAPP to prescribe the plans and policies of Department 6310 in meeting YMP Quality Assurance Program requirements.

This QAPP is consistent with the Sandia National Laboratories Quality Plan but does not repeat the contents of that document. By complying with the SNL Quality Plan, this document will be consistent with the requirements of DOE 5700.6 and AL 5700.6.

This QAPP is effective upon approval by the Yucca Mountain Project Office (YMPO) of DOE/NV.

POLICY

The Sandia National Laboratories (SNL) Nuclear Waste Repository Technology Department considers quality assurance an essential element of the Yucca Mountain Project. It is therefore the responsibility of each person working on the project for SNL to comply with the requirements and policies established by this QAPP and to use and adhere to the specific procedures supporting it.

In accordance with Yucca Mountain Project Office policy, Sandia National Laboratories assigns a Quality Assurance Level to each project technical activity for which it is responsible. Quality Assurance Level assignments are based on the definitions of QA Levels and the guidelines and method established in the YMP QA Plan. Regardless of the QA Level assigned, SNL will implement sound, cost-effective quality assurance practices necessary to accomplish the goal of obtaining a Nuclear Regulatory Commission (NRC) license for the geologic repository.

The implementation of a sound, defensible, and practical QA Program is an inherent and critical part of the management of Sandia activities for the Yucca Mountain Project. All management and staff are expected to know and adhere to the QA requirements that apply to their respective responsibilities. Management controls (e.g., commitment of resources, stop work orders, approval of actions, etc.) will be used to ensure that QA requirements are adhered to before, during, and after activities are performed.

1.0 ORGANIZATION

1.1 This section describes the general organization and responsibilities within the Nuclear Waste Repository Technology Department (Dept. 6310) at Sandia National Laboratories. Specific activities performed by each Sandia organization are derived from the YMP Work Breakdown Structure. The organization of the SNL NWRT Department is shown in Figure 1. The QA responsibilities of all organization elements shown on Figure 1 are described in the following paragraphs:

1.2 Nuclear Waste Repository Technology Department, 6310. This department provides administrative, technical, and financial management for all YMP activities conducted by Sandia.

1.2.1 Responsibility and Authority. The Manager of Department 6310 (Project Manager), who is the SNL YMP Technical Project Officer (TPO), is responsible for the establishment and execution of the SNL-NWRT-QAPP and for ensuring that Project activities for which Sandia is responsible are executed in accordance with this QAPP and implementing procedures consistent with the YMP QA Plan. The Department Manager may delegate to others the work of establishing and executing the Quality Assurance (QA) program, or any part thereof, but retains the responsibility therefor. Delegation of execution of the QAPP requirements shall be documented. The organizational structure, lines of communication, authority and duties of persons and organizations performing activities affecting quality are clearly established and delineated in writing. These activities affecting quality include both the performing functions of attaining quality objectives and the QA functions. While the line organization is responsible for performing activities properly, the QA organization or personnel performing QA functions will verify the performance of work through implementation of appropriate QA controls. The Division Supervisors are delegated the responsibility and authority to perform functions to attain quality objectives, including adhering to the QA Program. These responsibilities and authorities may be delegated to other organizations but the responsibility for attaining quality objectives is retained by the Division Supervisor, and ultimately retained by the TPO. The TPO has the authority to resolve disputes involving quality arising from difference of opinion between QA personnel and persons in the department staff or technical divisions. QA personnel may elevate the resolution of disputes to progressively higher organization levels, including the YMPO PQM if the dispute cannot be resolved within the organization.

1.2.2 QA Functions. The QA functions are those of assuring that an appropriate QA Program is established and executed effectively and of verifying, such as by checking, auditing, surveillance and inspection, that activities that affect quality have been performed

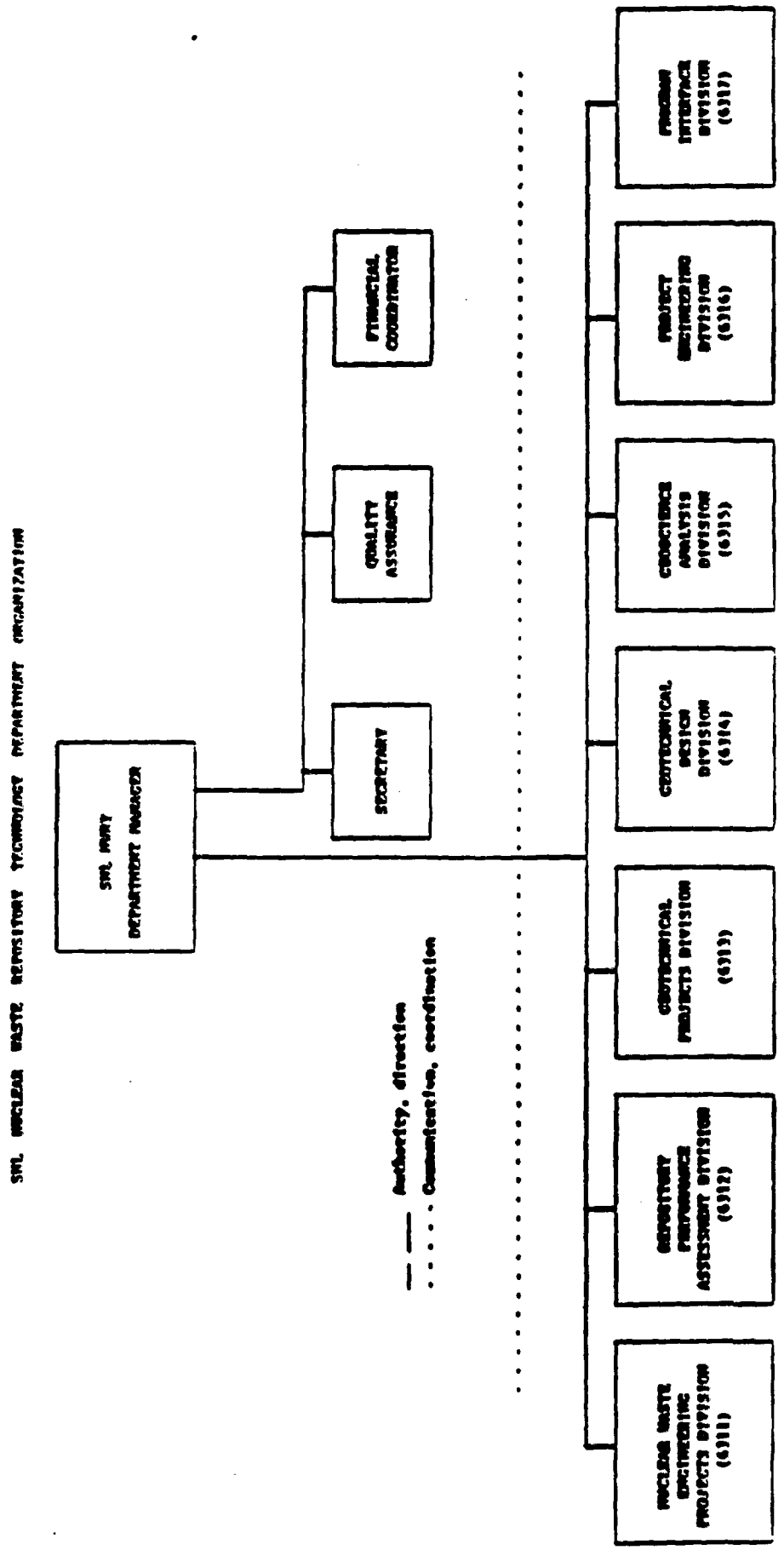
SNL NWRT
DEPARTMENT MANAGER
SECRETARY
QUALITY ASSURANCE
FINANCIAL COORDINATOR
Authority, direction
Communication, coordination
NUCLEAR WASTE ENGINEERING PROJECTS DIVISION (6311)
REPOSITORY PERFORMANCE ASSESSMENT DIVISION (6312)
GEOTECHNICAL PROJECTS DIVISION (6313)
GEOTECHNICAL DESIGN DIVISION (6314)
GEOSCIENCE ANALYSIS DIVISION (6315)
PRODUCT DISTRIBUTION DIVISION (6316)
PROGRAM INTERFACE DIVISION (6317)

FIGURE 1

correctly. The persons and organizations performing QA functions have sufficient authority, access to work areas, and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions through designated channels; to verify 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. This includes the ability to stop (or cause to be stopped) unsatisfactory work through established channels. Such persons or organizations have direct access to the Manager of Department 6310, where appropriate action can be effected, and report to this management level at which this required authority and organizational freedom are provided, including sufficient independence from cost and schedule.

A full-time dedicated QA Coordinator is responsible for directing and managing the overall QA Program. The QA Coordinator:

- has appropriate organizational position, responsibilities, and authority to exercise proper control over the QA Program,

- has management and QA knowledge and experience and is at a higher organizational level than the highest line manager (Division Supervisor) responsible for performing activities affecting quality and is sufficiently independent from cost and schedule,

- has responsibility for approval of QAPPs, changes thereto, and interpretations thereof and implementing procedures and all changes thereto,

- has effective communication channels with other senior management positions,

- has responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA Program implementation by the SNL organization and its subordinate organizations, and

  Neither the QA Coordinator nor other QA personnel considered "full-time dedicated" shall be assigned duties that would prevent full attention to QA responsibilities or that would conflict with the reporting and resolution of QA issues and problems.

The QA Coordinator may delegate his authority to perform QA functions to other individuals, organizations, or contractors.

1.2.3 Technical Divisions. The technical and administrative activities of the department are performed by seven divisions; each division has designated responsibilities within the YMP Work Breakdown Structure (Figure 2). Each division has a supervisor that has administrative responsibility for staff in that division. The programmatic and technical control of each division's activity is the responsibility of the supervisor. Achievement and maintenance of quality is the responsibility of individuals performing work and of their supervisors.

1.2.3.1 Division 6311: Engineering Projects Division. This division is responsible for design integration and surface facilities design development. It combines all the design activities into design deliverables, develops the design basis, and maintains overall control and review of design activities. In addition, this division performs analyses of preclosure safety performance of the repository.

1.2.3.2 Division 6312: Repository Performance Assessment Division. This division is responsible for postclosure performance assessment. Its responsibilities include developing methods to calculate radionuclide releases to the environment and developing techniques to certify that the methods are appropriate.

1.2.3.3 Division 6313: Geotechnical Projects Division. This division is responsible for testing associated with obtaining the rock mechanics properties of the tuffs at Yucca Mountain. It includes laboratory testing, field testing, analysis of geotechnical data, and the management and integration of Sandia's activities in the exploratory shaft.

1.2.3.4 Division 6314: Geotechnical Design Division. This division is responsible for development of the underground facility for the YMP Project. Its responsibilities include conceptual design of the underground facility, development of seal designs and materials, developing prototype equipment to demonstrate the validity of the design, and performing analyses to establish the adequacy of the underground design.

1.2.3.5 Division 6315: Geoscience Analysis Division. This division is responsible for the collection and interpretation of data describing the Yucca Mountain site. It maintains systematic data bases containing site information provided by other project participants. In addition, it uses these data to provide the analysis of the hydrologic system to establish the adequacy of the site in meeting regulatory requirements.

DEPARTMENT 6310
ORGANIZATIONAL RESPONSIBILITIES
Figure 2

Department 6310
Project Responsibilities

12911	Management
1293	Quality Assurance

Division 6311
System Eng. Design Int. and Surface Facility

12123	Cost Schedule
123211	Site Geology
12411	Repository Management
12412	Basis for Design
12413	Major Design Deliverables
12431	Site Preparation
12432	Surface Facilities
1244	Operations and Maintenance
1245	Decommissioning
12463	Preclosure Safety Analysis

Division 6312
Performance Assessment

1211	Systems Management and Integration
12142	Radionuclide Source Term
12143	Flow and Transport Model Validation
12144	Radionuclide Releases from Total System

Division 6313
Rock Mechanics Testing

124212	Field Testing
124213	Lab Properties
124214	Water Migration Analysis
12464	Performance Confirmation
12611	Exploratory Shaft Management, Planning, and Design Review
12612	ES Quality Assurance
12691	Exploratory Shaft Test Plan
126923	ES Geomechanical Testing
1260	ES Decommissioning
1272	Testing (Test Facilities)

Figure 2 (Cont'd.)

Division 6314
UG Design and Design Analysis

124211	Rock Mass Analysis
124221	Equipment Engineering
124231	Seal Performance Requirements
124232	Seal Materials Evaluation
124233	Seal Concepts Development
12433	Shafts/Ramps
12434	Underground Excavations
12435	Underground Services System
12461	Performance Code Development and Certification
12462	Design Analysis
12522	Site-Characterization Plan

Division 6315
Geologic Analysis and Data

12131	Tuff Data Base
12132	Computer Graphics
12134	Data-Base-Management Computer-Systems Support
12141	Flow and Radionuclide Transport

Division 6316
Project Engineering

12121	Systems Description
12122	Systems Studies
12124	Systems Engineering Integration
12133	Reference Information Base
12521	Regulatory Interactions
12541	Institutional Studies
12911	Management
12912	Interface Activities
12913	Geological Repository Program Support
12914	Records Management
1292	Project Control

Division 6317
Project Office Liaison

12912	Interface Activities

1.2.3.6 Division 6316: Project Engineering Division. This division is responsible for systems engineering integration of repository designs, maintenance of the YMP Reference Information Base, and various program support, control, and interface activities, as well as SNL YMP records management.

1.2.3.7 Division 6317: Program Interface Division. This division is responsible for direct and close communication and coordination with the Yucca Mountain Project Office. It is co-located with the YMPO.

1.3 Applicability of QAPP. The QA Program described in the QAPP applies to all items and activities (i.e., QA Levels I, II, and III) affecting quality. The SNL organizational structure and the responsibility of assignments are clearly established such that certain results, as described below, are obtained. The QA Program has been developed and executed to provide for all activities involving items important to both safety and isolation. Quality is achieved and maintained by requiring the technical divisions, who are designated by the TPO to perform functions to attain quality objectives, to adhere to the appropriate quality requirements for QA Levels I, II, and III activities. The assignment of work elements by the TPO, according to the YMP Work Breakdown Structure, is presented in Figure 2. Each work activity will have a quality level assigned and documented.

Quality achievement will be verified by persons or organizations not directly responsible for performing the work. Such QA functions will be performed by the independent QA organization and certain other personnel. For example, technical reviews will be performed by technically knowledgeable individuals who are not directly involved in performing the work under review. The quality assurance organization and technical division staff will be directly involved in the development and implementation of the QA Program for both repository design and site-characterization activities. The extent of the involvement of the QA organization with the technical organization is dependent on the specific activity and the subsequent effect upon repository safety and reliability and upon the complexity of the QA requirements involved.

1.4 Interfaces. The external interfaces between organizations and the internal interfaces between organizational units and changes thereto are defined and documented. The interfaces between SNL, the YMPO, other Participants, and NTS contractors are described herein, in the YMP QA Plan, and in YMP Administrative Procedures. From an overall Yucca Mountain Project standpoint, these interfaces are an exchange of technical requirements for work to be

performed and liaison until completion of work. The Yucca Mountain Project Administrative Procedures (APs) provide the implementing interface controls utilized by all Project participants while implementing procedures describe the methods of conducting inter-organizational activities.

1.4.1 Other Sandia Technical Organizations. Other organizations within Sandia National Laboratories support the YMP Project Department. Each of these organizations reports to one of the technical divisions within Department 6310. The authority and responsibility for performing activities and assuring the QA requirements will be met is delegated to the Division Supervisor for the supporting organization. Interface specifications consist of four primary documents which are transmitted and recorded. (1) A Task Definition Statement (TDS) is forwarded from the TPO to each supporting organization specifying:

- the responsible Division Supervisors in Department 6310 and in the supporting organizations,
- the tasks to be performed and their identification within the YMP WBS,
- the staff assigned to the task,
- the QA requirements and Quality Level associated with the task,
- the budget information for each task,
- the deliverables expected from each task, and
- the anticipated schedule for performing the tasks.

Prior to being forwarded to the supporting organization, the TDSs are reviewed by the SNL YMP QA organization.

(2) For supporting organizations performing or supporting experimentation or data collection, an Experiment or Test Procedure is developed for each major activity. The Experiment or Test procedure indicates how the activity will be performed. (3) For analyses or calculational activities, a Problem Definition Memo (PDM) is issued by the 6310 Technical Division Supervisor to the supporting organization. This PDM defines the analyses to be performed, the methods to be used, and the assumptions and given information for the analysis to be performed. (4) For design activities and studies, a Design Investigation Memo (DIM) is issued to the supporting organization. This document identifies design or

design study objectives, inputs methods, constraints, and design outputs desired. Additionally, for all deliverables, a technical report is prepared by the supporting organization. This report must be reviewed according to the review procedures of Department 6310.

1.4.2 Subcontractors. Sandia Department 6310 is supported by a number of subcontractors. Each subcontractor reports to Sandia through a contract monitor to one of the technical divisions or directly to the Department Manager. QA requirements, reviews, and audits are specified as part of their contracts with Sandia National Laboratories.

1.4.3 NTS Contractors. Department 6310 provides instructions for supporting work to be done by NTS Contractors via SNL Department 7130. The vehicle used for these interface communications is the Letter of Criteria, as specified in Project Administrative Procedure 5.10Q.

2.0 QUALITY ASSURANCE PROGRAM

2.1 Extent and Content of Quality Assurance Program

2.1.1 The SNL YMP Quality Assurance Program Plan (QAPP) provides the description of the SNL YMP QA Program and indicates the commitment to the applicable Yucca Mountain Project QA Plan requirements. The QAPP includes consideration of the technical aspects of the activities affecting quality and was generated by the QA organization with assistance from the technical staff. The QAPP states the policies and practices for applying QA requirements to the technical activities of the Yucca Mountain Project. This QAPP has been planned and will be implemented and maintained in accordance with the YMP QA Plan. Consequently, it is consistent with and addresses all of the applicable requirements of the YMP QA Plan. (The hierarchy of QA documents applicable to the SNL YMP Project are shown in Figure 3. With the exception of the Code of Federal Regulations, where deviations between the requirements of higher-tier QA documents (e.g., DOE 5700.6) and the YMP QA Plan exist, the requirements of the YMP QA Plan shall prevail.) Those QA Program requirement elements ("criteria") which are not applicable to SNL activities are so noted in this QAPP and a justification is included in a checklist based on the YMP QA Plan which has been provided to the YMPO. Management above or outside of the QA organization will regularly receive information as to the scope, status, adequacy, compliance, etc., of the QA Program. For example, the TPO will utilize both internal audits and management assessments to assess the adequacy of the QA Program and to help assure its effective implementation. Additionally, management shall perform readiness reviews as deemed appropriate. Readiness reviews shall apply to major scheduled/planned activities which could affect quality. Readiness reviews shall be used in verifying that specified prerequisites and programmatic requirements have been identified and accomplished prior to starting a major activity.

2.1.2 The Quality Assurance Program of the SNL organization consists of the QAPP plus appropriate implementing procedures required to provide and implement control over activities affecting quality. The control will be consistent with the importance of the activity. These procedures will be developed by qualified personnel and be reviewed and approved by the QA organization prior to implementation to assure that they implement the requirements stated in this QAPP. Implementing procedures correlated to the 18 sections of this QAPP are listed in Appendix B.

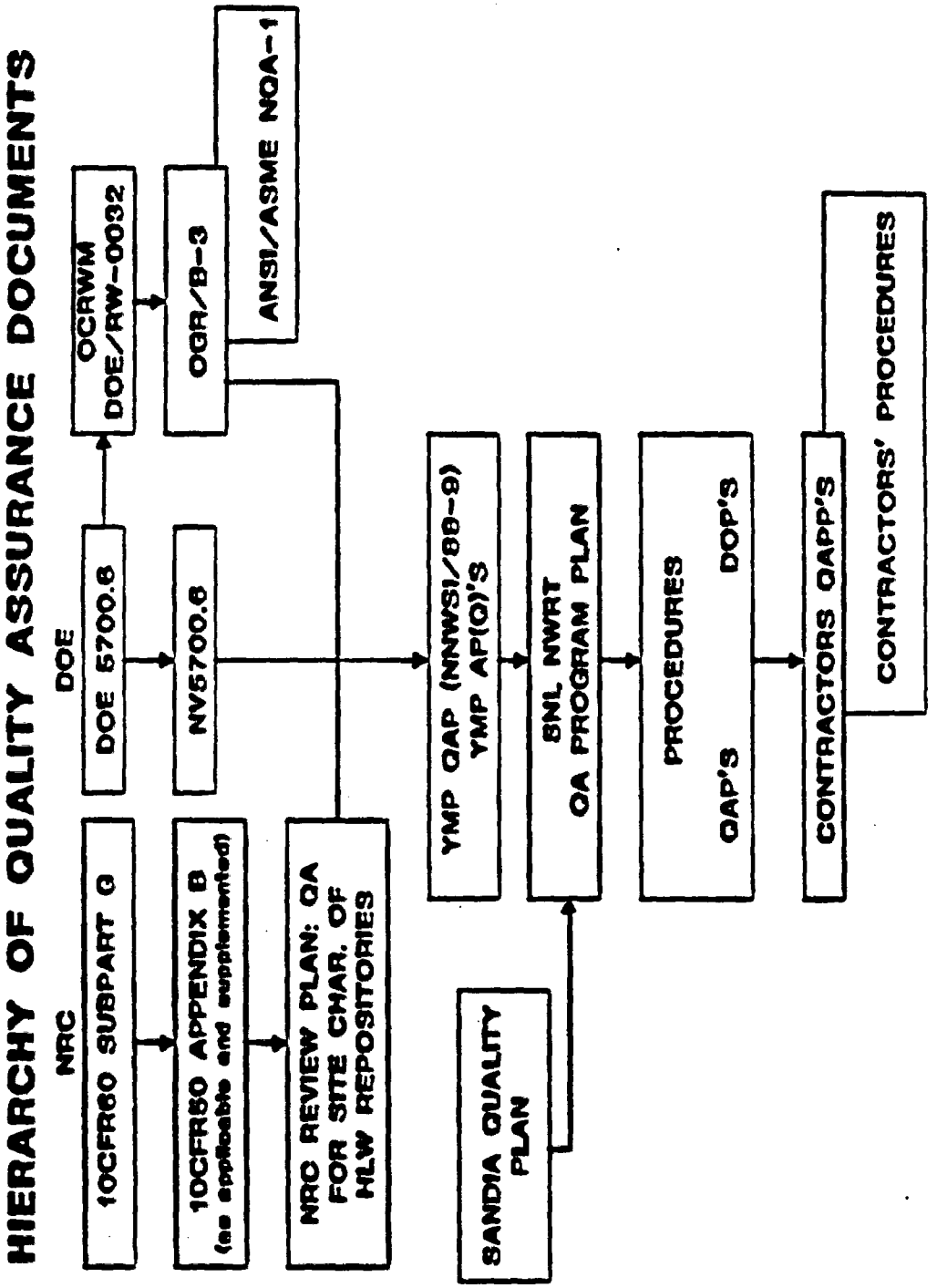
HIERARCHY OF QUALITY ASSURANCE DOCUMENTS
NRC
DOE
10CFR60 SUBPART G
DOE 5700.6
OCRWM DOE/RW-0032
10CFR50 APPENDIX B (as applicable and supplemented)
NV5700.6
OGR/B-3
ANSI/ASME NQA-1
NRC REVIEW PLAN: QA FOR SITE CHAR. OF HLW REPOSITORIES
YMP QAP (NNWSI/88-9) YMP AP(Q)'S
SANDIA QUALITY PLAN
SNL NWRT QA PROGRAM PLAN
PROCEDURES
QAP'S
DOP'S
CONTRACTORS QAPP'S
CONTRACTORS' PROCEDURES

Figure 3

This QAPP, and revisions thereto, shall be submitted to the YMPO for review prior to implementation. These submittals shall include a checklist based on the YMP QA Plan which identifies how and where each requirement of that document is addressed.

2.2 Use of Data Not Generated Under QA Controls

2.2.1 The YMP Quality Assurance Plan provides for the acceptance of data or data interpretations for use in licensing activities that were not generated under the controls of a QA plan which meets the requirements of 10 CFR 60, Subpart G. Specific methods for acceptance of this information are contained in an Yucca Mountain Project Administrative Procedure which meets the requirements of NUREG-1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories." Requirements applicable to this activity are contained in Appendix G of this document. Once accepted, this data is classified as "primary data" and may be used for licensing purposes.

2.2.2 Data that was collected after August, 1980, but prior to issuance of Revision 0 of this QA Program Plan (January, 1987) will be processed by means of nonconformance control procedures to determine its validity for licensing.

2.3 Approach to QA

2.3.1 The Yucca Mountain 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. 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, non-radiological health and safety, the NRC licensing requirements, the operability and maintainability of the repository, costs, and schedules. The SNL organization will identify the appropriate quality assurance levels for all items and activities within its scope of work that affect quality associated with site characterization, facility and equipment construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. Once assigned, the QA level for a particular item or activity will be applied by all personnel involved in the activity.

2.3.2 This QAPP complies with applicable requirements of the YMP QAP and will be implemented for each Project activity at the earliest practicable time consistent with the schedule for accomplishing the

activities. The SNL organization will assure that procedures required to implement the requirements of this document are properly documented, controlled, and mandated. The QAPP will be applied to all items and activities affecting quality throughout the life of the Yucca Mountain Project in accordance with the established policies, procedures, and instructions.

2.3.3 This QAPP provides control over activities that affect the quality of the identified structures, systems, and components to an extent consistent with their importance. The activities that affect quality will be accomplished under suitably controlled conditions. 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. The program will 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, other verification means, or a combination of these. The program will provide for indoctrination and, as necessary, training or education of personnel performing activities that affect quality to assure that suitable proficiency is achieved and maintained.

2.4 Application of Graded Quality Assurance

2.4.1 The requirements of this sub-section are applicable 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. 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) does not require QA level assignments.

2.4.2 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. 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 economic considerations.

2.4.3 This approach involves 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 ensuring that these items and activities are covered by a commensurate QA Program. 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 delivery of the item. Between these two extremes, there are varying degrees of QA to achieve the desired confidence in the quality of the completed line of activity. The graded approach set forth herein 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.

2.5 Quality Assurance Levels

2.5.1 The requirements specified in this section are to be used to apply the graded quality philosophy to all Yucca Mountain Project items and activities. The appropriate Quality Assurance Level for any item or activity will be determined by the application of decision criteria as provided by the YMP Administrative Procedures. The basis for the selection of the Quality Assurance Level and assigned QA requirements will be documented. The assigned Quality Assurance Levels and QA requirements must be submitted to the YMPO for review, resolution of comments, and approval prior to implementation or use. (It may be appropriate to exempt certain YMP items or activities from QA Level assignment. Requests for these exemptions shall be documented and shall contain sufficient justification to support the exemption request. Such requests will be submitted for approval by the YMPO.)

2.5.2 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 Yucca Mountain Project. The definition, application, and assignment of each of the three QA levels are described in the following discussion.

2.5.2.1 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. 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 postclosure 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.

2.5.2.2 QA Level II - 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 YMPO concerns, and the environment.

2.5.2.3 QA Level III - are those activities and items that are not classified as QA Levels I or II and that are not exempted from QA Level assignment.

2.6 <u>Application of Levels</u>

2.6.1 QA Level I is the most stringent level of quality assurance. 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. QA Level I activities which are on the Q-List (see App. A, Definitions) 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 by-product material (waste) at the geologic repository. QA Level I control and documentation must be applied to activities, including site characterization; scientific investigations; 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. 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. The repository also will utilize the natural barriers to afford long-term isolation. Within this context, QA Level I must be applied for near-term safety, as well as long-term isolation in the following cases:

- Where items and activities could effect the 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 whole body or to any organ, or 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.

- Where items and activities will 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 system.

- Where item and activities, 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.

2.6.2 QA Level II is the second highest level of quality assurance. QA Level II controls and documentation shall be applied to the Yucca Mountain 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. 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. 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. Therefore, Quality Assurance Level II must be applied to activities and items as follows:

- Where items and activities are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and could have a major impact on the nonradiological health 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 10 CFR 20.

- Where items and activities could affect the retrievability of waste up to the time of repository closure.

- When items and activities involve the nonradiological operational reliability and maintainability of engineered systems, structures, and 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 to QA Level II prior to execution. Where a particular item can be identified and defined during this phase, a separate QA level assignment may be established for that item. Once the QA Level is approved, design activities associated with the item shall be governed by the QA Level assigned to the item.

- Where items and activities, having failed, could result in a major cost overrun.

- Where items and activities, if failed, could result in a major schedule slippage.

Quality Assurance Level II activities may have as much importance as a Quality Assurance Level I activity; however, except when used to support a Quality Assurance Level I activity as indicated in the following, they do not provide primary information in the licensing efforts. In most cases, activities controlled in accordance with the Quality Assurance Level II program cannot be used subsequently to directly support Quality Assurance Level I activities, unless it can be substantiated that quality assurance requirements equivalent to those which would have been applied to a Quality Assurance Level I activity, were implemented or that a technical justification process is applied in accordance with the YMP AP or SOP concerning "Acceptance of Data or Data Interpretations not Developed Under the Yucca Mountain Project QA Plan."

2.6.3 QA Level III is the least stringent level of Quality Assurance. Level III Quality Assurance items and activities are such that they have no major function in the characterization of the site and design of the repository, but they require good practices for the intended use. Design phases which are purely preliminary and are conducted to define the range of alternatives/methods/equipment, which are felt to be worthy of more detailed study, shall be assigned a QA Level of III prior to execution. Those activities controlled in accordance with a Quality Assurance Level III program cannot subsequently be used to directly support Quality Assurance 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 prior to the complete implementation of the Yucca Mountain Project Quality Assurance Plan may be used in the licensing process as background or corroborative information.

2.6.4 The requirements contained in this QAPP apply to Quality Assurance Levels I and II items and activities, unless otherwise noted herein. The requirements imposed for QA Level III items and activities are those managerial, administrative, scientific, engineering, commercial, and laboratory practices that are commonly used by SNL, plus any requirements of this QAPP stated as applicable to QA Level III. Except where specifically required by policy documents or procedures, these practices on QA Level III items and activities need not be documented.

2.7 QA Overview

2.7.1 Each Yucca Mountain Project Participant shall perform overview of the QA activities of all organizations (including subcontractors doing supportive work) under their purview. Overview is to include the following as appropriate:

- The review and approval of QAPPs.
- Surveillance of activities affecting quality to verify compliance with requirements.
- Performance of quality audits to verify the adequacy and compliance of QA programs.

2.7.2 Procedures shall be used by this organization for the review of QA program documentation of those organizations under our purview for adequacy, completeness and relevance. The 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. Reviews of QA program documentation shall be recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance.

2.8 Management Assessments

2.8.1 Management assessments are to be conducted at least annually for determining the effectiveness of the system and management controls that are established to achieve and assure quality, and the adequacy of resources and personnel provided to the QA Program. Management is to verify that the QA Program is being effectively implemented and that personnel are trained to the QA requirements of the program.

2.8.2 This organization maintains an internal procedure for planning, organizing, performing, and documenting management assessments, including the analysis and reporting of the results and the tracking of recommendations. Copies of all management assessments are to be provided to the Project Manager, YMPO, and the YMPO PQM. Management of the SNL NWRT Department is responsible for the management assessment activity.

2.9 Personnel Selection, Familiarization and Training

2.9.1 The SNL YMP organization has established requirements for the selection, familiarization, and training of personnel performing or verifying activities that affect quality. Position descriptions establish requirements that set forth minimum personnel qualifications and provide for appropriate indoctrination or training or both, prior to initiation of activities that affect quality. 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.) will be certified in accordance with the detailed requirements specified in Appendices C, D, and E, as applicable.

2.9.2 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.

2.9.3 Personnel selected shall have education and experience commensurate with the minimum requirements specified in the position description. The education and experience of personnel is verified by the SNL Personnel Department prior to hiring and is then maintained current in appropriate private records. Such records shall be utilized by management personnel in selecting personnel. An evaluation of the capabilities of an individual will be based upon a comparison of their education, experience, and training against that established for the position. These evaluations will be documented by managers or supervisors responsible for the activities to be performed.

2.9.4 Prior to assigning personnel to perform activities affecting quality, they will be familiarized 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. Familiarization may be accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or other instructional methods.

- This QAPP
- Implementing Procedures and work instructions (applicable to the individual's responsibilities)
- Regulations
- Appropriate Project-Level Documents

This familiarization will also include information and perspective on the Project as a whole, SNL's role and organization, and other appropriate topics as determined by the individual's supervisor.

2.9.5 Prior to assigning personnel to perform quality affecting activities, training, if needed, will be conducted to gain the required proficiency. The training (in-depth instruction) will

include the principles, techniques, and requirements of the activity. 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.

2.9.6 After the initial personnel qualification evaluation, the job proficiency of personnel who perform activities affecting quality will be evaluated and documented at least annually. Proficiency evaluations will be performed in conjunction with periodic employee performance evaluations. Proficiency evaluations will be performed by managers or supervisors who have responsibility for the activities being performed or verified.

2.9.7 Records of personnel qualification evaluations, familiarization, training, and proficiency evaluations will be retained as lifetime QA records. These records will include, as a minimum, the items listed below.

- Records of a candidate's education, experience, and training.
- Records documenting verification of personnel education and experience.
- Records of familiarization which include the objective and content of the familiarization, date or dates of familiarization, and other applicable information.
- 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.
- Records of proficiency evaluation which include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.

3.0 SCIENTIFIC INVESTIGATION AND DESIGN CONTROL

3.1 Preparation of Planning Documents

3.1.1 Prior to the start of any scientific investigation or design activity, the responsible Task Leader will prepare a planning document for that activity. For Performance Assessment or Design activities, that planning document will be the Work Plan for the Work Breakdown Structure element involved. For scientific investigations categorized as site-characterization activities as defined in the National Waste Policy Act (as amended), Study Plans shall be utilized as the scientific investigation planning document. In both cases, the planning documents shall contain or reference the following, as a minimum:

- A description of the work to be performed and the proposed methodology for accomplishing the work including a discussion of the overall purpose for the work. References to any applicable regulations, requirements, performance criteria, key issues, issues, information needs, or higher level planning documents, for which the work is to be performed. This discussion will identify all of the factors and concerns which are important for the planning or the performance of the work.

- A description of any previous work which will be used in support of the WBS element or study activities, including the identification of the QA levels or QA controls under which that previous work was performed. (Note: this requirement does not apply to study plans.)

- A description of the work which is to be performed in the WBS element. This description will include or will reference the following, as may be appropriate:

- The methods, procedures, equipment, and computer codes which will be used or must be developed for the work.

- Any pertinent interfaces between this work and any other work, including all data, information, and item inputs from other work to this work, and all data, information, and item outputs from this work to other work.

- The products of the activity which will be produced, if applicable.

3.1.2 The planning document (Work Plan or Study Plan) will contain sufficient information such that an independent reviewer can determine the adequacy of the plan and the

appropriateness of the QA Level assignments to meet the stated purposes of the work.

3.1.3 For site-characterization activities, the purpose and key milestones of Study Plans are described in the SCP. The format and content of Study Plans shall meet the requirements of Appendix K.

3.2 Assignment of Quality Assurance Levels

3.2.1 Concurrent with the development of the planning document, the Quality Assurance Levels for all of the activities and tasks which are associated with it shall be assigned. (It may be necessary to assign or reassign QA Levels to items or activities specified in a plan prepared earlier. Therefore, QA Level assignment documents are not a part of the plans, even though they normally accompany them for review and approval.) The Quality Assurance Levels will be assigned in accordance with a procedure that satisfies the requirements specified in Yucca Mountain Project APs.

3.3 Review and Approval Process for Planning Documents

3.3.1 The SNL NWRT Department will conduct a technical review of the Work Plan or Study Plan. This review shall be performed by any qualified individual(s) other than those who developed the original plan. The originator's immediate supervisor can perform the review if the supervisor is the only available technically qualified individual and if the need is documented and approved in advance with the concurrence of the QA Coordinator. The results of this technical review and the resolution of any comments by the reviewer(s) shall be documented and shall become a part of the QA records.

3.3.2 The scientific investigation planning document will then be forwarded to the YMPO Project Quality Manager (PQM) for a technical, QA, and management review and approval by the appropriate Branch Chief and the PQM prior to implementation. Study plans shall also be reviewed and approved by OCRWM prior to implementation.

3.3.3 All technical changes in the scientific investigation planning document shall go through the same review and approval process as specified above. The SNL NWRT Department shall evaluate the impacts of such changes on the associated QA Level assignments.

3.3.4 A peer review of the scientific investigation planning document will be conducted when deemed necessary by YMPO.

3.4 Scientific Investigation Data Interpretation and Analysis

3.4.1 Interpretation/Analysis Documents

Interpretation/analysis shall be performed in a planned, controlled, and documented manner. 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. 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.

3.4.2 Documentation of Interpretation/Analysis

Documentation of interpretation/analysis shall include the following:

- 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 bases of application to the specific problem.
- Signatures and dates of review and approval by appropriate personnel.

3.5 Use of Computer Programs

Computer programs that are used for QA Level I and II analyses in scientific investigations or design shall be documented, controlled, and certified consistent with applicable and appropriate aspects of Subpart C and Appendix H of this QAPP. Documentation shall be consistent with guidance in NUREG-0856.

3.6 Peer Reviews

The SNL NWRT Department shall institute a peer review process, when applicable, to provide adequate confidence in the work being reviewed. Requirements for peer reviews are contained in Appendix J.

Subpart A: Scientific Investigation Control

3.7 Experiment Control

3.7.1 Experiments are conducted to establish characteristics or values not previously known. All experiments, regardless of QA Level, will be performed under controlled conditions and conducted in accordance with a procedure by qualified personnel.

3.7.2 Requirements for the use of Experiment Procedures, Technical Procedures, and Experiment Logbooks, including content, format, and responsibilities for implementation will be specified in implementing procedures. These documents incorporate requirements to assure that work is performed in accordance with written procedures, that all prerequisites have been met, that adequate instrumentation is available and used, that work is performed under suitable environmental conditions, and that results are documented and evaluated to assure that the requirements have been satisfied.

3.7.3 Documentation

Documentation which will be used for the control, quality assurance, and recording of experiments and research are Experiment Procedures, Technical Procedures, scientific notebooks, and other appropriate data recording forms and media. Procedures will be developed in accordance with requirements given in Section 5.0 and will be reviewed in accordance with this section. Modifications may be made to the technical aspects of Experiment or Technical Procedures by the PI utilizing the procedure. However, if the change or modification is not within the scope of the Study Plan, and if the investigation is not repeatable or the changes could potentially impact the waste isolation of the site or interfere with other site-characterization activities, all approvals required for the original procedure shall be obtained.

3.7.3.1 Experiment Procedures

Experiment Procedures will be prepared to provide instructions for the conduct of research efforts, regardless of QA Level of the activity (including QA Level III). However, these Experiment Procedures may vary in content and detail based on QA Level and

"maturity" of the research effort (Experiment Procedures for preliminary, scoping efforts are expected to be less specific than such procedures to be used for determination of parameter values intended to directly support licensing or for cases where it is not possible to deviate from a strict sequence of actions without endangering the validity of the results of the work).

Experiment Procedures for initial, scoping research may address such topics as the objective of the effort, the general approach, and the equipment to be utilized. During the conduct of the scoping effort, then, the investigator will record the actions taken, decisions made, and results achieved. Such documents are termed interactive procedures. Data gathered during such procedure development shall be clearly marked as to the circumstances of its collection, including a notation that such data is not to be used for inclusion in Project technical data bases.

Experiment procedures utilized for QA Level I or II scientific investigations shall provide for the following as appropriate:

- Requirements, objectives, methods, and characteristics to be tested or observed.

- Acceptance limits, if applicable, contained in applicable documents, including precision and accuracy.

- 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 provisions shall be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions are 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. 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 procedure.)

- 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.

Procedures shall be complete to the extent that another qualified individual may, at a later date, reproduce the results.

The potential sources of uncertainty and error in technical implementation procedures which must be controlled and measured to assure 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/instrumentation configuration, installation, and use that can further reduce risk of undetectable failure or malfunction.

Any procedural deviations or nonconformances, encountered during activities shall be documented, reported, and evaluated for significance.

3.7.3.2 Technical Procedures

Experiment Procedures will be supported by Technical Procedures when such procedures are necessary or appropriate to guide the use of laboratory or field data collection equipment or systems, to conduct standard measurement activities, or to guide standard data-collection-related processes (e.g., field sample collection to assure representativeness and/or randomness).

3.7.3.3 Format for Documentation

Documentation of scientific work, i.e., experiments and research, will be performed using bound logbooks or notebooks or other appropriate documents to provide a written record of the experiment

or research. This documentation shall be sufficient such that another qualified scientist or engineer can use the documents to retrace the investigation and confirm the results, or repeat the experiment and achieve the same results, without recourse for the PI.

3.7.3.3.1 Initial Entries

Prior to initiation of the experiment or research, the following entries, as a minimum, will be made:

- Title of the experiment or research (Experiment Procedure title and ID).
- Name of the qualified individual(s) performing the experiment or research.
- Description of the experiment's objective or objectives.*
- 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.*
- 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.*

* Not required to be entered in logbook, notebook, or data forms if completely stated in Experiment or Technical Procedure.

3.7.3.3.2 In-Process Entries

Entries to be made during the experiment or research, daily or as appropriate, will be sufficiently detailed so that another competent experimenter/researcher could repeat the experiment or research, and shall include:

- Date and name of individual making the entry.
- Actions taken to assure prerequisites have been met.
- Description of the experiment or research attempted, including detailed step-by-step process followed: either by reference to implementing procedure or by actual entry into the notebook.
- Description of any conditions which 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 prescribed by Paragraph 3.7.3.3.1 of this section.
- All data taken and a brief description of the results, to include notation of any unexpected results.
- Any deviations from the planned experiment or research.
- Any interim conclusions reached, as appropriate.

3.7.3.3.3 Final Entries

The final entries in the research record will have, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer. Final results and a summary of the outcome of the experiment will be provided in the resulting technical report, which will be cross-referenced to the experiment identification and entered into the SNL YMP Records Management System. These final results shall include a discussion of whether the experiment's objectives were achieved.

3.7.3.3.4 Scientific notebooks and other data records shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section 17.0.

3.7.4 The primary products from the scientific investigation process will be technical reports published by SNL; see Section 6.0 concerning controls on the approval and release of such reports. Additional products of these efforts will be data and information in the Project Technical Data Bases (the Reference Information Base and Site Engineering Properties Data Base).

3.8 <u>Interface Control</u>

3.8.1 Coordination

Interface controls will 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 in interfaces. 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 YMPO. Interfaces between SNL and its suppliers will be controlled in accordance with procedures established by this organization.

Ongoing field or laboratory scientific investigations shall be identified to preclude inadvertent interruption and to ensure operational compatibility. Such identification shall be clearly evident at the location at which the scientific investigation is being performed. Field investigations shall identify the location of the investigation.

3.8.2 Transmittal

The transmittal of information or items, including samples of natural or man-made materials, across interfaces shall be documented.

3.9 Verification of Scientific Investigations

3.9.1 Verification Planning

Planning for verification activities shall be accomplished and documented via verification procedures, instructions, or checklists. Verification procedures, instructions, or checklists 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).
- Recording identification of the verifier and the results of the verification.

3.9.2 Verification Hold Points

Mandatory verification hold points shall be established as necessary. When such hold points are established, work may not proceed beyond them without the specific consent of the responsible representative. 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.

3.9.3 Reporting Independence of Personnel

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. If these personnel are not part of the 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 processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. When these persons or organizations who perform the verification activities are not part of the QA organization, then the Quality Assurance organization shall overview and monitor the verification activity.

3.9.4 Close-Out Verification of Scientific Investigation Records

A close-out verification shall be performed upon the completion of each scientific investigation to assure that the QA records for that investigation are adequate and complete. Close-out verifications will be performed by the Data Records Management System Coordinator or other qualified individual who is equally knowledgeable in the operation of the SNL YMP Data Records Management System.

<u>Subpart B: Design Control</u>

3.10 <u>General</u>

3.10.1 The design will be defined, controlled, and verified. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This

includes general plans and detailed implementing procedures for data collection and analyses and related information such as test results and analysis. The data collection activities result from scientific investigations and produce design input. 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.

3.10.2 It is the policy of the Yucca Mountain 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. 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. 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.

3.10.3 Peer Review

For design activities 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. The peer review shall meet the requirements of Appendix J.

3.11 Design Input Requirements

3.11.1 Identification/Review/Approval of Input

Applicable design input, such as design bases, site-characterization data, performance and regulatory requirements, codes, standards, manufacturer's design data and quality standards, will be identified, documented and their selection reviewed and approved by the design organization and QA. The purpose of the review by the design organization is to determine if the input is appropriate and correct for use in the design of a particular system, structure, or component. 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 and that quality, inspection, or testing codes or standards required by the design are included as inputs. 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. Considerations for design inputs as they apply to specific items or systems are contained in Appendix J.

3.11.2 Changes to Design Input

Changes to approved design input, including the reason for the changes, will be identified, documented, approved, and controlled in accordance with a procedure.

3.12 Design Analysis Requirements for QA Level I & II Design Activities

3.12.1 Design Analysis Documents

Design analysis will be performed in a planned, controlled, and documented manner. 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. 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.

3.12.2 Documentation of Design Analysis

Documentation of design analysis shall include the following:

- Definition of the objective of the analysis.
- Definition of design input and their sources.
- A listing of applicable references.
- Results of literature searches or other background data.
- Identification of assumptions and indication of those which 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.

- Signatures and dates of review and approval by appropriate personnel, including QA personnel. The purpose of this QA review is to assure that the design analysis documentation is prepared, reviewed and approved in accordance with documented procedures and QA requirements.

3.13 Design Verification Requirements for QA Level I and II Design Activities

3.13.1 Identification/Documentation

Design control measures will be applied to verify the adequacy of design. The SNL NWRT Department will identify and document the verification method used, the results of the verification, and the verifier.

3.13.2 Timing of Verification

Verification of the adequacy of design will be performed prior to release for procurement, manufacture, construction or release to another organization for use in other design activities. In those cases where this timing cannot be met, the portion(s) of design which have not been verified shall be identified and controlled. In all cases, the verification will be completed prior to relying on the component, system, or structure to perform its function.

3.13.3 Extent of Verification

The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process as herein described, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, will be verified for each application. Known problems affecting the standardized or previously proven designs and their effects on other features will be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

3.13.4 Changes to Verified Designs

Changes to previously verified designs will require verification, including evaluation of the effects of those changes on the overall design (see also paragraph 3.14).

3.13.5 Personnel Performing Verification

Design verification shall be performed by any competent, qualified individual(s) or group(s) other than those who performed the original design. This includes:

- Individual(s) or group(s) from the originator's same organization.
- Individual(s) or group(s) from other organizations contracted for this purpose.
- 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 a singular design approach or rule out certain design considerations.
- The rationale for satisfying the two requirements above is documented and approved by management superior to the supervisor and by the QA Coordinator.

3.13.6 Methods of Design Verification

Design verification will be accomplished by any one or a combination of the following: design reviews, alternate calculations, qualification testing, or peer review.

3.13.6.1 Design reviews are detailed critical reviews to provide assurance that the design is correct and satisfactory. At a minimum, all items below will be considered during the review and the results of such deliberations shall be documented.

- 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 are they verified in accordance with the methods specified in Subpart C of this section?

3.13.6.2 Alternate calculations are a form of analysis which may be used to determine the adequacy of the original analyses. The use of alternate calculations shall include the review of assumptions, inputs and computer programs, when applicable.

3.13.6.3 Qualification tests that involve actual physical testing of systems, structures, or components may be used to verify the adequacy of design. Where design adequacy is to be verified by qualification tests, the tests will be identified and the test configuration will be clearly defined and documented. Testing will demonstrate adequacy of performance under conditions that simulate the extremes of the design envelope. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the design envelope. Where the test is intended to verify only specific design features, the other features of the design will be verified by other means. Test results will be documented and evaluated in accordance with procedures to ensure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification will be documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mockups, scaling laws will be established and verified. The results of model test work will be subject to error analysis, where applicable, prior to use in the final design work.

3.13.6.4 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.

3.14 <u>Design Change Control Requirements for QA Level I and II Design Activities</u>

Changes to approved designs, including field changes, will 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 YMPO will designate a new responsible organization. The designated organization will have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design. Errors and deficiencies in approved design and design information documents will be documented, and action taken to assure that all errors and deficiencies are corrected. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure will be reviewed and modified, as necessary.

3.15 Design Interface Control Requirements for QA Level I and II Design Activities

3.15.1 Identification/Responsibility

Internal and external design interfaces will be identified and design efforts will be coordinated among and within participating organizations. Interface controls will 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 involving design interfaces.

3.15.2 Information Transmitted Across Interfaces

Design information transmitted across interfaces will be documented and controlled. Transmittals shall identify the status of the design information provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal will be confirmed promptly by a controlled document.

3.16 Design Output Document Requirements for Quality Level I and II Design Activities

Design output documents will:

- Relate to the design input by documentation in sufficient detail to permit design verification/evaluation.
- Identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a

commercial grade item that, prior to its installation, 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 will be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

- 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. As a minimum, the review and approval cycle will include a technical review (i.e., design verification or evaluation) and a QA review (to assure that the design outputs were prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements).

3.17 <u>QA Records Requirements for Design Documents (Quality Level I and II Design Activities)</u>

Design documentation, including design inputs, analyses, drawings, specifications, approved changes thereto, evidence of design verification/evaluation, and records confirming interface control will be controlled, stored, and maintained as quality assurance records.

<u>Subpart C: Software Quality Assurance</u>

3.18 <u>Computer Software Control</u>

3.18.1 For a geologic repository, computer software used to perform analysis in support of the 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 analysis software shall be controlled at a level commensurate with the complexity of that software. In addition, the degree of control exercised over software will vary based on whether the software is obtained commercially or developed "in-house." Where commercial auxiliary software is used, all available documentation that provides evidence of their software QA efforts shall be obtained from the software supplier. Supplemental, detailed guidelines and requirements for the development, maintenance, security, and application of computer software based on the life-cycle model are contained in Appendix H of this QA Plan.

3.18.2 Software shall be placed under configuration management when software baseline items are approved, at the appropriate phase of the software lifecycle, but no later than prior to validation or

use for analysis. Software 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.

3.18.3 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 software, required action is documented, and the information concerning approved changes is transmitted to all affected organizations. Changes to computer software shall be subject to the same degree of verification and validation as the original software.

3.18.4 Testing of software, including new or modified software, shall be performed for those inputs and conditions necessary to exercise the software, 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 highest probability of detecting the most errors in order to identify under what conditions the software does not perform properly.

3.18.5 Except as allowed below, verification of computer software shall be performed prior to 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. It is desirable that model validation be completed prior to code use also. However, in those cases where this requirement cannot be met, the software which has not been verified or validated shall be identified and controlled. In all cases, the verification and validation of software shall be completed prior to relying on the software to support the license application.

3.18.6 Verification procedures shall assure to a reasonable extent 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.

Validation procedures shall assure to a reasonable extent that the model embodied in a computer code is a correct representation of the process or system which it is intended to represent.

3.18.7 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 degree of compliance with the requirements of this section. 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.

3.18.8 This organization shall prepare a description of the software design, test, and configuration management system and submit it to the Yucca Mountain Project Office for review and approval. The description shall:

- Provide criteria for application of the requirements of this section based on the complexity and importance of the software used to perform analysis in support of the design of a geologic repository.
- Indicate the methods to be used to develop computer program requirements, to translate those requirements into a detailed design, and to implement that design in executable code.
- 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.

3.18.9 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 this organization's general software QA plan.

3.19 Documentation of Computer Software

3.19.1 Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. This requirement may be met in part by existing documentation if properly referenced and related to the NUREG-0856 requirements. Appendix H provides detailed requirements on the content of the documentation for scientific and engineering software and other computer software used on the Yucca Mountain Project.

Software QA documents are considered to be QA Records and are subject to the requirements of Section 17 of this QA Program Plan.

3.20 Software Configuration Management

The SNL NWRT Department shall institute a software configuration management program appropriate to the projects conducted and shall provide documentation of this program to the Records Management System (RMS). The minimum requirements for this configuration management program shall be: (1) the inclusion of a unique identification, including software version numbers whenever feasible, in the output; (2) listings of the software; and (3) a brief chronology of the software versions, including descriptions of the changes made between versions.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Basic Requirements (applicable to all Quality Levels, except as noted)

Measures have been 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 Yucca Mountain Project. Procurement documents will be prepared, reviewed, approved, and issued in accordance with written procedures and policies established by this organization and the SNL Purchasing Organization.

4.1.1 Procurement Document Content

The SNL NWRT Department will assure that Purchase Requisitions and Requests for Quotes (RFQs) contain the following as deemed necessary:

- Statement of Work - Statement of the work to be performed by the supplier.

- Technical Requirements - Inclusion or reference to applicable and appropriate technical requirements, specifications, drawings, regulatory requirements, design or site investigation bases, data criteria, etc., including revisions thereto, that describe or specify the items or services to be provided.

- QA Requirements - Applicable and appropriate QA requirements for contractors and sub-tier contractors. Such contractors for QA Level I or II procurements shall be required to have a documented QA Program that is consistent with all, or appropriate portions of, the requirements of the YMP QA Plan.* Such QA Program documents will be reviewed and approved by this organization prior to the initiation of activities specified by the contract. Those which do not adequately define QA requirements, as judged by the QA representative of SNL, shall be corrected prior to initiation of activities. The extent of the QA Program required will depend upon the type and use of the item or service being procured and the QA Level of the item or activity. Procurement documents will require the contractor to incorporate appropriate QA Program requirements in sub-tier procurement documents. 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).

*It will not be required of contractors that their QA Program Plans address Peer Reviews, Readiness Reviews, or permanent storage of QA records. These topics will be controlled at the SNL or Project office organizational level.

- Documentation Requirements - Specification of reports, documentation, and submittal dates/times required by SNL. When specific QA records are required, their retention time and disposition requirements will be specified in accordance with Section 17.0. These requirements will be reflected at all tiers of procurement.

- Nonconformance Requirements - Purchasers' requirements for reporting and approving disposition of nonconformances.

- Acceptance and Inspection Criteria - Acceptability criteria applicable to purchased end-product hardware and equipment or the performance criteria applicable to purchased services.

- Right to Access - A statement that specifies that SNL personnel, appropriate YMPO personnel, or other YMPO-authorized representatives shall have access to facilities and quality records for audit purposes at each tier of procurement, all access to be arranged by SNL.

- Spare and Replacement Parts (QA Level I only) - Where major end items will be procured for which it is deemed necessary to maintain a stock of spare and replacement parts, the procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the delineation of the technical and quality-related data that are required for ordering these parts or assemblies. The technical and quality requirements shall be equal to or better than the original. 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. This evaluation shall address the interchangeability, function, and safety of the item and shall be documented.

4.1.2 Procurement Document Review - A review of procurement documents and changes thereto will be performed 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. The review will be performed and documented prior to contract award; Procurement document reviews will be performed by personnel who have access to pertinent information and who have adequate understanding of the requirements and intent of the procurement documents. The review will include, as a minimum, the cognizant technical organization and QA organization.

4.1.2.1 The SNL NWRT Department QA personnel will be responsible for review and approval of procurement documents (Purchase Requisition and RFQ's) to assure that:

- Topics listed in 4.1.1 are addressed, as applicable.
- Stated QA requirements are complete, correctly stated and appropriate as required by this QAPP and applicable procedures, inspectable, and controllable.
- The procurement documents have been prepared, reviewed and approved in accordance with stated requirements.

4.1.3 Procurement Document Changes

4.1.3.1 Procurement document changes shall be subject to the same degree of control, including reviews and approvals, as utilized in the preparation and processing of the original document.

4.1.3.2 Review of changes shall address the following:

- For all changes, the requirements of paragraph 4.1.2.1.
- For changes requested by the contractor or subcontractor that necessitate changes in design or site investigation criteria, the effects of such changes on the intent of the procurement documents or on the quality of the item or service to be furnished shall be determined and analyzed. For QA Level I procurements this analysis shall be completed and documented prior to contract award, for changes requested and incorporated during contract negotiations, or prior to implementation by means of contract changes, for changes requested after contract placement.

4.1.4 The SNL NWRT Department personnel responsible for the contracted tasks will assure, before technical work begins, that any required contractor QA Program is approved by this organization.

4.1.5 Management approvals for all purchase requisitions involving quality considerations will not be authorized until QA approval is obtained.

4.1.6 The SNL Purchasing Organization, as the only authorized contracting authority, is responsible for assuring that all purchasing policies and procedures for processing contract documents are carried out.

4.2 Distribution of Procurement Documents

SNL will forward to the T&MSS Project QA Department (QA Verification Division Manager) a copy of procurement documents, and changes thereto, as issued, when purchases involve QA Level I items or services. Only those procurement documents which identify the vendor, describe the scope of work and detail when work is to start, are required to be submitted.

5.0 INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

5.1 Activities affecting quality on the Yucca Mountain Project will be performed utilizing clear, complete, approved written instructions, procedures, drawings, or other documents. These documents will include or reference appropriate quantitative or qualitative acceptance criteria in cases where such acceptance criteria for determining that prescribed activities have been satisfactorily accomplished are appropriate. Each instruction or procedure shall identify QA records which are generated during implementation of the procedure. These documents will be controlled as required in Section 6.0 of this QAPP.

5.1.1 An independent review of all such instructions, procedures, plans, and drawings shall be performed by the originating organization to assure technical adequacy and inclusion of appropriate quality requirements. In those cases where the activities prescribed are not repeatable or have the potential to impact the waste isolation capability of the site or to interfere with other site-characterization activities, the review shall consider whether these considerations are adequately addressed or controlled.

5.1.2 QA implementing procedures will provide instructions for implementation and application of this QAPP. These QA implementing procedures are issued and controlled by the QA organization and apply to all applicable technical programs; see Appendix B for a listing of the QA implementing procedures.

5.1.3 Instructions for the control of scientific notebooks, plans, procedures, and other documentation that will be used in scientific investigations will be included in QA implementing procedures. (See Section III of this QAPP.)

5.1.4 Drawings will be produced in accordance with procedures that specify a systematic method for initiating, checking, approving, and issuing such drawings and controlling changes to those drawings.

5.2 Principal Investigators are individually responsible for ensuring that they have obtained approved documentation to perform their assigned tasks prior to initiation of those tasks. Instructions, procedures, and drawings (if applicable) will be used at the work location.

5.3 For QA Level I and II activities, a controlled distribution copy of all implementing procedures, plans, and instructions will be sent to the YMPO PQM and the T&MSS Project QA Department Manager.

6.0 DOCUMENT CONTROL

6.1 Department 6310 will maintain control of documents which specify quality requirements, or prescribe the conduct of activities affecting quality to ensure that the latest approved revision is in use by personnel of organizations performing work on the Yucca Mountain Project. Such control, expressed in a written procedure, will be maintained by:

- identification of those documents to be controlled;
- review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements prior to approval and issuance;
- limited, known distribution of those documents;
- distribution of revisions to the same list as originals;
- review and approval of revisions by the same organizations or personnel that approved originals;
- establishment of authority for document approval, review, and release for distribution; and
- removal of superseded documents from use.

6.2 A Master Document List shall be maintained to identify the current revision of controlled documents. Each current list will be sent to the YMPO PQM and the T&MSS Project QA Department Manager. It will be the document user's responsibility to ensure that the current version of a document is in use at the work location. It will additionally be the document holder's responsibility to discard superseded portions of documents upon receipt of updated revisions or to mark and control those superseded portions to preclude inadvertent use.

6.3 For documents to be published which report the results of scientific investigations or design efforts (Sandia reports, technical journal articles, conference papers) SNL will conduct a structured technical and editorial review in accordance with documented procedures (that contain specific criteria for the performance of the technical review) to ensure that these product documents are adequate, complete, correct, and ready for issue. These procedures will provide for assignment of review responsibilities and include YMPO review and approval for official SNL YMP publication.

6.4 Interface documents and documents that are designated for baseline control will be developed and controlled in accordance with QA implementing procedures and as specified in the Systems Engineering Management Plan or the YMP Administrative Procedures.

6.5 Changes to documents, other than those determined to be minor changes, are considered as major changes and will be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated by the organization responsible for the documents. The reviewing organization will have access to pertinent background data or information upon which to base their approval. In those cases where the activities prescribed are not repeatable or have the potential to impact the waste isolation capability of the site or to interfere with other site-characterization activities, the review shall consider whether these condsiderations are adequately addressed or controlled.

6.6 Minor changes to documents such as inconsequential editorial corrections do not require that the revised documents receive the same review and approval as the original documents. The authority to determine whether or not a proposed change is minor is delegated to the QA Coordinator. To avoid a possible omission of a required review, the QA Coordinator will review proposed minor changes and will approve such changes when appropriate.

6.7 The document control system will 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 as described in paragraph 6.1 of this section.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 Basic Requirements

Measures shall be established to ensure that purchased material, equipment, and services conform to the procurement documents. 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 source, and examination of products upon delivery. 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 and/or equipment is to be used prior to installation or use of such material and equipment. This documentary evidence shall be retained under the control of the YMP QA Records Management System 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.

7.2 Specific Requirements for Procurements in Support of QA Level I and II Activities

7.2.1 Commercial-Grade Items

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 7.2.1.2 and the requirements of Section 4.0 of this QAPP. If a scientific investigation requires commercial-grade items, they may be controlled by use of the following requirements (except paragraph 7.2.1.1) and Section 4.0.

7.2.1.1 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 output document. An alternate commercial-grade item may be supplied if the requester determines 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.

7.2.1.2 Source evaluation and selection, if it is determined necessary by this organization based on the complexity and importance to safety, shall be in accordance with 7.2.3.

7.2.1.3 Commercial-grade items shall be identified in the purchase order by the manufacturer's published product description (for example, the name and catalog number).

7.2.1.4 After receipt of a commercial-grade item, the purchaser (the requester) shall determine that the following conditions have been met:

- Damage was not sustained during shipment.
- The item received was the item ordered, in the proper quantity.
- Inspection and/or testing is accomplished by the requester, in accordance with written procedures, as deemed necessary, 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 12.0.
- Documentation, as applicable to the item, was received and is acceptable.

7.2.2 Procurement Planning

7.2.2.1 Procurement activities shall be planned and documented to ensure a systematic approach to the procurement process. Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities. Appropriate QA organization participation shall be provided for evaluation and selection of suppliers, verification of suppliers activities and receiving inspections. Planning shall determine:

- What is to be accomplished.
- Who is to accomplish it.
- How it is to be accomplished.
- When it is to be accomplished.

7.2.2.2 To ensure interface capability and a uniform approach to the procurement process, planning shall be accomplished as early as practicable and no later than at the start of those procurement activities that are required to be controlled.

7.2.2.3 Planning shall result in the documented identification of the methods to be used in procurement activities, the sequence of actions and milestones that indicate the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed as follows. Planning shall provide for the integration of the following:

- Procurement document preparation, review, and change control.
- Selection of procurement sources.
- Bid evaluation and award.
- Control of supplier performance by the SNL NWRT Department.
- Verification (Surveillance, inspection, or audit) activities including notification of hold-and-witness points.
- Control of nonconformances.
- Corrective action.
- Acceptance of item or service.
- QA records.

7.2.3 Source Evaluation and Selection

Those suppliers to be solicited for quotations on a particular procurement will be selected by the Sandia Contracting Representative (SCR) in the Sandia Purchasing Organization in accordance with current SNL Purchasing Instructions. The SCR's selection of suppliers shall be based on an evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents before the award of the contract. Measures for the evaluation and selection of procurement sources, which may be used by the SCR, include the following:

- The requests of the initiator of the procurement.
- Advertised capabilities of suppliers.
- The SCR's personal knowledge of suppliers' performance histories and capabilities.
- The supplier's history of providing an identical or similar product that performs satisfactorily in use. The supplier's history shall reflect current capability.

- The supplier's current quality assurance records supported by documented qualitative and quantitative information that can be objectively evaluated.

- The supplier's technical and quality capability as determined by a direct evaluation of his facilities and personnel and the implementation of his quality assurance program.

7.2.4 **Bid Evaluation**

7.2.4.1 Bid evaluation shall determine the extent of conformance to the request for quotations. This evaluation shall be performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:

- Technical considerations.

- QA requirements.

- Supplier's personnel.

- Supplier's production capabilities.

- Supplier's past performance.

- Alternates.

- Exceptions.

7.2.4.2 Before the award of the contract, resolutions or commitments to resolve unacceptable quality conditions resulting from the bid evaluation shall be obtained from the potential contractor.

7.2.5 **Supplier Performance Evaluation**

7.2.5.1 It is the policy of this organization that purchased materials, equipment, or service fully adhere to procurement document requirements when delivered or provided. Measures shall be established to communicate with the supplier and to verify supplier's performance, as deemed necessary by the purchaser. The measures shall include the following:

- Establishing and documenting an 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.

- Reviewing supplier documents that are generated or processed during activities fulfilling procurement document requirements.

- Identifying and processing necessary change information.

- Establishing methods of document/information exchange between purchaser and supplier.

- Establishing the extent of source surveillance and inspection activities. Note: If this organization utilizes another Participating Organization and/or NTS Support Contractor to perform YMP activities for which we are responsible, this organization may initiate a request to YMPO to conduct YMPO surveillance of the organization performing the work. The surveillance would be conducted to determine that the item or activity is being produced or performed in accordance with SNL requirements. These surveillances may utilize NTS Support Contractor personnel or personnel from this organization as technical advisors.

7.2.5.2 These verification activities shall be conducted as early as practicable. However, such verification activities shall not relieve the supplier of his responsibilities for verification of quality achievement.

7.2.5.3 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. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the supplier's activities.

7.2.5.4 Activities performed to verify conformance to requirements of procurement documents shall be recorded. Source surveillances and inspections, audits, 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 17.0.

This documentation will be evaluated to determine the supplier's QA Program effectiveness.

7.2.6 **Control of Reports Generated by Suppliers**

Deliverable reports that are generated by suppliers shall be controlled, handled, and approved in accordance with documented procedures. Means shall be implemented to ensure that the submittal of these documents is accomplished in accordance with the

procurement document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.

7.2.7 Control of Changes in Procured Items or Services

SNL shall ensure that measures to control changes in procurement documents are established, implemented, and documented and are in accordance with this document. SNL shall ensure that contractors are required to ensure that measures to control changes in their sub-tier procurement documents are established, implemented, and documented and are consistent with NNWSI/88-9, as appropriate to the procurement.

7.2.8 Acceptance of Item or Service

7.2.8.1 General - Methods are established for acceptance of an item or service being furnished by a supplier. However, the supplier shall be required to verify, prior to offering the item or service for acceptance, that the item or service being furnished complies with the procurement requirements. If it is required by the code, regulation, or contract requirement, then documentary evidence that items conform to procurement documents shall be available at the repository site before installation or use.

7.2.8.2 Methods of Acceptance - 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, a post-receipt test, or a combination thereof. Requirements applicable to these methods of acceptance are listed below.

Certificate of Conformance - When a certificate of conformance is used, the following minimum criteria shall be met:

- 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.

- The certificate shall be attested to by a person who is responsible for the quality assurance function and whose function and position are described in the supplier's QA Program.

- When the purchased material or equipment is reviewed for acceptance by Sandia, the requester will verify that the certificate of conformance meets the requirements specified herein.

- 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 this organization at intervals commensurate with the supplier's past quality performance.

Source Verification - 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. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.

Receiving Inspection - 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 activities and the demonstrated quality performance of the supplier. Receiving inspection shall be performed in accordance with established procedures, supplemented in certain cases by inspection instructions, to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; cleanliness, and proper quantity.

Receiving inspection shall be coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

Receiving inspections associated with engineered items shall be planned, performed, and documented in accordance with the requirements specified in paragraphs 10.2.2.1, 10.2.4, 10.2.6.2, and 10.2.7.1 of this document. Personnel selected to such receipt inspection activities shall have the experience or training

commensurate with the scope, complexity, or special nature of the activities. 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.

Post-Receipt Testing - When post-receipt testing is used, post-receipt test requirements and acceptance documentation shall be established mutually by both this organization and the supplier.

Acceptance of Services Only - In certain cases involving procurement of services only, such as third-party inspections, engineering and consulting; and installation, repair, overhaul, or maintenance work, the service shall be accepted by either any or any combination of the following methods:

- Technical verification of data produced.
- Surveillance and/or audit of the activity.
- Review of objective evidence for conformance to the procurement document requirements such as the results of the work itself, e.g., reports or documents generated, certifications, etc.

7.2.9 Control of Supplier Nonconformances

7.2.9.1 Supplier nonconformances identified during receipt inspection or post-receipt testing will be controlled in accordance with Section 15.0, and Sandia Laboratories Instructions concerning "Deviation from Requirements" in purchases.

7.2.9.2 Suppliers will be required to establish and document methods for disposition of items or services that do not meet procurement document requirements. These methods shall provide for:

- Evaluation of nonconforming items.
- Submittal of nonconformance reports to this organization by the supplier as directed by SNL. These submittals shall include the supplier-recommended disposition (e.g., use as-is or repair) and technical justification for that disposition. Nonconformances to the procurement requirements or SNL-approved documents that consist of one or more of the following shall be submitted to this organization for approval of recommended disposition:
    - Technical or material requirement is violated.

- Requirement in supplier documents, which has been approved by the purchaser, is violated.
- Nonconformance cannot be corrected by continuation of the original process or by rework.
- 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.

- Purchaser disposition of supplier recommendation.
- Verification of the implementation of the disposition.
- Records of nonconformances that are submitted by the supplier shall be maintained.

Approval of the recommended disposition shall be in accordance with documented procedures.

8.0 IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA

8.1 General

8.1.1 The requirements of this section apply to the identification and control of items, samples, and data. The requirements for items are stated in paragraph 8.2, for samples in paragraph 8.3, and for data resulting from scientific investigations in paragraph 8.4. Requirements for items apply to activities related to engineered items and do not apply to scientific investigations. Requirements for samples and data apply to scientific investigation activities and do not apply to engineered items.

8.2 Identification and Control of Engineered Items

8.2.1 Identification. Engineered items to which QA Levels I or II have been assigned shall be identified to assure that only correct and accepted items are used or installed. The identification shall be verified prior to installation or use. Identification shall be maintained either on the item, their containers, or in documents traceable from receipt until installation.

8.2.2 General. Items of production (batch, lot, component, part) shall be identified from the initial or fabrication of the items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document.

8.2.2.1 Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impracticable or insufficient, physical separation, procedural control, or other appropriate means shall be employed.

8.2.2.2 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. 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.

8.2.2.3 When specified by codes, standards, or specifications 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.

8.2.2.4 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.

8.2.3 Control. 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 records.

8.3 Identification and Control of Samples

8.3.1 A procedure shall be developed and implemented to assure that samples are identified and controlled in a manner consistent with their intended use. This procedure shall define the responsibilities (including interface between organizations) for collection, identification, handling, storage, transportation and the generation of records.

8.3.2 Identification. 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 described and used. 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.

8.3.3 General. Samples shall be identified by placing the identification directly on the sample, on their container or on records traceable thereto. 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.

8.3.3.1 Procedures shall be developed and implemented to assure that sample collection methods, techniques and related equipment produce the intended sample. Sample handling methods shall be developed, documented and utilized to assure that all samples meet the objectives dictated by the scientific investigation, for which the samples are collected.

8.3.3.2 Storage methodology shall be developed and implemented to assure that samples are maintained in predetermined physical conditions commensurate with their intended purpose. Samples intended for

long-term storage shall receive appropriate treatment to assure that they do not degrade during storage. Long-term is not defined herein and shall be defined by the Principal Investigator for individual samples depending on the sensitivity of the samples to storage conditions.

8.3.3.3 Transportation methods shall be described and effected by procedures or instructions prescribing appropriate containers, handling, and any other environmental or safety consideration for the sample(s). Where multiple organizations are involved, appropriate procedures or instructions shall define responsibilities and documentation methods to be used.

8.3.3.4 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.

8.3.3.5 Measures shall be taken to maintain sample identification while in storage. 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. Physical segregation of samples to preclude mixing with like samples shall be used to the maximum degree practical.

8.3.3.6 Where samples are controlled by more than one organization, organizational responsibilities shall be clearly established in procedures developed and implemented for this purpose.

8.3.3.7 Records generated as a result of sample testing shall be handled in accordance with Section 17.0.

8.4 Identification and Control of Data

8.4.1 Identification - Data generated from YMP scientific investigation shall be identified to assist in the determination of its correct use. Identification of such data shall be provided in documents, information systems, or both, in which such data appear.

8.4.2 General - The identification of Yucca Mountain Project data shall include a reference to the origin of the data (test, experiment, report, publication, etc.) and an indication of the QA Level assigned to the activity which produced the data.

8.4.2.1 Control measures shall be established and implemented to assure that Yucca Mountain Project data are properly identified. These measures shall include verification of the identification of such data prior to release for use for data resulting from QA Level I or II activities.

8.4.2.2 Where data are the results of the efforts of more than one organization, the organizational responsibilities for that data will be clearly established, within this organization's authority to do so, in procedures developed and implemented for this purpose. The documentation resulting from the scientific investigation involving more than one organization shall be annotated to show which organization produced what portion of the data.

9.0 CONTROL OF PROCESSES

9.1 General Requirements

9.1.1 The requirements of this section apply to engineered items and scientific investigations for process control. The requirements for special processes apply to QA Level I and II engineered items only. Measures will be established to ensure that processes that affect quality of items or services are controlled.

9.1.2 Special processes that control or verify quality will be accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

9.2 Process Control

9.2.1 All processes affecting quality of items or services will be controlled by instructions, procedures, drawings, checklists, or other appropriate means. These means will ensure that process parameters are controlled, that specified environmental conditions are maintained, and that records are maintained which document the conduct of the activity.

9.2.2 Identification of Special Processes. 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. The portions of this organization's activities involving the use of special processes are those whose results must meet certain specifications, i.e., fabrication and manufacturing activities for engineered items. Welding, heat treating, and nondestructive examination are identified as special processes when the process controls or verifies quality. Field and laboratory experiment activities do not qualify as special processes. The necessary requirements for qualifications of personnel, procedures, or equipment will be specified or referenced in the procedures or instructions either for processes that are not covered by existing codes or standards or for processes where the quality requirements for an item or test exceed those of existing codes or standards.

Conditions necessary for accomplishment of the special process will be included in procedures or instructions. These conditions will include proper equipment, controlled parameters of the special process and calibration requirements. The requirements of applicable codes and standards, including acceptance criteria for the special process, will be specified or referenced in the

procedures or instructions. Organizations responsible for performing work involving special processes will develop written plans for qualification of personnel, procedures, and equipment. these plans will be reviewed by the QA organization for compliance with requirements.

9.2.3 **Qualification of Special Process Procedures.** Such procedures will be qualified in accordance with applicable codes, standards or other specifications. The program for qualification of procedures will be specified in documents prepared by cognizant Department 6310 technical personnel (such as Work Plans). The responsible QA organization will provide appropriate reviews to assure compliance with these requirements.

9.2.4 **Qualification of Personnel Performing Special Processes.** Such personnel will be trained, qualified, and certified in accordance with written procedures. Such training, qualification, and certification is the responsibility of the division or contractor performing the work. These procedures will be reviewed by the responsible QA organization for compliance with requirements. Qualification will utilize the actual working procedure to the extent possible. Where codes, standards or specifications are applicable to the process (e.g., AWS welding standards), the personnel qualifications of those documents will be incorporated in the personnel qualification program.

9.2.5 **Special Process Equipment.** Special process equipment will be checked out, qualified, and certified in accordance with specified requirements implemented in procedures which have been reviewed by the responsible QA organization prior to use in an application that affects quality. These activities will implement the requirements of applicable codes, standards, and specifications. Equipment checkout, qualification, and certification is the responsibility of cognizant technical personnel (e.g., the PI) or the contractor organization performing the work.

9.2.6 Personnel, equipment, and procedure qualification may be conducted concurrently by means of the subject personnel carrying out the subject approved special process procedure using the subject equipment under known, controlled conditions. They will all be considered qualified if the expected results of the process are attained.

9.2.7 **Special Process Records.** Records of currently qualified personnel, procedures, and equipment for special processes will be maintained by organizations who perform such special processes. Special process verification methods and criteria will also be documented and retained. These records will be incorporated in the SNL YMP Records Management System.

10.0 INSPECTION AND SURVEILLANCE

10.1 General Requirements

10.1.1 The requirements of this section apply to the inspection and surveillance required to verify conformance of an engineered item or of an activity, respectively, to specified requirements. The requirements for inspection, applicable to examination or measurement to verify conformance of an item to specified requirements, are stated in paragraph 10.2. The requirements for surveillance, applicable to monitoring or observing to verify conformance of an activity to specified requirements, are specified in paragraph 10.3. Inspections required by this section and audits required by Section 18.0 shall be supplemented by surveillance activities as appropriate.

10.2 Inspection Requirements

These requirements apply only to engineered Q-list items and do not apply to scientific investigation activities.

10.2.1 General

Implementing procedures will 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. The results of all inspection activities shall be documented by the inspecting organization.

10.2.2 Personnel

10.2.2.1 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. 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 processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. 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 overview and monitor the inspection activity.

10.2.2.2 Each person who verifies conformance of items for purposes of acceptance will be qualified to perform the assigned inspections or tests. The qualification of personnel performing inspection and test activities will be certified in writing. Personnel selected to perform inspection and test activities will have the experience or training commensurate with the scope, complexity, or special nature of the activities. Personnel will also be indoctrinated as to the technical objectives and requirements of any applicable codes and standards and the QA program elements that are to be employed. In order to accomplish the above, personnel who perform inspection and testing to verify item conformance to specified requirements for the purpose of acceptance will be qualified in accordance with Appendix C. The qualification of nondestructive examination personnel will be in accordance with Appendix D.

10.2.3 Inspection Hold Points

Mandatory inspection or witness hold-points specified by the Principal Investigator, and approved by the QA organization, will be established as necessary. When such hold or witness points are established, work may not proceed without the specific consent of the responsible representative. These hold or witness points will be indicated in appropriate documents controlling the activity. Consent to waive any specified hold or witness point will be documented before work can be continued beyond the designated hold or witness point.

10.2.4 Inspection Planning and Sampling

Planning for inspection activities shall be accomplished and documented via inspection procedures, instructions, or checklists. Inspection procedures, instructions, or checklists shall provide for the following:

- 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.

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

10.2.5 In-Process Inspection and Monitoring

10.2.5.1 Inspection of items in-process shall be performed for work activities where it is necessary to perform such inspections to verify the quality of the items. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided.

10.2.5.2 Where a combination of inspection and process monitoring 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. Both inspection and process monitoring shall be provided when other techniques cannot provide adequate control.

10.2.5.3 Where required, controls shall be established and documented for the coordination and sequencing of activities at established inspection points during successive stages of the process.

10.2.6 Final Inspection

10.2.6.1 Final inspection will include a records review of the results and resolution of nonconformances identified by prior inspections. The final inspection will be planned to reach a conclusion regarding conformance of the item to specified requirements.

10.2.6.2 Completed items will 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. If not previously examined, quality records will be examined for adequacy and completeness.

10.2.6.3 The item's acceptance will be documented and approved by identified authorized personnel.

10.2.6.4 Modifications, repairs, or replacements of items performed subsequent to final inspection will require reinspection or retests, as appropriate, to verify acceptability.

10.2.7 Records

10.2.7.1 The following are the requirements for records of individual inspections which will be retained in accordance with Section 17.0. As a minimum, inspection records shall identify the following:

- Item inspected
- 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 (i.e., method of inspection)
- Inspection criteria, including identification of drawing, specification, etc. (and applicable revision)
- Equipment used during the inspection
- Evidence as to the acceptability of 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.

10.3 Surveillance Requirements

10.3.1 Surveillances of Yucca Mountain Project site-investigation activities will be scheduled and performed based on the activity's relative impact, its importance, the complexity of the work, or its purpose. Such surveillances shall be conducted in accordance with a procedure prepared by this organization and shall be carried out on either a scheduled or as-needed basis. The timing and number of surveillances will be determined by the QA organization in conjunction with responsible technical parties. Specific requirements applicable to surveillance activities are stated in 10.3.2 through 10.3.5.

10.3.2 These surveillances will be conducted by a team consisting of one or more qualified individuals, except as specified below. These personnel shall either be technical personnel, QA personnel, or both. Qualification of surveillance personnel shall be in accordance with criteria (e.g., education, experience, knowledge of

technical and/or QA requirements) established in an implementing procedure. Surveillance personnel shall not report directly to the immediate supervisors who are responsible for the work to be surveilled.

10.3.3 Surveillances are to be performed to written checklists or surveillance plans whenever practical. These plans or checklists shall identify characteristics, methods, and acceptance criteria shall provide for recording objective evidence of results, and accuracy of the equipment necessary to perform surveillance.

10.3.4 For surveillances of scientific investigations, the surveillance team shall be comprised of one or more qualified technical personnel and one or more QA personnel. The technical member or members of such surveillance teams shall be familiar with the Work Plan for the subject scientific investigation.

10.3.5 As a minimum, surveillance records shall identify the following:

- Activity subject to the surveillance.
- Date of surveillance.
- Name of individual performing the surveillance.
- Identification of the organization(s), activities, or items surveilled, including the name or names of personnel contacted.
- Surveillance criteria. 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."
- Equipment used during the surveillance, if applicable.
- Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance. Nonconformances or deficient activities shall be handled in accordance with the requirements of Sections 15.0 and 16.0, as applicable. Deficiencies and nonconformances identified during surveillances are to be documented and monitored until verification of effective corrective action is completed.
- Results.
- Statement of acceptability or unacceptability of the activity surveilled.

10.4 Records of inspection personnel qualification will be established and maintained by the SNL organization. The actual examinations used to qualify inspectors will also be retained as part of the record files.

11.0 TEST CONTROL

11.1 General Requirements

11.1.1 Tests required to verify conformance of an engineered item or system to specified requirements and to demonstrate that items or systems will perform satisfactorily in service will be planned and executed. Characteristics to be tested and test methods to be employed will be specified. Test procedures will be implemented by trained and appropriately qualified personnel. The requirements of this section apply to engineered items and do not apply to scientific investigation activities.

11.1.2 Test requirements and acceptance or rejection criteria, including required levels of precision and accuracy, will be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated by cognizant SNL technical personnel. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests shall be controlled. Test requirements and acceptance or rejection criteria shall be based on specified requirements contained in applicable design or other pertinent documents.

11.2 Test Procedures

11.2.1 Test procedures will be prepared in accordance with the requirements of Section 5.0 of this QAPP and will specify how the test is performed. QA implementing procedures concerning the preparation of test procedures shall contain criteria for determining when a test is required.

11.2.2 Test procedures will 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. Prerequisites will include the following as applicable: (1) calibrated instrumentation available and operable; (2) other appropriate equipment available and operable; (3) completeness of item to be tested; (4) trained or appropriately qualified personnel available; (5) condition of test equipment and the item to be tested; (6) attainment of suitable and controlled environmental conditions; and (7) readiness for data acquisition and storage.

11.2.3 Test procedures used for these tests will be prepared, reviewed, and approved to ensure that requirements defined in paragraph 3.13 concerning design verification are adequately addressed. They will prescribe mandatory inspection hold points (as required).

11.2.4 As part of test preparation, in order to properly develop and execute test procedures, the potential sources of uncertainty and error in the test process which must be controlled and measured to assure that tests are well controlled will be identified.

11.2.5 Test procedures shall contain instructions concerning how the test is to be performed and methods for documenting test data.

11.3 Alternative Test Procedures

In lieu of specially prepared written procedures, appropriate sections of related documents can be used, such as American Society for Testing and Materials (ASTM) methods, supplier manuals, equipment maintenance instructions, approved drawings, or travelers with acceptance criteria. Such documents shall include adequate instructions to ensure the required quality of work. The use of such documents or parts thereof shall be documented and reviewed to ensure the requirements of paragraph 11.2.2 are met.

11.4 Test Results and Records

11.4.1 Tests results will be documented, including methods of data analysis, and their conformance with acceptance criteria evaluated by a responsible authority (e.g., the Principal Investigator) to assure that test requirements have been satisfied.

11.4.2 Test records will, as a minimum, identify the following:

- Item tested.
- Data of test.
- Tester or data recorder identification.
- Type of observation.
- Results and acceptability.
- Action taken in connection with any deviations noted.
- Person evaluating results.

11.5 Test Personnel Qualification

For acceptance test personnel qualification requirements, see Appendix C of this QAPP.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 General

12.1.1 Measures will 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 period to maintain accuracy within necessary limits, such that measured values are accurate representations of true physical values. The scope of the program for the control of measuring and test equipment includes all such equipment or systems used to calibrate, measure, gage, test, or inspect either to control or to acquire data to verify conformance to specified requirements, or to establish characteristics or values not previously known in activities categorized as QA Level I or II. Principal Investigators may utilize this control system in QA Level III activities.

The responsibilities of the QA organization and technical organizations will be described for the establishment, implementation and assurance that the calibration program is effective.

The methodology for control of measuring and test equipment is described in paragraphs 12.2 through 12.4, below.

12.2 Selection

12.2.1 The selection of measuring and test equipment will 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 Principal Investigator will be responsible for ensuring the adequacy of the equipment.

12.2.2 When deemed appropriate, the type, range, and accuracy, of a measuring device shall be specified or recorded in test, inspection, and data collection documents. Each device shall have a unique identification number. This number shall be recorded on the data sheet, log, etc., along with the measurement taken, to ensure traceability to the measurement of the device that was used to take the measurement.

12.3 Calibration and Control

12.3.1 Calibration - Measuring and test equipment will be calibrated against certified equipment having known valid relationships to the National Bureau of Standards or other nationally recognized standards and will be calibrated, adjusted, and maintained at prescribed intervals. For certain devices, they shall be

calibrated prior, and in certain cases also subsequent, to use. If no nationally recognized standards exist, the basis for calibration will be documented. 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. The management authorized to perform this function shall be identified in implementing procedures.

12.3.2 Control - The method and interval of calibration for each item will be defined, based on the type of equipment, its stability characteristics, required accuracy, intended use, degree of usage, and other conditions that affect measurement control. 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. If measuring and test equipment is found to be out of calibration, an evaluation will be made and documented by the Principal Investigator or his designee of the validity of previous results obtained and of the acceptability of items previously inspected, tested or of data gathered since the last calibration. Devices that are out of calibration will be tagged or segregated and will not be used until they have been recalibrated. If any measuring or test equipment is found to be out of calibration consistently, then it will be repaired or replaced. A calibration will be performed when the accuracy of equipment is suspect.

12.3.3 Non-precision Devices - Calibration and control measures are not required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.

12.4 <u>Handling and Storage</u>

Measuring and test equipment will be handled properly and stored to maintain accuracy.

12.5 <u>Records</u>

Records will be maintained and equipment will be marked suitably to indicate calibration status. Calibration records shall identify the calibration procedure (including revision) utilized to perform the calibration.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 QA Level I and II Requirements

13.1.1 Written procedures shall be prepared and used which provide for the identification, packaging, handling, shipping, preservation, and storage of both sample materials and hardware important to safety, waste isolation, or site characterization. The objective of these procedures is to preclude damage, loss, deterioration by environmental conditions, or substitution of items. Such procedures may be in the form of a QA implementing procedure. When they are required for critical, sensitive, perishable, or exceptionally expensive articles, the Principal Investigator is responsible for preparing specific procedures or instructions that provide for the above activities. These specific procedures and instructions may be included within Purchase Order requirements, Technical Procedures, Shippers, or other work or inspection documents.

13.1.2 When required for particular items, special equipment (e.g., containers, shock absorbers, accelerometers) and special protective environments designed to maintain the characteristics of the items (e.g., inert gas atmosphere, moisture-impermeable coatings, temperature maintenance, etc.) shall be specified and provided, and their existence will be verified.

13.1.3 When determined necessary by the PI, equipment designer or requester to ensure safe and adequate handling, special handling tools and equipment shall be utilized and controlled by operators trained or experienced in their use. If such special handling tools and equipment exist, they will be inspected and tested, appropriate to their use and design, in accordance with procedures and at specified times (e.g., prior to use) to verify that they are maintained adequately.

13.1.4 The PI or requester, as appropriate, will determine the necessity for and specify instructions for marking and labeling for packaging, shipment, handling, and storage in order to identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.

13.2 Requirements for Quality Assurance Level III

13.2.1 Measures may be established at the discretion of the PI, based on the cost, criticality, fragility, perishability, and configuration of items to control the identification, packaging, handling, storage, shipping, cleaning, and preservation of material (including samples) and equipment to prevent damage or deterioration. Such measures may be expressed in Technical Procedures, Shippers, procurement documents, or other work or inspection instructions.

14.0 INSPECTION AND TEST STATUS

The requirements of this section apply to engineered items; they may be applied to scientific investigations at the discretion of the Principal Investigator, Task Leader, or QA Coordinator.

14.1 Indication of Status

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, the status of inspection and test activities shall be identified either on the items or in documents traceable to the items.

14.2 Methods of Indicating Status

Status shall be maintained through indicators, such as physical location and tags, markings, stamps, inspection records or other suitable means. Procedures describing status indicators and their use shall contain actual examples of each type of indicator.

14.3 Application and Removal of Status Indicators

The authority for application and removal of status indicating tags, markings, labels, and stamps shall be specified in procedures governing inspection and test status.

15.0 CONTROL OF NONCONFORMING CONDITIONS

15.1 General Requirements

15.1.1 Measures will be established to control items that do not conform to requirements to prevent their inadvertent installation or use. These measures will include documented procedures for identification, documentation, evaluation, segregation (when practical), disposition, and notification to affected organizations. All personnel involved in Yucca Mountain Project activities are responsible for reporting nonconformances in accordance with established nonconformance requirements listed below. In addition, activities which are carried out in a manner which is not in accordance with requirements, rendering their results potentially unacceptable or questionable, will be similarly controlled.

15.1.2 The requirements of paragraphs 15.2 through 15.9, inclusive, apply to nonconforming QA Level I and II items. The requirements of paragraph 15.10 apply to QA Level III nonconforming items.

15.2 Identification

15.2.1 Identification of nonconforming items will be made by marking, tagging, or other methods that shall not adversely affect the end use of the item. The identification will be legible, easily recognizable, and shall contain the nonconformance report number. The nonconformance report number will be a sequential number preceded by an organizational acronym. If tags are used, they will be securely attached to avoid loss during handling. If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate will be identified.

15.2.2 Work on the nonconforming item will be stopped until completion of the action specified in the nonconformance report disposition. If only a specific portion of the item is in nonconformance, then that specific area will be identified and work may proceed on the remaining areas. If work on a nonconforming item must be continued (conditional release), prior to implementation of the disposition, the TPO and the YMPO shall approve such continuance. Requests for conditional releases on nonconforming items will include documented justification that the following conditions are met:

- The nonconforming item can be removed or corrected at a later date without damage to, or contamination of the associated permanent facility equipment or structures.

- The nonconforming item remains accessible for inspection.
- The nonconforming item is evaluated and limitation(s) for use of the equipment or system is established.
- Traceability and identification of the nonconforming item are maintained.

Requests for conditional release of an activity which involves a nonconformance will include written justification indicating that the following conditions are met:

- That portion of the activity proposed for continuance is unaffected by the nonconforming aspect of the activity, or
- The activity can be resumed satisfactorily by simply adhering to existing procedural controls.

15.3 Logging

15.3.1 The SNL QA organization will maintain a nonconformance control log to track nonconformances. This log will contain the following information:

- The nonconformance report number.
- A brief description of the nonconformance 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).

15.4 Segregation

15.4.1 When practical, nonconforming items will be segregated by placing them in a clearly identified and designated hold area until the nonconformance is resolved properly. When segregation is impractical or impossible because of physical conditions, such as size, weight, or access limitations, other precautions will be employed to preclude inadvertent use of a nonconforming item.

15.5 Disposition

15.5.1 Nonconforming characteristics will be reviewed and recommended dispositions of nonconformances shall be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item will be controlled pending an evaluation and an approved disposition by authorized personnel. Distribution of nonconformance documentation will be to all affected organizations.

15.5.2 The responsibility and authority for the evaluation, resolution, and close-out of nonconformances will be defined and documented. Those personnel assigned signature approval of the disposition will be identified. QA organization responsibilities relating to nonconformances will be described. Personnel performing evaluations to determine a disposition will 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.

15.5.3 The person or organization (e.g., the Principal Investigator) assigned the responsibility of resolving the nonconformance will ensure the following:

- 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 provides reference to any approved design documents, procedures, plans, work orders, etc., that are to be used for the correction of the nonconformance condition.
- The technical details for correction of the nonconformance condition are adequate for the recommended disposition.
- If continuance has been requested, justification for the activity to continue has been documented and approved by SNL, and by the appropriate YMPO Branch Chief and the YMPO PQM.
- 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 nonconformance report.
- The disposition of nonconforming items has identified and documented the correction as repair, rework, use-as-is, or reject/scrap.

- The disposition has identified the people or organizations responsible to implement the disposition. In cases where action is required of individuals or organizations outside the PIs organization, written concurrence with these actions shall be obtained by the PI. If appropriate, internal interfaces between organizational units and external interfaces between Yucca Mountain Project participants shall be clearly described.

15.5.4 In those cases where the responsible organization proposes a disposition of "repair," YMPO shall approve the proposed disposition prior to implementation. In the case of a proposed disposition of "use-as-is," the nonconformance report will be forwarded to YMPO for approval after all actions necessary to support technical justification of the disposition have been completed. The appropriate YMPO Branch Chief and the YMPO PQM shall approve nonconformance report dispositions involving "repair" or "use-as-is" determinations and conditional release recommendations.*

15.5.5 The action taken to correct the nonconforming item will be verified and documented. Repaired or reworked items will be reexamined in accordance with applicable procedures and with the original acceptance criteria, unless nonconforming item disposition has established alternate acceptance criteria.

15.6 Repetitive Nonconformances

When repetitive or recurring nonconforming conditions are identified, an evaluation will be made as to whether or not further programmatic corrective action is warranted to preclude repetition. This corrective action will be beyond the scope of the action taken for the disposition on the existing nonconformance reports and shall be processed in accordance with SNL corrective action procedures.

15.7 Trending

Nonconformance reports will be periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances. Results will be reported to department management for review and assessment.

* Applicable only when a disposition of "repair" or "use-as-is" results in a departure from specific YMPO-approved requirements for repository system deliverable items.

15.8 Document Distribution

Copies of nonconformance reports for items will be sent to the YMPO PQM and to the T&MSS Project QA Department (QA Engineering Division Manager) by the originating organization upon issuance and upon closure. The original nonconformance reports will be sent to the YMPO for approval as required by paragraph 15.5.4 of this section.

15.9 QA Level III

For QA Level III items, and at the discretion of the PI, all or any specific aspects of the process described above may be used to document nonconformances. As a minimum, however, the following actions must occur.

15.9.1 The PI must identify and describe the nonconformance in the logbook pertinent to the activity. Items must be controlled by the PI to prevent their use, processing, delivery or installation until corrective action is taken.

15.9.2 The PI must describe corrective actions taken to correct the nonconforming item and any other affected items or activities in the logbook.

16.0 CORRECTIVE ACTION

16.1 General

A corrective action system is defined herein that ensures that conditions adverse or potentially adverse to quality are identified promptly 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. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability. Significant conditions include, but are not limited to breakdowns in the Quality Assurance program and repetitive nonconformances. Upon discovering or receiving notification that a significant condition adverse to quality or unusual occurrence exists, each Yucca Mountain Project Participant shall ensure that:

- Immediate actions have been taken to remedy the specific condition(s).
- Causative factors have been determined.
- 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.

16.3 Follow-Up Action

The QA organization shall document concurrence of the adequacy of proposed corrective actions to assure that QA requirements will be satisfied. Follow-up action shall be taken by the QA organization to verify proper implementation of this corrective action and to close out the corrective action. The organization responsible for implementing the corrective action shall assure that the corrective action is completed in a timely manner.

16.4 Trending

Corrective action reports shall be periodically analyzed by the QA organization to show quality trends. Results shall be reported to upper management for review and assessment.

16.5 Distribution of Documents

Copies of corrective action reports shall be sent to the SAIC/T&MSS Project QA Department (QA Engineering Division Manager) by the originating organization upon issuance and closure. Those that document significant conditions adverse to quality shall be reported to the appropriate OCRWM Associate Director by the YMPO.

17.0 QUALITY ASSURANCE RECORDS

17.1 Basic Policy and Requirements

17.1.1 Records that furnish documentary evidence of quality shall be specified, prepared, and maintained in accordance with this section and applicable Yucca Mountain Project AP's. This shall include the requirements that all records be legible, identifiable, and retrievable.

17.1.2 A document or other item is not considered a QA Record until it satisfies the definition of a QA Record as defined below. The term records, used throughout this section is to be interpreted as QA Records. QA 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. A completed record is a document that will either receive no more entries or whose revision would normally consist of reissue of the document; and is signed and dated by the originator and, as applicable, by personnel authorized to approve the document. Records shall be distributed, handled and controlled in accordance with written procedures. All records (including superseded records) shall be processed into the YMP Records System for retention.

17.1.3 A record system shall be established at the earliest practicable time consistent with the schedule for accomplishing work activities.

17.1.4 The record system shall be defined, implemented, and enforced in accordance with a written QA implementing procedure and instructions prepared in accordance with Section 5.0 of this QAPP. These procedures and instructions shall establish requirements and responsibilities for transmittal, distribution, retention, maintenance, and disposition of QA records.

17.1.5 The procedure that defines the implementation of the record system shall identify measures to be implemented for the preservation and safekeeping of the records before storage and for the prevention of delays between record completion and storage at the Project Record Center.

17.1.6 Minimum Records - Sufficient records shall be specified, prepared, and maintained to furnish documentary evidence of activities that affect quality. The records shall include at least the following: procurement documents, data acquisition logbooks, experiment procedures, the results of reviews, inspections, tests, audits, monitoring or work performance, and materials analyses. Also, the records shall include closely related equipment, personnel, and procedure qualification documents. A list of typical QA Records is provided in Appendix F.

17.2 Applicability and Retention

17.2.1 The requirements of this section apply to all QA records that have been completed, regardless of the QA level designator assigned to such records.

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

17.3 Detailed Requirements

17.3.1 Generation of Records. The applicable specifications, procurement documents, implementing procedures, test procedures, technical procedures, or other documents shall specify the records to be generated, supplied, or maintained. Documents that are designated to become records shall be legible, accurate, complete, reproducible, microfilmable, and appropriate to the work accomplished. Documents that are designated to become records shall be completed in a permanent, indelible medium such that they are legibly reproducible and microfilmable and in accordance with the Yucca Mountain Project Administrative Procedures Manual.

17.3.2 Validation of Records. Documents shall be considered valid records only if they have been dated, and either stamped, initialed, or signed by authorized personnel or otherwise authenticated. This authentication may take the form of a statement by the responsible individual or organization. This organization shall maintain a list which contains the signatures and initials of the personnel authorized to authenticate records. Handwritten signatures are not required if the document is identified clearly as a statement by the reporting individual or organization. Records may be originals or reproduced copies.

17.3.3 Receipt of Records

17.3.3.1 The SNL YMP Records Management staff is responsible for receiving records and for organizing and implementing a system of receipt control of records for permanent and temporary storage in accordance with approved procedures. As a minimum, the receipt control system shall include the following:

- A method for designating the required records and for identifying the records received (the Master Index of SNL YMP Records Files).

- Procedures for receipt and inspection of incoming records.

- A method for submittal of the completed records to the storage facility without unnecessary delay.

17.3.3.2 The receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.

17.3.3.3 The Records Management staff shall provide protection from damage or loss during the time that the records are in their possession.

17.3.4 Records Identification

17.3.4.1 Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which it applies. Additionally, each record shall be provided with a unique identification number or other designation which is directly traceable to controlling programmatic information (date, title, subject, author, file code, etc.) and which shall not be repeated anywhere in the Yucca Mountain Project.

17.3.4.2 The records indexing system(s) shall include the location of the record within the record system(s).

17.3.4.3 The records identification system is subject to the review and approval of (or may be specified by) the Yucca Mountain Project Office or its designee, to ensure consistency throughout the Project.

17.3.5 Storage. Records shall be controlled from the time they are complete until the time they are stored in a permanent storage facility. Temporary storage, preservation, safekeeping, and retrievability of completed records shall be in accordance with the requirements applicable to permanent storage of records. The records shall be stored in locations and storage facilities as stated in 17.3.9. Before the records are stored, a written storage procedure shall be prepared and responsibility shall be assigned for enforcing the requirements of that procedure. As a minimum, this procedure 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.
- The method for maintaining control of and accountability for records removed from the storage facility.
- A method for filing supplemental information (see 17.3.8).

17.3.6 **Preservation.** Records shall be stored in a manner to preclude deterioration of the records. The following requirements shall apply:

- Provisions shall be made in the storage arrangement(s) 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 (such as radiographs, photographs, negatives, microfilm, magnetic material, etc.) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

17.3.7 **Safekeeping.** Measures shall be established to preclude the entry of unauthorized personnel in the storage area. These measures shall guard against larceny and vandalism. Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records. These measures shall be accomplished within 90 days following determination that either a record has been lost or a record has been damaged to a degree that it is no longer complete or legible.

17.3.8 **Corrected Information in Records.** Records may be corrected in accordance with written procedures that provide for appropriate review or approval by the originating organization. The correction shall include the data and the identification of the person authorized to issue such correction and shall not obliterate the corrected data.

17.3.9 **Storage Facility.** 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; infestation of insects, mold, or rodents.

All reproducible and one-of-a-kind records will be maintained by SNL in "alternate single facility" storage (two-hour fire-protection-rated vault meeting National Fire Protection Association 232-1975) at SNL until transmitted to the Project Record Center.

17.3.10 **Retrieval.** Storage systems shall provide the retrieval of information in accordance with planned retrieval times based upon the record type. A list shall be maintained that designates those personnel who shall have access to the files. Records maintained by this organization shall be accessible to YMPO (DOE personnel). Except for certain proprietary documents related to procurements, those records shall also be accessible to designees of the YMPO.

17.3.11 **Disposition.** Records that are accumulated at various locations, prior to transfer, are made accessible to YMPO through this organization's records system. The Records Management staff shall inventory the submittals, acknowledge receipt, and process these records in accordance with procedures which implement this document.

Various regulatory agencies (e.g., DOE, OSHA, MSHA) have requirements concerning records that are within the scope of this document. The most stringent requirements shall be used to determine final dispositions.

18.0 AUDITS

18.1 General

A system of planned, periodic audits shall be established to provide an objective evaluation of the quality-related practices, procedures, instructions, activities, and items including the review of documents and records to ensure that the QA Program is effective and properly implemented for QA Level I and II activities. The audits shall be performed in accordance with a written procedure using checklists by appropriately trained personnel who do not have direct responsibilities in the areas being audited. Audit results shall be documented, and they shall be reported to and reviewed by management having responsibility in the area audited. Tracking systems shall be instituted for audit findings to assure that all findings are appropriately addressed and to identify quality trends. All deficiencies and nonconformances identified during audits are to be documented and monitored until verification of effective corrective action occurs. The audited organization shall describe in a formal report the corrective action to be taken to address findings, and shall submit the report to the SNL NWRT Department and their own responsible management. Follow-up action, including verification of corrective action or reaudit of specific areas, shall be performed where appropriate.

These audits will be scheduled, planned, conducted, and reported as described in paragraph 18.2 through 18.7, below.

The audit program shall be supplemented by surveillances performed by persons independent of the activity.

18.2 Scheduling

18.2.1 Internal and external QA audits shall be scheduled in a manner that shall provide coverage and coordination with ongoing QA Program activities. Audits shall be scheduled at a frequency compensurate with the status and importance of the activity and shall be initiated early enough to verify the establishment of effective QA. 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. The audit schedule shall be evaluated periodically and revised as necessary to assure that coverage is maintained current. Revisions of the audit schedule will be documented. Regularly scheduled audits may be supplemented by additional audits of specific subjects, to provide adequate coverage.

18.2.2 **Internal Audits** - All Elements of SNL's QA Program Plan shall be audited at least annually. 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.

18.2.3 **External Audits** - Elements of the QA Program of external organizations (direct contractors) performing QA Level I or II work shall be audited at least annually or once during the life of the activity, whichever is shorter, with the following exception: 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. The justification for not performing audits of vendors whose activities are less than four months in duration shall be documented and approved by the QA Coordinator prior to implementation of the activity. A copy of the document justification shall be provided to the YMP Quality Manager. Pre-award or post-award audits will fulfill this requirement for audits of external organizations. These supplier audits shall be documented and shall take into account where applicable, (1) review of supplier's furnished documents and records such as certificates of conformance, nonconformance reports, 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.

18.2.4 **Joint Audits** - If more than one Participant buys from a single supplier, this organization may either perform or arrange for an audit of the supplier on behalf of itself and other Participants to reduce the number of external audits of the supplier. The scope of such audits 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. Audits of other YMP Participant Organizations or Contractors will not be conducted by SNL.

18.3 <u>Preparation</u>

Audit preparation shall include the items specified below.

18.3.1 Audit Plan

The designated Lead Auditor shall develop and document an audit plan for each audit. 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.

18.3.2 Personnel

This organization shall select and assign auditors who are independent of any direct responsibility for the performance of the activities that they are to audit. There are no specific requirements for the use of technical specialists (personnel with special expertise in the technical areas to be audited) as auditors, however they may be used to increase the effectiveness of audits. For internal audits, the personnel who have direct responsibility for performing the activities to be audited shall not be involved in the selection of the audit team. In order that the audit process be meaningful and effective, the personnel conducting audits shall have organizational freedom from audited organizations and carry the support and authority of the QA Coordinator and the TPO concerning audit matters. See Appendix E for QA audit personnel qualification requirements.

18.3.3 Selection of Audit Team

An audit team shall be identified before the beginning of each audit. 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. The audit team leader shall identify any technical specialists who will participate in the audit and include this information in the audit plan. Such audit team members shall have appropriate technical expertise or experience in the work being audited. Multidisciplinary audit teams shall be employed when activities to be audited involve more than a single technical area. The Lead Auditor shall ensure that the audit team is prepared before the audit begins.

18.4 Performance

Audits shall be performed in accordance with a procedure 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. 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. 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. The audit results shall be documented by audit personnel and shall be reviewed by management having responsibility for the area audited. Conditions that require prompt correction action shall be reported immediately to the management of the audited organization. Audit findings shall be reviewed with the audited organizations at a closing meeting.

18.5 Reporting

18.5.1 The audit report shall be compiled by the audit team, signed by the Lead Auditor, and issued within 30 calendar days. It shall include the following information, as appropriate.

- 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; and
- Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

18.6 Response

Management of the audited organization or activity shall be requested to 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. The adequacy of audit responses shall be evaluated by or for this organization.

18.7 Follow-up Action

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. An analysis of audit

results shall be performed by the QA organization to identify quality trends. The results of the analysis shall be reported to responsible management for review, assessment, and appropriate action. An audit tracking system will be maintained to indicate the extent of completion of the audit and the close-out of findings.

18.8 Records

18.8.1 Audit records are QA records and shall include:

- Identification of the organization(s), activities, or items audited and the individual(s) contacted during the audit(s).
- Description of any deficiencies, 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.

18.8.2 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.

18.9 Distribution of Documents

The SNL YMP organization will send copies of external and internal audit schedules and changes thereto, to the T&MSS Project QA Department (QA Verification Division Manager).

APPENDIX A

YUCCA MOUNTAIN PROJECT DEFINITIONS

This appendix contains definitions of terms as presented in the YMP QA Plan. SNL-specific terms are indented.

ACCEPTANCE CRITERIA: Specified limits defined in codes, standards, or other requirement documents placed on 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 YMP 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) which influences or affects the achievement or verification of the objectives of the Yucca Mountain Project as depicted in the WBS Dictionary.

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

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

AUDITOR: An individual qualified in accordance with requirements consistent with Appendix E, who assists in the conduct of audits.

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.

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.

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

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

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

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

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

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.

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.

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

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.

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 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 are is also known as the site.

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.

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 design requirements upon which the detailed final design is based.

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

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

DEVIATION: A departure from specified requirements.

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

DOCUMENT: Any 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.

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, etc.).

EXTERNAL AUDIT: An audit of those portions of another organizations'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 OGR Program or other Federal regulatory documents.

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.

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: As it applies to structures, systems, and components, 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 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 10 CFR 60, Subpart E).

INDOCTRINATION: Instruction provided to personnel for familiarization with programmatic and work-oriented documents applicable to the assigned activity; synonymous with "familiarization."

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.

LEAD AUDITOR: An individual, qualified and certified in accordance with requirements consistent with Appendix E, who organizes and directs audits, reports audit findings, and evaluates corrective action.

LIFETIME RECORDS: Quality Assurance Records that furnish evidence of the quality and completeness of data, items, and activities affecting quality. All Yucca Mountain Project QA Records are classified as Lifetime Records.

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

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

YMP PROJECT PARTICIPANTS: An all inclusive term used to describe (generically) the various organizations involved in the Yucca Mountain Project. This term includes the YMPO, Participating Organizations, and NTS Support Contractors.

YMP PROJECT PERSONNEL: All U.S. Department of Energy, Participating Organization, and NTS Support Contractor personnel involved in Yucca Mountain Project activities.

YMP PROJECT QUALITY ASSURANCE PLAN (QAP): The document that describes the planned, systematic quality assurance requirements that are applicable to the Yucca Mountain Project Project.

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

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

NTS: Nevada Test Site

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

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

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.

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 review, audits, and surveillances, 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 Yucca Mountain Project 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 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.

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.

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.

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

PERFORMANCE CONFIRMATION: The program of tests, experiments, and analyses that is conducted to 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 Quality Assurance Level I requirements and is necessary for the resolution of the NRC performance objectives of 10CFR60 in accordance with the Yucca Mountain Project Issues Resolution Strategy. This includes information that has been qualified and accepted in accordance with Yucca Mountain Project AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the Yucca Mountain Project QA Program."

PRINCIPAL INVESTIGATOR (PI) [DOE DEFINITION]: 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 is synonymous with Task Leader at SNL.)

> PRINCIPAL INVESTIGATOR (PI) [SNL DEFINITION]: An individual assigned responsibility for the conduct of a particular scientific investigation or design activity. There may be more than one such activity within a particular WBS element.

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

EXPERIMENT PROCEDURES: Activity definition documents that provide detailed requirements and provide primary control for implementation of experiments. Experiment Procedure content will delineate quality assurance provisions and includes, but is not limited to, objective(s), method, list of key equipment, specifying responsibilities for performing the experiment and a list and description of any technical procedure(s) needed for conduct of the experiment. Experiment Procedures may involve more than one experiment. These procedures may be prepared by contractors, subject to approval by Department 6310.

TECHNICAL PROCEDURES: Detailed implementing procedures for experiments that are a set of written instructions that define technical requirements, constraints, the type, range, and accuracy of measuring devises, and the procedural steps to accomplish a particular task (such as operating a particular lab system). These procedures may be prepared by contractors, subject to approval by Department 6310.

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.

PURCHASER: The organization responsible for the establishment of procurement requirements and for the issuance or 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 are subject to the QA requirements of 10 CFR 60, Subpart G.

QA ORGANIZATION: The group of personnel on the SNL NWRT Department staff who are specifically assigned to perform QA functions.

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 10 CFR 60, Subpart G quality assurance program or existing data qualified in accordance with Appendix G of the YMP 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 10 CFR 60, Subpart G Quality Assurance program, include data gathering, performance assessments, and those activities that could affect a natural barrier's ability to isolate waste.

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

> QUALITY ASSURANCE COORDINATOR: The person on the staff of SNL Department 6310 who has primary staff responsibility for establishment and implementation of the SNL YMP Quality Assurance Program.

QUALITY ASSURANCE LEVEL I: A designator applied to 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 an 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 from the site to the accessible environment after permanent closure. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

QUALITY ASSURANCE LEVEL II: A designator applied to 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 YMPO concerns, and the environment.

QUALITY ASSURANCE LEVEL III: A designator applied to those technical activities and items not classified as QA Levels I or II.

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 Program will be accomplished.

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., audits, 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 reissue of the document (or documentation), and that is signed and dated by the originator and, as applicable, by approval personnel.

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 the project.

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

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

REPOSITORY: See Geologic Repository Operations Area.

RETRIEVAL: The act of intentionally removing radioactive waste from the underground location at which the waste has 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, surveillance, or Quality Assurance audit.

SAMPLE: Natural materials obtained from the NTS or other locality with the intent of obtaining field or laboratory data pertinent to safety, waste isolation, retrievability, or site characterization (e.g., rock, minerals, soil, gas, liquid, plant, or animal materials in the form of cores, cuttings, etc.) in support of the Yucca Mountain Project.

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, and 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.

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 judgement or trial and error methods, or both.

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

SITE 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 situ testing at depth as needed to determine the suitability of the site for a geologic repository. It does not include preliminary borings and geophysical testing needed to decide whether or not site characterization should be undertaken.

SPECIAL PROCESS: A process, the results of which are highly dependent on the control of the process 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.

SUPPLIER: An individual or organization under contract to provide items, or services to the DOE/NV, to a Participating Organization, or to an NTS Support Contractor for Yucca Mountain Project activities.

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

TASK LEADER: The person who is assigned responsibility for accomplishment of the Sandia portions of a specific Work Breakdown Structure (WBS) element (synonymous with the DOE term "Principal Investigator").

TECHNICAL PROJECT OFFICER (TPO): The individual within each Yucca Mountain Project Participant's organization who has been assigned overall responsibility for the organization's scope of work as detailed in the Work Breakdown Structure (WBS) Dictionary.

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 trace 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.

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 (COMPUTER MODEL): 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 (1) physical data or (2) results of a verified and validated code designed to perform the same type of analysis (i.e., benchmarking with a validated code). Peer review may be used for model validation if it is the only available means for validating a model.

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 or not items, processes, services, or documents conform to specified requirements. (Synonym - "confirmation," when used in software QA context, to avoid confusion with "computer code verification.")

VERIFICATION (COMPUTER CODE): Assurance that a computer code correctly performs the operations specified in a numerical model (NUREG-0856).

WAIVER: Documented authorization to depart from specified requirements.

WASTE MANAGEMENT PROJECT OFFICE (YMPO): The organization to which the U.S. Department of Energy, Nevada Operations Office (DOE/NV), has assigned the responsibility of administering and coordinating the activities of various Participating Organizations and NTS Support Contractors associated with the Yucca Mountain Project.

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

APPENDIX B

SNL YMP QUALITY ASSURANCE IMPLEMENTING PROCEDURE MATRIX

No.	PROCEDURE TITLE	RELATED SNL YMP QAPP SECTION
QAP 1-1	QAPP Control	1.0, 2.0
QAP 1-3	Procedure for Quality-Related Work Stoppage	1.0
QAP 1-4	Resolution of QA-Related Disputes	1.0
DOP 2-1	Procedure for Task Definition Statements	1.0, 3.0
DOP 2-2	Study Plan Requirements	2.0,3.0,5.0,6.0,App.K
QAP 2-3	Work Plans	2.0, 3.0
DOP 2-4	Analysis Control and Verification	2.0, 3.0
QAP 2-5	Training and Familiarization Procedures	2.0
DOP 2-6	Qualification and Certification of Project Personnel	2.0
QAP 2-7	Qualification of Quality Assurance Program Audit Personnel	18.0, App. E
DOP 2-8	Conduct and Reporting of Management Assessments	2.0
DOP 2-9	Readiness Reviews	2.0
QAP 2-10	Assignment of QA Levels	2.0, 3.0
QAP 2-11	Determination of Appropriate QA Controls	2.0
DOP 3-1	Preparing, Reviewing, Approving, and Issuing Engineering Drawings	3.0, 5.0
DOP 3-2	Software Quality Assurance Requirements	3.0, App. H
DOP 3-3	Analysis Definition Requirements	2.0, 3.0
DOP 3-4	Design Investigation Control	2.0, 3.0

APPENDIX B

SNL YMP QUALITY ASSURANCE IMPLEMENTING PROCEDURE MATRIX

No.	PROCEDURE TITLE	RELATED SNL YMP QAPP SECTION
DOP 3-5	Design Control and Verification	3.0
DOP 3-6	Design Change Control	3.0
DOP 3-8	Reference Information Base Change Control	3.0
DOP 3-9	Interface Control of YMP Engineering Design	3.0
DOP 3-10	YMP Routine Design Calculations	3.0
DOP 3-12	Peer Review	3.0, App. J
DOP 3-13	Technical Reviews of Documents	3.0
DOP 3-14	Qualification of Data or Data Analyses not Developed Under the Yucca Mountain Project QA Plan	3.0, App.G
DOP 3-15	Providing Instructions for NTS Contractor Work	1.0
DOP 4-1	Procurement Document Requirements	4.0, 7.0
DOP 5-1	Quality Assurance and Department Operating Procedure Requirements	5.0
DOP 5-2	Technical Procedure Requirements	3.0, 5.0, 6.0, 11.0
DOP 5-3	QA Review of Department Operating Procedures	5.0
DOP 6-1	Document Control System Procedures	5.0, 6.0
DOP 6-2	Procedure for Reviewing, Approving, and Issuing YMP Technical Information Documents	6.0
DOP 7-1	Procurement Planning	7.0

APPENDIX B

SNL YMP QUALITY ASSURANCE IMPLEMENTING PROCEDURE MATRIX

No.	PROCEDURE TITLE	RELATED SNL YMP QAPP SECTION
DOP 7-2	Evaluation for Acceptance of Purchased Items or Services	7.0
DOP 8-1	Sample Identification and Handling Requirements	Sections 8.0 and 13.0 pertaining to samples
DOP 8-2	Procedure for Operation of the YMP Core Library	Sections 8.0 and 13.0
QAP 10-1	Surveillance Requirements	10.0
DOP 11-1	Experiment/Equipment Test Procedure Requirements	3.0, 5.0, 6.0 11.0
DOP 11-2	Requirement for Experiment/Test Logbooks	3.0
DOP 11-3	Data Records Management System Interaction	17.0
DOP 12-1	Calibration Program	12.0
DOP 14-1	Status Indication of Items	14.0
DOP 13-1	Identification, Handling, Shipping, and Storage Procedures for Items and Materials	Section 13.0, 8.0 for Items and Materials Only
QAP 15-1	Nonconformance Reporting and Controls	15.0
QAP 16-1	Corrective Action Requirements	16.0
QAP 16-2	Deviation Reporting	16.0
QAP 16-3	QA Program Status Reporting (Trend Analysis)	15.0, 16.0
DOP 17-1	Records Management	17.0
DOP 17-2	DRMS Operation	17.0
QAP 18-1	Audit Requirements	18.0

APPENDIX C

REQUIREMENTS FOR THE QUALIFICATION OF INSPECTION AND TEST PERSONNEL

1.0 GENERAL

The following are the requirements for the qualification of personnel who perform inspection and testing to verify conformance of engineered items to specified requirements for the purpose of determining acceptability. The requirements for the qualification of personnel performing nondestructive examination are specified in Appendix D.

2.0 FUNCTIONAL QUALIFICATIONS

Three levels of qualification shall be utilized depending on the complexity of the functions involved. 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.

2.1 LEVEL I PERSONNEL CAPABILITIES

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

2.2 LEVEL II PERSONNEL CAPABILITIES

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. 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.

2.3 LEVEL III PERSONNEL CAPABILITIES

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

3.0 EDUCATION AND EXPERIENCE QUALIFICATIONS

These education and experience requirements should be considered with recognition that other factors commensurate with the scope, complexity or special nature of the activity may provide reasonable assurance that a person can competently perform a particular task. Other factors which may demonstrate capability in a given job are previous performance or satisfactory completion of capability testing. These factors and the basis for their equivalency shall be documented.

3.1 LEVEL I EDUCATION AND EXPERIENCE REQUIREMENTS

- Two years of related experience in equivalent inspection or testing activities; or
- High school graduation and six months of related experience in equivalent inspection or testing activities; or
- Completion of college level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspection or testing activities.

3.2 LEVEL II EDUCATION AND EXPERIENCE REQUIREMENTS

- One year of satisfactory performance as a Level I in the corresponding inspection or test category or class; or
- High school graduation plus three years of related experience in equivalent inspection or testing activities; or
- 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
- Graduation from a four-year college plus six months of related experience in equivalent inspection activities or testing activities.

3.3 LEVEL III EDUCATION AND EXPERIENCE REQUIREMENTS

- Six years satisfactory performance as a Level II in the corresponding inspection or test category or class; or
- 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

- 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

- Graduation from a four-year college plus five years related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility.

4.0 CERTIFICATION

4.1 QUALIFICATION REQUIREMENTS

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. 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 which require qualification. 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.

4.2 PERSONNEL SELECTION

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.

4.3 INDOCTRINATION

Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards, the Quality Assurance Program Plan, and procedures that are to be employed.

4.4 TRAINING

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. 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. Training shall also be provided, as deemed necessary, on those changes to the QAPP and implementing procedures that affect previous training.

4.5 DETERMINATION OR INITIAL CAPABILITY

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.

4.6 EVALUATION OF PERFORMANCE

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

4.7 CERTIFICATION OF QUALIFICATION

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

- Employer's name.
- Identification of person being certified.
- Activities certified to perform.

- o Basis used for certification that includes such factors as;
  - Education, experience, and training (when necessary).
  - Test results (where applicable).
  - Results of capability demonstration.
- o Results of periodic evaluation.
- o Results of physical examination (when required).
- o Signature of employer's designated representative who is responsible for such certification.
- o Dates of certification and certification expiration.

4.8 PHYSICAL

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.

APPENDIX D

REQUIREMENTS FOR THE QUALIFICATIONS OF NONDESTRUCTIVE EXAMINATION PERSONNEL

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.

1.0 CERTIFICATION

1.1 APPLICABLE DOCUMENTS

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

1.2 PROGRAM

The responsible organization shall establish written procedures for the control and administration of NDE personnel training, examination, and certification.

1.3 CERTIFICATION OF QUALIFICATION

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

- Employer's name.
- Identification of person being certified.
- Activities certified to perform.
- Basis used for certification that includes such factors as;
  - Education, experience, and training (when necessary).
  - Test results (where applicable).
  - Results of capability demonstration.
- Results of periodic evaluation.

- Results of physical examination (when required).
- Signature of employer's designated representative who is responsible for such certification.
- Dates of certification and certification expiration.

1.4 PHYSICAL

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.

APPENDIX E

REQUIREMENTS FOR THE QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL

1.0 GENERAL

This Appendix provides 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 amplified 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.

1.1 QUALIFICATION OF AUDITORS

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. 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 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.

1.1.1 ORIENTATION

Orientation to provide a working knowledge and understanding of this document and the auditing organization's procedures for implementing audits and reporting results.

1.1.2 TRAINING PROGRAMS

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

1.1.3 ON-THE-JOB-TRAINING

On-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

1.2 QUALIFICATION OF LEAD AUDITORS

An individual shall meet the requirements listed below before being designated a Lead Auditor:

1.2.1 COMMUNICATION SKILLS

The prospective Lead Auditor shall have the capability to communicate effectively, both orally and in writing. These skills shall be attested to in writing by the Lead Auditor's employer.

1.2.2 TRAINING

Prospective Lead Auditors shall have training to the extent necessary to ensure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor:

- 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 Yucca Mountain Project.
- General structure of Quality Assurance programs and applicable elements as defined in this document.
- Auditing techniques of examining, questioning, evaluating, and reporting; method of identifying and following up on corrective action items; and closing out audit findings.
- Audit planning in the function related to quality for the following activities: site characterization (scientific investigation), 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 to include applicable elements of the audit program.

1.2.3 AUDIT PARTICIPATION

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. One of the audits shall be a nuclear Quality Assurance audit that shall be performed within the year prior to qualification.

1.2.4 EXAMINATION

The prospective Lead Auditor shall pass an examination or set of examinations that shall evaluate his comprehension of and ability to apply the body of knowledge identified in Paragraph 1.2.2 above. The exams may be oral, written, practical, or any combination of the three types. If any portion of the organization is oral, written documentation of the oral examination questions/contact shall be maintained. The development and administration of the examination shall be in accordance with Paragraph 1.4 of this section.

1.3 MAINTENANCE OF QUALIFICATION

1.3.1 MAINTENANCE OF PROFICIENCY

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. These evaluations shall be documented.

1.3.2 REQUALIFICATION

Lead Auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. 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.

1.4 ADMINISTRATION

1.4.1 ORGANIZATIONAL RESPONSIBILITY

Training of auditors shall be the responsibility of the employer. 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. The Lead Auditor shall, prior to 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.

1.4.2 QUALIFICATION EXAMINATION

The development and administration of the examination for a Lead Auditor required by Paragraph 1.2.4 is the responsibility of the employer. 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. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type or types and content of the examination or examinations shall be retained by the employer.

1.5 CERTIFICATION OF QUALIFICATION

Each Lead Auditor shall be certified by his employer as being qualified to lead audits. As a minimum, this certification shall document the following:

- Employer's name.
- Lead Auditor's name.
- Date of certification or recertification.
- Basis of qualification (i.e., education, experience, communication skills, training, examination, etc.).
- Signature of employer's designated representative who is responsible for such certification.

APPENDIX F

TYPICAL QUALITY ASSURANCE RECORDS

The following is a list of typical QA records for the SNL Yucca Mountain Project. Within the Yucca Mountain Project, the retention period for these records is "lifetime." QA Records will be submitted to the Project Records Center from the SNL Records Center.

Contract-Related Records

Contracts
Contract Change Amendments
Purchase Requisitions
Requests for Quotations
Proposals (Bids)
Evaluation-of-Proposal Documents
QA-Requirements-for-Procurements Documents
Documents which relate to acceptance or rejection of items or services
Receiving Inspection Reports
Sole Source Justification

Technical Data Base Records

SEPDB Job Log and Product Log
RIB Change Control Documentation
RIB Baseline Documentation

Research/Experimentation/Data Acquisition Records

Experiment Procedures
Test Procedures
Technical Procedures
Sample Custody Records
Sample or Site Prop. Records
Data
Calibration Records
Analysis Records
Logbooks/Notebooks
Technical Reports

Design Records

Design Investigation Memos
Engineering Drawings and Maps
Engineering Notebooks (completed)
Technical Reports
Design Specifications
Design Verification Records

Performance Assessment Analysis Records

Problem Definition Memos
Task Acceptance Memos
Authorization to Proceed Memo
Technical Reports
Analysis Verification Records

Quality Assurance

Audit Records
Corrective Action Reports
Certification and Qualification Records
Personnel Familiarization Records
Nonconformance Control Records
QA Level Assignment Records
Special-Process-related Records
Surveillance Documentation
Training Records

Software QA Records

Code Certifications
Source Codes
Configuration Management Records
Discrepancy Reports
Users' Manual
Theoretical Manual
Verification Reports
Validation Records

APPENDIX G

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

1.0 GENERAL

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 10 CFR 60, Subpart G.

2.0. METHODS FOR QUALIFICATION OF EXISTING DATA

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

a. The execution of the peer review process in accordance with the requirements of Appendix H of this QAPP.

b. 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. 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. The amount of corroborating data needed shall be dealt with on a case-by-case basis in the documented reviews for qualification.

c. 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.

d. Demonstrating that the existing data was collected under a QA program which is equivalent to a 10 CFR 60, Subpart G QA program.

3.0 SELECTION AND DOCUMENTATION OF QUALIFICATION METHODOLOGY

3.1 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.

Additional confidence/credibility can be achieved when a combination of methods is used.

3.2 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 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:

a. 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.

b. The technical adequacy of equipment and procedures used to collect and analyze the data.

c. The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).

d. The environmental conditions under which the data were obtained, if germane to the quality of data.

e. The quality of reliability of the measurement control program under which the data were generated.

f. The extent to which conditions under which the data were generated may partially meet Subpart G.

g. Prior uses of the data and associated verification processes.

h. Prior peer or other professional reviews of the data and their results.

i. Extent and reliability of the documentation associated with the data.

j. Extent and qualify of corroborating data or confirmatory testing results.

k. The degree to which independent audits of the process that generated the data were conducted.

l. The importance of the data to showing that the proposed repository design meets the performance objectives of 10 CFR 60, Subpart E.

m. 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

REQUIREMENTS FOR COMPUTER SOFTWARE USED TO SUPPORT THE YUCCA MOUNTAIN PROJECT

1.0 OBJECTIVES

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. The software requirements are intended to ensure quality and to provide the Nuclear Regulatory Commission (NRC) with part of the basis on which they will evaluate the soundness of the software used.

The appendix supplements Section 3.0 of this QA Program Plan and shall be used in conjunction with that section as applicable.

2.0 APPLICABILITY

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. This organization shall establish written procedures that assure the requirements of this appendix are implemented in a consistent and systematic manner. The extent to which these requirements apply shall be defined by a software QA plan and will be related to the nature, complexity, and importance of the software applications.

3.0 TERMS AND DEFINITIONS

Terms and definitions used in this appendix for Yucca Mountain Project software are defined below:

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.

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

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.

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 (1) a hand calculation, (2) an analytical solution or approximation, or (3) a verified code designed to perform the same type of analysis (benchmarking).

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

Life cycle: See software-development life cycle.

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.

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 (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.

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.

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, content, design, and current progress of a code.

4.0 SOFTWARE VERIFICATION AND MODEL VALIDATION

Software verification and model validation activities will be performed as described in the applicable software QA plan.

4.1 SOFTWARE VERIFICATION

Verification plans by the responsible project organization shall employ methods such as inspections, analyses, demonstrations, and tests 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.

Verification activities shall be performed according to written procedures relative to specific hardware configurations. The amount of verification activity shall be determined by the type and complexity of the software. The results of verification shall be documented in accordance with Section 6.0 and reviewed in accordance with Section 7.0 of this appendix.

4.2 MODEL VALIDATION

Model validation activities shall be performed according to written procedures to demonstrate that models embodied in computer software are correct representations of the process or system for which they are intended. This shall be accomplished by comparing software results against 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 shall be documented for their use. 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 according to Section 6.0 and reviewed according to Section 7.0 of this appendix.

5.0 SOFTWARE CONFIGURATION MANAGEMENT

A software configuration management system shall be established to assure positive identification of software and control of all software baseline changes.

5.1 CONFIGURATION IDENTIFICATION

Software configuration baseline items shall be identified at the appropriate phase of the software life cycle. Approved changes to a baseline shall be added to the baseline as updates. A baseline plus 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 to software configuration items by revision identifiers.

- Facilitates placement of the software configuration item in a relationship with other configuration items.

5.2 CONFIGURATION CHANGE CONTROL

Changes to 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. Assurance shall be provided that only authorized changes are made to software baselines and software configuration items.

5.3 CONFIGURATION STATUS ACCOUNTING

The information that is needed to mange software configuration items shall be recorded and reported. This information shall include the approved configuration identification, the status of formal proposals for changes to software configuration items, the implementation status of approved changes, and all information to support the functions of configuration identification, and configuration control.

6.0 DOCUMENTATION

Documentation is required as defined in the applicable software QA plan. The following is acceptable documentation of computer software used on the Yucca Mountain Project. Additional documentation may also be identified in the software QA plan.

6.1 MANDATORY DOCUMENTATION

The following documentation is mandatory as applicable to the particular software and shall be provided (consistent with NUREG 0856) to meet the requirements of this QA Program Plan.

- Software Requirements Specification
- Software Design and Change Documentation
- Software Summary
- Mathematical and Numerical Models
- User's Manual
- Verification and Validation Documentation
- Code Assessment and Support
- Continuing Documentation and Code Listings

6.2 SOFTWARE LIFE-CYCLE DOCUMENTATION

The following describes software life-cycle documentation.

6.2.1 SOFTWARE LIFE-CYCLE REQUIREMENTS SPECIFICATION

Software requirements documentation shall outline the requirements that the software must fulfill. A specified capability of software should be called 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 are to perform.
- Performance - the time-related issues of software operation such as speed, recovery time, response time, etc.
- 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, maintainability, etc.
- External Interfaces - interactions with other participants, hardware, and other software.

6.2.2 SOFTWARE LIFE-CYCLE DESIGN DOCUMENTATION

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.
- A description of life-cycle verification activities.

6.2.3 SOFTWARE LIFE-CYCLE IMPLEMENTATION DOCUMENTATION

Software implementation documentation shall address the following as applicable:

- Source code listings.
- Revised requirements documents.
- Revised design documents.

Any design changes made to the requirement and design-phase documents shall be assessed as to the impact to the design. The revised requirement and design-phase documents shall be reviewed at the same review level as the original documents.

6.2.4 SOFTWARE LIFE-CYCLE TESTING DOCUMENTATION

Life-cycle testing activities shall be documented. Software testing documentation should include a plan that describes the tasks and criteria for accomplishing the verification of the software in this phase. The documentation should also specify the hardware and system software configuration(s) for which the software is designed. In those cases where testing is used to ensure that requirements were met in the software design, test documentation shall provide traceability from requirements to design as implemented in the code. This documentation should also include a report of the results of the execution of the life-cycle verification activities. THis report should include the results of all reviews, audits and tests,and a summary of the status of the software.

7.0 REVIEWS

Documentation produced during software development, acquisition, implementation, testing, and use will be subject to appropriate reviews as described in the applicable software QA plan.

7.1 MANDATORY REVIEWS

Mandatory documents (consistent with Section 6.1 of this Appendix) shall be reviewed in accordance with review procedures established by this organization in the software QA plan.

The adequacy of verification activities shall be reviewed and the adequacy of model-validation activities shall be reviewed.

7.2 SOFTWARE LIFE-CYCLE REVIEWS

Reviews of software life-cycle activities may be performed for each life-cycle phase completed. The procedures used for reviews should identify the reviewers and their responsibilities.

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

The following reviews shall be performed as applicable:

7.2.1 SOFTWARE LIFE-CYCLE REQUIREMENTS REVIEW

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

7.2.2 SOFTWARE LIFE-CYCLE DESIGN REVIEW

The software design review should be held at the completion of the software design documentation. This review evaluates the technical adequacy of the design approach and assures that the design satisfies all the requirements in the requirements documentation. The complexity of the software design may require the performance of multiple design reviews.

7.2.3 SOFTWARE LIFE-CYCLE IMPLEMENTATION REVIEW

The software implementation review is an evaluation of the completed software life-cycle requirements, design, and implementation processes.

7.2.4 SOFTWARE LIFE-CYCLE TESTING REVIEW

The software testing review is an evaluation of the adequacy of completed software life-cycle verification activities.

8.0 DISCREPANCY REPORTING AND CORRECTIVE ACTION

Formal procedures shall be established by each project participant for software discrepancy reporting and corrective action. This discrepancy reporting system shall be integrated with the configuration management system to assure formal processing of discrepancy resolutions.

Software discrepancy procedures shall assure 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 to software configuration items are entered into baselines.
- Preventive and corrective actions provide for appropriate notification or organizations to which controlled copies have been distributed.

9.0 MEDIA CONTROL AND SECURITY

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

10.0 SOFTWARE ACQUISITION, PROCUREMENT, AND TRANSFER

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

Software requests by participating organizations shall include appropriate criteria to enable the software received to comply, as much as possible, with the requirements of this QA plan. Requirements not satisfied at the time when 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 for distribution 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 required to make the software functional.

11.0 SOFTWARE QUALITY ASSURANCE PLAN

The SNL NWRT Department shall prepare a software QA plan that describes the software development, acquisition and applications undertaken by this organization. The software QA plan shall identify the:

- Organizational responsibilities for the management and control of software.
- Software products to which the software QA plan applies.
- Criteria for meeting the requirements set forth in this appendix to the applicable software.
- Software life-cycle model used.
- Required documentation.
- Software configuration-management system.
- Verification and validation methodologies.
- Discrepancy reporting and corrective actions.
- Software review procedures.

Software life-cycle management is a requirement, and each participant shall present the specific software life-cycle controls for their organization in their software QAP. A generic life-cycle that presents the conceptual life-cycle management steps is presented in Section 11.1.

11.1 SOFTWARE LIFE CYCLE

Organizations implementing software activities 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.

The following life-cycle elements shall apply as appropriate for the specific life-cycle model defined, interpreted, and described in the applicable software QA plan.

11.1.1 LIFE-CYCLE REQUIREMENTS PHASE

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

- A 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.
- The information necessary to design the software without prescribing the software design itself.

11.1.2 LIFE-CYCLE DESIGN PHASE

During the design phase, a software design based on the requirements is specified, documented, and systematically reviewed. The design specifies the overall structure (control and data flow), and the reduction of the overall structure into 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 planing for design-based test cases.
- The review and analysis of the software design.

11.1.3 LIFE-CYCLE IMPLEMENTATION PHASE

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

Verification activities during this phase consist of:

- The possible modification of test cases necessary due to design changes made during coding.
- The examination of source code listings to assure adherence to coding standards and conventions.

11.14 LIFE-CYCLE TESTING PHASE

The testing phase consists of verification activities. A major portion of software verification may be accomplished during this phase. The verification activities will include:

- Execution of the test cases and evaluation of the results.
- Evaluation of the completed software to assure adherence to the requirements.
- The preparation of a report describing the results of software verification accomplished during testing.

Model validation will be conducted in accordance with Section 4.2 of this appendix. Because model validation is application dependent, model validation will not be completed at this stage.

11.1.5 LIFE-CYCLE INSTALLATION AND CHECKOUT PHASE

During this phase, the software may become part of a system incorporating other software components, the hardware, and production data. 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.

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.

11.1.6 LIFE-CYCLE OPERATIONS AND MAINTENANCE PHASE

During the operations and maintenance phase, the software has been approved for operational use. Maintenance activity shall consist of identification of errors and notification of users. Further activities may consist of maintenance of the software to remove 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.

12.0 SOFTWARE APPLICATIONS

Procedures shall be established 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 assure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.

Procedures shall be established for documenting software applications that perform technical calculations to ensure that these applications and the results of these applications can be independently reproduced.

Procedures will 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 employed to develop the input data, and appropriate user documentation for performing the application or analysis.

APPENDIX I

DESIGN INPUTS

Design inputs include many characteristics and functions of an item of 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:

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 issue, 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, an duration of exposure.

7. Interface requirements including definition of the functional and physical interfaces involving structures, systems, and components.

8. Material requirements including such items as compatibility, electrical insulation properties, protective coating, and corrosive 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 net 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 equipment.

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.

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.

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.

APPENDIX J

REQUIREMENTS FOR PEER REVIEW

1.0 GENERAL

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.

2.0 APPLICABILITY OF PEER REVIEW

2.1 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.

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

a. Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.

b. Decisions or interpretations having significant impact on performance-assessment conclusions will be made.

c. Novel or beyond the state-of-the-art testing, plans and procedures, or analyses are or will be utilized.

d. Detailed technical criteria or standard industry procedures do not exist or are being developed.

e. Results of tests are not reproducible or repeatable.

f. Data or interpretations are ambiguous.

g. Data adequacy is questionable--such as, data may not have been collected in conformance with the established QA program.

2.3 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.

3.0 STRUCTURE OF PEER REVIEW GROUP

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

a. The complexity of the work to be reviewed.

b. Its importance to establishing that safety or waste-isolation performance goals are met.

c. The number of technical disciplines involved.

d. The degree to which uncertainties in the data or technical approach exist.

e. The extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.

3.2 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.

4.0 ACCEPTABILITY OF PEERS

4.1 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 reviews. Each peer shall have recognized and verifiable technical credentials in the technical area that the peer has been selected to review.

4.2 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., finding 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.

5.0 PEER REVIEW PROCESS

5.1 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.

5.2 The peer review group shall evaluate and report on:

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.

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

6.0 PEER REVIEW REPORT

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

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.

e. The signature of each peer review group member.

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

FORMAT AND CONTENT REQUIREMENTS FOR SCP STUDY PLAN

1.0 PURPOSE AND OBJECTIVES OF STUDIES

1.1 Describe the information that will be obtained in the study. Briefly discuss how this information ill be used; and

1.2 Provide the rationale and justification for the information to be obtained by the study. 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. 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.

2.0 RATIONALE FOR SELECTED STUDY

2.1 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

2.2 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.

2.3 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:

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;

h) Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and

i) Interrelationships involving significant interference among tests and ESF design and construction, as appropriate (refer to Section 8.4 of the SCP or its references for specific ESF design information).

DESCRIPTION OF TESTS AND ANALYSES

3.1 Since studies are comprised of tests and analyses, provide for each type of test:

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, ESF elements, repository layout, stratigraphic units, depth, and test location);

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;

c) Specify the tolerance, accuracy, and precision required in the test, where appropriate;

d) Indicate the range of expected results of the test and the basis for those expected results;

e) List the equipment required for the test and describe briefly any such equipment that is special;

f) Describe techniques to be used for data reduction and analysis of the results;

g) Discuss the representativeness 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;

h) Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests, and

i) Relationship of the test to the set performance goals and confidence levels.

3.2 For each type of analysis:

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;

b) Describe the methods of analysis, including any analytical expressions and numerical models that will be employed;

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 I. Reference the applicable QA requirements.

d) Identify the data input requirements of the analysis;

e) Describe the expected output and accuracy of this analysis; and

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.

APPLICATION OF RESULTS

4.1 Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies).

4.2 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 form the studies described above, and refer to any use of the results for model validation).

4.3 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); and

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

SCHEDULE AND MILESTONES

5.1 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;

5.2 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

5.3 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 SCP.

cc: K Hooks
J. Blanton

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Document Title: SNL NNWSI Quality Assurance Program Plan (SLTR88-0001)

Revision: C **Document date:** 04/10/89 **Number of pages:** 151

Control number: 00045

Summary: Numerous detailed changes throughout the QAPP; sidebars not used because text changes are so comprehensive.

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