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NEVADA NUCLEAR WASTE STORAGE

INVESTIGATIONS

QUALITY ASSURANCE PLAN

NNWSI/88-9

REVISION 2 | 2

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NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT

QUALITY ASSURANCE PLAN

REVISION 2 2

UNITED STATES DEPARTMENT OF ENERGY
NEVADA OPERATIONS OFFICE
LAS VEGAS, NEVADA

PREFACE

This document is the eighth revision of the Nevada Nuclear Waste Storage Investigations (NNWSI) Project Quality Assurance (QA) Plan. This document was previously designated as NVO-196-17 but has been renumbered as NNWSI/88-9. 2

This NNWSI Project QA Plan is a requirements document which was developed from QA requirements imposed on the NNWSI Project by the Office of Civilian Radioactive Waste Management (OCRWM), the U.S. Department of Energy (DOE), and the U.S. Nuclear Regulatory Commission (NRC). Accordingly, this document establishes the QA requirements that are applicable to the NNWSI Project participants.

Note that the term Nevada Nuclear Waste Storage Investigations (NNWSI) Project is superseded by Yucca Mountain Project and the term Waste Management Project Office (WMPO) is superseded by Yucca Mountain Project Office (Project Office). These changes will be reflected in a future revision to this document.

This revision reflects changes made to the Introduction, Sections II, III, V, VI, XII, XV, XVIII, Appendix A, Appendix H, Appendix I, and Appendix J. In addition, Appendix K was added. The changes made to this document are noted with line-by-line revision indicators throughout. In addition, the changes are summarized as follows:

- The signature page and title page were revised to correspond to the revision level of the document.
- The Preface was revised to indicate the basis for the changes to NNWSI/88-9, Rev. 1 and to provide a revised summary of the changes.
- The Table of Contents was updated to revise page numbers as necessary.
- The List of Effective Revisions was updated to reflect the current revision level of each section of the NNWSI QA Plan and to correct editorial errors.
- The Introduction, para. 2.2.2 was revised to remove the requirement for OCRWM review and approval of Project quality-related administrative procedures. This is consistent with the OCRWM QA Requirements document. In addition, editorial corrections were made to para. 2.8.1. 2
- Section II, para. 1.0, first subparagraph, was revised to remove requirements relative to Project Office submittal of quality-related administrative procedures to OCRWM for review and approval (see above bullet). In addition, the scope of the Quality Assurance Program was clarified.
- Section II, para. 1.0, third subparagraph was revised to insert "higher-tier" before "documents" in the third line for clarification and to exclude the CFRs.

- Section II, para. 1.2 was revised to remove the requirement for WMPO review and approval of NNWSI Project Participant non-technical implementing procedures based on OCRWM direction.

- Section II, para. 1.2, second paragraph was revised to be consistent with the OCRWM QAR.

- Section II, para. 1.5.1 was deleted to eliminate redundancy. (i.e. Appendix A contains a definition of "Q-List). In addition the heading for para. 1.5.2 was deleted and para. 1.5.2 was revised for consistency with Appendix I. The heading for para. 1.5 was revised to be consistent with the remaining text.

- Section II, paras. 2.1.1/2.1.4/2.2.4. Changes were made to these paragraphs to clarify that QA requirements can be selectively applied to Level I items and activities commensurate with its importance to safety and/or waste isolation.

- Section III, para. 1.1.1.1 was revised to require that scientific investigation planning documents describe the proposed methodology for performing the work and that these planning documents provide identification, explanation, and justification for areas where scientific notebooks will be used.

- Section III, para. 1.1.2 was revised to clarify control of site characterization activities and to provide reference to Appendix K for study plan requirements. 2

- Section III, para. 1.3.1 was revised to remove the statement regarding cursory supervisory reviews since the definition of technical reviews in Appendix A adequately precludes a cursory review.

- Section III, para. 1.6.1 was revised to clarify the controls for scientific investigations when scientific notebooks are used to document the work. In addition, provisions were made for modifications to technical implementing procedures and the first sentence was revised for editorial clarity.

- Section III, para. 1.6.2 was revised to add requirements for the modification of technical implementing procedures. In addition, the parenthetical notation "as required" was removed from the fourth bullet since it was redundant with the lead in sentence which contains the words "as appropriate" and applies to all the bullet items.

- Section III, para. 1.6.2, seventh bullet was changed to "methods of data reduction" since data analysis is adequately covered by paragraph 1.4 of Section III.

- Section III, para. 1.6.4.1 was revised to provide additional requirements for the initial entries to scientific notebooks and to clarify that these initial entries are considered to be the "general procedure" for performing the work. Additionally, provisions were established for modifications to these initial entries.

- Section III, para. 1.6.4.2. The last bullet was revised to clarify documentation of the final results of scientific investigations and renumbered as para. 1.6.4.4.

- Section III, para. 2.4.6.1, last bullet was revised to remove reference to the NNWSI Project Administrative Procedure Manual.

- Section III. A new paragraph 3.1.6 was inserted to provide for the use of computer software which has not been verified or validated. Subsequent paragraphs were renumbered accordingly. Paragraph 3.1.9 (old paragraph 3.1.8) was modified to remove reference to the NNWSI Project Administrative Procedures Manual.

- Section III, para. 3.2, last sentence was revised for editorial clarity.

- Section V, para. 1.0 and 3.0, were revised to clarify that requirements for work performed using the scientific notebook method are contained in Section III, para. 1.6. In addition, para. 3.0 of this section was modified to reflect that scientific notebooks are subject to QA records requirements. 2

- Section V, para 2.0 was revised to clarify review criteria for instructions, procedures, plans and drawings.

- Section VI, para. 2.1 was revised to clarify review criteria for changes to documents.

- Section XII, para. 2.1 was revised to clarify the control of M&TE when used to determine specified tolerance requirements.

- Section XV, para. 1.4.4. The last two bullets were deleted since para. 3.0 establishes requirements for periodic trending of nonconformances for root cause determination.

- Section XVIII, para. 1.2.2. The last portion of the paragraph was renumbered as para. 1.2.3 and titled "Joint Audits". In addition, requirements for external audits were strengthened.

- Section XVIII, para 2.3. The fifth bullet was modified to clarify nonconformance control requirements for surveillances.

- Appendix A. The term "Computer Code Validation" was changed to "Computer Model Validation" to correspond more accurately with the definition.

- Appendix A. The terms "Authentication" and "Validation" are new and were added to enhance understanding of QA Records

- Appendix A. The term "Q-List" was modified and the term Quality Activities List was added for consistency with Appendix I.

- Appendix A. The definition of "Corroborative Data" was revised for consistency with Appendix G and NUREG-1298.

- Appendix H, paragraph 1.0 was revised to clarify software QA requirements. Requirements for verification and/or validation of computer software were revised and relocated to paragraph 5.0. Paragraph 2.0 was revised to clarify applicability. Paragraphs 4.0, 4.1 and 4.1.2 were revised to clarify that flexibility exists for the selective application of software QA requirements. Editorial clarifications were made to Section 5.1, 5.2 and model validation approaches were enhanced. In Sections 6.1, 6.2 and 6.3, configuration management controls were revised and clarified. Section 7.0 was revised to accommodate participant software QA development documentation plans and Section 7.3 and 7.4 were clarified. Section 8.0, 8.1, 8.3 and 8.4 were also edited to improve review activities. In addition, editorial enhancements were made to paragraphs 11.0 and 12.0. 2

- Appendix I was revised for consistency with NUREG-1318 requirements.

- Appendix J, paragraphs 4.1 and 6.1 were revised for consistency with NUREG-1297.

- Appendix K is a new appendix which was added to establish requirements for the format and content of study plans. These requirements were extracted from the SCP management plan.

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Signature Page	2	12/9/88	
Title Page	2	12/9/88	
Preface	2	12/9/88	2
Table of Contents	2	12/9/88	
List of Effective Revisions	2	12/9/88	
Policy Statement	0	5/19/88	
Introduction	2	12/9/88	2
Section I - Organization	0	5/19/88	
Section II - Quality Assurance Program	2	12/9/88	2
Section III - Scientific Investigation and Design Control	2	12/9/88	
Section IV - Procurement Document Control	0	5/19/88	
Section V - Instructions, Procedures, Plans, and Drawings	2	12/9/88	2
Section VI - Document Control	2	12/9/88	
Section VII - Control of Purchased Items and Services	0	5/19/88	
Section VIII - Identification and Control of Items	0	5/19/88	
Section IX - Control of Processes	0	5/19/88	
Section X - Inspection	0	5/19/88	
Section XI - Test Control	1	8/26/88	
Section XII - Control of Measuring and Test Equipment	2	12/9/88	2
Section XIII - Handling, Shipping and Storage	0	5/19/88	
Section XIV - Inspection, Test, and Operating Status	0	5/19/88	

Section XV - Control of Nonconforming Items	1	12/9/88	2
Section XVI - Corrective Action	0	5/19/88	
Section XVII - Quality Assurance Records	0	5/19/88	
Section XVIII - Audits	2	12/9/88	2
Appendix A - Terms and Definitions	2	12/9/88	
Appendix B - Design Inputs	0	5/19/88	
Appendix C - Requirements for Inspection and Test Personnel	0	5/19/88	
Appendix D - Requirements for NDE Personnel	0	5/19/88	
Appendix E - List of Typical QA Records	0	5/19/88	
Appendix F - Requirements for Audit Personnel	0	5/19/88	
Appendix G - Requirements for Qualification of Existing Data not Generated Under the Control of the NNWSI Project QA Plan	1	8/26/88	
Appendix H - Requirements for Computer Software	1	12/9/88	2
Appendix I - Requirements for Q-List	1	12/9/88	
Appendix J - Requirements for Peer Review	1	12/9/88	
Appendix K - Format and Content Requirements for SCP Study Plans	0	12/9/88	

POLICY

It is the policy of the U.S. Department of Energy, Nevada Operations Office (DOE/NV) that the achievement of quality in fulfilling the responsibilities for the NNWSI Project is essential to success. To meet this objective, we must establish effective networks of management plans and procedural controls and take the necessary actions to demonstrate to the public our ability to safely and efficiently handle and dispose of spent nuclear fuel and high-level radioactive waste. Concurrently, we must demonstrate compliance with legislative, regulatory, and DOE requirements for control and documentation of quality.

In order to meet our management responsibilities for achieving and assuring quality, the DOE/NV has established the Waste Management Project Office (WMPO) and delegated appropriate authority to the Project Manager, WMPO for the management and direction of the NNWSI Project. The Project Manager, WMPO has direct primary responsibility and accountability for the execution and implementation of the NNWSI Project in accordance with the NNWSI Project Plan, Project Charter, and Project Management Plan.

Consequently, the WMPO has developed this Quality Assurance Plan. Its requirements establish a framework for consistency in the continuing development of quality assurance plans and implementing procedures at all levels of the NNWSI Project.

Nick C. Aquilina
Manager, Nevada Operations Office

1.0 OVERVIEW OF THE NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS (NNWSI) PROJECT

The NNWSI Project was established by the U.S. 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 that is currently under evaluation is on and adjacent to the Nevada Test Site (NTS). Evaluation of the site 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 DOE activities will support the U.S. Nuclear Regulatory Commission (NRC) licensing decisions and will assess risks to public radiological health and safety with regard to the geologic repository. Therefore, the establishment of quality assurance requirements is essential in order to specify the method of control for quality aspects of the work. The Quality Assurance Program applies to all systems, structures, and components important to safety, to design and characterization of barriers important to waste isolation and to activities related thereto. These activities include: site characterization, scientific investigation, facility and equipment design, procurement, and construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. Figure 1 details the hierarchy of Quality Assurance (QA) criteria to be applied to the NNWSI Project. The QA requirements placed on the NNWSI Project are established from three main sources:

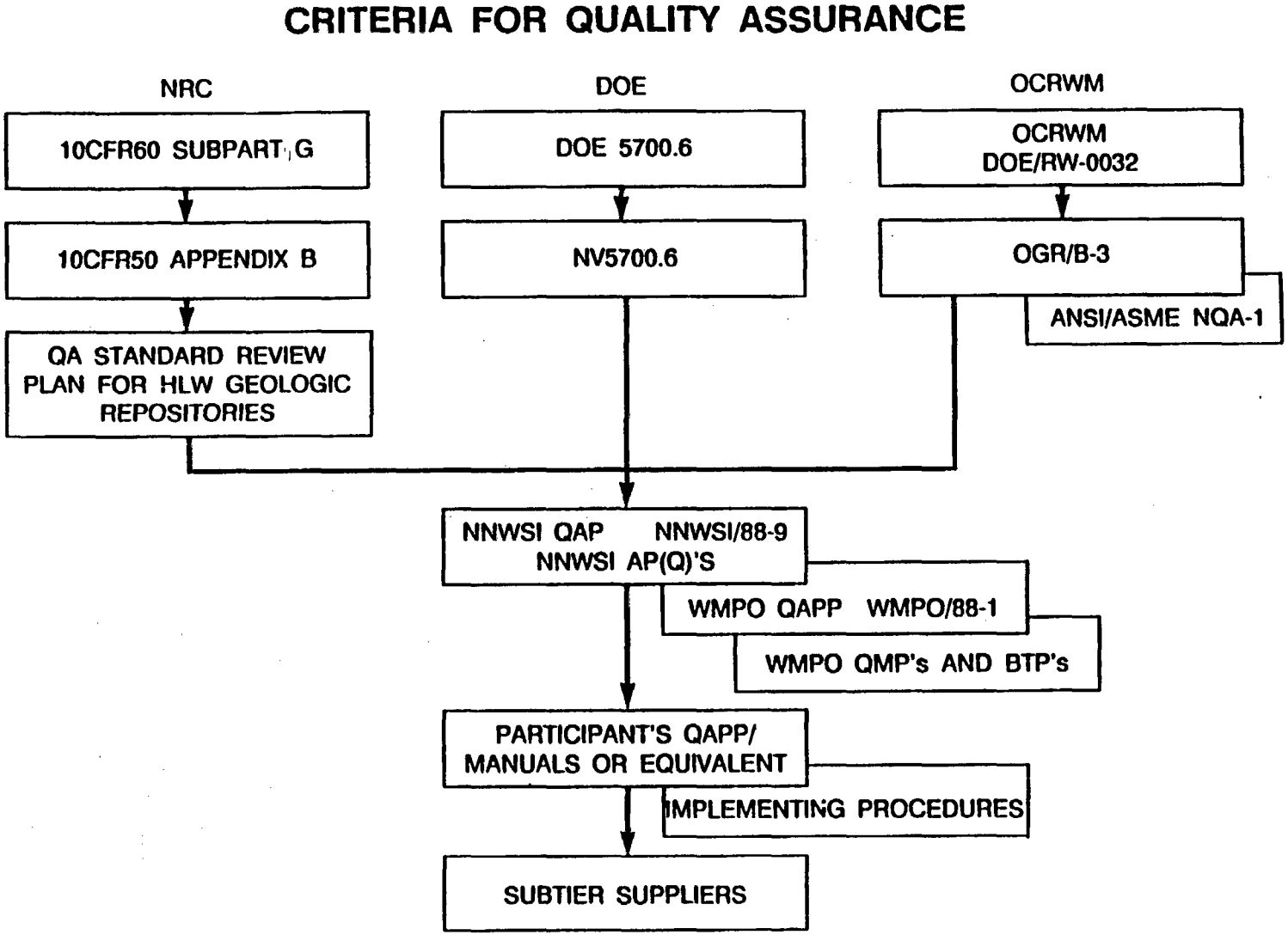
U.S. Nuclear Regulatory Commission (NRC)

- 10CFR60 Subpart G, Disposal of High Level Radioactive Wastes in Geologic Repositories - Quality Assurance
- 10CFR50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories (June, 1984)

U.S. Department of Energy (DOE)

- DOE 5700.6B (9/23/86), Quality Assurance
- NV 5700.6-6 (3/13/87), Quality Assurance

Figure 1


CRITERIA FOR QUALITY ASSURANCE
NRC
DOE
OCRWM
10CFR60 SUBPART G
DOE 5700.6
OCRWM DOE/RW-0032
10CFR50 APPENDIX B
NV5700.6
OGR/B-3
ANSI/ASME NQA-1
QA STANDARD REVIEW PLAN FOR HLW GEOLOGIC REPOSITORIES
NNWSI QAP NNWSI/88-9
NNWSI AP(Q)'S
WMPO QAPP WMPO/88-1
WMPO QMP's AND BTP's
PARTICIPANT'S QAPP/ MANUALS OR EQUIVALENT
IMPLEMENTING PROCEDURES
SUBTIER SUPPLIERS
CRITQA PUB/5-18 88

Office of Civilian Radioactive Waste Management (OCRWM)

- o OCRWM Quality Assurance Management Policies and Requirements (October, 1985)
- o OGR/B-3, OGR Quality Assurance Plan for High Level Radioactive Waste Repositories (August, 1986)
- o ANSI/ASME NQA-1, American National Standard for Quality Assurance Program Requirements for Nuclear Facilities (ANSI/ASME NQA-1-1986)

The Waste Management Project Office (WMPO) has used the QA criteria from these documents, plus any additional criteria deemed necessary by the WMPO, to develop the NNWSI Quality Assurance Plan. The NNWSI Quality Assurance Plan is used by the WMPO to establish the QA requirements for the NNWSI Project Participants. A detailed description of the criteria applicable to each investigative phase of the Project is contained in individual Quality Assurance Program Plans (QAPPs) prepared by each organization that is responsible for directing or conducting an assigned task, or both.

The WMPO has been assigned responsibility for administering and coordinating Project activities. The WMPO requires each NNWSI Project participant to prepare and submit a QAPP that covers their task activities. All QAPPs prepared by the NNWSI Project participants shall meet the requirements set forth in this plan.

2.0 ORGANIZATION OF THE PROJECT WITH RESPECT TO QUALITY ASSURANCE

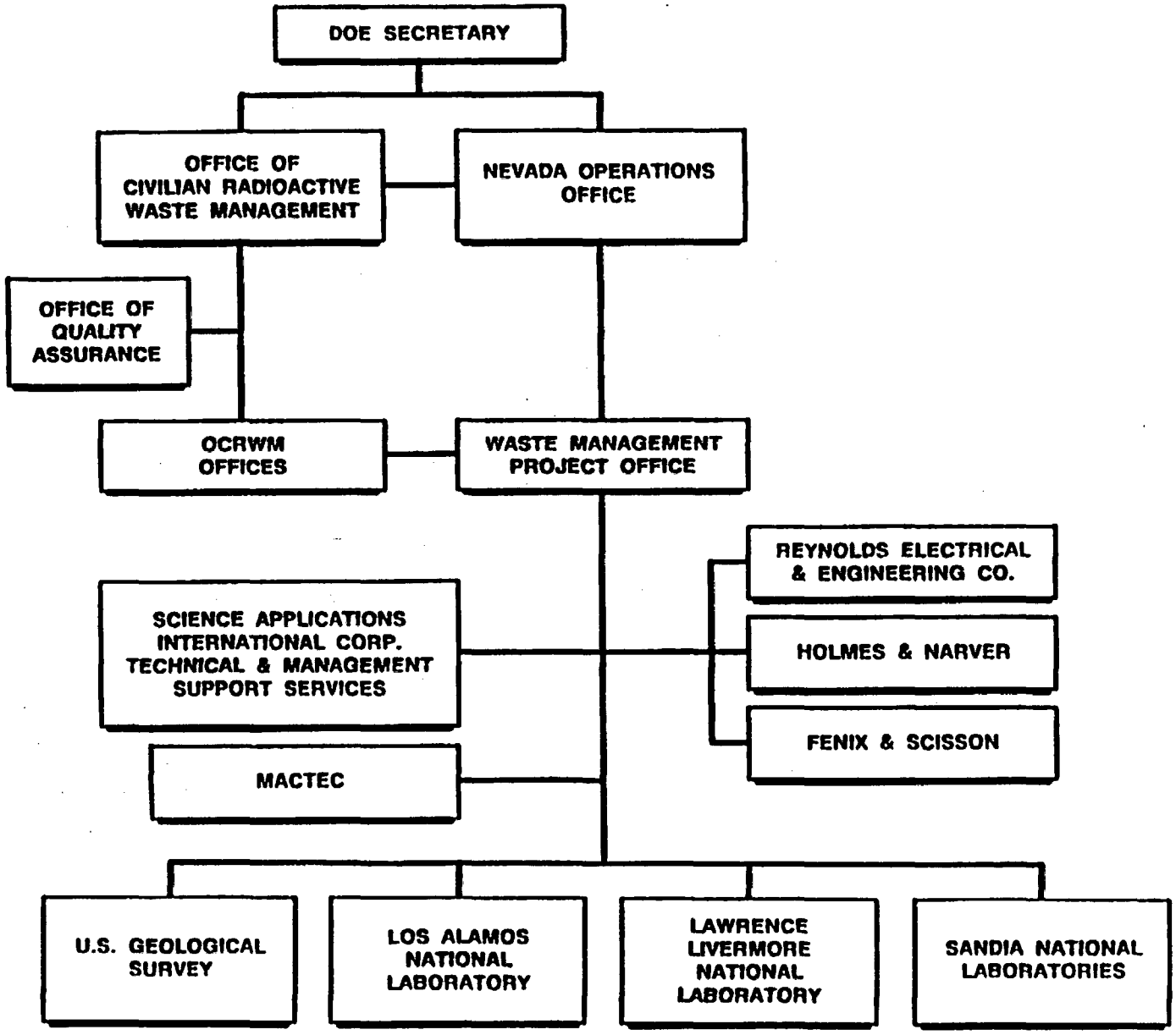
These paragraphs describe organizational responsibilities and interfaces with the Nevada Nuclear Waste Storage Investigations (NNWSI) Project with respect to Quality Assurance. The organization of the Project is shown in Figure 2. The NNWSI Project Work Breakdown Structure Dictionary (WBS) provides the technical and management responsibilities of each Participating Organization and Nevada Test Site (NTS) Support Contractor. A definitive description of the Quality Assurance (QA) responsibilities are contained in the Quality Assurance Program Plans (QAPPs) of each NNWSI Project participant. Specific organization requirements which must be addressed in the QAPPs of each NNWSI Project participant are contained in Section I of this document.

2.1 DEPARTMENT OF ENERGY (DOE)

The Secretary, U.S. Department of Energy Headquarters (DOE/HQ), was given the responsibility to carry out the Nuclear Waste Policy Act (NWPA) of 1982. This responsibility has been delegated by the DOE Secretary to the Office of Civilian Radioactive Waste Management (OCRWM) for the integration of QA and management policies and requirements for the overview of the activities performed by DOE field operations offices. The DOE/NV operations office has been delegated the responsibility for the implementation of the technical and QA activities of the NNWSI Project.

Figure 2

NNWSI PROJECT ORGANIZATION



2.2 DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)

The U.S Department of Energy Headquarters (DOE/HQ), Office of Civilian Radioactive Waste Management, provides programmatic and policy guidance to the WMPO to assure that adequate QA and technical objectives of the program are achieved.

2.2.1 OCRWM OFFICES

The OCRWM is comprised of the following offices: Program Administration and Resources Management, Facilities Siting and Development, Systems Integration and Regulation, and External Relations and Policy. These OCRWM offices provide direction to WMPO for the implementation of the OCRWM program objectives.

2.2.2 OCRWM OFFICE OF QUALITY ASSURANCE

The OCRWM Office of Quality Assurance provides QA guidance and overview to the NNWSI Project by (1) review and approval of the NNWSI Quality Assurance Plan and the WMPO QAPP; (2) specifying applicable requirements which are contained in the OCRWM Quality Assurance Plan; and (3) performance of QA audits and surveillances of the WMPO. 2

2.3 DOE/NV OPERATIONS OFFICE

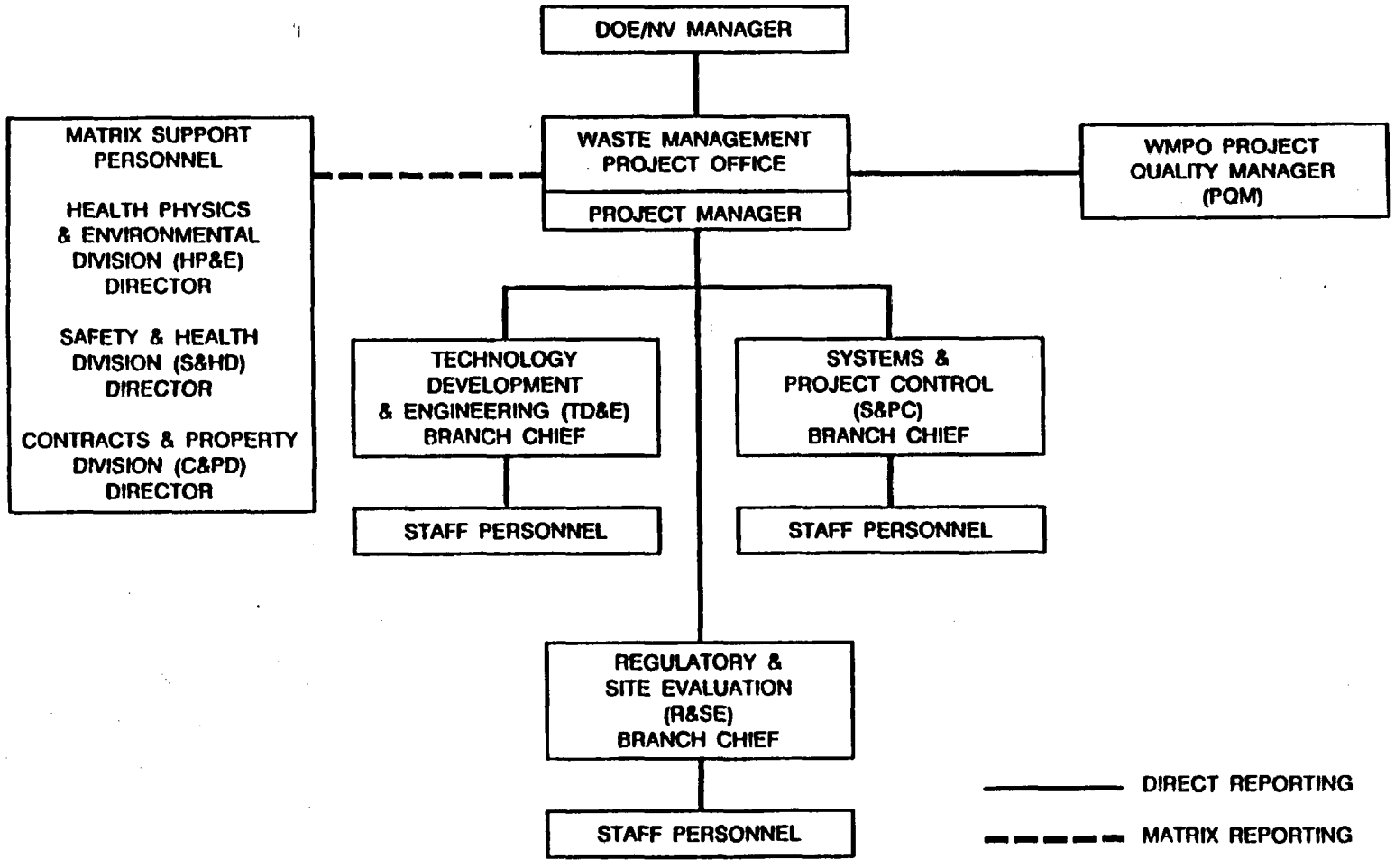
The DOE/NV Manager has the ultimate responsibility and accountability for the NNWSI Project in the Nevada Operations Office. The Waste Management Project Office (WMPO) has been established within the DOE/NV organization for the management of the NNWSI Project. The WMPO operates as a part of the DOE/NV under the programmatic direction of the DOE/HQ Office of Civilian Radioactive Waste Management (OCRWM). In matters of Department policy, DOE/NV works and cooperates with DOE/OCRWM in establishing a consistent QA approach for accomplishing the objectives of the Geologic Repository Program managed by the DOE/OCRWM.

2.4 WASTE MANAGEMENT PROJECT OFFICE (WMPO)

The WMPO has sole responsibility for authorization of work and management and technical direction of the activities of the Participating Organizations and NTS Support Contractors through the issuance of technical and programmatic guidance, technical integration of the Project, Project planning and documentation, and QA programmatic guidance. Technical adequacy of the work performed shall be determined via audits, design reviews, technical reviews, management assessments, etc., as appropriate. In addition, the WMPO is responsible for conducting the technical activities described under the responsibilities of the appropriate WMPO Branch Chief. An organizational chart depicting the WMPO organization is provided in Figure 3.

Figure 3

WMPO ORGANIZATION



The Project Manager, WMPO is responsible for the NNWSI Project management which encompasses: (1) planning and directing activities; (2) establishing goals and objectives, and assessing progress toward the attainment of those goals; (3) administration of procurement of materials and services; (4) preparation and issuance of technical and programmatic guidance; (5) organization and conduct of peer reviews; (6) compliance with laws, regulations, and DOE policies; and (7) other administrative duties. In addition, the Project Manager, WMPO is responsible to ensure implementation of the WMPO QA Program for the conduct of WMPO quality related activities and the implementation of corrective actions.

The technical responsibilities of the WMPO focus in three areas, each under the direction of a Branch Chief. Each Branch Chief is responsible for implementing the QA program in his/her area of responsibility. The QA responsibilities of the WMPO are accomplished through the efforts of the WMPO Project Quality Manager (PQM) and his organization. The overall responsibility to assure that quality assurance control and documentation is maintained throughout the Project is retained by the WMPO.

The WMPO utilizes a matrix management organizational concept to support NNWSI Project activities. The administrative responsibility for DOE/NV personnel supporting the NNWSI Project remains with the respective DOE/NV organizational element, while the functional responsibility of DOE/NV personnel performing NNWSI Project activities is to the WMPO. Personnel from Participating Organizations and NTS Support Contractors may also be matrixed to the WMPO. The organization of WMPO with respect to Quality Assurance is shown in Figure 3 as one organization with the major DOE/NV divisions that provide matrix support staff. The DOE/NV staff assists the Project Manager, WMPO by providing reviews, recommendations, and expertise on various aspects of the NNWSI Project in terms of their respective responsibilities as established in accordance with the matrix management approach. Matrix support personnel work under the implementing procedures of the WMPO QAPP.

SAIC/T&MSS provides broad technical, operational, and managerial support for NNWSI Project activities and performs these functions in accordance with the requirements of the WMPO QA Program Plan. SAIC/T&MSS efforts involve both the direct provision of technical, scientific, and institutional expertise and the management and integration of support provided by all Project participants in connection with planning, design, field investigations, laboratory work, construction, and regulatory licensing and institutional activities related to the NNWSI Project. SAIC/T&MSS assists the WMPO in such areas as (1) the identification and analysis of, and compliance with, applicable statutory, regulatory, and program requirements, (2) the development and execution of project management plans and strategies, (3) the monitoring and coordination of work performed by project participants, including the review of their work for completeness, technical sufficiency, and compliance with project requirements, (4) the preparation of assigned management, technical, and scientific reports and studies, (5) the presentation to the public, the program office, and affected federal, state, and other agencies of project positions, plans, and other project related information, (6) the execution, on an assigned basis, of any of the activities specified by the OCRWM approved work breakdown structure, and (7) quality assurance.

2.5 REGULATORY AND SITE EVALUATION BRANCH

The Regulatory and Site Evaluation Branch is responsible for (1) Site Characterization in field and laboratory activities (including geology, hydrology, geochemistry, geophysics, drilling, seismology, radiation safety, climate, meteorology, in-site testing in the Exploratory Shaft Facility (ESF), and sample management facilities); (2) performance assessment (including code development, analysis, and radionuclide release calculations); (3) Nuclear Regulatory Commission (NRC) interactions (including site visits, work shops, Appendix 7 meetings, and reviews of regulations); (4) preparation of project documents required by the Nuclear Waste Policy Act and the NRC (including preparation of the Site Characterization Plan (SCP), SCP updates, study plans, technical input to the Environmental Impact Statement (EIS) and license application, project position papers, and prelicensing topical reports for use in the license application to NRC); (5) site investigation documents - evaluation and approval of reports that contain data and interpretations from site characterization; and (6) review and approval of NNWSI Project quality related documents as defined in WMPO QMP-06-03, "Document Review/Acceptance/ Approval."

2.6 TECHNOLOGY DEVELOPMENT AND ENGINEERING BRANCH

The Technology Development and Engineering Branch is responsible for (1) systems description, analysis, and integration; (2) waste package design and development; (3) design, construction and operation of major test facilities; (4) operational safety; (5) repository engineering including conceptual design, rock mechanics, and borehole sealing; (6) instrument and equipment development; (7) exploratory shaft design, construction, and operation; (8) engineering and technical support for Project plans, reports, and presentations; and (9) review and approval of NNWSI Project quality related documents as defined in WMPO implementing procedures.

2.7 SYSTEMS AND PROJECT CONTROL BRANCH

The Systems and Project Control Branch is responsible for (1) administration and management support to integrate and control the NNWSI Project including preparation of networks, monitoring milestones, and overseeing issuance of Project documentation, (2) records management/information management system; (3) quality assurance records administration; (4) configuration management; (5) transportation; (6) socioeconomics; (7) institutional liaison; (8) Project training; (9) review and approval of NNWSI Project quality related documents as defined in WMPO implementing procedures; and (10) environmental analysis and support.

2.8 PROJECT QUALITY MANAGER (PQM)

The WMPO PQM is responsible for directing and managing the overall NNWSI Project QA Program and has appropriate organizational position,

responsibilities, and authority to exercise proper control over the WMPO QA Program. This position is occupied by an individual with appropriate QA knowledge and experience. The PQM reports functionally to the Project Manager, WMPO for the maintenance and implementation of the NNWSI Project QAP and the WMPO QAPP. The PQM is at the same or higher organizational level as the highest line manager responsible for activities affecting quality and is sufficiently independent from cost and schedule considerations. The PQM has effective communication channels with other senior management positions. An organization chart depicting the WMPO QA organization is shown in Figure 4.

Support by the PQM to the NNWSI Project includes (1) approval of the NNWSI Project QAP, NNWSI/88-9 (formerly NVO-196-17), (2) approval of quality related NNWSI Project Administrative Procedures (AP-Q), (3) approval of NNWSI Project Participant QAPPs and changes thereto, (4) the approval of the WMPO QAPP, NVO-196-18, its implementing procedures, and all changes thereto, (5) the responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA program implementation by the WMPO and NNWSI Project Participants through the direction of audits and surveillances, and (6) coordination of WMPO QA activities. The PQM is supported by the SAIC/T&MSS Project QA Department to conduct these activities.

The NNWSI Project QA organizational structure is such that if disputes in QA arise between the PQM and others (e.g., Branch Chiefs, Project Participants, etc.), the disputes will be directed to the Project Manager, WMPO for arbitration. If not satisfied with the decision, the PQM has the authority to have the DOE/NV Manager arbitrate. If still not satisfied with the resolution of the problem, the PQM has the responsibility to notify OCRWM.

2.8.1 SAIC/T&MSS PROJECT QA DEPARTMENT

(FORMERLY REFERRED TO AS: QUALITY ASSURANCE SUPPORT CONTRACTOR/QASC)

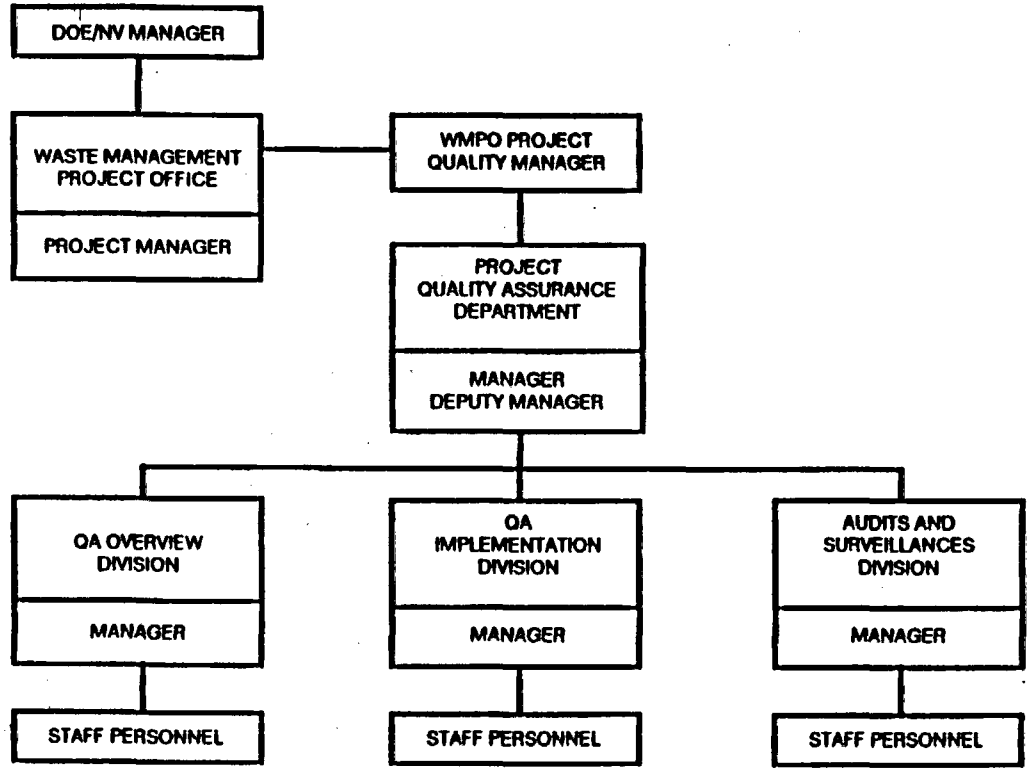
The responsibilities of the SAIC/T&MSS Project QA Department are to provide support to the PQM in the development, maintenance, documentation, administration, and implementation of the NNWSI Project QAP, and the WMPO QAPP. SAIC/T&MSS Project QA Department activities include conducting and participating in QA audits; overview; QA surveillance and monitoring of WMPO integrated technical activities; policy guidance; review of the QAPPs prepared by the participating organizations and NTS support contractors for compliance to the NNWSI Project QA Plan, NNWSI/88-9 (formerly NVO-196-17); and review of NNWSI Project quality related documents as defined in WMPO implementing procedures for compliance to Project QA requirements. 2

2.9 HEALTH PHYSICS AND ENVIRONMENTAL DIVISION (HPE)

Upon the request of WMPO, the Health Physics and Environmental Division (HPE) may provide matrix support personnel to WMPO and are responsible for review of procedures, facility designs, and operations plans applicable to radiological monitoring of the environment, radiological health of the public and radiological workers, compliance with environmental laws, and radiological operations of the DOE/NV, its contractors, or the national laboratories at NTS. The HPE acts on requests for support submitted by participating organizations through WMPO and provides design reviews, advice, and assistance to WMPO.

Figure 4

WMPO QA ORGANIZATION



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2.10 SAFETY AND HEALTH DIVISION (S&HD)

Upon the request of WMPO, the Safety and Health Division (S&HD) may provide matrix support personnel to WMPO and are responsible for review of procedures, facility designs, and operations plans applicable to the occupational health and industrial and fire safety of site workers and facilities. The S&HD acts on requests for support submitted by participating organizations through WMPO and provides document reviews, advice, and assistance to the WMPO.

2.11 CONTRACTS AND PROPERTY DIVISION (CPD)

Upon the request of WMPO, the Contracts and Property Division (CPD) may provide matrix support personnel to the WMPO and are responsible for preparing and negotiating contracts and other agreements with the national laboratories and other federal agencies (except the NRC for which DOE/HQ is responsible) on behalf of the DOE/NV in support of the NNWSI Project. The CPD acts on requests for support submitted by WMPO and provides procurement package reviews, advice, and assistance to WMPO.

3.0 SAIC/T&MSS ORGANIZATION

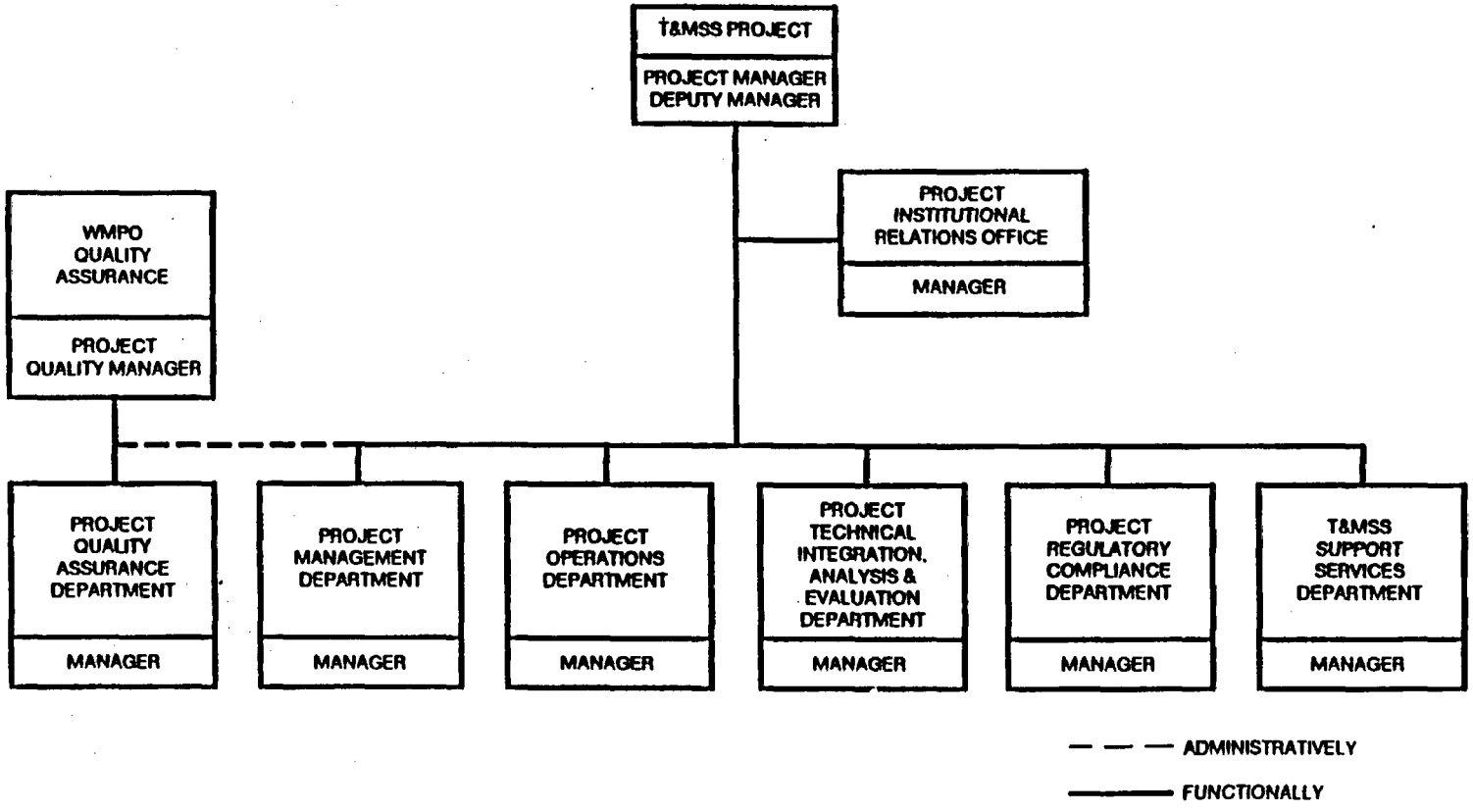
The SAIC/T&MSS organization is comprised of six major operating departments and a Project Institutional Relations Office reporting to the Project Manager. In addition, the Project QA Department reports administratively to the Project Manager (T&MSS) and functionally to the WMPO Project Quality Manager to assure independence. The following section describes the organization, relationships, responsibilities, and authorities of the T&MSS organization in its role as the integrating contractor for the WMPO in support of the NNWSI Project. An organization chart depicting the SAIC/T&MSS organization down to the department level is shown in Figure 5.

3.1 The Project Manager (T&MSS) reports directly to the Project Manager, WMPO. He has authority over all T&MSS personnel assigned to the NNWSI Project and is responsible for the management and performance of T&MSS activities in support of the WMPO.

The Project Manager (T&MSS) is responsible to ensure implementation of the WMPO QAPP and its implementing procedures for the conduct of all T&MSS quality related activities. He is also responsible for meeting the requirements of tasks performed by T&MSS for the WMPO. These requirements include staffing, control of costs, meeting schedules, and approval of deliverables. The Project Manager (T&MSS) is the primary contact with the WMPO and the primary spokesman for T&MSS. He is also responsible for the implementation of corrective actions in cases of deficiencies in the quality of T&MSS activities or items, as documented in audits and surveillances by WMPO QA or other organizations.

Figure 5

SAIC/T&MSS ORGANIZATION



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3.2 The Deputy Manger (T&MSS) reports to the Project Manager (T&MSS) and is delegated to act for the Project Manager (T&MSS) in his absence. He is responsible to assist the Project Manager (T&MSS) in the implementation of the WMPO QAPP and its implementing procedures thru coordination of the activities of the six SAIC/T&MSS Department Managers in the performance of their respective functions.

3.3 Project Management Department

The Project Management Department provides (1) overall management and integration for NNWSI Project management and Project Control WBS elements, management of T&MSS and Project plans and procedures, training of staff in both Project and T&MSS procedures and technical subject matter, and quick response support to client requests (e.g., briefings to outside organizations and DOE Headquarters); (2) management analysis and evaluation, including performance evaluation/reporting and performance measurement; (3) information management (including system operations, information integration, information systems development, and technical data management); and (4) Project configuration management support.

3.4 Project Operations Department

The Project Operations Department provides (1) engineering documentation and design reviews specifically related to waste package, repository, and exploratory shaft facility designs; (2) geotechnical services, including operation of the NNWSI Project Sample Management Facility and various field studies; (3) regional studies, including transportation, land access, and socioeconomics; and (4) environmental programs, including environmental and radiological field programs.

3.5 Project Technical Integration, Analysis, and Evaluation Department

The Project Technical Integration, Analysis, and Evaluation Department provides (1) technical integration across the NNWSI Project in systems, waste package, site, repository, regulatory, and institutional, exploratory shaft facility, and test facilities; and (2) technical evaluation and analysis of the site characterization plans and other technical documents.

3.6 Project Regulatory Compliance Department

The Project Regulatory Compliance Department provides (1) nuclear regulatory compliance support, including regulatory interaction and planning and regulatory review; and (2) environmental regulatory compliance support, including permitting and planning.

3.7 Project Quality Assurance Department

The Project Quality Assurance Department provides (1) quality assurance overview; (2) quality assurance implementation support, including development of plans and procedures; and (3) audits and surveillances of all Project activities. The department's functions are further described in paragraph 2.8.1 of this section.

3.8 T&MSS Support Services Department

The T&MSS Support Services Department provides (1) T&MSS administrative support, including personnel services and support to and coordination with sector contractor administration; (2) computer services, including software development and support, operations, and systems support; and (3) publication services, including technical editing, word processing, and graphics.

3.9 Project Institutional Relations Office

The Project Institutional Relations Office provides support in DOE interactions with the State of Nevada and other affected public parties.

4.0 PARTICIPATING ORGANIZATIONS AND NTS SUPPORT CONTRACTORS

This section identifies the major organizations participating in the Project, the designated functions of these organizations and their relationship with the WMPO. Participating organizations and NTS support contractors are responsible to the WMPO for technical activities assigned to them as specified in the NNWSI Project WBS Dictionary and Project specific technical plans. The technical activities are to be accomplished in accordance with the QA requirements in the NNWSI Project QAP, NNWSI/88-9, (formerly NVO-196-17) and their respective QAPPs when approved by the WMPO.

4.1 NTS Support Contractors

4.1.1 Fenix and Scisson, Inc. (F&S)

Fenix and Scission, Inc. is the Exploratory Shaft Facility (ESF) architect-engineer (A-E) for drilling and mining for the NNWSI Project. Responsibilities also include field surveillance and inspection of drilling and mining, and subsurface facilities construction and testing.

4.1.2 Holmes and Narver, Inc. (H&N)

Holmes and Narver, Inc. is the ESF A-E responsible for the design of the underground support systems and the above-ground facilities. Responsibilities include field surveillance and inspection of facilities construction. Additionally, they provide Material Test Laboratory support, nondestructive examination services, and field surveying services, microfilming, and archival storage of NNWSI Project records.

4.1.3 Reynolds Electric and Engineering Company (REECo)

Reynolds Electric and Engineering Company is the prime support contractor providing support for subsurface and surface construction, drilling, and mining. REECo assists in the operation and maintenance of the site facilities and provides procurement and logistical activities for the NNWSI Project when requested.

4.2 PARTICIPATING ORGANIZATIONS

4.2.1 Lawrence Livermore National Laboratory (LLNL)

Lawrence Livermore National Laboratory is responsible for the development of the waste package for emplacement in tuff, which includes the definition of the package environment, material development and testing, package design, performance analysis, and testing; and provides assistance to other NNWSI Project participants in areas of specialized expertise.

4.2.2 Los Alamos National Laboratory (LANL)

Los Alamos National Laboratory is responsible for nuclide migration, geochemistry, mineralogy, and petrology studies. Los Alamos acts as the lead technical organization for the coordination and scheduling of the ES testing program. Los Alamos also provides assistance to other NNWSI Project participants in areas of specialized expertise.

4.2.3 Sandia National Laboratories (SNL)

Sandia National Laboratories is responsible for (1) repository systems development; (2) data management and analysis; (3) systems performance assessment of the repository; (4) conceptual design of the repository; (5) determining the thermal and mechanical properties of the host rock; (6) repository sealing performance requirements, materials, evaluation, design, and testing; and provides assistance to other NNWSI Project participants in areas of specialized expertise.

4.2.4 United States Geological Survey (USGS)

The United States Geological Survey is responsible for (1) site characterization of geology, hydrology, tectonism, volcanism, and seismicity; (2) acts as lead technical participant for the site characterization drilling activities; and (3) provides assistance to other NNWSI Project participants in areas of specialized expertise.

SECTION I

ORGANIZATION

1.0 QUALITY ASSURANCE RESPONSIBILITIES OF PROJECT PARTICIPANTS

The Nevada Nuclear Waste Storage Investigations (NNWSI) Project Participants shall be responsible for the establishment and execution of a Quality Assurance Program Plan (QAPP). The participants may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the Quality Assurance (QA) program, or any part thereof, but shall retain the responsibility therefore. The delegation of execution of the QA Program Plan requirements shall be documented. The organizational structure, lines of communication, authority and duties of persons and organizations performing activities affecting quality shall be clearly established and delineated in writing. These activities affecting quality include both the performing functions of attaining quality objectives and the QA functions. While the line organization is responsible for performing these activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.

2.0 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 the quality functions have been performed correctly. The persons and organizations performing QA functions shall 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 shall have direct access to responsible management at a level where appropriate action can be effected and shall report to a management level at which this required authority and organizational freedom are provided, including sufficient independence from cost and schedule.

2.1 DEDICATED QA POSITIONS

The person responsible for directing and managing the overall NNWSI Project Participant QA program shall be identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. This person shall have appropriate management and QA knowledge and experience and shall be at the same or higher organization level as the highest line manager responsible for performing activities affecting quality and sufficiently independent from cost and schedule. 0

Personnel in this position shall have responsibility for approval of (1) QAPPs, changes thereto, and interpretations thereof and (2) implementing procedures and all changes thereto. This position shall have effective communication channels with other senior management positions. Personnel in this position shall have the responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA program implementation by that organization and its subordinate organizations. Full-time dedicated QA positions are to be established by the Waste Management Project Office (WMPO), Participating Organizations, and the Nevada Tests Site (NTS) Support Contractors. The management position that retains overall authority and responsibility for the QA Programs as well as personnel considered to be "full-time dedicated" shall not be assigned duties that would prevent full attention to NNWSI Project QA responsibilities or that would conflict with the reporting and resolution of QA issues and problems related to the NNWSI Project.

2.2 AUTHORITY

Authority for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and others shall be identified. This authority shall include the ability of QA personnel to elevate the resolution of disputes to progressively higher organization levels through established channels including the WMPO PQM, if the dispute cannot be resolved within the organization.

2.3 ORGANIZATIONAL STRUCTURE

Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations at which the activities are to be performed, the organizational structure for executing the QA program may take various forms provided that the persons and organizations assigned the QA functions have the required authority and organizational freedom. The QA responsibilities of all organizational elements depicted on organization charts shall be described.

3.0 QUALITY ASSURANCE PROGRAM PLAN

A Quality Assurance Program Plan (QAPP) shall apply to all items and activities of an organization affecting quality. The organizational structure and the responsibility of assignments shall be clearly established such that certain results, as described below, are obtained.

3.1 ACHIEVEMENT AND MAINTENANCE OF QUALITY

Quality is achieved and maintained by those who have been assigned responsibility for performing work.

3.2 VERIFICATION

Quality achievement is verified by persons or organizations not directly responsible for performing the work. Verification of conformance to established requirements (acceptance) is accomplished by individuals or groups within the QA organization unless specifically exempted elsewhere in this document.

4.0 MULTIPLE ORGANIZATIONS

If more than one organization is involved in the execution of activities affecting quality, then the responsibility and authority of each organization shall be established clearly and documented.

4.1 DOCUMENTATION OF INTERFACES

The external interfaces between organizations and the internal interfaces between organizational units and changes thereto shall be documented. All interface responsibilities shall be defined and documented. Interfaces between the WMPO, the Participating Organizations, and the NTS Support Contractors shall be described in the QAPPs of the respective organizations. From an overall NNWSI Project standpoint, these interfaces are exchanges of technical requirements of work to be performed and liaison until completion of work. The NNWSI Project Administrative Procedures (APs) provide the implementing interface controls utilized by all of the NNWSI Project participants while Participating Organization and NTS Support Contractor implementing procedures describe the methods of conducting inter-organizational interfaces.

The organizational structure for executing the QA programs varies from organization to organization, and each one shall be described in the individual organization's QAPP. The Technical Project Officer of the respective Participating Organizations and the respective NTS Support Contractors are responsible to the WMPO Project Manager to ensure that the Project activities for which they are responsible are performed to a QAPP and implementing procedures that are consistent with this QAP.

SECTION II

QUALITY ASSURANCE PROGRAM

1.0 EXTENT OF THE QUALITY ASSURANCE PROGRAM

The Quality Assurance (QA) Program for the NNWSI Project consists of the NNWSI Quality Assurance Plan (QAP), the QA Program Plans of the Waste Management Project Office (WMPO), the Participating Organizations, and the Nevada Test Site (NTS) Support Contractors, and the QA and technical procedures required to implement these documents. The NNWSI Project Office will submit this QAP and the WMPO QAPP to the OCRWM Director, Office of Quality Assurance for approval. Pending receipt of this approval, QA plans may be issued by WMPO for interim use. When any QA plan is issued for interim use, the transmittal record shall be appropriately marked to indicate that it is for interim use. Final QA plans will include a signature block for approval by the Director, Office of Quality Assurance. 2

Each NNWSI Project Participant shall develop a Quality Assurance Program Plan which shall provide the description of the organization's QA program and indicate the commitment to the applicable NNWSI Project QA requirements given herein. Each Quality Assurance Program Plan (QAPP) shall include consideration of the technical aspects of the activities affecting quality and shall be generated by the respective QA organization with assistance from the technical staff. The QAPP shall provide instruction to implement and apply the QA requirements to the technical activities of the NNWSI Project. It shall be planned, implemented, and maintained in accordance with this document and be consistent with and address all of the applicable requirements of this NNWSI QA Plan. Management above or outside of the QA organization shall regularly receive information as to the scope, status, adequacy, compliance, etc. of the QA Program. 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 prior to starting a major activity.

The hierarchy of criteria applicable to the Project are shown in Figure 1 of the Introduction of this document. With the exception of the CFR, where deviations between the requirements of the higher-tier documents referenced in that Figure and this QAP exist, the requirements of this document shall prevail. 2

1.1 QA CRITERIA

The QA Criteria and specific requirements associated with these criteria have been adapted to the NNWSI Project activities through this QA plan and shall be addressed in the QAPPs of the WMPO, the Participating Organizations, and NTS Support Contractors. When a specific criteria is not applicable to an organization's activities, it shall be noted in the QAPP and recorded on the checklist required in paragraph 1.2 below with justification of its exception.

1.2 CONTENTS OF THE QAPP

The Quality Assurance Program of each organization shall consist of the QAPP plus appropriate implementing procedures required to provide and implement control over activities affecting quality. The control shall be consistent with the importance of the activity. These procedures shall be developed by qualified personnel and be reviewed and approved by the cognizant QA organization prior to implementation to assure that they meet all the requirements of their QAPP. 2

The QAPP of each Participating Organization and NTS Support Contractor shall be submitted to the WMPO for review prior to implementation and shall include a checklist based on this NNWSI QAP which identifies how and where each requirement of this document is addressed. The WMPO is also required to complete a checklist based on NNWSI/88-9 (formerly NVO-196-17) for the preparation of the WMPO QAPP. The QAPP of each Project Participating Organization and NTS Support Contractor shall be reviewed, comments resolved, and the document approved by the WMPO within a timely manner. 2 2

1.3 QAPP VERIFICATION

Assurance that the QA requirements have been adequately addressed and effectively implemented will be provided by the WMPO with support from the SAIC/T&MSS Project QA Department during the review and approval of each organization's QAPP, monitoring and surveillance operations, and audits of activities. The Participating Organizations' and NTS Support Contractors' management shall also monitor their respective QAPPs through internal audits to assess the adequacy of their program and assure its effective implementation.

1.4 USE OF DATA NOT GENERATED UNDER QA CONTROLS

The QA program for the NNWSI Project provides for the acceptance of existing data for use in licensing activities that were not generated under the controls of a QA Program which meets the requirements of 10 CFR 60, Subpart G. Specific methods for acceptance of this information are contained in NNWSI Project Administrative Procedure 5.9Q. This procedure shall meet the requirements of NUREG - 1298 "Qualification of Existing Data for High-Level Nuclear Waste Repositories" (February, 1988). These requirements are contained in Appendix G to this QA Plan. Once accepted, this existing data is classified as "primary data" for licensing purposes.

1.5 METHODOLOGY FOR FORMULATING THE "Q" LIST AND QUALITY ACTIVITIES LIST

The WMPO shall prepare the appropriate NNWSI AP or APs for determining the items and activities to be placed on the Project Q-List and Quality Activities List. Procedure(s) shall meet the requirements of NUREG - 1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements" (April, 1988). These requirements are contained in Appendix I to this QA Plan. 2

1.6 APPROACH TO QA

The NNWSI 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, nonradiological health and safety, the U.S. Nuclear Regulatory Commission (NRC) licensing requirements, the operability and maintainability of the repository, costs, and schedules. The Participating Organizations or WMPO shall identify the appropriate quality assurance levels for all items and activities that affect quality associated with site characterization, facility and equipment construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. Once assigned, the QA level for a particular item or activity shall be applied by all NNWSI Project participants involved in the activity.

1.7 APPLICATION OF QA

A QAPP that complies with the requirements of this document, NNWSI/88-9 (formerly NVO-196-17), shall be established by each NNWSI Participant at the earliest practicable time consistent with the schedule for accomplishing the activities. Each QAPP shall assure that procedures required to implement the requirements of this document are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official. The QAPP shall be applied throughout the life of the NNWSI Project in accordance with the established policies, procedures, and instructions. The QAPP shall apply to all items and activities affecting quality. It also shall identify the major organizations participating in the project and the designated functions of these organizations. The QAPP shall provide control over activities that affect the quality of the identified structures, systems, and components to an extent consistent with their importance. The activities that affect quality shall 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 shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection, test, peer review, or a combination of these. The program shall provide for indoctrination and, as necessary, training of personnel performing activities that affect quality to assure that suitable proficiency is achieved and maintained.

The WMPO shall regularly assess the status and adequacy of the QA Programs of the Participating Organizations and NTS Support Contractors by means of overview, surveillance, and audit activities.

2.0 APPLICATION OF GRADED QUALITY ASSURANCE

2.1 SCOPE

2.1.1 EXTENT OF APPLICATION

The requirements of this section are applicable (as defined herein) to all items and activities that affect quality during geologic repository site characterization, facility and equipment design, procurement and construction, facility operation, performance confirmation, permanent closure, decommissioning, and dismantling of surface facilities. The preparation of administrative and management planning documents shall not require QA level assignments, except for project level documents which are specifically required by the Nuclear Waste Policy Act of 1982 (as amended), or are required for licensing. In addition, procurement of administrative items (i.e., office supplies) do not require QA level assignments. The WMPO shall develop a Project administrative procedure for the application of graded QA. The procedure shall be in consonance with the QA requirements specified herein. It may be necessary to exempt certain NNWSI items and activities from QA Level assignment. Requests for exemptions shall be documented and shall contain sufficient justification to support the exemption request. Such exemptions shall be approved by the WMPO PQM. 2

2.1.2 PURPOSE OF A GRADED QA PROGRAM

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.

2.1.3 DETERMINATION OF THE DEGREE TO WHICH APPLICATION IS NECESSARY

This approach involves (1) identifying those items and activities whose failure could cause undue risks to the public and facility personnel or extended interruption of facility operation with critical economic losses, or both, and (2) ensuring that these items and activities are covered by a commensurate QA program. Alternatively, an item whose failure or malfunction could result only in operational inconvenience or negligible economic loss may deserve only a quality inspection by the purchaser upon the delivery of the item. Between these two extremes, there are varying degrees of QA to achieve the desired confidence in the quality of the completed line of activity.

2.1.4 FLEXIBILITY OF QA REQUIREMENT SELECTION

The graded approach set forth here provides flexibility in the selection of the quality assurance requirements to be applied to an item or activity that is commensurate with the relative importance of the role or function assigned to the item or activity. 2

2.2 REQUIREMENTS

The requirements specified in this section are to be used to apply the graded quality philosophy to all NNWSI Project items and activities.

2.2.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QA REQUIREMENTS

The appropriate Quality Assurance Level for any item or activity shall be determined by the application of decision criteria as provided by the NNWSI Administrative Procedures. The basis for the selection of the Quality Assurance Level and assigned QA requirements shall be documented. The assigned Quality Assurance Levels and QA requirements must be submitted to the WMPO for review, resolution of comments, and approval prior to implementation or use. This review and approval shall be performed by the WMPO PQM and appropriate WMPO Branch Chiefs.

2.2.2 SELECTION OF SPECIFIC QA LEVELS

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 NNWSI Project. The definition, application, and assignment to each of the three QA levels are described in the following discussion.

2.2.2.1 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 post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

2.2.2.2 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 WMPO concerns, and the environment.

2.2.2.3 QA Level III - are those activities and items not classified as QA Levels I or II.

2.2.3 APPLICATION OF LEVELS

2.2.3.1 QA LEVEL I

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 will provide the primary data input to the basis for the NRC to authorize construction and to issue a license for the DOE to receive and possess source, special nuclear, and byproduct material (waste) at the geologic repository. QA Level I control and documentation must be applied to activities, including site characterization, scientific investigation, facility and equipment design, procurement, and construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities when they are specifically concerned with the protection of the public's health and safety with respect to a radiological hazard.

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 as per the following:

- Where items and activities could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, or result in, an 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 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 items and activities that, having failed, could cause a failure of a QA level I item, or irretrievable loss of QA level I data.

- The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) will be assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationalships. 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.

2.2.3.2 QA LEVEL II

QA Level II is the second highest level of quality assurance. QA Level II controls and documentation shall be applied to the NNWSI 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 that 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 non-radiological 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 10CFR20.

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

- Where items and activities that involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components.

- The design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/method/equipment is preferred, shall be assigned a QA Level of II prior to execution. Where a particular item can be identified and defined during this phase, a separate QA Level assignment may be made for that item. Once the QA Level for such an item is identified and approved, design procurement and construction activities shall be governed by the QA Level assigned to the item.

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

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

Quality Assurance Level II activities may have as much importance as Quality Assurance Level I activities; 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 a 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 NNWSI AP 5.9Q "Acceptance of Data and Data Interpretations Not Developed Under the NNWSI Project QA Program."

2.2.3.3 QA LEVEL III

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 NNWSI Project Quality Assurance Plan may be used in the licensing process as background or corroborative information.

2.2.4 GENERAL

The requirements contained in this document 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 the organizations participating in the NNWSI Project. 2

3.0 QA ACTIVITIES

3.1 OVERVIEW

Each NNWSI 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.

3.2 REVIEW AND APPROVAL OF QA PROGRAMS

Procedures are to be established by each NNWSI Project Participant for the review of QA program documentation of those organizations under their 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.

4.0 MANAGEMENT ASSESSMENT

4.1 FREQUENCY OF MANAGEMENT ASSESSMENTS

Management assessments are to be conducted at least annually for determining (1) the effectiveness of the system and management controls that are established to achieve and assure quality, and (2) 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.

4.2 PERFORMANCE OF MANAGEMENT ASSESSMENTS

Management assessments are to be performed by the WMPO and each NNWSI Project Participant. Each organization is to develop its internal procedures for planning, organizing, performing, and documenting the management assessment conducted, 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, WMPO and the WMPO PQM. The Project Manager, WMPO will make appropriate submittals of management assessment reports to OCRWM. Management above or outside the QA organization shall be responsible for the management assessment activity.

5.0 PERSONNEL SELECTION, INDOCTRINATION, AND TRAINING PROCEDURES

5.1 ESTABLISHMENT OF REQUIREMENTS

All NNWSI Project participants shall establish requirements for the selection, indoctrination, and training of personnel performing or verifying activities that affect quality. The requirements shall establish position descriptions that set forth minimum personnel qualifications and provide for appropriate indoctrination or training or both, prior to initiation of activities that affect quality. In addition to the following requirements for indoctrination and training, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, nondestructive examiners, etc.) shall be certified in accordance with the detailed requirements specified in Appendix C, D, or F, as applicable.

5.1.1 POSITION DESCRIPTION

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.

5.1.2 PERSONNEL QUALIFICATION EVALUATION

Personnel selected shall have education and experience commensurate with the minimum requirements specified in the position description. Relevant education and experience shall be verified. This verification shall be documented. The initial capabilities of an individual shall be based upon an evaluation of their education, experience, and training and compared to those established for the position. Evaluations shall be documented by managers or supervisors responsible for the activities to be performed.

5.1.3 INDOCTRINATION

Prior to assigning personnel to perform activities affecting quality, they shall be indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the work to be accomplished. Indoctrination may be accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or other instructional methods.

- QAPP's
- Implementing Procedures and Work Instructions (applicable to the individual's responsibilities).
- Regulations
- Project level Documents

5.1.4 TRAINING

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

5.1.5 PROFICIENCY EVALUATION

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

5.1.6 RECORDS

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

5.1.6.1 Personnel Qualification Evaluation Records

Records of the verification and evaluation of a candidate's education, experience, and training, compared to those required for the position.

5.1.6.2 Indoctrination Records

Records of indoctrination which include the objective and content of the indoctrination, date or dates of indoctrination, and other applicable information.

5.1.6.3 Training Records

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.

5.1.6.4 Proficiency Evaluation Records

Records of proficiency evaluation shall include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.

SECTION III

SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL

1.0 SCIENTIFIC INVESTIGATION CONTROL

1.1 PREPARATION OF PLANS

1.1.1 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

Prior to the start of any scientific investigation, the responsible Principal Investigator (PI) shall develop a scientific investigation planning document for that investigation. Scientific investigations categorized as site characterization activities as defined in the Nuclear Waste Policy Act (as amended) shall utilize study plans as the scientific investigation planning document. The WMPO shall conduct a technical, QA, and management review of scientific investigation planning documents and approve the document prior to implementation. Study plans shall also be reviewed and approved by OCRWM prior to implementation. Such planning documents shall contain or shall reference the following:

1.1.1.1 Description of Work to be Performed

A description of the work to be performed in the scientific investigation and the proposed methodology for accomplishing the work including a discussion of the overall purpose for the work shall be provided in the scientific investigation planning document. References to any applicable regulations, requirements, performance criteria, key issues, issues, information needs, higher level scientific investigation planning documents, or Work Breakdown Structure (WBS) items, for which the work is to be performed shall also be provided. This discussion shall identify all of the factors and concerns that are important for the planning or the performance of the scientific investigation including identification, explanation, and justification for areas where scientific notebooks are to be used. 2 2

1.1.1.2 Description of previous work

A description of any previous work which will be used in support of the scientific investigation, including the identification of the Quality Assurance Levels, or Quality Assurance (QA) controls, under which that previous work was performed. Note: This requirement does not apply to study plans.

1.1.2 PLANNING DOCUMENTS

The scientific investigation planning document shall contain a level of detail which would enable an independent reviewer to determine the appropriate QA Level to be applied to the investigation. For Site Characterization activities, the purpose and key milestones of study plans is described in the SCP. The format and content of study plans shall meet the requirements of Appendix K of this QA Plan. 2

1.2 ASSIGNMENT OF QUALITY ASSURANCE LEVELS

1.2.1 ASSIGNMENT

Once a scientific investigation planning document, as specified in Paragraph 1.1.1 of this section has been developed, the Quality Assurance Levels for all of the items and activities which are associated with that work, may be assigned. It may be necessary in some cases to assign Quality Assurance Levels to the items and activities within a plan that was prepared earlier.

Therefore, the Quality Assurance Level assignments are not a part of the planning documents themselves, even though they would normally accompany those planning documents and go through the same review and approval process.

1.2.2 CONFORMANCE

Scientific investigation planning documents shall be prepared and Quality Assurance Levels shall be assigned in accordance with the methods specified in the Nevada Nuclear Waste Storage Investigations (NNWSI) Project Administrative Procedures Manual.

1.3 REVIEW AND APPROVAL PROCESS

1.3.1 RESPONSIBILITY

The responsible Participating Organization shall conduct a technical review of the scientific investigation planning document. This review shall be performed by any qualified individual(s) other than those who developed the original planning document. In exceptional cases, the originator's immediate supervisor can perform the review if the supervisor is the only technically qualified individual, and if the need is individually documented and approved in advance with the concurrence of the QA manager of the originating organization. The results of this technical review, and the resolution of any comments by the reviewer or reviewers, shall be documented, and shall become a part of the QA records. 2

1.3.2 WASTE MANAGEMENT PROJECT OFFICE REVIEW

The WMPO Project Quality Manager and the appropriate WMPO Branch Chief shall review and approve the scientific investigation planning document prior to implementation. The WMPO PQM shall return the planning document to the responsible organization's TPO upon completion of the WMPO review and approval cycle. Study plans shall also be reviewed and approved by OCRWM prior to implementation.

1.3.3 PEER REVIEW

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

1.4 SCIENTIFIC INVESTIGATION DATA INTERPRETATION AND ANALYSIS

1.4.1 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.

1.4.2 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.

1.5 USE OF COMPUTER PROGRAMS

Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subsection 3.0 and Appendix H of this QA Plan. The documentation and control measures shall be consistent with the guidance contained in NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."

1.6 THE USE OF SCIENTIFIC NOTEBOOKS VERSUS THE USE OF TECHNICAL IMPLEMENTING PROCEDURES

1.6.1 DOCUMENTATION

There are two methods which can be used for the quality assurance, documentation and control of scientific work. These are the scientific notebook system and the technical implementing procedure system. | 2

The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgment, trial and error methods, or developing the methodology by which an activity will be accomplished. When the scientific notebook system is used, the study plan or scientific investigation planning document shall be the controlling document used to perform the activity since it describes the proposed approach or general procedure for accomplishing the work. Alternatively, the technical implementing procedure system will generally be used when qualified personnel are performing repetitive work which does not include the use of a high-degree of professional judgment or trial and error methods in the performance of the work. 2
Detailed technical implementing procedures are required when it is not possible to deviate from a prescribed sequence of actions, without endangering the validity of the results that will be obtained from the work. Modifications may be made to these procedures as detailed in Para. 1.6.2. Logbooks or appropriate forms or both are used, particularly in repetitive work, to document the performance of the work according to the technical implementing procedure, and to maintain absolute control over all other aspects of the work.

1.6.2 TECHNICAL IMPLEMENTING PROCEDURES

Detailed technical implementing procedures together with appropriate logbooks and other supporting documents, shall be used whenever the work is repetitive. Such technical implementing procedures shall be developed in accordance with the requirements given in Section V of this document and reviewed for compliance with the requirements of this section of the QA Plan. Modifications may be made to the technical aspects of technical implementing procedures by the individual utilizing the procedure. If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer. 2

Requirements and acceptance or rejection criteria, including required levels of precision and accuracy, shall be provided or approved by the organization responsible for the scientific investigation, unless otherwise designated.

Technical procedures utilized for 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. 2

- 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. 2

- Provision for ensuring that prerequisites have been met.

- Special training or qualification requirements for personnel performing the scientific investigation.

- Personnel responsibilities.

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

1.6.2.2 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.

1.6.2.3 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.

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

1.6.3 SCIENTIFIC NOTEBOOKS

Scientific notebooks along with other appropriate documents may be used to document scientific investigations and experiments. In such cases, this documentation shall be sufficient such that another qualified scientist can use the notebook to retrace the investigation and confirm the results, or repeat the experiment and achieve the same results without recourse to the PI.

1.6.4 FORMAT FOR DOCUMENTATION

Documentation of scientific work i.e. experiments and research shall be performed using bound logbooks or notebooks to provide written record of the experiment or research.

1.6.4.1 Initial Entries

Where appropriate, and prior to initiation of the experiment or research, the following entries, as a minimum, shall be made 2

- o Title of the experiment or research.
- o Name of the qualified individual or individuals performing the experiment or research.
- o Description of the experiment's objective or objectives and the proposed approach or procedure for achieving these objectives. This may be accomplished by reference to the appropriate study plan or other scientific investigation planning document which controls the work. 2
- o 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.
- o Calibration requirements.
- o Dated signature of the individual or individuals making the initial entries.
- o Special training or qualification requirements.
- o Documentation of suitable and controlled environmental conditions, if applicable.
- o Required levels of precision and accuracy shall be identified. 2
- o 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. 2

The initial entries described above are considered to be a "general" procedure and shall be entered into the scientific notebook prior to beginning an investigation. Modifications may be made by the individual performing the investigation. If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site, or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer. 2

1.6.4.2 In-process Entries

Entries to be made during the experiment or research, daily or as appropriate, shall 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.
- Provisions for assuring 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 1.6.4.1 of this section.
- All data taken and a brief description of the results, to include notation of any unaccepted results.
- Any deviations from the planned experiment or research.
- Any interim conclusions reached, as appropriate. 2

1.6.4.3 Final Entries

The final entries in the record shall have, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer.

1.6.4.4 Final Results

Final results and a summary of the outcome of the experiment or research shall be documented (e.g. in a technical report). This shall include a discussion of whether the experiment's objectives as outlined in the initial entries (Paragraph 1.6.4.1) were achieved. This documentation shall become part of the QA records of the activity. 2

1.7 CHANGE CONTROL

All changes in scientific investigation planning documents shall go through the same review and approval process as specified in Paragraph 1.3 of this section. The Participating Organization shall be responsible for evaluating the impacts of such changes on the associated Quality Assurance level assignments.

1.8 INTERFACE CONTROL

1.8.1 COORDINATION

Internal and external scientific investigation interfaces shall be identified and scientific investigation efforts shall be coordinated among and within Participating Organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among and within Participating Organizations for the review, approval, release, distribution and revision of documents involving scientific investigation interfaces. Interfaces within a participating organization shall be coordinated according to procedures developed by that participating organization. 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 WMPO. Interfaces between Participating Organizations and their suppliers shall be controlled in accordance with procedures established by the Participating Organization. Ongoing field or laboratory scientific investigations shall be identified to preclude inadvertent interruption and to ensure operational compatability. 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.

1.8.2 TRANSMITTAL

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

1.9 VERIFICATION OF SCIENTIFIC INVESTIGATIONS

1.9.1 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 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.

- o Acceptance and rejection criteria.
- o Identification of required procedures, drawings, and specifications (including revisions).
- o Recording identification of the verifier and the results of the verification.

1.9.2 VERIFICATION HOLD POINTS

Mandatory verification hold-points shall be established as necessary. When such hold points are established, work may not proceed 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.

1.9.3 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 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 verification activities are not part of the formal QA organization (i.e., part of line management), then the quality assurance organization shall overview and monitor the verification activity.

1.10 SURVEILLANCE OF SCIENTIFIC INVESTIGATIONS AND EXPERIMENTS

1.10.1 LOGISTICS OF SURVEILLANCE

The QA organization within the Participating Organization shall perform surveillances of all scientific investigations, as may be deemed appropriate for the purposes and the complexity of the work. The QA surveillance team for a scientific investigation shall consist of one or more qualified technical individuals and one or more QA personnel. The timing and the number of surveillances shall be determined by the QA surveillance team that is formed for this work. Surveillances will be performed in accordance with the requirements specified in Section XVIII of this document.

1.10.2 SURVEILLANCE TEAM

The technical member or members of the QA surveillance team shall be familiar with the plan for the scientific investigation.

1.11 REPORTS, CONCLUSIONS, AND RECOMMENDATIONS

The Participating Organization shall have implementing procedures for the technical review and approval of the results of scientific investigations. These procedures shall include the WMPO in the review and approval cycle of the Final report.

1.12 CLOSE-OUT VERIFICATION

The Participating Organization shall perform a close-out verification upon the completion of any scientific investigation to assure that the QA records for that investigation are adequate and complete. This will be done because it may be a considerable period of time after the work is completed and before the investigation is used in the licensing process. Close-out verifications shall be performed by a team consisting of qualified technical personnel as well as QA personnel.

2.0 DESIGN CONTROL

2.1 GENERAL

2.1.1 DEFINITION

The design shall 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.

It is the policy of the NNWSI 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.

2.1.2 QUALITY ASSURANCE LEVEL ASSIGNMENT

All design phases shall be assigned a Quality Assurance Level prior to execution in accordance with the methods specified in the NNWSI Project Administrative Procedures Manual.

2.1.3 QUALIFICATION OF PERSONNEL

Personnel performing design work shall be indoctrinated, trained, and qualified in accordance with the requirements of Section II of this document. Instructions, procedures and drawings for design work shall be in accordance with the requirements of Section V of this document.

2.1.4 PEER REVIEW

For design activities including design output documents which involve use of untried or beyond state-of-the-art testing and analysis procedures and methods, or where detailed technical criteria and requirements do not exist or are being developed, a peer review shall be conducted. The peer review shall meet the requirements of Paragraph 4.0 of this section of the NNWSI Project Quality Assurance Plan (QAP).

2.2 DESIGN INPUT

2.2.1 IDENTIFICATION, REVIEW AND APPROVAL OF INPUT

Applicable design input, such as site characterization data, criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards, shall be identified, documented, and their selection reviewed and approved by the responsible design organization and the responsible QA organization. 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. 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.

2.2.2 CHANGES TO DESIGN INPUT

Changes to approved design input, including the reason for the changes, shall be identified, documented, approved, and controlled by the responsible design organization.

2.2.3 CONSIDERATIONS FOR DESIGN INPUT

Considerations for design inputs as they apply to specific items or systems are contained in Appendix B of this document.

2.3 DESIGN ANALYSIS

2.3.1 DESIGN ANALYSIS DOCUMENTS

Design analyses shall 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.

2.3.2 DOCUMENTATION OF DESIGN ANALYSES

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 the QA review is to assure that the documentation is prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

2.3.3 USE OF COMPUTER PROGRAMS

Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subparagraph 3.0 and Appendix H of this QA Plan.

2.4 DESIGN VERIFICATION

2.4.1 IDENTIFICATION AND DOCUMENTATION

Design control measures shall be applied to verify the adequacy of design and verification shall be performed in a timely manner. The responsible design organization shall identify and document the verification method used, the results of the verification, and the verifier.

2.4.2 TIMING OF VERIFICATION

Verification of the adequacy of design shall 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 can not be met, the portion or portions of design which have not been verified shall be identified and controlled. In all cases, the verification shall be completed prior to relying on the component, system, or structure to perform its function.

2.4.3 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 in accordance with Paragraph 2.4 of this section, 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, shall be verified for each application. Known problems affecting the standardized or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

2.4.4 CHANGES TO VERIFIED DESIGNS

Changes to previously verified designs shall require verification including evaluation of the effects of those changes on the overall design.

2.4.5 PERSONNEL PERFORMING VERIFICATION

Design verification shall be performed in accordance with the requirements of Paragraph 2.4.6 of this Section by any competent, certified individual or individuals or certified group or groups other than those who performed the original design. This includes the following:

2.4.5.1 Individuals or groups from the originator's same organization.

2.4.5.2 Individuals or groups from other organizations contracted for this purpose.

2.4.5.3 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. The QA manager shall also concur with this rationale.

2.4.6 METHODS OF DESIGN VERIFICATION

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

2.4.6.1 Design Reviews

Design reviews are detailed critical reviews to provide assurance that the design is correct and satisfactory. At a minimum, the items below shall 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 verified in accordance with the methods specified in paragraph 3.0 of this Section. 2

2.4.6.2 Alternate Calculations

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 a review of the appropriateness of assumptions, inputs and computer programs or other calculation method used.

2.4.6.3 Qualification Tests

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 shall be identified. The test configuration shall be clearly defined and documented.

Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mock-ups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design work.

2.4.6.4 Peer Review

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.

2.5 DESIGN CHANGE CONTROL

2.5.1 CHANGES TO APPROVED DESIGNS

Changes to approved designs, including field changes, shall be justified and subjected to design control measures commensurate with those applied to the original design and approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the WMPO shall designate a new responsible organization. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design. Errors and deficiencies in approved design and design information documents shall be documented, and action taken to assure that all errors and deficiencies are corrected. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

2.6 DESIGN INTERFACE CONTROL

2.6.1 IDENTIFICATION AND RESPONSIBILITY

Internal and external design interfaces shall be identified and controlled and design efforts shall be coordinated among and within responsible design organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among and within responsible design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

2.6.2 INFORMATION TRANSMITTED ACROSS INTERFACES

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

2.7 DESIGN OUTPUT REQUIREMENTS

2.7.1 DESIGN OUTPUT DOCUMENTS

Design output documents shall:

2.7.1.1 Relate to the design input by documentation in sufficient detail to permit design verification.

2.7.1.2 Identify assemblies or components or both 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 or testing or both, to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

2.7.1.3 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 shall include the participation of the technical and QA elements of both the responsible design organization and the WMPO. The purpose of the QA review is to assure that the documents are prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

2.8 DESIGN DOCUMENTS AS QA RECORDS

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

3.0 SOFTWARE QUALITY ASSURANCE REQUIREMENTS

3.1 COMPUTER SOFTWARE DOCUMENTATION AND CONTROL

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.

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

3.1.1 Each organization participating in the NNWSI Project shall prepare a description of their software design, test and configuration management system, and submit it to the next higher program organizational level 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.

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

3.1.3 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 baseline, 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 level of approval, verification, and validation as the original software.

3.1.4 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.

3.1.5 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.

3.1.6 Verification and validation of computer software shall be performed prior to the use of such software to perform technical calculations in support of site-characterization, performance assessment analyses, and the design, analysis, and operation of repository structures, systems, and components. In those cases where this requirement cannot be met, the portion or portions of software which have not been verified and 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. 2

3.1.7 Verification and validation procedures shall assure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system. 2

3.1.8 Existing software shall be qualified for use. This qualification shall be based on the ability of the software to provide acceptable results for specific applications and compliance with the requirements of this section. 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. 2

3.1.9 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 each organizations software QA Plan and procedures. 2

3.2 DOCUMENTATION OF COMPUTER SOFTWARE

Documentation of scientific and engineering software shall include the following, as a minimum:

- Software requirements specification;
- Software design and change documentation;

- Description of mathematical models and numerical methods;
- Software verification and validation documentation;
- User documentation;
- Code assessment and support;
- Continuing documentation and code listings; and
- Software summary.

This documentation is considered to be a QA Record and is subject to the requirements of Section XVII of this QA Plan. Appendix H to this QA Plan provides detailed requirements on the content of the documentation for this software and other computer software used on the NNWSI Project. 2

3.3 SOFTWARE CONFIGURATION MANAGEMENT

All Participating Organizations and NTS Support Contractors shall institute a software configuration management program appropriate to the projects they conduct 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 PEER REVIEWS

All Participating Organizations and NTS Support Contractors shall institute a peer review process, when applicable, to provide adequate confidence in the work being reviewed. Peer reviews shall meet the requirements of NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories" (Feb. 1988). These requirements are contained in Appendix J to this QA Plan.

5.0 TECHNICAL REVIEWS

When technical reviews are required, they shall be conducted in accordance with procedures that contain specific criteria for the performance of the technical review.

SECTION IV

PROCUREMENT DOCUMENT CONTROL

1.0 REQUIREMENTS

1.1 MEASURES TO ASSURE ADEQUATE QUALITY

Measures shall be established to ensure that applicable regulatory requirements, design or site investigation bases, and other requirements that are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services utilized on the Nevada Nuclear Waste Storage Investigations (NNWSI) Project. To the extent necessary, procurement documents of Participating Organizations and Nevada Test Site (NTS) Support Contractors, shall require sub-tier contractors to provide a Quality Assurance (QA) program that is consistent with the pertinent provisions of this NNWSI Quality Assurance Plan as required for the specified Quality Assurance Level.

1.2 WMPO PROCURED SERVICES

Waste Management Project Office (WMPO) initiated procurements for services shall be controlled through the use of the Federal Acquisition Regulations (FAR) and Department of Energy Acquisition Regulations (DEAR). When the WMPO procures services from contractors or requests services from national laboratories and supporting Federal agencies, the WMPO shall prepare work agreements, memos of understanding, interagency agreements, management agreements, or other suitable documents.

2.0 ADDITIONAL REQUIREMENTS FOR QA LEVEL I ACTIVITIES

2.1 CONTENT OF PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement shall include provisions for the items listed below, as deemed necessary by the purchaser:

2.1.1 SCOPE OF WORK

A statement of the scope of the work to be performed by the supplier shall be in the procurement documents.

2.1.2 TECHNICAL REQUIREMENTS

Technical requirements shall be specified in the procurement documents. Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall provide for

identification of test, inspection, and acceptance requirements of the purchaser for monitoring and evaluating the supplier's performance.

2.1.3 QA REQUIREMENTS

2.1.3.1 Procurement documents shall require that the supplier have a documented QA program that implements either portions or all of the requirements of this document. Quality Assurance Program Plans (QAPPs) and documents of subcontractors for Quality Assurance Level I purchases shall be reviewed and approved by the procuring Project participant. Those which do not adequately define QA requirements, as judged by the QA representative of the Project participant, shall be corrected prior to initiation of activities specified by the purchase order or contract. The extent of the program required shall depend upon the type and use of the item or service being procured. The procurement documents shall require the supplier to incorporate appropriate QA program requirements in subtier procurement documents.

2.1.3.2 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).

2.1.4 RIGHTS OF ACCESS

At each tier of procurement, the procurement documents shall provide for access to the suppliers' facilities and records for inspection or audit by the purchaser, appropriate WMPO personnel, or other WMPO authorized representatives. WMPO access to subtier contractor facilities shall be arranged by the contracting organization.

2.1.5 DOCUMENTATION REQUIREMENTS

The procurement documents at all tiers shall identify the documentation required to be submitted to the purchaser. The time of submittal shall also be established. If the purchaser requires the supplier to maintain specific QA records, then the retention times and disposition requirements shall be specified in accordance with Section XVII of this QA Plan.

2.1.6 NONCONFORMANCE

The procurement documents shall prescribe the purchaser's requirements for reporting and approving disposition of nonconformances.

2.1.7 SPARE AND REPLACEMENT PARTS

The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate 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. The evaluation shall

consider the interchangeability, function and safety of the item. The evaluation shall be documented.

2.2 PROCUREMENT DOCUMENT REVIEW

A review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective supplier or suppliers include appropriate provisions to assure that items or services will meet the specified requirements. The review shall be performed and documented prior to contract award. Procurement document reviews shall be performed by personnel who have access to pertinent information and who have adequate understanding of the requirements and intent of the procurement documents. The review shall include, as a minimum, the cognizant technical organization and QA organization. The review by the QA organization shall assure that the following requirements are met:

- QA requirements are correctly stated, inspectable, and controllable.
- There are adequate acceptance and rejection criteria.
- Procurement documents have been prepared, reviewed, and approved in accordance with this QA Requirements document.

2.3 PROCUREMENT DOCUMENT CHANGES

Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. Changes that are made as a result of the bid evaluation or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed and documented prior to contract award. Review of changes shall include the following considerations:

- Appropriate content shall be included in procurement documents as required by Paragraph 2.1 of this Section.
- Additional or modified design or site investigation criteria shall be determined.
- Analysis of exceptions or changes requested or specified by the supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished.

2.4 DISTRIBUTION OF PROCUREMENT DOCUMENTS

Participating Organizations and NTS Support Contractors shall forward to the SAIC/T&MSS Project QA Department (QA Verification Division Manager), 0

a copy of purchase documents, and changes thereto, as issued, when purchases involve Quality Assurance Level I items or services. Only those purchase documents which identify the vendor, describe the scope of work, and detail when work is to start are required to be submitted to the SAIC/T&MSS Project QA Department.

SECTION V

INSTRUCTIONS, PROCEDURES, PLANS AND DRAWINGS

1.0 GENERAL

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings, of a type appropriate to the circumstances except as noted in paragraph 3.0 of this Section. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Instructions and procedures shall include a section which identifies the QA records which are generated during implementation of the document. If plans are used in lieu of procedures, then these plans shall also include or reference appropriate acceptance criteria and identify the QA records which are generated. These documents, including drawings, shall be controlled as required in Section VI of this document. 2

2.0 REVIEWS

An independent review of all instructions, procedures, plans and drawings shall be performed by the originating organization to assure technical adequacy and inclusion of appropriate quality requirements. If applicable, this review shall consider whether or not the activities are repeatable, have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities. 2

3.0 INSTRUCTIONS FOR SCIENTIFIC NOTEBOOKS

The Participating Organizations shall prepare instructions for the control of scientific notebooks, plans and the other documentation that will be used in scientific investigations. When scientific notebooks are used to document scientific investigations, the requirements of Section III, paragraph 1.6 shall prevail over the requirements of this Section. Scientific notebooks shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section XVII of this document. 2

4.0 DISTRIBUTION

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

SECTION VI

DOCUMENT CONTROL

1.0 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

1.1 METHODS

The preparation, review, approval, and issuance of documents such as instructions, procedures, plans and drawings, including changes thereto, shall be controlled through the implementation of methods that assure that only correct documents are used. Document control shall be applied to the following:

- Documents containing or specifying quality requirements.
- Documents that prescribe activities affecting quality.

The document control system shall be documented, and the QA organization shall provide the appropriate review, resolution of comments, and concurrence with respect to quality-related aspects of the documents.

1.2 IMPLEMENTATION

Implementation of document control shall provide for the following:

- Identification of documents to be controlled.
- Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.
- Review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements, prior to approval and issuance.
- A method for the removal or marking of obsolete or superseded documents to prevent inadvertent use.
- A method for assuring that the correct and applicable documents are available at the location where they are to be used.
- A master list or equivalent to identify the correct and updated revisions of documents.
- Coordination of interface documents.

2.0 DOCUMENT CHANGES

2.1 MAJOR CHANGES

Changes to documents, other than those defined below as minor changes are considered as major changes and shall 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 document. The reviewing organization shall have access to pertinent background data or information upon which to base their approval and, if applicable, shall specifically consider whether or not the activities being changed are repeatable, have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities. 2

2.2 MINOR CHANGES

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.

3.0 DISTRIBUTION OF DOCUMENTS

3.1 DOCUMENT CONTROL SYSTEM

The document control system shall assure that documents requiring verification are not released prior to verification or, if they must be released before verification, they are uniquely identified as such and controlled in accordance with Paragraph 1.2 of this section. A master list or equivalent used to identify the correct, current and updated versions of documents shall be submitted to the WMPO PQM and the SAIC/T&MSS Project Quality Assurance Department Manager.

SECTION VII

CONTROL OF PURCHASED ITEMS AND SERVICES

1.0 GENERAL 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 or subcontractor source, audit, 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 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 Waste Management Project Office (WMPO) QA Records Management System (QARMS) and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, that are to be met by the purchased material and equipment. Specific requirements for the control of purchased items and services are listed below.

1.1 PROCUREMENT PLANNING

1.1.1 GENERAL

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 Quality Assurance (QA) organization participation shall be provided for evaluation and selection of suppliers, verification of suppliers activities and receiving inspections. Planning shall determine the following:

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

1.1.2 PROCUREMENT TIMING

To ensure interface compatibility 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.

1.1.3 PROCUREMENT METHODS

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 below. Planning shall provide for the integration of the following:

- Procurement document preparation, review, and change control.
- Selection of procurement sources.
- Purchaser control of supplier performance.
- Verification (surveillance, inspection, or audit) activities by purchaser, including notification for hold-and-witness points.
- Control of nonconformances.
- Corrective action.
- Acceptance of item or service.
- QA records.

1.2 SOURCE EVALUATION AND SELECTION

1.2.1 SELECTION OF SUPPLIERS

The selection of suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents before the award of contract.

1.2.2 SOURCE EVALUATION AND SELECTION MEASURES

Procurement source evaluation and selection measures shall be implemented by the purchaser and shall provide for identification of the purchaser's organizational responsibilities for determining supplier capability.

1.2.3 MEASURES FOR EVALUATION AND SELECTION OF PROCUREMENT SOURCES

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

- Evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history shall reflect current capability.

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

- Supplier's technical and quality capability as determined by a direct evaluation of their facilities and personnel and the implementation of his QA program.

1.3 BID EVALUATION

1.3.1 EXTENT OF CONFORMANCE

Bid evaluation shall determine the extent of conformance to the procurement documents. 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.

1.3.2 RESOLUTION OF UNACCEPTABLE QUALITY ASSURANCE CONDITIONS

Before the award of the contract, the purchaser shall resolve or obtain commitments to resolve unacceptable quality assurance conditions resulting from the bid evaluation.

1.4 SUPPLIER PERFORMANCE EVALUATION

1.4.1 INTERFACE MEASURES

The purchaser of items and services shall establish measures to interface with the supplier. The measures shall include the following:

- Documentation of the understanding between purchaser and supplier of the provisions and specifications of the procurement documents.

- Requiring the supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements.

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

- Identifying and processing necessary change information. Measures to control changes in procurement documents shall be established, implemented and documented in accordance with the requirements of this QA Plan.

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

1.4.2 VERIFICATION MEASURES

1.4.2.1 EXTENT OF VERIFICATION

The purchaser of items and services shall establish measures to verify supplier's performance, as deemed necessary by the purchaser. The measures shall establish the extent of source surveillance and inspection activities.

NOTE: When a Participating Organization, or Nevada Test Site (NTS) Support Contractor, utilizes another Participating Organization or NTS Support Contractor for NNWSI activities for which they are responsible, the user organization shall initiate a request to WMPO to conduct a WMPO surveillance of the organization performing the work. The surveillance shall be conducted to determine that the item or activity is being produced or performed in accordance with the user organization's requirements. These surveillances may utilize NTS Support Contractor or Participating Organization personnel as technical advisors. 0

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

1.4.2.2 Record of Verification Activities

Activities performed to verify conformance to requirements of procurement documents shall be recorded. Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented. These completed documents shall be considered QA records and shall be controlled in accordance with Section XVII of this Quality Assurance Plan (QAP). The purchaser shall ensure that this documentation is evaluated to determine the supplier's QA program effectiveness.

1.5 CONTROL OF DOCUMENTS GENERATED BY SUPPLIERS

Documents 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.

1.6 ACCEPTANCE OF ITEM OR SERVICE

1.6.1 METHODS FOR ACCEPTANCE

Methods shall be established for the acceptance of an item or service being furnished by the supplier. Prior to offering the item or service for acceptance, the supplier shall verify that the item or service being furnished complies with the procurement requirements. Purchaser methods used to accept an item or related service from a supplier shall be either a supplier certificate of conformance, a source verification, a receiving inspection or post-installation test at the facility site, or a combination thereof. Requirements applicable to these methods of acceptance are listed below.

1.6.1.1 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 identify any procurement requirements that have not been met, together with an explanation and the means by which to resolve the nonconformances.
- The certificate shall be attested to by a person who is responsible for this QA function and whose function and position are described in the purchaser's or supplier's QA program.
- The certificate system, including the procedures to be followed in filling out a certificate and the administrative procedures for the review and approval of the certificates, shall be described in the purchaser's or supplier's QA program.

- Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification shall be conducted by the purchaser at intervals commensurate with the supplier's past quality performance.

1.6.1.2 Source verification

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.

1.6.1.3 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 documentation and the demonstrated quality performance of the supplier. Receiving inspection shall be performed in accordance with established procedures and inspection instructions to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. 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 Section X, Para. 2.1, 4.0, 4.1, 6.1, 9.0 and 9.1 of this document. Personnel selected to 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. 0

1.6.1.4 Post-Installation testing

When post-installation testing is used, post-installation test requirements and acceptance documentation shall be established mutually by both the purchaser and the supplier.

1.7 ACCEPTANCE OF SERVICES ONLY

1.7.1 PROCUREMENT 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 purchaser shall accept the service by any or any combination of the following methods:

SECTION XIV

INSPECTION, TEST, AND OPERATING STATUS

1.0 INDICATION OF STATUS

The requirements of this section apply to engineered items and do not apply to scientific investigations. The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status indicators shall also provide for indicating the operating status of systems and components of the facility, such as by tagging valves and switches, to prevent inadvertent operation.

2.0 METHODS OF INDICATING STATUS

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

3.0 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, test, and operating status.

SECTION XV

CONTROL OF NONCONFORMING ITEMS

1.0 GENERAL REQUIREMENTS

Measures shall be established to control items that do not conform to requirements to prevent their inadvertent installation or use. These measures shall include documented procedures for identification, documentation, evaluation, segregation (when practical), disposition, and notification to affected organizations. All personnel involved in Nevada Nuclear Waste Storage Investigations (NNWSI) Project activities are responsible for reporting nonconformances in accordance with their established nonconformance control procedures. These procedures shall be consistent with the minimum requirements listed below.

1.1 IDENTIFICATION

1.1.1 METHOD OF IDENTIFICATION

Identification of nonconforming items shall be made by marking, tagging, or other methods that shall not adversely affect the end use of the item. The identification shall be legible, easily recognizable, and shall contain the nonconformance report number. The nonconformance report number shall be a sequential number preceded by an organizational acronym (e.g, LLNL-1, USGS-6, etc). If tags are used, they shall be securely attached to avoid loss during handling.

1.1.2 EXCEPTIONS

If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.

1.1.3 CONDITIONAL RELEASE

Work on the nonconforming item shall be stopped until completion of the action specified in the Nonconformance Report (NCR) disposition. If only a specific portion of the item is in nonconformance, then that specific area shall be identified and work may proceed on the remaining areas. If work on a nonconforming item must be continued (conditional release) prior to implementation of the disposition, the Waste Management Project Office (WMPO) shall approve such continuance. Requests for conditional releases on nonconforming items shall 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.

1.2 LOGGING

1.2.1 NONCONFORMANCE CONTROL LOG

Each NNWSI Project participant shall maintain a nonconformance control log to track nonconforming items. This log shall contain the following information:

- The nonconformance report number.
- A brief description of the nonconforming condition.
- Identification of the person or organization responsible for determining and carrying out the nonconformance disposition.
- The status of each nonconformance report (open or closed).

1.3 SEGREGATION

1.3.1 HOLD AREA

When practical, nonconforming items shall be segregated by placing them in a clearly identified and designated hold area until they are dispositioned properly.

1.3.2 ALTERNATIVE

When segregation is impractical or impossible because of physical conditions, such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.

1.4 DISPOSITION

1.4.1 NONCONFORMANCE CHARACTERISTICS

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

- 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.

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1.4.2 RESPONSIBILITY AND AUTHORITY

The responsibility and authority for the evaluation, disposition, and close-out of nonconforming items shall be defined and documented. Those personnel assigned signature approval of the disposition shall be identified. Quality Assurance (QA) responsibilities relating to nonconformances shall be described.

1.4.3 PERSONNEL

Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area that they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

1.4.4 DISPOSITIONING OF NCR

The person or organization assigned the responsibility of dispositioning the NCR shall 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 has referenced any approved design documents, procedures, plans, work orders, etc., that are to be used for the correction of the nonconforming condition.
- The technical details for correction of the nonconforming condition are adequate for the recommended disposition.
- If continuance has been requested, justification for the activity to continue has been documented and approved by the appropriate WMPO Branch Chief and the WMPO 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 NCR.
- Disposition has identified and documented the correction as repair, rework, use-as-is, or reject/scrap.
- Disposition has identified the people or organization responsible to implement the disposition.

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1.4.5 WMPO APPROVAL

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

1.4.6 CORRECTIVE ACTION

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

1.4.7 INTERFACES

Internal interfaces between organizational units and external interfaces between NNWSI Project participants shall be clearly described.

2.0 REPETITIVE NONCONFORMANCES

When repetitive or recurring nonconforming conditions are identified, an evaluation shall be made as to whether or not further programmatic corrective action is warranted to preclude repetition. This corrective action shall be beyond the scope of the action taken for the disposition on the existing NCRs and shall be processed in accordance with corrective action procedures developed by each NNWSI Project participant.

3.0 TRENDING

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

4.0 DISTRIBUTION OF DOCUMENTS

Copies of nonconformance reports for items shall be sent to the WMPO PQM and the SAIC/T&MSS Project QA Department (QA Engineering Division Manager) by the originating organization upon issuance and upon closure. The original nonconformance reports shall be sent to the WMPO for approval as required by Paragraph 1.4.5 of this section.

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SECTION XVI

CORRECTIVE ACTION

1.0 GENERAL

A corrective action system is to be defined in the Quality Assurance Program Plan (QAPP) of each Nevada Nuclear Waste Storage Investigations (NNWSI) Project Participant and NTS Support Contractor. This system shall ensure that conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as practical. 0

1.1 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 NNWSI Project Participant shall ensure that:

- Immediate actions have been taken to remedy the specific condition(s). 0
- 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.

1.2 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. 0

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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. 0

1.3 CORRECTIVE ACTION

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.

2.0 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. 0

2.0 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. 0

SECTION XVII

QUALITY ASSURANCE RECORDS

1.0 GENERAL REQUIREMENTS

Records that furnish documentary evidence of quality shall be specified, prepared, and maintained in accordance with NNWSI Administrative Procedures which shall meet the requirements of this Section. This shall include the requirements that all documents be legible, identifiable, and retrievable.

1.1 DEFINITION

A document or other item is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined below. The term records, used throughout this Section is to be interpreted as Quality Assurance Records. Quality Assurance Records include (1) individual documents that have been executed, completed, and approved and that furnish evidence of the quality and completeness of data (including raw data), and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents, such as plans, correspondence, documentation of telecons, specifications, technical data, books, maps, papers, photographs, and data sheets; (5) magnetic media; and (6) other materials that provide data and document quality, regardless of the physical form or characteristic. A completed record is a document that will either receive no more entries or whose revision would normally consist of the 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 superceded records) shall be retained for the NNWSI Project. 0 0

1.2 ESTABLISHING A RECORD SYSTEM

A record system or systems shall be established by each NNWSI Project participant at the earliest practicable time consistent with the schedule for accomplishing work activities.

1.2.1 RECORDS MANAGEMENT

The record system shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation prepared in accordance with Section V of this document. The records management activities to be performed by the NNWSI Project Participating Organizations, Nevada Test Site (NTS) Support Contractors, and the Waste Management Project Office (WMPO) when processing QA records are detailed in the NNWSI Project Administrative Procedures Manual.

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The WMPO shall prepare a NNWSI Project Information Management System Plan and shall submit the plan to OCRWM for review and approval. The records management plan shall: 0

- Identify the types of records to be generated, purchased, or maintained, including all records referenced in pertinent final reports and other documents.
- Identify the methods to be used to comply with all applicable records requirements, including those to be used to control in-process records.
- Identify and define the responsibilities of pertinent organizations, including the QA organization.

Consistent with applicable regulatory requirements, the WMPO shall establish requirements concerning record types and retention that shall include duration, location, and assigned responsibility.

1.2.2 MINIMUM RECORDS

Sufficient records shall be specified, prepared, and maintained to furnish documented evidence of activities that affect quality. The records shall include at least the following: operating logs, the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. Also, the records shall include closely related data such as qualifications of personnel, procedures, and equipment. A list of typical QA records is contained in Appendix E.

1.2.3 CONTROL OF RECORDS

Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition of QA records shall be established and documented.

1.3 PRESERVATION OF RECORDS

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

1.4 RETENTION CLASSIFICATION

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

The WMPO shall prepare a NNWSI Project Information Management System Plan and shall submit the plan to OCRWM for review and approval. The records management plan shall: 0

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Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition of QA records shall be established and documented.

1.3 PRESERVATION OF RECORDS

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

1.4 RETENTION CLASSIFICATION

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

2.0 GENERATION OF RECORDS

2.1 RECORDS SPECIFICATION

The applicable design specifications, procurement documents, implementing procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for the WMPO.

2.1.1 QUALITY OF RECORDS

Documents that are designated to become records shall be legible, identifiable, accurate, complete, reproducible, microfilmable, and appropriate to the work accomplished.

2.1.2 COMPLETION OF RECORDS

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

3.0 VALIDATION OF RECORDS

3.1 METHODS OF VALIDATION

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

3.2 AUTHENTICATION LIST

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

4.0 RECEIPT OF RECORDS

4.1 RECEIPT CONTROL

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

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- A method for designating the required records.
- A method for identifying the records received.
- Procedures for receipt and inspection of incoming records.
- A method for submittal of completed records to the storage facility without unnecessary delay. 0

4.2 PROTECTION OF RECORDS

The individual or organization responsible for receiving records shall provide protection from damage, deterioration, or loss during the time that the records are in their possession.

5.0 RECORDS IDENTIFICATION

5.1 IDENTIFICATION DESIGNATION

Records or indexing systems, or both, shall provide sufficient information to permit identification between the record and the items or activities to which it applies. Records shall be clearly identified by a unique number or other designation which is directly traceable to controlling programmatic information (e.g., project, contract number, task number, preparing organization, author, date, title, subject, etc.). This unique identification number or other designation shall not be repeated anywhere in the Nevada Nuclear Waste Storage Investigations (NNWSI) Project. The Waste Management Project Office (WMPO) or its designee shall review and approve the records identification system of all its contractors and subcontractors to ensure consistency.

5.2 INDEXING SYSTEM

The records shall be indexed and the indexing system or systems shall include, as a minimum, the location of the record within the records system or systems.

6.0 PERMANENT STORAGE FACILITY

Records shall be controlled from the time they are complete until the time they are stored in a permanent storage facility. Temporary storage, preservation, safe keeping, and retrievability of completed records shall be in accordance with the requirements applicable to the permanent storage of records. The use of dual storage facilities is an acceptable alternative to a single fire-rated, environmentally controlled facility.

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6.1 STORAGE LOCATION

The records shall be stored in a predetermined location or locations that meets the requirements of applicable standards, codes, and regulatory agencies.

6.2 STORAGE PROCEDURE

Before the records are stored, a written storage procedure shall be prepared and responsibility 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 (see Paragraph 4.1 of this section).
- The rules governing access to and control of the files.
- The method for maintaining control of and accountability for records removed from the storage facility.
- A method for filing supplemental information (see Paragraph 9.0 of this section). 0

7.0 PRESERVATION

Records shall be stored in a manner approved by the organization or organizations responsible for storage. In order to preclude deterioration of the records, the following requirements shall apply:

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

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8.0 SAFEKEEPING

8.1 MEASURES TO PRECLUDE ENTRY

Measures shall be established to preclude the entry of unauthorized personnel in the storage area. These measures shall guard against larceny and vandalism.

8.2 REPLACEMENT, RESTORATION, OR SUBSTITUTION

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.

9.0 CORRECTED INFORMATION IN RECORDS

9.1 METHOD

Records may be corrected in accordance with written procedures that provide for appropriate review or approval by the originating organization.

9.2 IDENTIFICATION

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

10.0 STORAGE FACILITY

The following requirements apply to both permanent and temporary record storage facilities.

10.1 CONSTRUCTION AND MAINTENANCE OF 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; and infestation of insects, mold, or rodents.

10.2 METHODS

The two satisfactory methods of providing storage facilities are (1) single and (2) dual; these are detailed in the following sections.

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10.2.1 SINGLE FACILITY

Design and construction of a single record storage facility shall meet the following criteria:

- It shall have reinforced concrete, concrete block, masonry, or equal construction.
- It shall have a floor and roof with drainage control and if a floor drain is provided, then a check valve (or equivalent device) shall be included.
- It shall have doors, structures and frames, and hardware that shall be designed to comply with the requirements of a minimum two hour fire rating.
- Sealant shall be applied over walls as a moisture or condensate barrier.
- Surface sealant shall be placed on the floor to provide a hard wearing surface to minimize concrete dusting.
- It shall have foundation sealant and provisions for drainage.
- It shall have forced-air circulation with a filtration system.
- It shall have a fire protection system.
- Only those penetrations used exclusively for fire protection, communication, lighting, or temperature and humidity control are allowed. All such penetrations shall be sealed or dampered to comply with the minimum two-hour fire protection rating.
- The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing.
- If the facility is located within a building or structure, then the environment and construction of that building can provide a portion or all of these criteria.

10.2.2 ALTERNATE SINGLE FACILITIES

The following are acceptable alternatives to the criteria for a single facility:

- Two-hour fire rated vault that meets National Fire Protection Association (NFPA) 232-1975.
- Two-hour fire rated Class B file containers that meet the requirements of NFPA 232-1975.

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- Two-hour fire rated file room that meets the requirements of NFPA 232-1975 with the following additional provisions.

  - An early-warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station.

  - Records storage in fully enclosed metal cabinets.

  - Adequate access and aisle ways.

  - Work that is not associated directly with record storage or retrieval shall be prohibited in the file room.

  - Smoking, eating, or drinking shall be prohibited in the file room.

  - Two-hour fire rated dampers or doors in all boundary penetrations.

10.2.3 DUAL FACILITIES

If storage at dual facilities for each record is provided, then the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Neither facility is required to satisfy the requirements of Paragraphs 10.2.1 or 10.2.2 but shall meet the other requirements of this document.

11.0 RETRIEVAL

11.1 PROVISIONS

Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type. Final reports shall contain a listing, by unique number or other designation, that enables prompt retrieval of all documents used to compile or evaluate the report. This listing shall include, as a minimum, all referenced documents, peer review or other review documents, computer codes, data sheets, procedures, and test plans. All documents referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineers handbook, etc., shall be retrievable from the Records Management System (RMS).

11.2 PERSONNEL

A list shall be maintained that designates those personnel who shall have access to the files.

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11.3 ACCESSIBILITY

Records maintained by a Participating Organization or Nevada Test Site (NTS) Support Contractor at their facility or other location (on an interim or other basis) shall be accessible to the WMPO or its designated alternate.

12.0 DISPOSITION

12.1 ACCESSIBILITY AT VARIOUS LOCATIONS

Records that are accumulated at various locations, prior to transfer, shall be made accessible to the WMPO either directly or through the procuring organization.

12.2 CUSTODIAN

The custodian shall inventory the submittals, acknowledge receipt, and process these records in accordance with this document or the procedures implementing this document.

12.3 REQUIREMENTS OF REGULATORY AGENCIES

Various regulatory agencies have requirements concerning records that are within the scope of this document. The most stringent requirements shall be used to determine final dispositions.

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SECTION XVIII

AUDITS

1.0 GENERAL REQUIREMENTS

All Nevada Nuclear Waste Storage Investigations (NNWSI) Project activities will be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall Quality Assurance (QA) program and to determine their effectiveness. Each NNWSI Project participant shall include in their Quality Assurance Program Plan (QAPP) a system of planned, periodic audits 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. The audits shall be performed in accordance with written procedures using checklists by appropriately trained personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented, reported to, and reviewed by responsible management. Tracking systems shall be instituted for audit findings to assure that all findings are appropriately addressed and to identify quality trends. All deficiencies, nonconformances, and potential quality problems identified during the audit are to be documented and monitored until verification of effective corrective action is made. 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 auditing organization and their own responsible management.

Followup action, including verification of corrective action or reaudit of specific areas, shall be performed.

1.1 NNWSI PROJECT AUDITS

The NNWSI Project audit program will be executed at the Project level by the Waste Management Project Office (WMPO) and at the activity level by individual Participating Organizations and NTS Support Contractors.

1.1.1 WMPO AUDITS

The SAIC/T&MSS Project QA Department shall develop a schedule defining the WMPO audits planned for each fiscal year. This schedule shall be approved and issued by the WMPO as an annual planning document. As a minimum, WMPO shall audit all NNWSI Project participants annually. The audits shall cover the entire scope of the participants' QAPP. Additional audits may be conducted when a unique need arises or when an audit is requested by a Participating Organization or NTS Support Contractor. Participating Organizations and NTS Support Contractors shall be audited to verify the effectiveness and adequacy of implementation of all elements of their respective QAPPs and this QA Plan. These audits will eliminate the need for Participating Organizations or NTS Support Contractors to conduct audits of each other.

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1.1.2 PARTICIPATING ORGANIZATION AND NTS SUPPORT CONTRACTOR AUDITS

Each Participating Organization and NTS Support Contractor shall conduct internal (covering their entire QAPP, on an annual basis) and external (direct subcontractor) audits of activities under its direct control, but they will not conduct audits of each other. These audits will be scheduled, planned, conducted, and reported as described in their respective QAPPs and this Quality Assurance Plan (QAP). External and internal audit schedules, dates, and changes thereto, shall be sent to the SAIC/T&MSS Project QA Department (QA Verification Division Manager). 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.

1.2 SCHEDULING

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 commensurate with the status and importance of the activity and shall be initiated early enough to assure effective QA. Each NNWSI Project Participant shall perform or arrange for annual evaluations of suppliers. This evaluation shall be documented and shall take into account, where applicable, (1) review of supplier furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions; (2) results of previous source verifications, audits, and receiving inspections; (3) operating experience of identical or similar products furnished by the same supplier; and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.

1.2.1 INTERNAL AUDITS

Applicable elements of an organization's QAPP shall be audited at least annually or at least once during the life of the activity, whichever is shorter. 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.

1.2.2 EXTERNAL AUDITS

Elements of an external organization's QA program shall be audited at least annually or once during the life of the activity, whichever is the shorter period, with the following exception: 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

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activities are less than four months in duration shall be documented and approved by the responsible QA Manager prior to implementation of the activity. A copy of the documented justification shall be provided to the Yucca Mountain Project Office PQM.

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1.2.3 JOINT AUDITS

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

1.3 PREPARATION

Preparation for an audit shall include the items listed below.

1.3.1 AUDIT PLAN

The auditing organization 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.

1.3.2 PERSONNEL

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

1.3.3 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 the technical specialists, if any, who will participate in the audit and include this information in the audit plan. Audit team members selected to participate in audits for technical consideration purposes 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 audit team leader shall ensure that the audit team is prepared before the audit begins.

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

1.3 PREPARATION

Preparation for an audit shall include the items listed below.

1.3.1 AUDIT PLAN

The auditing organization 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.

1.3.2 PERSONNEL

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

1.3.3 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 the technical specialists, if any, who will participate in the audit and include this information in the audit plan. Audit team members selected to participate in audits for technical consideration purposes 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 audit team leader shall ensure that the audit team is prepared before the audit begins.

1.4 PERFORMANCE

Audits shall be performed in accordance with written procedures using checklists as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity. 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 corrective action shall be reported immediately to the management of the audited organization. Audit findings will be reviewed with the audited organizations at a closing meeting.

1.5 REPORTING

The audit report shall be signed by the audit team leader and should be issued within 30 calendar days. This report 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.
- Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

1.6 RESPONSE

Management of the audited organization or activity shall investigate adverse audit findings; determine root cause; schedule corrective action, including measures to prevent recurrence; and, within thirty calendar days of receipt of the audit report, notify the appropriate organizations in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization.

1.7 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.

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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.

1.8 RECORDS

1.8.1 AUDITS

As a minimum, audit records shall include the following:

- 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.

1.8.2 PERSONNEL RECORDS

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.

2.0 SURVEILLANCES

The NNWSI Project audit program shall be supplemented by independent surveillance activities. The purpose of a surveillance is to monitor or observe items or activities to verify conformance to specified requirements. These surveillances shall be conducted by the WMPO, the Participating Organizations and the NTS Support Contractors, and shall be either scheduled or implemented on a random basis.

Measures for the surveillance of site investigation activities shall be established and executed in accordance with procedures prepared by the organization performing the activity. Surveillances shall be scheduled and conducted based on the activity's relative impact or importance, or both, to the NNWSI Project. All deficiencies, nonconformances, and potential quality problems identified during surveillances are to be documented and monitored until verification of effective corrective action is made. Specific requirements applicable to surveillance activities are as follows:

2.1 PLANNING

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

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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".

2.2 REPORTING INDEPENDENCE

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

2.3 RECORDS

As a mininum, surveillance records shall identify the following:

- Item or activity.
- Date of surveillance.
- Name of individual performing the surveillance.
- Identification of the organization(s), activities, or items surveilled, including the name or names of personnel contacted.
- Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance. Nonconformances shall be handled in accordance with the requirements of Section XV or XVI, as applicable. 2
- Surveillance criteria.
- Equipment used during the surveillance.
- Results.
- Acceptance statement.

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- Results.
- Acceptance statement.

APPENDIX A

TERMS AND DEFINITIONS

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 areas.

ACTIVITIES THAT AFFECT QUALITY: Deeds, actions, work, or performance of a specific function or task. The NNWSI 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 NNWSI Project as depicted in the WBS Dictionary.

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

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

inspection activities performed for the sole purpose of process control or product acceptance.

AUTHENTICATION (QA RECORDS): Authentication is the act of attesting that the information contained within a document is accurate, complete, and appropriate to the work accomplished. Authentication is accomplished by one of the following methods: (1) a stamped, initialed, or signed, and dated document; (2) a statement by the responsible individual or organization; or (3) issuing a document which is clearly identified as a statement by the reporting individual or organization. A document cannot become a Quality Assurance (QA) record until it has been authenticated. 2

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.

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

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.

COMPUTER MODEL VALIDATION: Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (NUREG-0856). Usually accomplished by comparing code results to (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. 2

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).

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.

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.

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

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 area is also known as the site.

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

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

CORROBORATIVE DATA: Existing data used to support or substantiate other existing data. 2

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

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

DESIGN INPUT: Those criteria, parameters, bases, or other 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 organization's QA program that is neither under the direct control nor within the organizational structure for the auditing organization.

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

FUNCTIONAL CHARACTERISTICS: Those attributes of a repository or its structures, systems, and components that determine its performance with respect to safety, reliability, operability, and other design criteria established in the 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: 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 10CFR60, Subpart E).

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

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

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

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

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

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

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

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

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

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

NNWSI PROJECT PERSONNEL: All U.S. Department of Energy Participating Organizations, and NTS Support Contractor personnel involved in NNWSI Project activities.

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

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

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

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

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 reviews, 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 NNWSI 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 personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Peer reviews are in-depth, critical reviews and evaluations of documents, material or data that require interpretation or judgment to verify or validate assumptions, plans, results or conclusions or when the conclusions, material or data contained in a report go beyond the existing state of the art.

A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work. In contrast to peer review, the term "technical review" refers to a review to verify compliance to predetermined requirements; industry standards; or common scientific, engineering, and industry practice.

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

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

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

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

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.

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

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

PRIMARY DATA: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable Quality Assurance Level I requirements and is necessary for the resolution of the NRC performance objectives of 10CFR60 in accordance with the NNWSI Project Issues Resolution Strategy. This includes information that has been qualified and accepted in accordance with NNWSI Project AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the NNWSI Project QA Program."

PROCUREMENT DOCUMENT: Purchase requisitions, purchase orders, letters of intent, work authorization letters, drawings, contracts, specifications, instructions, or any document that provides a means 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 must be covered under the QA requirements of 10 CFR 60, Subpart G. 2

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

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

QUALIFICATION TESTING: Demonstration that an item meets design requirements.

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

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

QUALITY ACTIVITIES LIST: A list of those major activities conducted during site characterization, construction, operation,or closure that relate to natural barriers important to waste isolation. These activities, which must be covered under the 10 CFR 60, Subpart G Quality Assurance program, include data gathering, per- formance assessments, and those activities that could affect a natural barrier's ability to isolate waste. 2

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

QUALITY ASSURANCE LEVEL I: those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public. Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or

beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

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

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

QUALITY ASSURANCE PROGRAM PLAN (QAPP): The document that describes the organization's Quality Assurance Program, the applicable QA requirements, and defines how compliance with the QA criteria will be accomplished.

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

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

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

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

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

REPOSITORY: See Geologic Repository Operations Area.

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

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

RIGHT OF ACCESS: The right of a purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or Quality Assurance audit.

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

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

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

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

SITE: Location of the controlled area.

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

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.

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

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.

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

VERIFICATION: The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether or not items, processes, services, or documents conform to specified requirements.

WAIVER: Documented authorization to depart from specified requirements.

WASTE MANAGEMENT PROJECT OFFICE (WMPO): The organization to which the 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 NNWSI Project.

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

VALIDATION (QA RECORDS): Validation is the act of reviewing a document or document package to ensure it is complete, authenticated, reproducible, and microfilmable. 2

APPENDIX B

DESIGN INPUTS

Design inputs include many characteristics and functions of an item or system. These inputs vary depending on the application; however, it is desirable to consider at least the following listed inputs as they apply to specific items or systems of the repository:

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, and 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 corrosion resistance.

9. Mechanical requirements such as vibration, stress, shock, and reaction forces.

10. Structural requirements covering such items as equipment foundations and pipe supports.

11. Hydraulic requirements such as pump 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 requirements.

14. Layout and arrangement requirements.

15. Operational requirements under various conditions such as repository startup, normal repository operation, repository emergency operation, special or infrequent operation, system abnormal or emergency operation, repository decontamination, decommissioning, and dismantling.

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.

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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 to specified requirements for the purpose of 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. 0

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 shall be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the inspection or test activity may provide reasonable assurance that a person can competently perform a particular task. 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 equivalence 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 of 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 a least two years of this experience associated with nuclear facilities or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility.

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. 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. 0

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, elements of the Quality Assurance Program Plan, and procedures that are to be employed. 0

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 with regard to those changes to the QAPP and implementing procedures that affect previous training. 0

4.5 DETERMINATION OF 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. 0

4.6 EVALUATION OF PERFORMANCE

The job performance of inspection and test personnel shall be revaluated 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.
- 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 examinations (when required).
- Signature of employer's designated representative who is responsible for such certification.
- 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.

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APPENDIX D

REQUIREMENTS FOR THE QUALIFICATIONS OF NON-DESTRUCTIVE 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 CERTIFICATE OF QUALIFICATION

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

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

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- 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.

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APPENDIX E

LIST OF TYPICAL QA RECORDS

The following is a list of typical QA records. The nomenclature of these may vary for each Participating Organization and NTS Support Contractor. The NNWSI Project retention period is defined as lifetime. (1) QA records will be submitted to the Project Records Center by the originating organization of the record.

1.0 SITE CHARACTERIZATION

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

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2.0 DESIGN RECORDS

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

3.0 PROCUREMENT RECORDS

- Procurement specifications.
- Purchase order including amendments.

4.0 MANUFACTURING RECORDS

- Applicable code data reports.
- As-built drawings and records (Note: As-built drawings and records shall correctly identify the installed condition of the item. The type of as-built drawings and records to be maintained shall be specified).
- Certificate of compliance.
- Eddy-current examination final results.
- Electrical control verification tests results.

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- Ferrite test results.
- Heat treatment records.
- Liquid penetrant examination final results.
- Location of weld filler material.
- Magnetic particle examination final results.
- Major defect repair records.
- Material properties records.
- Nonconformance reports.
- Performance test procedure and results records.
- Pipe and fitting location report.
- Pressure test (hydrostatic or pneumatic).
- Radiographs (for in-service inspection applications).
- Radiograph review records.
- Ultrasonic examination final results.
- Welding procedures.

5.0 INSTALLATION AND CONSTRUCTION RECORDS

5.1 RECEIVING AND STORAGE - NONCONFORMANCE REPORTS

5.2 CIVIL

- Concrete cylinder test reports and charts.
- Concrete design mix reports.
- Concrete placement records.
- Inspection reports for channel pressure tests.
- Material property reports on containment liner and accessories.
- Material property reports on metal containment shell and accessories.
- Material property reports on reinforcing steel.

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- Material property reports on reinforcing steel splice sleeve material.
- Procedure for waste package vessel pressure proof test and leak rate tests and results.
- Reports of high strength bolt torque testing.
- Soil compaction test reports.
- Location and description of structural support systems.
- Details, methods of emplacement, and location of seals used.

5.3 WELDING

- Ferrite test results.
- Heat treatment records.
- Liquid penetrant test final results.
- Material property records.
- Magnetic particle test final results.
- Major weld repair procedures and results.
- Radiographs (for in-service inspection application).
- Radiograph review records.
- Weld location diagrams.
- Weld procedures.

5.4 MECHANICAL

- Cleaning procedures and results.
- Code data reports.
- Installed lifting and handling equipment procedures, inspection, and test data.
- Lubrication procedures.
- Material properties records.
- Pipe and fitting location reports.

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- Pipe hanger and restraint data.
- Pressure test results (hydrostatic or pneumatic).
- Safety valve response test procedures.

5.5 ELECTRICAL AND INSTRUMENTATION AND CONTROL

- Cable pulling tension data.
- Cable separation data.
- Cable splicing procedures.
- Cable terminating procedures.
- Certified cable test reports.
- Relay test procedures.
- Voltage breakdown test results on liquid insulation.

5.6 GENERAL

- As-built drawings and records.
- Final inspection reports and releases.
- Nonconformance reports.
- Specifications and drawings.
- Details of equipment, methods, progress, and sequence of work.
- Construction problems.
- Anomalous conditions encountered.

6.0 PRE-OPERATIONAL AND START-UP TEST RECORDS

- Automatic emergency power source transfer procedures and results.
- Final system adjustment data.
- Pressure test results (hydrostatic or pneumatic).

- Instrument alternating current (AC) systems and inverters test procedures and reports.
- Offsite power source energizing procedures and test reports.
- Onsite emergency power source energizing procedure and test reports.
- Pre-operational test procedures and results.

7.0 OPERATION RECORDS

- Records and drawing changes that identify repository design modifications made to systems and equipment described in the Final Safety Analysis Report.
- Radioactive waste inventory, emplacement location, and transfer records.
- Offsite environmental monitoring survey records.
- Waste shipment records.
- Repository radiation and contamination survey results.
- Radiation exposure records for individuals entering radiation control areas.
- Records of gaseous and liquid radioactive material released to the environment.
- Records of transient or operational cycles for those repository components designed for a limited number of transients or cycles.
- Training and qualification records for members of the repository operating staff.
- In-service inspection records.
- Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments.
- Meeting minutes of the Repository Nuclear Safety Committee and licensee nuclear review board.
- Surveillance activities, inspections, and calibrations required by the technical documents.
- Records of repository tests and experiments.

- Changes made to Operating Procedures.
- Sealed source leak-test results.
- Records of annual physical inventory of all sealed source material.
- Logs of repository operation.
- Records and logs of maintenance activities, inspection, repair, and replacement of principal items of structures, systems, and components
- Operational, shift supervisor, and control-room logs.
- Licensee event reports.
- Fire protection records.
- Nonconformance reports.
- Repository equipment operations instructions.
- Security plan and procedures.
- Emergency plan and procedures.
- Quality Assurance and Quality Control Manuals.
- Records of activities required by the security plan and procedures.
- Applicable records noted in other section of this appendix for any modification or new construction applicable to structures, systems, or components.
- Evaluation of results of reportable safety concerns as required by regulations.
- Annual environmental operating report.
- Annual repository operating report.
- Location and description of dewatering systems.

APPENDIX F

REQUIREMENTS FOR THE QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL

1.0 GENERAL

This Appendix provide requirements for the qualification of Lead Auditors. A Lead Auditor organizes and directs audits, reports audit findings, and evaluates corrective action. This Appendix also provides 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. Auditors either shall have or shall be given appropriate training or orientation to develop their competence to perform required audits. The competence of personnel to perform the various auditing functions shall be developed by one or more of the methods listed below.

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 NNWSI Project.
- General structure of Quality Assurance programs and applicable elements as defined in this document.
- Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.
- Audit planning in the functions related to quality for the following activities: site characterization (scientific investigations), design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility. 0
- 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 made within the year prior to qualification.

1.2.4 EXAMINATION

The prospective Lead Auditor shall pass an examination that shall evaluate his comprehension of and ability to apply the body of knowledge identified in Paragraph 1.2.2 above. The test may be oral, written, practical, or any combination of the three types. If any portion of the examination is oral, written documentation of the oral examination questions/content shall be maintained. The development and administration of the examination shall be in accordance with Paragraph 1.4 of this section. 0

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.

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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 10CFR60, Subpart G. 1

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 J of this QA Plan.

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 10CFR60, 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. 1

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. 1

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 to the qualification of the existing data. The level of confidence in the existing data shall be commensurate with the intended use of the data. Attributes which shall be considered in the qualification process are:

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 and 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 quality 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 A HIGH-LEVEL NUCLEAR WASTE REPOSITORY LICENSE APPLICATION

This appendix provides detailed requirements for the development, maintenance, and security of computer software. It supplements Section III of this QA plan and shall be used in conjunction with that section.

1.0 OBJECTIVES

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 attainment of software quality is dependent on the control of the entire software development process, and is not assured solely by inspection and test of the end product. This appendix prescribes appropriate systematic practices that shall: 1

- Reduce the likelihood of defects entering executable code during development.
- Ensure that the end product answers the requirements of its intended application.
- Reduce the likelihood that defects will be introduced into executable code during later maintenance and modification.

2.0 APPLICABILITY

The detailed requirements set forth in this appendix apply to computer software used to produce or manipulate data which is used directly in site characterization, and the design, analysis, performance assessment, and operation of repository structures, systems, and components. The extent to which these requirements apply is related to the nature, complexity, and importance of the software application. The application of specific requirements shall be prescribed in plan(s) for software quality assurance and in written policies and procedures. 1 1

3.0 TERMS AND DEFINITIONS

Terms and definitions for NNWSI Project software are contained in Appendix A to this QA Plan.

4.0 SOFTWARE LIFE CYCLE

Organizations implementing software development activities shall adhere to a software life cycle model that requires that software development or acquisition proceed in a traceable, planned, and orderly manner. The relative emphasis placed on each phase of the software development cycle will depend on the nature and complexity of the software being developed.

Each phase of the software development cycle shall provide specific attributes that shall be incorporated into verification and validation activities. The documentation for each phase of the software development cycle shall be reviewed and approved as specified in each organization's software QA Plan. An example of one such model is described below:

Requirements

Design

Implementation

Test

Installation and Checkout

Operation and Maintenance

4.1 SOFTWARE QA PLAN

The application of the software life cycle to the development and/or use of the software shall be as described in the Software Quality Assurance Plan.

4.1.1 A software QA plan shall be prepared for each software development/application effort at the start of the software life cycle. This plan may be prepared individually for each piece of software or may exist as a generic document to be applied to all software prepared within an organization. The software QA plan shall identify:

- The software products to which it applies.
- The organizations responsible for software quality and their tasks and responsibilities.

- Required documentation.

- The required software reviews.

The software QA Plan should reference any standards, conventions, techniques, or methodologies which guide the software development, and describe methods to assure compliance to the same. 1

4.1.2 Within the software QA plan, software lifecycle management shall be described. Each participant shall present the specific software lifecycle controls for their organization in their software QA Plan. The following lifecycle elements shall apply, as appropriate, for the specific lifecycle model defined, interpreted, and described in each organizations software QA plan. 1

4.1.2.1 Requirements Phase

During this phase requirements that pertain to functionality, performance, design constraints, attributes, and external interfaces of the completed software shall be specified, documented, and reviewed. These requirements shall possess 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. 1

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

4.1.2.2 Design Phase

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

Design phase verification and validation activities during this phase shall consist of:

- The generation of design-based test cases.

- The review and analysis of the software design.

- The verification of the software design.

4.1.2.3 Implementation Phase

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

Verification and validation activities during this phase shall 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.

4.1.2.4 Testing Phase

During the testing phase the design as implemented in code shall be exercised by executing the test cases. Failure to successfully execute the test cases may require the modification of the requirements, the design, the implementation, or the test plans and test cases.

Verification and validation activities during this phase shall consist of:

- The evaluation of the completed software to assure adherence to the requirements.
- The preparation of a report on the results of software verification and validation.

4.1.2.5 Installation and Checkout Phase

During this phase the software becomes 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 shall be enhanced and used for installation testing.

4.1.2.6 Operations and Maintenance Phase

During the operations and maintenance phase the software has been approved for operational use. Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the software environment (adaptive maintenance). Software modifications shall be approved, documented, tested (including regression testing as appropriate), and controlled in accordance with Paragraph 5.0.

5.0 SOFTWARE VERIFICATION AND VALIDATION

Verification and validation plans by the responsible project organization shall employ methods such as inspection, analysis, demonstration, and test to assure that the software adequately and correctly performs all intended functions, and that the software does not perform any function that either by itself or in combination with other functions can degrade the entire system.

Verification and validation activities shall be planned and performed relative to specific hardware configurations. The amount of verification and validation activity shall be determined by the type and complexity of the software. Prior to use for a licensing activity, verification and validation of the final version of the software product shall be accomplished by an independent individual or organization, one who did not work on the original software. The results of all verification and validation activities shall be documented. 1

Verification and/or validation of computer software should be performed in two stages:

1. By the individual generating or modifying the software

2. By an independent individual or organization, one who did not work on the original software.

The first stage should involve activities (i.e., iterations of tests and runs) to arrive at a final product. It is not required to document all of the activities performed to satisfy the software developer. 1 1

5.1 VERIFICATION

Verification activities shall be integrated into all applicable phases of the software life cycle and shall be performed to an extent proportional to the critical importance of the software. Software verification shall be performed to assure that the software requirements are implemented in the software design, and the software design is implemented in code. Appropriate methods such as inspection, analysis, test, or demonstration shall be applied to accomplish verification objectives. 1

5.2 VALIDATION

Validation activities are performed to demonstrate that the model as embodied in the computer software is a correct representation of the process or system for which it is intended. This is 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 made for their use. 1 1

When data are not available from the sources mentioned above, alternative approaches used shall be documented. Alternative approaches may include peer review and comparisons with the results of similar analysis performed with verified software. The results of software validation shall be documented.

6.0 SOFTWARE CONFIGURATION MANAGEMENT

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

6.1 CONFIGURATION IDENTIFICATION

A configuration baseline shall be identified at the completion of each major phase of the software development cycle. Approved changes to a baseline shall be added periodically to the baseline as updates. A baseline plus updates shall specify the most recent software configuration. Updates shall be incorporated into subsequent baselines. Both baselines and updates shall be defined by their composition of software configuration items.

A labeling system for configuration items shall be implemented that:

- Uniquely identifies each configuration item or version number.
- Identifies changes to configuration items by revision.
- Places the configuration item in a relationship with other configuration items.

6.2 CONFIGURATION CHANGE CONTROL

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

6.3 CONFIGURATION STATUS ACCOUNTING

The information that is needed to manage software configuration items shall be recorded and reported. This information shall include a listing of the approved configuration identification, the status of proposed changes to the configuration, the implementation status of approved changes, and all information to support the functions of configuration identification, and configuration control. 1

7.0 DOCUMENTATION

Minimum acceptable lifecycle documentation of computer software developed or modified for use on the Yucca Mountain Project shall be specified in each participants software QA plan(s). The documentation provided shall describe the following, as applicable. Additional documentation may also be identified in the software quality assurance plan for each Yucca Mountain Project participant's software project. 1

7.1 SOFTWARE REQUIREMENTS SPECIFICATION

A specific capability of software can be called a requirement only if its achievement can be verified by a prescribed method. Software requirements documentation shall outline the requirements that the proposed software must fulfill. The requirements shall address the following:

- 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.

7.2 SOFTWARE DESIGN DOCUMENTATION

Software design documentation is a document or series of documents that shall contain:

- 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.
- Code assessment and support documentation and descriptions of mathematical models and numerical methods as required by NRC publication NUREG-0856.
- Continuing documentation, code listings, and software summary forms as required by NUREG-0856.

7.3 SOFTWARE IMPLEMENTATION DOCUMENTATION

Any design changes made to the requirement and design phase documents shall be assessed as to the impact on the design. The revised requirement and design phase documents shall be reviewed to the same level of review as the original documents. The results of this phase should be the basis for the software verification and validation plan(s). 1

7.4 SOFTWARE VERIFICATION AND VALIDATION DOCUMENTATION (TEST)

Software verification and validation documentation shall include a plan that describes the tasks and criteria for accomplishing the verification of the software in each phase, and the validation of the software. The documentation shall also specify the hardware and system software configuration pertinent to the software. The documentation shall be organized in a manner that allows traceability to both the software requirements and the software design. This documentation will also include a report on the results of the execution of the software verification and validation activities. This report shall include the results of all reviews, audits, and tests, and a summary of the status of the software. 1

7.5 USER DOCUMENTATION

User documentation shall be prepared in accordance with NUREG-0856 and shall include a description of:

- Program considerations, options, and initialization procedures.
- Anticipated error situations and how the user can correct them.
- Internal and external data files, their input sequence, structures, units, and ranges.
- Input and output options, defaults, and formats.

- o System interface features and limitations.
- o Information for obtaining user and maintenance support.
- o Sample problems.

8.0 REVIEWS

Reviews of software development activity shall be performed as each life cycle phase is completed to assure the completeness and integrity of each phase of development. The procedures used for reviews shall identify the participants and their specific responsibilities during the review and in the preparation and distribution of the review report. 1

The documentation for all reviews shall contain a record of review comments, a plan, and timetable for the resolution of the review comments, and the personnel responsible for this resolution.

After review comments are resolved, the approved documents shall be updated and placed under configuration management.

8.1 SOFTWARE REQUIREMENTS REVIEW

The review of software requirements shall be performed at the completion of the software requirements documentation. This review shall assure that the requirements are complete, verifiable and consistent. The review shall also assure that there is sufficient detail available to complete the software design. 1

8.2 SOFTWARE DESIGN REVIEW

The software design review will be held at the completion of the software design documentation. This review shall evaluate the technical adequacy of the design approach, and assure that the design answers all the requirements in the requirements documentation. The complexity of the software design may require the performance of two design reviews; one at the completion of the overall software architecture, and the second at the completion of the total design.

8.3 SOFTWARE IMPLEMENTATION REVIEW

The software implementation review is an evaluation of the completed requirements, design, and implementation process prior to independent verification and validation. 1

8.4 SOFTWARE VERIFICATION AND VALIDATION REVIEW

The software verification and validation review is an evaluation of the adequacy of verification and validation plans or procedures and completed software verification and validation activities. The review results in an approval of verification and validation documentation. 1

9.0 DISCREPANCY REPORTING AND CORRECTIVE ACTION

A formal procedure of software discrepancy reporting and corrective action shall be established. This discrepancy reporting system shall be integrated with the configuration management system to assure formal processing of discrepancy resolutions.

Software discrepancy reporting and corrective action procedures shall assure that, as a minimum: 1

- Defects are documented and corrected.
- Defects are assessed for criticality and impacted as previous applications.
- Corrections are reviewed and approved before changes to the software configuration are made.
- Preventive and corrective actions provide for appropriate notification of affected organizations.

10.0 MEDIA CONTROL AND SECURITY

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

11.0 ACQUIRED SOFTWARE

Procedures shall be established for controlling the transfer of computer software from an outside source to a user organization and from a user organization to an outside requesting organization. Software transfer requests of the organization (or purchases) from an outside source shall include appropriate criteria to enable the software received to comply, as much as possible, with the requirements of this QA Plan and the needs of the organization's computer system. Those requirements not met by the software received shall be completed by the organization in the relative phase of the software life cycle that is incomplete or, if that is not possible, the reason shall be documented and maintained with the software and distributed to the users. 1 1

Configuration management change controls shall be established for documenting the conversion of software to be used on a computer system, and/or peripheral hardware, other than that for which it was designed. Conversion includes all modifications and tests made to input/output or the source code or additional software written to run the original software on the new system. Software conversion shall be documented and maintained for the specific version of the software and the computer system on which it is installed. Software conversion changes shall be evaluated and activities performed in accordance with the appropriate configuration management system elements. 1

12.0 COMPUTER SOFTWARE APPLICATIONS

Organizations shall establish procedures for controlling the application of verified and/or validated computer software to technical calculations in support of site-characterization or design, analysis, performance assessment, and operation of repository structures, systems, and components. 1

Organizations shall establish procedures for documenting and reviewing software application and analyses and assuring that all results are accurate and reproducible. Requirements shall be established for identifying or otherwise marking record copies of all analyses and supporting documentation. Supporting documentation includes computer output (results), code input data including data bases and original sources/references of and assumptions used to obtain such data, code design, user's and/or operation manuals, verification/validation test results and/or hand calculations.

Technical calculations using software shall be performed with applicable computer codes and with software operating procedures defined sufficiently to allow independent repetition of the entire computation.

Controls shall be established for generating and documenting software used to perform technical calculations. All auxiliary software used should be included in documentation of technical calculations performed and should be included in independent review as part of the calculation. 1

All applications of computer software shall be independently reviewed and approved to assure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.

APPENDIX I

REQUIREMENTS FOR THE IDENTIFICATION OF ITEMS AND ACTIVITIES SUBJECT TO QUALITY ASSURANCE REQUIREMENTS

1.0 GENERAL

This Appendix provides requirements for identification of structures, systems and components important to safety in the pre-closure phase and for identification of the barriers important to waste isolation in the post closure phase which are to be listed on the "Q-List"; and for identification of those major activities conducted during site characterization, construction, operation or closure that relate to natural barriers important to waste isolation and which are to be listed on the Quality Activities List. 1

2.0 QUALITY ASSURANCE CRITERIA FOR LICENSING

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

2.1 QUALITY ASSURANCE CRITERIA FOR THE Q-LIST AND QUALITY ACTIVITIES LIST 1

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

2.2 CRITERIA FOR NON-Q-LIST ITEMS

Certain items that are not important to safety and/or waste isolation shall also be addressed in the license application to demonstrate compliance with 10 CFR Part 60 requirements such as those associated with meeting the design criteria contained in 10 CFR 60.131(a) for protection of worker health 1

and safety. While these items are not subject to the QA Level I requirements of this QA Plan, QA Level II requirements shall be applied. Additional guidance related to this subject can be found in NUREG-1318, (April, 1988), paragraph 5.1(b). 1

2.3 DATA NOT COLLECTED UNDER A 10 CFR 60 SUBPART G QA PROGRAM

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

3.0 IDENTIFICATION OF ITEMS IMPORTANT TO SAFETY

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

3.1 Probabilistic Risk Analysis (PRA) may be used to the extent practicable, to support the identification of structures, systems, and components important to safety in the license application. Use of this approach for the operations phase of the HLW program is consistent with the approach prescribed by the EPA standard (40 CFR Part 191) for the overall system containment following emplacement of waste in a geologic repository. In cases where data are limited, engineering judgment and conservative bounding assumptions shall be used. Conservative assumptions shall include non-mechanistic failures where information and/or experience are not adequate to reliably determine failure modes and accident scenarios. However, non-mechanistic failures need not be considered where failure modes and mechanisms are understood and failure rates can be determined. 1

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

3.3 PRAS shall utilize the following techniques:

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

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

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

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

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

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

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

3.4 REDUNDANCY

The use of redundant structures, systems, and components is a method of providing additional assurance that necessary safety functions will be performed if an accident occurs and that the accident dose limit will not be exceeded. In a redundant system, the failure of one train of the system shall not comprise or prevent the associated safety function from being performed. 1

For the high-level waste repository, 10 CFR 60 [60.131(b)(5)(ii)] addresses requirements for redundancy. The items needed to provide redundancy of items important to safety shall also be on the Q-List.

3.5 USE OF PREVIOUSLY ESTABLISHED GUIDELINES AND STANDARDS

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

3.6 RETRIEVAL

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

4.0 IDENTIFICATION OF ITEMS AND ACTIVITIES IMPORTANT TO WASTE ISOLATION

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

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

The items and activities important to waste isolation shall include:

- Components of the engineered barrier system relied on to meet the performance objectives.
- Elements of the natural barrier system (e.g., host rock, and geochemical retardation characteristics) relied on to meet the performance objectives.

- Activities necessary to demonstrate that the performance objectives will be met, including collection of data to characterize the site or performance of engineered barriers.

- Activities in the preclosure phase that could effect post-closure performance.

The broad performance objectives for waste isolation provide some flexibility in allocating credit among the various components of the natural and engineered barrier systems to meet each objective. For example, a 300 to 1000 year lifetime for the waste package might be achieved by a combination of performance from each of the components in the waste package or by a single component, such as the canister. The allocation of performance among the various components of the natural and engineered barrier system for each performance objective will provide the basis for determining which barriers are important to waste isolation. Performance assessments shall be conducted on these barriers to ascertain that those relied on will meet the waste isolation and containment performance objectives of 10 CFR Part 60. The initial allocations of performance will provide a basis for determining what site characterization testing will be needed. The initial allocations of performance among the barriers is likely to change based on the results of performance assessments using data collected during site characterization.

It is expected that most of the data collected during the site characterization phase can potentially be used in the license application performance assessments. During the early phase of characterization in particular, when little is known about the site and the importance of data characterizing it, data collection activities shall be controlled in accordance with the QA Level I requirements of this QA Plan. However, there may be cases where it is known that data are not needed for performance assessments, or will be duplicated later in accordance with QA Level I requirements of this QA Plan and therefore would not have to be performed in accordance with the QA Level I requirements at this time. For example, scoping tests or tests to examine the feasibility and appropriateness of a data collection technique may not need to be performed in accordance with the QA Level I requirements of this QA Plan. 1

5.0 SUBMITTAL REQUIREMENTS

5.1 LICENSE APPLICATION

A description of the QA program to be applied to items important to safety and/or waste isolation shall be submitted with the license application. The submittal shall identify the structures, systems, and components important to safety and describe the analyses used in this identification. It should also identify the barriers important to waste isolation falling under the QA program and describe the evaluations used to identify these barriers [10 CFR 60.21(c) (1)(ii)(C)]. A Quality Activities List, as defined in Section 1.0, should also be provided listing major site characterization, isolation, operation, and performance confirmation activities under the QA program. 1

5.2 SITE CHARACTERIZATION PLANS

The following information related to the Q-List should be submitted in the Site Characterization Plan:

- A description of the QA program to be applied to items and activities during the site characterization phase.
- A preliminary Q-List identifying major structures, systems, and components important to safety, engineered barriers important to waste isolation and the methodology used to develop the list.
- A list of major site characterization activities (Quality Activities List) and the QA requirements which apply to them.
- A general description of the process by which the preliminary Q-List will be revised as the design advances.

Plans for development and implementation of a QA program to demonstrate that non-Q-List licensing requirements are met should also be described in the Site Characterization Plan.

6.0 GRADED APPLICATION OF QA MEASURES

The 10 CFR 60 Subpart G requirements can be met using graded QA measures and should be applied to items and activities important to safety and/or waste isolation based on considerations such as the following:

- The impact of malfunction or failure of the item, or the impact of erroneous data associated with data collection activities, on safety or waste isolation.
- The complexity of design or fabrication of an item, or design and implemen- tation of a test, or the uniqueness of an item of test.
- The special controls and surveillance needed over processes, tests, and equipment.
- The degree to which functional compliance can be demonstrated by inspection or test.
- The quality history and degree of standardization of the item or test.

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

APPENDIX J

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 a 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 an 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

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 reviewers. Each peer shall have recognized and verifiable technical credentials in the technical area that the peer has been selected to review. 1

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. funding considerations) it may be difficult to meet the independence criteria without reducing the technical quality of the peer review. When the independence criteria cannot be met, a documented rationale shall be included in the peer review report.

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 peer review group chairperson and shall be signed by each peer review group member. The peer review report shall include the following: 1

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.

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 will 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 Rational 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)/

3.0 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 of the test including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results;

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 1. Reference the applicable QA requirements. 0

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.

4.0 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 from 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.

UNCONTROLLED

SCIENTIFIC INVESTIGATIONS AND SPECIAL PROCESSES

PURPOSE

The term "special" processes historically has been applied to processes used to produce items that are physical structures. The quality of the results of such processes (e.g., welding) may be uncertain and highly dependent on the mechanical or interpretive skills of the individual performing the work. For these reasons, additional controls were placed on the conduct of such work, e.g., the requirements for the procedure to be used being subjected to added tests and the individual being tested to provide additional confidence in the skills of the worker. The predictable results of such "special" process controls provides adequate confidence and reasonable assurance that the process, when applied, will provide an end product meeting the original design intent.

In contrast, processes used in scientific investigations focus on the controlled collection, preparation and analysis of data; the results of which are intended to meet the licensing requirements for a geologic repository as specified in 10CFR60. This paper discusses the nature of processes in scientific investigations, the distinction between traditional special processes and describes the controls used to assure the quality of the data gathered through the use of such processes.

DISCUSSION

Scientific investigations involve a large number of different processes, both laboratory and field, directed to the collection and analysis of data derived principally from the natural environment in and around Yucca Mountain. This includes studies of the waste package environment. There are at least four parts to any scientific investigation; the collection of data, the preparation of data, its analysis and its interpretation. All of these activities are controlled processes which receive appropriate reviews and approvals as required by the quality program. We focus in this report on the first three activities since these are the ones most likely to be interpreted as involving special processes.

The scientific studies include a wide range of activities some of which are:

1. Cutting and retrieving core from boreholes;

2. Waxing core;

3. Identifying the minerals in a sample of tuff through x-ray diffraction analysis of a powdered specimen;

4. Identifying minerals in a sample of tuff using thin section analysis;

5. Preparing and analyzing geophysical logs from a borehole;

6. Determining ground water level through monitored boreholes;

7. Determining the chemistry of pore waters extracted from a core; and

8. The shaping of a piece of core for resistivity or induced polarization measurements.

This is a typical list and is not all inclusive, however, these scientific investigations utilize various analytical instruments which measure some parameter(s). The main variable is the material and it is the variability in some parameter or subset of parameters that is the object of the analysis. Note that because most of this material is natural we do not know in advance the parameters and their variability. The instruments used in analyses provide information (output) due to a specific response between some input of energy and the material being examined. The output is the results of a set of physical and chemical laws that govern the interaction between the input energy (e.g., x-ray beam of some intensity) and the material (e.g., a mineral).

Theoretical and empirical evidence of the adequacy of these analytical instruments (with their associated procedures) to produce the desired results are established in a number of ways, principally through appropriate calibration of the instrument and through correlation with existing scientific literature. Given that the analysis is performed correctly, we are confident that the results reflect the parameter we want to measure because there is a large body of literature which supports our reading of the output. Further, this body of published support was obtained through controlled laboratory processes utilizing calibrated equipment and has broad acceptance throughout the scientific community. Fundamentally, it is the mass of technical literature describing known responses of material to known physical and chemical laws that gives us confidence in our results.

The criteria in 10 CFR 50, Appendix B, represents an adequate set of controls for the instrumental analysis used in scientific investigations without the need to categorize such processes as special. Sections of the QA Plan which are application to the topic of this report are:

Section II: QA Program - Personnel selected shall have education and experience commensurate with the minimum requirements specified in the position description.

Section III: Scientific Investigation and Design Control - Criteria for the planning, review/approval, and performance of scientific investigations are prescribed. Scientific notebooks and/or technical implementing procedures are used for describing how the work is to be done and for documenting the activity. Surveillances of scientific investigations are conducted to ensure that procedures are followed and documented.

Section IV: Procurement Document Control - Technical requirements for equipment and services used in data collection, preparation and analysis are adequately documented.

Section V: Instructions, Procedures, Plans and Drawings - Activities affecting quality shall be prescribed and performed in accordance with documented instructions, procedures, plans or drawings. A technical review of the documents used to implement the activities is required.

Section VI: Document Control - applicable current documents are available at the location where they are to be used.

Section VII: Control of Purchased Items and Services - Measures are established to ensure that purchased material, equipment and services conform to the procurement documents.

Section VIII: Identification, Control of Items, Samples and Documents - Procedures shall be developed and implemented to ensure that samples are identified and controlled in a manner consistent with their intended use.

Section IX: Control of Processes - Measures shall be established to ensure that processes that affect quality of items or services are controlled either by instruction, procedures, or other appropriate means.

Section XII: Control of Measuring and Test Equipment -- Measures shall be established to ensure that tools, gages, instruments, and other measuring and test equipment used in activities that affect quality are properly controlled, calibrated, and adjusted at specific periods to maintain accuracy within necessary limits.

Section XIII: Handling, Shipping, and Storage - Measures shall be established to control packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss or deterioration.

Section XV: Control of Nonconforming Items -- Measures shall be established to control items that do not conform to requirements to prevent their inadvertent installation or use.

Section XVI: Corrective Action - A corrective action system is defined to ensure that significant conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as practical.

Section XVII: QA Records - Records that furnish documenting evidence of quality shall be specified, prepared and maintained in accordance with NNWSI Administrative Procedures.

Section XVIII: Audits - All NNWSI Project activities will be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall QA Program and to determine their effectiveness. The audit program will be supplemented by independent surveillance activities.

It is important to recognize then that there are controlled processes governing the collection, preparation and analysis of data in scientific investigations. The interest is not in the sample per se, but in physical or chemical parameters obtained from the sample. Data is gathered from a sample the precise parameters of which are not known in advance. If the processes controlling the collection, preparation and analysis of the material are adequate and documented as having been followed during the activity by qualified scientists or technicians (Sections II, III and V), reasonable assurance that the data accurately represents the correct value(s) is obtained. To further ensure the quality of the work, instruments used in the data collection and analysis processes are calibrated (Section XII) before and after measurements are made.

While it is true that standards are included in the analysis of materials (e.g., standard tables for the identification of minerals from x-ray diffraction data), there are no standards for the sample itself. That is to say there may or may not be clay in the sample and one or more clay mineral species may be present. Similarly a technician may use standard solutions (National Bureau of Standards (NBS) Standards) to calibrate the recording instrument prior to a chemical analysis. This calibration indicates that the instrument is reading values within an acceptable range and sensitivity.

The preparation of many samples must meet certain standards, but these can be evaluated with objective tests the results of which are not solely dependent on the certification and/or qualification of the operator and the procedures. For example: thin sections must be cut to a thickness of 30 microns (evaluated by recognizing the appropriate birefringence "color" of the contained minerals in polarized light); core specimens in resistivity and induced polarization measurements must be shaped on a saw (shape is measurable) and waxed core wrapped at the drill site to preserve the contained volume of fluids (preservation determined by weighing the sample at the drill site and weighing it at the laboratory) illustrate this. In all of these examples the uncertainty about the quality of the data (i.e., does the sample measure up to standards) is very low.

Although there are some parallels between control of processes and special processes there are significant differences.

1. The examples cited in 10 CFR 50, Appendix B, and in NQA-1 of the application of special processes are focused on items that are to be a permanent part of a facility rather than the collection of data. Special processes as defined in Basic Requirement #9 are as follows: "Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

2. The quality of the resulting items is solely a function of the processes having been performed and tested by qualified personnel using qualified procedures. Since one cannot directly test for the quality of the item (e.g., an item undergoing welding), its quality can only be assumed predicated on the confidence that the material will, when subjected to the same process variables as those used during process qualification, yield the same material or chemical properties. It is necessary to establish the qualifications of the operator through some established requirements (e.g., a written certification test or a performance test).

The scientists and technicians performing scientific investigation are qualified on the basis of their academic record and/or work experience (Section II) prior to their appointment. Procedures in scientific investigations receive a technical review for adequacy and completeness (Sections II, III, and V). Quality is further ensured through calibration of the instruments used in data collection, preparation, and analysis (Section XII). Audits and surveillances are conducted to be sure that procedures are being followed and the work properly documented (Section XVIII).

3. The item to be incorporated as a permanent part of a facility must meet certain pre-established criteria, codes or standards. In special processes both the materials being used and the controlling variables on the process being applied to the materials are known quantities and are included in the industry wide standards or codes required for such activities.

The parameters for materials being studied in scientific investigations are not known in advance. The purpose of the investigation is to determiine the characteristics of the material. Except for situations where the size, amount or shape (e.g., a 4-inch piece of whole core) of a sample is specified (and these are all measurable features) the sample itself cannot meet some predetermined acceptance criteria.

The evaluation of processes in scientific investigations involves several steps. Initially the purpose of the process (which may

consist of one or more technical procedures) must be detailed in the Scientific Investigation Plan (SIP) and the adequacy of the process determined through technical review. Individual technical procedures also reveive a technical review. If a proposed process is beyond the state of the art, a peer review is utilized. These review processes are mechanisms for qualifying processes. A review of a process must determine whether the process is adequate for the purpose of the SIP. Adequate as used in scientific investigations means that the process addresses the issues detailed in the SIP and that there is sufficient confidence that the results generated by the process can be used in licensing. As part of the review process, the reviewers must determine if the controls specified in the 18 criteria of 10 CFR 50, Appendix B are adequately built into the technical procedure(s) to produce quality results (i.e., results in which there is a high degree of confidence that they are acceptable for use in licensing). Calibration of measuring equipment, confirmatory or corroborative measurements by independent processes, and the use of the 18 criteria exclusive of special processes appear to be sufficient to ensure quality results in scientific investigations.

SUMMARY

Processes in scientific investigations are oriented toward the collection and the analysis of data, not toward preparing an item for use as part of a permanent structure. Pre-established acceptance criteria for samples or for the results of data collection and analysis does not normally exist in scientific investigations. The main variable is the sample or material and it is this variability in some parameter or subset of parameters that is the object of an instrumental and/or chemical analysis.

Process controls which have traditionally been utilized where the product of an activity could be sensitive to the mechanical abilities of the worker (as in welding) or to the interpretative abilities (as in nondestructive examination) will not provide added assurance that the results of a scientific investigation will be substantially more accurate. There are many scientific processes used where the results do not depend on the ability or understanding of the process by the technician or scientist at all (e.g., automated ultraviolet spectroscopy).

The results of all scientific investigation processes used in the High-Level Waste Repository program depend on the technical abilities of the scientists and technicians to apply the laws of physics, chemistry, engineering and other sciences. This is supported by a very large volume of scientific data already in existence and accepted by the scientific community and regulatory bodies. The imposition of special process controls will not provide increased assurance that the results of a scientific investigation is more correct or accurate than those controls currently used.

APPLICATION OF CRITERION 10 "INSPECTION",

It is the policy of the NNWSI Project that scientific investigations are conducted to discover and interpret the nature and extent of natural phenomena. It is important to emphasize the words "discover" and "interpret" when describing the goals of scientific investigations. Discovery is the process of acquiring knowledge that was previously unknown. Interpretation, of course, is the "...act of explaining the meaning of". Scientific investigations are unique in the sense that such activities do not have established acceptance criteria which may be used to verify conformance.

Predetermined acceptance criteria is an essential element in the conduct of inspections. Traditionally, inspections are performed to verify conformance of an engineered item to predetermined acceptance criteria. This same approach is inappropriate for verification of scientific investigations because such activities rely on discovery and the interpretation of those natural and physical laws of science that aid in the explanation of the phenomena. It follows that the requirements of Criterion 10, "Inspection" are not appropriate for use where scientific investigations must be controlled. However, controls are necessary.

The NNWSI QAP describes a set of quality assurance requirements for scientific investigations that when properly implemented provide a high degree of confidence that the results of such activities are accurate and complete. The approach given by the NNWSI QAP assures the following:

- a thorough plan of the investigation is prepared and approved
- a technical review of the plan is completed by the participant
- activities are governed by technical procedures or in instances where a high degree of technical expertise is necessary, the use of scientific notebooks is required
- computer programs are verified and validated
- interfaces, both internal and external to the investigations are identified and controlled
- surveillances, which include technical team members, are performed to verify compliance
- a close out verification is performed by the participant to assure adequacy and completeness

From the description of the controls given by the NNWSI QAP it is clear that scientific investigations are activities, not items. It is also clear that such controls are intended to capture the essence of an activity whose purpose is to discover and interpret.

APPLICABILITY OF THE REQUIREMENTS OF CRITERION 11.0, "TEST CONTROL," TO SCIENTIFIC INVESTIGATIONS

The NNWSI QA Plan (NNWSI/88-9) indicates that test control (Criteria XI) of 10 CFR 50, Appendix B, applies to engineered items but does not apply to scientific investigations. This paper is intended to document the Project's rationale and approach to satisfy the intent of Criteria XI.

For engineered items, the requirements of 10 CFR 50, Appendix B, will be met by implementation of ANSI/ASME NQA-1-1986. These requirements are supplemented in the NNWSI QA Plan (NNWSI 88/9), Section 11.0, "Test Control," by the incorporation of guidance provided in the NRC Review Plan for QA Programs for Site Characterization of High Level Nuclear Waste Repositories.

The controls applied to scientific investigations are identified in Section III, Para. 1.0, of the NNWSI/88-9 document. The following comparison with the NRC Review Plan, Chapter 11.0, depicts how the requirements for the controls that are applicable to scientific investigations have been incorporated. Where appropriate, the requirements of ANSI/ASME NQA-1-1986 for control of tests have also been incorporated.

It is important to note that there are two basic kinds of documentation which can be used for quality assurance, documentation, and control of scientific work. These are the scientific notebook system and the technical implementing procedure system. The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgement or trial and error methods, or both, in their work. Alternatively, the technical implementing procedure system will generally be used when qualified technicians are performing repetitive work which does not include the use of professional judgement or trial and error methods in the performance of the work. Detailed technical implementing procedures are required when it is not possible to deviate from a strict sequence of actions, without endangering the validity of the results that will be obtained from the work. Logbooks or appropriate forms or both are used, particularly in repetitive work, to document the performance of the work according to the technical impelementing procedure, and to maintain absolute control over all other aspects of the work. The following indicates where the NRC Review Plan requirements are implemented for procedures and scientific notebooks.

NRC Review Plan Requirement 11.1

The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for (a) determining when a test is required or how and when testing activities are performed, and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.

Response

The NNWSI Site Characterization Plan describes the program for scientific investigation. The work is further controlled in Section III, Para. 1.1, by requiring the preparation of scientific investigation plans for individual activities.

It is not appropriate in most cases for individual procedures to address when a test or testing activities are performed. Scientific investigation activities cannot necessarily be scheduled as construction activities (e.g., take one concrete cylinder for every 50 C.Y. concrete poured). Procedures do, however, clearly define the sequence of steps to be performed for proper implementation.

Training requirements for site personnel are covered in Section II of the QAP. For both scientific notebooks (Para. 1.6.4.1, 7th bullet) and technical implementing procedures (Para. 1.6.2, 9th bullet) it is required that any special training or qualification requirements be clearly defined.

Section III, Para. 1.9, and Section XVIII of the QAP define QA organization overview of scientific investigation activities.

NRC Review Plan Requirement 11.2

"Test plans and procedures are reviewed in accordance with the verification requirements in Section 3."

Response

This requirement is stated in Section III, Para. 1.3 (for plans) and Para. 1.6.2 (for procedures).

NRC Review Plan Requirement 11.3

"The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified."

Response

This requirement is stated in Section III, Para. 1.6.4.1, 9th bullet (for scientific notebooks) and Section III, Para. 1.6.2.2 (for technical implementing procedures).

NRC Review Plan Requirement 11.4

"Test procedures or instructions provide the following:

a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy."

Response

This requirement is stated in Section III, Para. 1.6.2, 1st and 2nd bullets (for technical implementing procedures, with the notation that acceptance limits are to be supplied only if applicable). These requirements are not applicable to scientific notebooks since the end product of research or experiment is data which is used to establish acceptance limits.

b. "Instruction for performing the test."

Response

This requirement is stated in Section III, Para. 1.6.2, 1st bullet (for technical implementing procedures). This requirement is not applicable to scientific notebooks since the purpose of experiment or research is to establish methodology.

c. "Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage."

Response

For scientific notebooks the applicable portions of this requirement are stated in Section III, Para. 1.6.4.1 and for technical implementing procedures in Section III, Para. 1.6.2, 3rd bullet.

d. "Mandatory inspection hold points (as required)."

Response

This requirement is stated in Section III, Para. 1.6.2, 4th bullet (for procedures), with the clarification of "mandatory verification points," as inspections are not applicable to scientific investigation. This requirement is not applicable to scientific notebooks since at that phase of research, the methodology of process is not established.

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

Response

This requirement is stated in Section III, Para. 1.6.2, 5th bullet (for procedures). This requirement is clarified by also adding that accept/reject criteria means that 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. This requirement is not applicable to scientific notebooks as during this phase of research acceptance/rejection criteria are being developed.

f. "Methods of data analysis."

Response

For technical implementing procedure this requirement is stated in Section III, Para. 1.6.2, 7th bullet. This requirement is not applicable to scientific notebooks as data is the end product.

g. "Methods of documenting or recording test data and results."

Response

This requirement is stated in Section III, Para. 1.6.2, 6th bullet (for technical implementing procedures). It is not applicable to scientific notebooks as the activity methodology has not been established at this point. Therefore, the data or its format cannot be readily determined.

h. "Provisions for assuring test prerequisites have been met."

Response

This requirement is stated in Section III, Para. 1.6.2, 8th bullet (for technical implementing procedures) and Section 1.6.4.2, 2nd bullet (for scientific notebooks).

NRC Review Plan Requirement 11.5

"Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3."

Response

This requirement is stated in Section III, Para. 1.9 and 1.11.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

OCT 14 1988

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10/14/88

Mr. Ralph Stein, Acting Associate Director
Office of Systems Integration and Regulations
Office of Civilian Radioactive Waste
Management
U. S. Department of Energy, RW-24
Washington, D. C. 20545

Dear Mr. Stein:

On August 15, 1988, the U. S. Department of Energy (DOE) forwarded Revision 1 of the Nevada Nuclear Waste Storage Investigation (NNWSI) "Quality Assurance Plan" (hereafter the 88-9 QA Plan) for the Yucca Mountain project, for U. S. Nuclear Regulatory Commission (NRC) staff review and acceptance. Our review conclusions are in the enclosed Safety Evaluation (SE). In it, we have concluded that, with the exception of six needed modifications identified in Section V of this evaluation, the 88-9 QA Plan meets the requirements of Subpart G of 10 CFR Part 60 and Appendix B to 10 CFR Part 50, as applicable. Our staffs have recently discussed and agreed on these modifications and incorporating them into the plan should be straightforward.

It was our mutual goal to resolve all open items on the 88-9 QA Plan in our meeting on July 8, 1988 and to issue the SE within 30 days. However, at the conclusion of that meeting, several open items remained. Since that time, our staffs have been discussing approaches for resolving open items. These approaches will be incorporated into the next revision of the 88-9 QA Plan. An alternative approach to resolving these items was for the NRC staff to issue the SE with the open items simply identified, without any expectation that resolution could be achieved quickly. While it has taken more time than originally expected, the approach we selected has led to our agreement on the resolution of all open items and we are optimistic about being able to formally close them out when they are documented.

We request that you provide a revised plan, within thirty days, which incorporates the modifications that the SE describes. The staff will then issue a supplement to the SE that acknowledges that the necessary changes have been made.

DOE may make changes to the 88-9 QA Plan if the changes do not reduce the commitments that DOE previously made to and which were accepted by NRC. Changes that reduce DOE's commitments should be submitted to and accepted by NRC before implementation. A copy of this letter and SE should be included with each controlled copy of the 88-9 QA Plan. One copy should be resubmitted to NRC.

The 88-9 QA Plan addresses, in a general manner, design control and the assignment of quality levels to design phases. At the July 18 and 19, 1988 exploratory shaft facility (ESF) meeting, however, it was established that DOE's approach to implementing ESF design control was unacceptable to the NRC staff. The staff believes that lack of an adequate design control process is a root cause of many of the outstanding ESF design issues. These NRC concerns

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have been expressed in the August 5 and August 22, 1988 letters to you. Since design control is an important element in the repository program, NRC will monitor the implementation of the quality assurance (QA) aspects for design control closely. NRC will consider successful implementation of these aspects a significant factor in determining the acceptability of the overall DOE QA program.

During our review, DOE provided additional clarification on how 10 CFR Part 50, Appendix B, Criteria IX ("Control of Special Processes"), X ("Inspections"), and XI ("Test Control") would be applied to site characterization activities. The additional clarification described how Appendix B controls from these criteria were incorporated into Section III of the 88-9 QA Plan, which addresses scientific investigations. This information was included in the July 15, 1988 meeting minutes for the July 8, 1988 meeting and in the August 15, 1988 DOE submittal of the 88-9 QA Plan to NRC. The NRC staff urges DOE to include this clarification as part of the 88-9 QA Plan. It is a useful explanation for persons using the plan and eliminates possible misinterpretation.

In summary, with the incorporation of the agreed upon modifications to resolve the open items, the staff finds the plan fully acceptable. Should you have any questions on our review, please contact Bill Belke of my staff on (301) 492-0445.

Sincerely,

John J. Linehan

John J. Linehan, Chief
Project Management and Quality
Assurance Branch
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: L. Barrett, OCRWM
R. Loux, State of Nevada
C. Gertz, DOE/NV

SAFETY EVALUATION

1. INTRODUCTION

The U.S. Department of Energy, Nevada Operations Office (DOE/NV) established the Nevada Nuclear Waste Storage Investigations (NNWSI) Project to investigate whether Yucca Mountain is a suitable site for the high-level radioactive waste repository. The NNWSI Project will perform investigations that will address items and activities which could affect the radiological health and safety of the public (i.e., those items and activities important to safety or waste isolation) and that the U. S. Nuclear Regulatory Commission (NRC) regulates.

To demonstrate compliance with legislative, regulatory, and DOE requirements for control and documentation of quality, DOE/NV has established the Waste Management Project Office (WMPO) to manage and to direct the NNWSI Project. To establish a framework for consistency in the development of quality assurance (QA) plans and implementation procedures at all levels of the NNWSI Project, WMPO has developed the NNWSI Project QA Plan, NNWSI/88-9 (hereafter 88-9 QA Plan). The 88-9 QA Plan establishes the QA requirements for the NNWSI Project organizations. All NNWSI organizations (i.e. WMPO, Nevada Test Site (NTS) Support Contractors and Participating Organizations) must meet the requirements described in the 88-9 QA Plan and incorporate them into their QA program plans and procedures.

NRC staff has prepared this Safety Evaluation (SE), which documents the NRC's review of the information that DOE/NV submitted in its 88-9 QA Plan, Revision 1. The 88-9 QA Plan addresses NRC's regulations, positions, and guidance documents on QA. This SE describes the regulatory criteria against which the 88-9 QAP was reviewed, summarizes the content of the 88-9 QA Plan, and provides a basis for NRC staff acceptance of it.

There are several limitations on the scope of this review. The 88-9 QA Plan is a higher tier requirements document. Therefore, this review does not include the QA program plans and procedures that each of the organizations in the NNWSI Project will prepare and the implementation of these into the site and laboratory investigations. The QA program plans and procedures will be designed to meet the requirements of the 88-9 QAP Revision 1. NRC staff will review and accept these plans (after DOE incorporates necessary changes) at a later date. The staff will also review the incorporation into the technical programs of the administrative controls of the QA program described in the above plans and procedures during its planned technical reviews of, for example, the Site Characterization Plan (SCP), study plans, and technical procedures, and its onsite inspections, audits, and observations of DOE audits.

2. BACKGROUND

On August 25, 1986, the NRC provided comments to DOE on the 88-9 QA Plan (formerly 196-17, Revision 4, dated January 14, 1986). Similarly, on November 21, 1986, the NRC provided comments to DOE on NNWSI-SOP-02-01, dated January 31, 1986, "Quality Assurance Program Plan Requirements for NNWSI Project Participating Organizations and NTS Support Contractors."

The purpose of this latter document was to delineate the QA requirements to be addressed in the QA program plans of the participating organizations and NTS support contractors. DOE provided responses to the above NRC comments on January 20, 1988 and discussed these at a March 18, 1988 meeting at the NRC Headquarters in Rockville, Maryland. The 196-17 QA Plan and NNWSI-SOP-02-01 documents were subsequently incorporated into what is currently the 88-9 QA Plan. On May 19, 1988, DOE submitted the 88-9 QA Plan (Rev. 0) for NRC staff review. The NRC staff had 30 open QA items as a result of its review of the 88-9 QA Plan and DOE responses to the August 25, 1986 and November 21, 1986 NRC requests for additional information. NRC and DOE discussed these open QA items at a July 8, 1988 meeting at the NRC Headquarters in Rockville, Maryland. Other participants included representatives from the State of Nevada, the General Accounting Office, the Utility Nuclear Waste Management Group, and private industry.

At this meeting, DOE provided responses to NRC's open items and amended responses to DOE's previous resolutions on NNWSI-SOP-02-01. The major items that were resolved at the meeting concerned how DOE was addressing the NRC staff's Technical Positions on "Peer Review", "Qualification of Existing Data", "Q-List", and "Documentation of Computer Codes", (NUREGs 1297, 1298, 1318, and 0856 respectively); software QA; inspections; and special processes. NRC identified three open items (QA measures for study plans, NRC review of the Office of Civilian Radioactive Waste Management (OCRWM) QA program, and QA measures for conceptual designs) that do not affect the review of the 88-9 QA Plan but will be tracked on the master list of open items which had been discussed at a July 7, 1988 meeting between DOE and NRC. Based on the above, the NRC staff concluded it had sufficient information on which to base an SE for the 88-9 QA Plan.

The NRC staff used the following review criteria to determine whether the 88-9 QA Plan appropriately addressed Appendix B to 10 CFR Part 50:

- "NRC Review Plan - Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Facilities";[1]
- American National Standards Institute (ANSI)/American Sociaty of Mechanical Engineering (ASME) NQA-1 - 1986;[2]
- Regulatory Guide 1.28[3] (endorses ANSI/ASME NQA-1-1983);
- Criteria from ANSI/ASME NQA-3[4] (Revision 1, 2/88) on design data control;
- NRC staff Technical Position on Peer Review,[5]
- NRC staff Technical Position on Qualification of Existing Data,[6]
- NRC staff Technical Position on Q-List,[7] and
- NRC staff Technical Position on Documentation of Computer Codes for High-Level Waste Management.[8]

3. STAFF EVALUATION

The following sections describe in detail the staff's evaluation of the 88-9 QA Plan for each of the 18 criteria of Appendix B, 10 CFR Part 50. Each section identifies the areas of the 88-9 QA Plan reviewed by the staff, summarizes the QA measures that apply (from the criteria listed above), and the content of the 88-9 QA plan and, where necessary, provides NRC staff analysis of DOE's justifications for various approaches taken to fulfill the requirements of Subpart G of 10 CFR Part 60. The staff's finding on the approach outlined in the 88-9 QA Plan is also presented.

3.1 "Organization" (Criterion I)

The staff reviewed the description of "Organization" provided in the Introduction and Section I of the 88-9 QA Plan. The criteria identified in Section 2 of this SE were used to assess the description. These criteria, in summary, are:

a. The responsibilities for establishing and implementing the QA program shall be established.

b. Persons performing QA functions shall have sufficient independence, authority, and organizational freedom to identify, initiate, recommend, and provide solutions to quality problems.

c. The responsibilities for achieving and assuring quality shall be clearly established.

Figure 1 shows the organization of the NNWSI Project for QA. The Secretary, DOE Headquarters (DOE/HQ), is responsible for executing the Nuclear Waste Policy Act of 1982. The Secretary has delegated this responsibility to OCRWM to integrate QA and management policies and requirements for the overview of the activities that the DOE/NV field operations office performs. The OCRWM provides programmatic and policy guidance to DOE/NV to assure that adequate QA and technical objectives of the project are achieved. The OCRWM Office of Quality Assurance is responsible for: (1) reviewing and approving the 88-9 QA Plan, the quality-related administrative procedures, and the WMPO Quality Assurance Program Plan; (2) specifying the appropriate requirements contained in the OCRWM Quality Assurance Program Plan; and (3) performing QA audits of the WMPO.

For the Nevada Operations Office, the DOE/NV Manager has ultimate accountability and responsibility for the NNWSI Project. Within the DOE/NV organization is the WMPO, which has been established to manage the NNWSI Project, under the programmatic direction of the OCRWM. The DOE/NV field operations office is responsible for the implementation of the QA and technical activities of the NNWSI Project.

The WMPO is responsible for authorizing work and the management and technical direction of the activities that the respective Participating Organizations and NTS Support Contractors conduct. This is accomplished through the issuance of technical and programmatic guidance; technical integration, planning, and QA programmatic guidance.

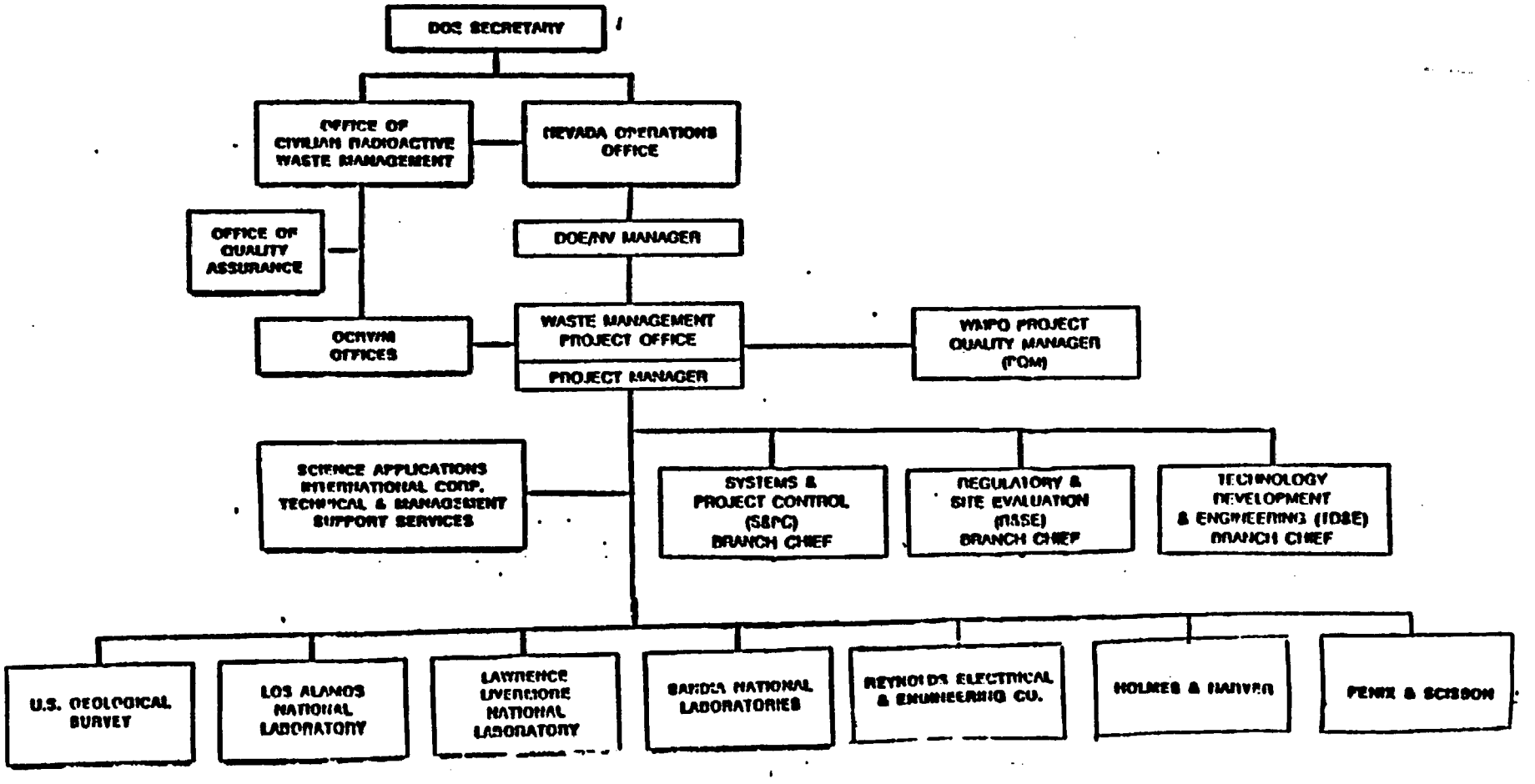

FIGURE 1 NNWSI PROJECT ORGANIZATION

The WMPO Project Manager, reporting to the DOE/NV Manager, is responsible for the NNWSI Project actions, which include: (1) planning and directing; (2) establishing goals and objectives and assessing progress toward achieving these goals; (3) administering procurement of materials and services; (4) issuing technical and programmatic guidance; (5) organizing and conducting peer reviews; (6) complying with applicable regulations, laws, and DOE policies; and (7) implementing the WMPO QA program.

Reporting to the WMPO Project Manager are three technical branches, each under the direction of a branch chief. The Regulatory and Site Evaluation Branch is responsible for: (1) site characterization in field and laboratory activities; (2) performance assessment; (3) interactions with the NRC; (4) preparation of project documents; (5) site investigation documents; and (6) review and approval of NNWSI Project quality-related documents.

The Technology Development and Engineering Branch is responsible for: (1) systems description, analysis, and integration; (2) waste package design and development; (3) design, construction and operation of major test facilities; (4) operational safety; (5) repository engineering, including conceptual design, rock mechanics, and borehole sealing; (6) instrument and equipment development; (7) exploratory shaft design, construction, and operation; (8) engineering and technical support for project plans, reports, and presentations; and (9) review and approval of NNWSI Project quality-related documents, as defined in WMPO implementing procedures.

The Systems and Project Control Branch is responsible for: (1) administration and management support; (2) records management/information management system; (3) QA records administration; (4) configuration management; (5) transportation; (6) socioeconomics; (7) institutional liaison; (8) project training; (9) review and approval of NNWSI Project quality-related documents, as defined in WMPO implementing procedures; and (10) environmental analysis and support.

Also reporting to the WMPO Project Manager is the WMPO Project Quality Manager (PQM), who is responsible for directing and managing the NNWSI QA Program. The PQM has sufficient organizational position and authority to exercise control over the WMPO QA Program. The reporting relationship of the PQM is such that this position is the same or higher than the highest line manager responsible for activities affecting quality. The PQM is also sufficiently independent from cost and schedule considerations, when opposed to safety considerations, to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. Responsibilities of the PQM include: (1) approval of the NNWSI QA Plan; (2) approval of the quality-related implementing procedures and changes thereto; (3) coordinating WMPO QA activities; and (4) verifying the adequacy and effectiveness of the QA plans, requirements, and QA program implementation by the WMPO and NNWSI project participants through audits and surveillances. Reporting to and supporting the PQM is the Science Applications International Corporation's Technical and Management Support Services (SAIC/T&MSS). Resolution of disputes involving quality, between QA personnel and others, will be directed to the PQM and, if necessary, referred to the DOE/NV Manager. If a dispute cannot be resolved within the DOE/NV organization, it will be referred to the OCRWM, for ultimate resolution.

SAIC/T&MSS provides the PQM support which includes: (1) audit and surveillance of QA and technical activities; (2) provision of policy guidance; (3) review of support contractors' and participating organizations' QA program plans; and (4) review of NNWSI implementing procedures for compliance with the NNWSI Project requirements.

Quality throughout the NNWSI program is to be verified through checking, review, surveillance, inspection, testing, and audit to determine whether an item or activity conforms to specified requirements. Consistent with ANSI/ASME NQA-1-1986, the 88-9 QA Plan requires that individuals who perform the quality verification who are not directly responsible for performing the actual work activity. The QA organization is required to overview and monitor the inspection activity. All responsibilities relating to QA program development and achieving and assuring quality are to be documented in the QA program plan of each participating organization.

The NRC staff has assessed the above and the additional information on the organization described in the 88-9 QA Plan. The staff finds that it meets the regulatory review criteria described in Section 2 (Background) of this SE, pertaining to Criterion I of Appendix B to 10 CFR Part 50.

3.2 "Quality Assurance Program" (Criterion II)

The staff reviewed the description of the QA program provided in the 88-9 QA Plan in Section II, "Quality Assurance Program"; Appendix C, "Requirements for the Qualification of Inspection and Test Personnel"; Appendix D, "Requirements for Qualification of Non-Destructive Examination Personnel"; Appendix F, "Requirements for the Qualification of Quality Assurance Program Audit Personnel"; and Appendix I, "Requirements for the Identification of Items and Activities to be Included on the Q-List" against the criteria identified in Section 2 of this evaluation. These criteria, in summary, are:

a. Activities that affect quality shall be planned and documented.

b. The QA program shall be documented in policies, procedures and instructions.

c. Management shall regularly assess the QA program for adequacy and implementation.

d. Personnel performing work affecting quality shall be indoctrinated and trained.

e. Items and activities important to safety or waste isolation shall be identified and controlled under Appendix B, Part 50, as applicable.

f. Activities affecting quality shall be accomplished under controlled conditions.

g. The QA program shall provide control over items and activities to an extent consistent with their importance to safety.

As previously noted, the 88-9 QA Plan is a requirements document which must be met by DOE/NV and all participating organizations and support contractors. The 88-9 QA Plan and all quality-related project procedures and changes thereto, shall be submitted to OCRWM for approval. QA program plans of each participating organization and participating contractor shall be submitted to and approved by YMPO. A graded application of quality is applied to items and activities, commensurate with the importance of their roles or functions in the NNWSI Project. The NNWSI Project has committed to portions of NUREG-1318, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements." This guidance document defines methods by which items and activities important to safety or waste isolation, a subset of the overall items and activities within the repository program, are to be identified. However, the staff positions in Section 4 of the NUREG are not exactly repeated in the 88-9 QA Plan and no justification was provided for the deviations from the staff positions. DOE should either endorse the staff positions, or where exceptions are desired, identify the exceptions and justify their adequacy. This item is identified in Section 5, "Open Items," for future action by DOE.

NNWSI has developed a three level system for grading QA measures. Its Level I contains items and activities important to safety or waste isolation. NRC regulates all of these. Level II contains items and activities defined by reliability, maintainability, public and repository worker non-radiological health and safety, repository worker radiological health and safety, and other operational factors that could have an impact on DOE and WMPO concerns and the environment. NRC regulates some of the activities within Level II. Level II QA requirements are similar to those in Level I (i.e., Appendix B to 10 CFR Part 50), except that deviations are permissible within Level II provided that adequate justification has been documented and WMPO has approved it. Level III items and activities are those which have no major function in the characterization of the site and design of the repository. The controls applied are those managerial, administrative, scientific, engineering, commercial and laboratory practices that are commonly used by the participating organizations in the project. NRC will not regulate any of the activities within Level III, if DOE classifies them properly.

Other basic provisions from the criteria have been adopted and elaborated on in the 88-9 QA Plan. Management assessments are required to be conducted annually to independently determine the adequacy and effectiveness of the QA program implementation. All NNWSI participants are required to establish requirements for the selection, indoctrination, and training of personnel performing or verifying activities affecting quality. Position descriptions shall indicate minimum qualifications and provide for indoctrination or training before incumbents perform a quality-affecting activity. The indoctrination and training program ensures that personnel performing activities affecting quality are knowledgeable in QA/quality control requirements, implementing procedures and instructions, and that

they have competence and skill in the performance of their quality-related activities. It also provides for the retraining of personnel performing activities affecting quality.

The NRC staff finds the 88-9 QA Plan description for the QA program meets the regulatory review criteria described in Section 2, ("Background"), of this SE, pertaining to Criterion II of Appendix B to 10 CFR Part 50, with the exception of Open Item No. 4, identified in Section 5 of this evaluation.

3.3 "Design Control" (Criterion III)

The staff reviewed the description of "Scientific Investigation Control and Design Control" provided in Section III of the 88-9 QA Plan against the criteria defined in Section II of this SE. The staff also reviewed several appendices in the 88-9 QA Plan in its evaluation. These were Appendix B, "Design Inputs"; Appendix G, "Requirements for Qualification of Existing Data Not Generated Under a QA Program Meeting the Requirements of 10 CFR Part 60 Subpart G"; Appendix H, "Requirements for Computer Software Used to Support a High-Level Nuclear Waste Repository License Application"; and Appendix J, "Requirements for Peer Review." The staff review criteria in Section 2, in summary, are:

a. Measures shall be established to assure that the regulatory requirements and design bases are correctly translated into specifications, drawings, procedures, and instructions for items important to safety or waste isolation.

b. The design control program includes general plans and detailed procedures for site characterization data collection and analysis.

c. Appropriate quality standards shall be specified.

d. Interfaces between design organizations shall be controlled.

e. Designs shall be verified for adequacy by individuals or groups other than those who performed the original design.

f. Design changes shall be subject to control measures commensurate with those applied to the original design.

g. For design or design activities which involve use of untried or beyond the state of the art techniques, or where detailed technical criteria and requirements do not exist, a peer review should be conducted.

h. Verification and validation should be performed on computer software.

For design control, DOE has adopted the positions in NQA-1-1986. The description for design control in the 88-9 QA Plan includes the use of specifications, drawings, design criteria and component performance requirements for the natural and engineered components of the repository system. The data resulting from scientific investigations will be used to produce design input. Design controls include measures for peer review;

design analysis; design input, output, and verification; design analysis; change control; internal and external interface control; and control of computer software used to perform design analysis. DOE has committed to the staff Technical Position NUREG-0856 "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management" and extensive additional controls for controlling computer software.

The 88-9 QA Plan, as an upper-tier requirements document, appropriately addresses in a general manner the QA controls to be applied to conceptual designs, including basic assumptions about the site contained in the SCP and study plans. The NRC staff has identified concerns with the implementation of these general requirements and will be tracking these items formally and separately to assure that they are satisfactorily resolved.

The 88-9 QA Plan has included both scientific investigations (i.e., collection and analysis of data providing design input) and conventional design activities within Section III, which addresses Criterion III of Appendix B to 10 CFR Part 50, "Design Control". This approach is consistent with the staff's definition of design control in the QA Review Plan. In addition, DOE has also included within its "Scientific Investigation Control" section measures from Criteria IX ("Control of Special Processes"), X ("Inspections"), and XI ("Test Control"). At the request of the staff, DOE provided a justification for this approach and either demonstrated that the controls identified in Section 3 for scientific investigations were equivalent to those in the above three criteria, or in some cases, were not appropriate due to the nature of the work. A number of additional controls were added in response to the staff's questions. An explanation of DOE's approach to these criteria of Appendix B follows.

Criterion IX of Appendix B, "Control of Special Processes," requires that measures be established to assure that special processes be controlled and accomplished by qualified personnel using qualified procedures in accordance with codes, standards, specifications, etc. A special process is a process, the results of which are highly dependent upon 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. Site characterization data collection activities cannot be inspected or tested after completion to measure their quality.

NNWSI has incorporated controls into Section III of the 88-9 QA Plan which address those required by Criterion IX of Appendix B, Part 50. The 88-9 QA Plan includes requirements for qualification of all personnel performing activities affecting quality, including those performing scientific investigations. NNWSI has also included provisions for qualification or verification of procedures. The 88-9 QA Plan allows for technical reviews or peer reviews of procedures and processes to assure that they are suitable for their intended use. This general approach is acceptable to the staff and will be verified for appropriate implementation in staff technical audits and reviews of procedures.

NNWSI has also incorporated controls from Criterion X of Appendix B, "Inspections," into the section on scientific investigations. NNWSI will use surveillances of scientific investigations to help assure that such

investigations are being performed in accordance with procedures. NNWSI will apply its independence and qualification requirements to those persons performing surveillances. Technical personnel are required for all surveillance teams, along with QA personnel. NNWSI will monitor deficiencies, non-conformances, and potential quality problems until it verifies that personnel have taken corrective action.

Criterion X of Appendix B requires that personnel perform inspections for each work operation where necessary to assure quality. In lieu of inspections of each work operation, the 88-9 QA Plan contains requirements for periodic surveillances, use of qualified individuals (scientists and technicians) to perform work, and verifications of completed work. The staff finds the approach that the 88-9 QA Plan adopts is appropriate for scientific work.

NQA-1 Supplement 10S-1 contains provisions for final inspections of items to assure that they conform to requirements. For scientific investigations, NNWSI will conduct technical reviews of results of completed work and will use a close-out verification by technical personnel to assure that the records are adequate and complete. The staff finds this approach for verification in lieu of a final inspection to be acceptable and appropriate for the work to be performed.

The 88-9 QA Plan also incorporates controls from Section XI of Appendix B, "Test Control", into the section on scientific investigations. This section of Appendix B was written for confirmatory tests of items such as safety-related components in a nuclear power plant to determine if they meet specified requirements. Many site characterization activities will produce data whose values are not known before testing and which will not fall within predetermined numerical acceptance criteria. Nevertheless, many of the controls of Section XI apply to data collection, and the staff requested DOE to furnish a detailed comparison of the staff positions in the NRC QA Review Plan vs. the requirements in Section III. This comparison was furnished in the August 19, 1988 letter forwarding the 88-9 QA Plan Rev. 1 to the staff. The controls incorporated include the use of technical procedures and/or lab notebooks for the documentation and control of the work, calibration of equipment, development of an overall test program (which includes the SCP program of testing), identification of test requirements, and others. The staff finds the measures applied to Criterion XI of Appendix B to scientific investigations to be acceptable.

The 88-9 QA Plan has outlined two different approaches for documenting scientific investigations described in study plans or scientific investigation plans. For investigations involving a high-degree of professional judgment by qualified individuals or trial and error methods, or both, scientific notebooks will be used. The documentation in the notebook is to be sufficient such that another qualified scientist can use the notebook to retrace the investigation and confirm the results, or repeat the experiment and achieve the same results without recourse to the principal investigator.

For repetitive work performed by qualified technicians which does not include the use of professional judgment or trial and error methods, a detailed technical implementing procedure will be utilized. Detailed technical procedures are required when it is not possible to deviate from a strict sequence of actions without endangering the validity of the results that will be obtained from the work. These procedures are subject to formal and rigorous change control.

The staff has several concerns with the approach outlined. First, when scientific notebooks are utilized, there appear to be inadequate provisions to assure that tests which could affect the waste isolation capabilities of the site, interfere with other site characterization tests, or which are not repeatable (and therefore if performed incorrectly would preclude obtaining needed site data) will be appropriately controlled. Although study plans are to identify tests which could affect these three areas, there appears to be no controls to assure that investigations conducted with scientific notebooks are controlled to assure that these three areas are not affected. The individual responsible for an experiment is solely responsible for the details of its implementation.

The staff believes that additional controls need to be added to the 88-9 QA Plan to address this concern. For example, a change in a test that is conducted using scientific notebooks that is outside of the scope of the study plan or investigation plan, or could potentially impact any of the three areas addressed above should be subjected to additional review.

Second, the current criteria for tests using detailed implementing procedures are, the staff believes, unnecessarily restrictive and discourage their use in situations where detailed procedures are beneficial. They are to be used "when it is not possible to deviate from a strict sequence of actions without endangering the validity of results that will be obtained from the work." Changes to them are to be rigorously controlled. The staff believes that allowance should be made for tests where a procedure can be prepared with an appropriate level of detail (which is not necessarily a strict sequence of actions) and changed more easily in the field than is currently allowed. Such a practice would encourage the use of more procedures (as opposed to scientific notebooks), with their additional controls and assurance that work will be performed adequately.

Third, the 88-9 QA Plan currently requires that certain initial entries be included in scientific notebooks prior to beginning an experiment. These include the objective, identification of equipment and materials, calibration requirements, and others. The staff believes that a general procedure as to how the initial work is to be conducted should also be included as an initial entry, rather than rely only on in-process entries. Alternatively, the 88-9 QA Plan could reference detailed information on approaches for conducting experiments in the study plans.

Finally, the approach outlined in the 88-9 QA Plan for scientific investigations using scientific notebooks appears to conflict with the NRC/DOE agreement from the May 7-8, 1986 meeting on SCP level of detail. The staff believes the approach in the 88-9 QA Plan is acceptable when the above items are satisfactorily addressed, and these should be incorporated into any other documents which have been developed to implement the NRC/DOE meeting agreements for technical procedures. Furthermore, the NRC/DOE agreement regarding DOE providing NRC with non-standard procedures for review should be changed to DOE making all procedures and scientific notebooks available for NRC review and audit at DOE or DOE contractors' offices.

The 88-9 QA Plan includes a commitment to follow the guidance contained in the NRC Generic Technical Positions, "Peer Review for High-Level Nuclear Waste Repositories," (NUREG-1297) and "Qualification of Existing Data for High-Level Nuclear Waste Repositories," (NUREG-1298). Certain of the specific positions from NUREGs 1297 and 1298 were not entirely consistent with the 88-9 QA Plan and are carried as Open Items 1 and 2 in Section 5 of this SE. Open item 3, concerning provisions for precision and accuracy for initial entries in the records for experiments or research (from Criterion XI in the NRC 1984 Review Plan) was inadvertently omitted from the 88-9 QA Plan and will be included in the next revision to the 88-9 QA Plan.

The NRC staff has assessed the above and the additional information provided for "Design Control" and "Scientific Investigation Control" in the 88-9 QA Plan, and finds that it satisfactorily addresses the regulatory review criteria described in Section 2 (Background) of this SE with respect to Criteria III, and IX, X, and XI as they pertain to scientific investigations, except as noted previously and in Section 5 of this report.

3.4 "Procurement Document Control" (Criterion IV)

The staff reviewed Section IV of the 88-9 QA Plan against the criteria identified in Section 2 of this SE. The criteria which pertain to Procurement Document Control, in summary, are:

a. Procurement documents shall include all applicable requirements.

b. Procurement documents shall require contractors or subcontractors to develop a QA program implementing portions or all of the requirements of Appendix B.

The 88-9 QA Plan has incorporated the guidance in NQA-1-1986 and the NRC QA Review Plan. It includes a requirement to assure that applicable regulatory and technical requirements, design bases, and other necessary requirements are included in procurement documents. Suppliers are required to have a program implementing portions or all of NQA-1-1986. The staff finds the requirements adopted in the 88-9 QA Plan to be acceptable.

3.5 "Instructions, Drawings, and Procedures" (Criterion V)

The staff reviewed Section V of the 88-9 QA Plan, "Instructions, Drawings, Plans, and Procedures," against the criteria listed in Section 2 of this SE. These criteria, in summary, are:

a. Activities affecting quality shall be accomplished in accordance with instructions, procedures, and drawings.

b. Instructions, procedures, and drawings shall include or reference acceptance criteria.

The 88-9 QA Plan has incorporated the basic requirements of Appendix B, the QA Review Plan, and NQA-1. It has added plans to the basic requirements of Appendix B. The staff finds the requirements adopted in the 88-9 QA Plan for control of instructions, procedures, plans and drawings to be acceptable.

3.6 "Document Control" (Criterion VI)

The staff reviewed Section VI of the 88-9 QA Plan against the criteria listed in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established for the preparation, review, approval and issuance of documents that prescribe activities affecting quality.

b. Document changes shall be properly controlled.

The 88-9 QA Plan requires that the preparation, reviews, approval, and issuance of documents be controlled to assure that only correct documents are used. Documents are to state appropriate quality requirements and provide for the identification of responsibility for preparing, reviewing, approving and controlling changes thereto. Obsolete documents are required to be controlled and a master list established to identify the current list of documents.

The 88-9 QA Plan has incorporated the provisions of NQA-1-1986 and the NRC QA Review Plan. The staff finds requirements adopted for Section VI, "Document Control", to be acceptable.

3.7 "Control of Purchased Items and Services" (Criterion VII)

The staff reviewed Section VII of the 88-9 QA Plan, Control of Purchased Items and Services, against the criteria listed in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established to assure that purchased material, equipment, and services conform to procurement documents.

b. Measures shall be established for source evaluation and selection.

c. Objective evidence of quality shall be furnished by the contractor or subcontractor.

d. The effectiveness of the control of quality by contractors and subcontractors shall be periodically assessed.

The 88-9 QA Plan has incorporated the guidance from the NRC QA Review Plan and NQA-1-1986 addressing each of the requirements listed above. Requirements are included in the 88-9 QA Plan which address procurement planning, source evaluation and selection, bid evaluation, supplier performance evaluation, control of supplier-generated documents, control of changes in items or service, acceptance of items or services, control of non-conformances, and requirements for commercial grade items.

The staff finds the requirements listed in Section VII of the 88-9 QA Plan acceptable.

3.8 "Identification and Control of Items" (Criterion VIII)

The staff reviewed Section VIII of the 88-9 QA Plan, "Identification and Control of Items, Samples, and Data" against the criteria in Section 2 of this SE. The 88-9 QA Plan has expanded the scope of this section from the requirements in Appendix B of 10 CFR Part 50, which only addresses the identification and control of items. The NRC QA Review Plan added samples within this criterion. DOE has also included under this section certain measures for control of data, in addition to those it has prescribed in Section III of the 88-9 QA Plan, "Scientific Investigation Control."

The requirements from the criteria listed in Section 2 of this SE, in summary, are:

a. Items and samples shall be identified and controlled according to procedures.

b. Correct identification of samples is verified and documented before release for use or analysis.

c. Items shall be identified throughout fabrication, erection, installation and use of the item.

d. Identification should be on the sample or its container when possible, or on records traceable thereto.

Section VIII of the 88-9 QA Plan contains the provisions from NQA-1-1986 for controlling items, which is an acceptable method to the staff for meeting the requirements of Appendix B of 10 CFR Part 50. The 88-9 QA Plan also contains provisions for control of samples which meet the guidance in the NRC QA Review Plan, Section 8.

The 88-9 QA Plan also contains several additional requirements for control of data under this section. All data are to be identified to assist in the determination of their correct use. This identification is to be verified as correct before releasing the data for use.

The staff finds the requirements listed in the 88-9 QA Plan for identification and control of items and samples acceptable.

It should be noted that the staff will be reviewing the detailed procedures for control of samples in the new sample management facility of the NNWSI project to assure that the general requirements identified in the 88-9 QA Plan are acceptably translated into detailed procedures.

3.9 "Control of Special Processes" (Criterion IX)

The staff evaluated Section IX of the 88-9 QA Plan against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

a. Processes affecting the quality of items or services shall be controlled.

b. Special processes that control or verify quality, such as welding, heat treating, and non-destructive examination, shall be performed using qualified personnel using qualified procedures in accordance with specified requirements.

The 88-9 QA Plan has incorporated the guidance in NQA-1-1986 for fulfilling the requirements for process control in Appendix B and the NRC QA Review Plan, as they relate to engineered items. The QA Review Plan does not address whether Criterion IX controls apply to scientific investigations. In this review, the staff evaluated the controls for scientific investigations using the requirements in Criterion IX of Appendix B. DOE identifies these controls within Section III of the 88-9 QA Plan, and the staff evaluation of the adequacy of those controls is discussed in Section 3.3 of this SE.

Based on the incorporation of NQA-1-1986 requirements for control of processes related to engineered items and the inclusion of appropriate controls for scientific investigations (see Section 3.3), the staff finds the approach in the 88-9 QA Plan for process control acceptable.

3.10 "Inspection" (Criterion X)

The staff evaluated Section X of the 88-9 QA Plan against the criteria identified in Section 2 of this SE. The criteria, in summary, are:

a. Inspections to verify conformance of an item or activity to specified requirements shall be planned and executed.

b. Inspections shall be performed by individuals other than those who performed or directly supervised the activity being inspected.

c. Hold points should be used, as appropriate.

d. Examinations, measurements, or tests shall be performed for each work operation, where necessary.

e. Process monitoring shall be used where necessary to assure quality.

The 88-9 QA Plan has included provisions addressing the guidance in the NRC QA Review Plan and NQA-1-1986, with the exceptions that inspections are to be applied only to engineered items, and that inspectors need not be part of the QA organization (unless special expertise is needed). With respect to the first deviation, Section 3.3 of this SE describes the DOE controls to be applied to scientific investigations and evaluates their acceptability. With respect to the staff position in the NRC QA Review Plan that all inspectors be within the QA organization, the staff has changed its position to be consistent with and has been superseded by the guidance in NQA-1, which has been endorsed by the NRC since the issuance of the NRC QA Review Plan. In addition, the position in the NRC QA Review Plan is contrary to findings in the Ford Study (NUREG-1055, pg. 3-23 and 3-24).

The approach described in the 88-9 QA Plan is acceptable to the staff.

3.11 Test Control (Criterion XI)

The staff reviewed the 88-9 QA Plan Section XI against the criteria in Section 2 of this SE. These criteria, in summary, are:

a. A test program shall be established to assure that all structures, systems, and components will perform satisfactorily in service.

b. The program shall be performed in accordance with written test procedures which incorporate test requirements and acceptance limits.

c. Test procedures shall include provisions for assuring that all prerequisites for a test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

d. Test results shall be documented and evaluated.

"Testing" is defined in NQA-1-1986 as "an element of verification for determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions."

Consistent with the above, the 88-9 QA Plan applies these controls to engineered items only. Although most scientific investigations do not fall under this definition of testing, the staff requested DOE to either incorporate the controls from Section XI of Appendix B and the NRC QA Review Plan into the 88-9 QA Plan, or provide justifications for why they did not apply. DOE's responses and the staff evaluation of them are discussed in Section 3.3. The 88-9 QA Plan includes most of the above provisions within that section, rather than Section XI of the plan.

For engineered items, the 88-9 QA Plan incorporates guidance in NQA-1-1986 and the NRC QA Review Plan. The staff finds the DOE approach for test control to be acceptable.

3.12 "Control of Measuring and Test Equipment" (Criterion XII)

The staff reviewed the description in Section XII of the 88-9 QA Plan against the criteria in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted to maintain accuracy within the necessary limits.

The 88-9 QA plan has incorporated the provisions from NQA-1-1986 and the NRC QA Review Plan. The scope of the program includes all measuring and test equipment or systems used to calibrate, measure, gauge, test, or inspect either to control or to acquire data to verify conformance to a specified requirement or to establish characteristics or values not previously known. The staff finds the requirements described in the 88-9 QA Plan to be acceptable.

3.13 "Handling, Shipping, and Storage" (Criterion XIII)

The staff reviewed the 88-9 QA Plan against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established to control the handling, storage, shipping, cleaning, and preservation of material and equipment.

b. When necessary, special protective environments, such as an inert gas atmosphere, shall be specified and provided.

The 88-9 QA Plan has adopted the provisions of NQA-1-1986 for material and equipment. However, the NRC QA Review Plan expanded the scope of this criterion to cover samples collected during site characterization. In lieu of addressing samples in this section, the 88-9 QA Plan has incorporated the controls from the NRC QA Review Plan and other controls into Section VIII, Part B, "Identification and Control of Samples." The staff reviewed these controls in Section VIII of the 88-9 QA Plan and finds them acceptable for meeting the requirements of Appendix B, Part 50.

3.14 "Inspection, Test, and Operating Status" (Criterion XIV)

The staff reviewed the 88-9 QA Plan against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

a. The status of inspections and tests performed on items shall be established by markings, such as stamps, tags, labels, routing cards or other suitable means.

b. These status markings shall provide for identification of items which have passed required inspections and tests.

c. Measures shall be established for indicating the operating status of structures, systems, and components, such as by tagging of valves and switches, to prevent inadvertent operation.

Consistent with the language above (taken from Appendix B, the NRC QA Review Plan, and NQA-1-1986), the 88-9 QA Plan applies a requirement of Criterion XIV to engineered items only. DOE provided a detailed rationale for this approach in the meeting of July 8, 1988, which is documented in the minutes dated July 15, 1988.

The objective of Criterion XIV is to preclude inadvertent omission of required acceptance inspections and tests of nuclear plant components. This criterion also requires, for reasons of safety, the tagging of individual valves, switches, etc. to prevent their inadvertent operation. In as much as scientific investigations are not directly related to safety as are nuclear plant components the controls of Criterion XIV do not apply. Alternatively, NNWSI has established the following controls to assure that data collected from scientific investigations are valid:

a. For any scientific investigation activity that is critical or complex, a formal documented readiness review is held.

b. Data collection test plans and procedures are required to contain mandatory hold/surveillance points at critical areas.

c. QA and technical personnel perform in-process monitoring of data collection activities through supervisory review, surveillance, and technical/QA audits.

d. Anomalies and deficiencies occurring during data collection are documented, evaluated, dispositioned, and tracked until verification of final resolution.

e. Resultant data from scientific investigation activities are documented, analyzed, and evaluated in accordance with the applicable requirements of Criterion III of the 88-9 QA Plan to assure their validity.

f. Final reports on data collection activities are subjected to a technical or peer review in accordance with the requirements specified in Criterion III of the 88-9 QA Plan.

The objective of all of these controls is to assure that data are adequate when used in analyses of the repository.

In addition, to reduce the risk of losing data in the lab or the field due to inadvertent interruption, the 88-9 QA Plan requires in Section III that ongoing field and lab investigations be clearly identified at the location at which they are being conducted.

For engineered items, the 88-9 QA Plan has adopted the guidance in NQA-1-1986 and the NRC QA Review Plan.

The staff finds the approach described in the 88-9 QA Plan for criterion XIV of Appendix B acceptable.

3.15 "Control of Nonconforming Items" (Criterion XV)

The staff reviewed the 88-9 QA Plan against the criteria in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established to control items and activities which do not conform to requirements.

b. Nonconforming items and activities shall be reviewed and accepted, rejected, repaired, or reworked in accordance with procedures.

The 88-9 QA Plan has adopted the guidance in NQA-1-1986 and the NRC QA Review Plan for control of nonconforming items. This approach is acceptable to the staff for meeting the requirements of Appendix B. However, the 88-9 QA Plan is unclear as to whether the requirements in Section XV will be applied to nonconformances generated during surveillances of scientific investigations, a staff position in the NRC QA Review Plan. Although nonconformances are referenced in Section III, "Control of Scientific Investigations," and in Section XVIII, "Audits" (where surveillance requirements are described), there is no direct connection to Criterion XV. DOE should clarify whether the requirements in Section XV apply to nonconformances generated during surveillances. Until this is resolved, this item will remain open. It is identified in Section 5 of this report.

3.16 "Corrective Action" (Criterion XVI)

The staff reviewed the 88-9 QA Plan against the criteria in Section 2 of this SE. The criteria, in summary, are:

a. Measures shall be established to assure that conditions adverse to quality are promptly identified and corrected.

b. For significant conditions adverse to quality, (i.e., which if uncorrected would have a serious effect on safety or operability), the cause of the condition and the corrective action taken shall be documented and reported to management.

The 88-9 QA Plan has included the guidance in NQA-1-1986 and the NRC QA Review Plan for meeting the above criteria. The staff finds this approach acceptable.

3.17 "Quality Assurance Records" (Criterion XVII)

The staff reviewed Section XVII, "Quality Assurance Records," and Appendix E of the 88-9 QA Plan against the criteria in Section 2 of this SE. The criteria, in summary, are:

a. Records furnishing evidence of quality shall be maintained.

b. Records include results of reviews, inspections, tests, audits, monitoring of work performance, materials analyses, qualifications of personnel, procedures, and equipment.

c. Records shall be identifiable and retrievable.

d. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

The 88-9 QA Plan incorporates the provisions of the NRC QA Review Plan and NQA-1-1986 as requirements for project participants. Appendix E contains a list of "typical" QA records for site characterization which is, however, not as complete as the current draft of NQA-3. The 88-9 QA Plan defines generally the criteria for defining QA records, so that the smaller scope in this list of typical records is not a deviation from the requirements. Also, NQA-3 is only a draft standard and its final list of typical records could be different from that currently in place. The staff will assure that complete records are being maintained in its audits and observations of DOE audits.

All records have been defined by the 88-9 QA Plan as lifetime records and are required to be retained for the life of the project. The 88-9 QA Plan does not address at this time the post-closure records required to be retained to fulfill the requirements of 10 CFR Part 60, Section 60.51. However, since all records are being retained for the life of the project, this item does not need to be resolved during the site characterization phase of the repository. The staff will review and evaluate DOE's scope of post-closure records before issuing an amendment to the license application for permanent closure.

The 88-9 QA Plan has included within the scope of QA records only those which provide evidence of the quality of data taken from samples and not the sample itself since there is no current regulatory requirement to classify samples as QA records. However, there may be requirements under the proposed rule for the Licensing Support System (LSS) for their retention. DOE should be aware of these possible future requirements for the LSS. This item is not being considered as an open item because there is no existing regulatory requirement.

The staff finds the 88-9 QA Plan approaches for meeting the requirements of Appendix B, Criterion XVII to be acceptable.

3.18 "Audits" (Criterion XVIII)

The staff reviewed the 88-9 QA Plan against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

a. QA audits shall be planned and documented to verify compliance with all aspects of the program and to determine the effectiveness of the program.

b. The preparation, performance, reporting, response, and follow-up of audit activities shall be controlled.

c. Follow-up action shall be taken where indicated.

The 88-9 QA Plan has incorporated the provisions of NQA-1-1986 and the NRC QA Review Plan for audits. Staff position 18.1 of the NRC QA Review Plan states that DOE should audit prime contractors and representative subcontractors, consultants and vendors to assess the effectiveness of the prime contractor's program (i.e., the program participants). The staff believes that the guidance in NQA-1-1986, NQA-3, and Regulatory Guide 1.28, is an appropriate interpretation of this position. These require that all DOE program participants audit contractors, subcontractors and consultants, as applicable. The staff will audit and monitor the effectiveness of subcontractors', consultants', and vendors' programs during its own audits and observations of audits within the DOE program.

Although not an explicit staff position in the NRC QA Review Plan, nor a requirement in NQA-1-1986, DOE has committed to using technical specialists on some audits. In practice, DOE has been using technical specialists in most cases. The staff believes this is an essential practice highlighted in the Ford Study (NUREG-1055). The staff will continue to monitor DOE's use of technical specialists to help assure that a technical input is used by the audit teams to assess the effectiveness of the program.

The 88-9 QA Plan has also included requirements for surveillances in Section XVIII, "Audits." These requirements are in excess of those required by 10 CFR Part 50, Appendix B or the various guidance documents.

The staff finds the approaches outlined in the 88-9 QA Plan acceptable.

4. CONCLUSION

The NRC staff reviewed the 88-9 QA Plan for the NNWSI Project and has verified that it meets the criteria of 10 CFR Part 60, Subpart G and Appendix B to 10 CFR Part 50, as applicable. The NRC guidance to address Subpart G is contained in the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories," and staff Technical Positions on "Peer Review", "Existing Data", "Q-List", and "Documentation of Computer Codes" (NUREGs 1297, 1298, 1318 and 0856 respectively). In addition, ANSI/ASME NQA-1-1986, Regulatory Guide 1.28 (endorses ANSI/ASME NQA-1-1983), and selected portions of NQA-3 (Draft 3 Revision 1, 2/88) were used as review criteria. The NRC staff review of the 88-9 QA Plan concludes that it meets the guidance listed above or DOE has provided acceptable alternatives with the exception of the open items identified in Section 5. The 88-9 QA Plan describes alternatives in the areas of special processes; inspection; testing; and inspection, test, and operating status, whereby the controls do not fully apply to scientific investigations. The NRC staff has evaluated these exceptions and finds they are acceptable alternatives.

On the basis of its detailed review and evaluation of the 88-9 QA Plan, the NRC staff concludes that the 88-9 QA Plan contains adequate requirements and planned and systematic controls that address each of the appropriate criteria of Appendix B to 10 CFR Part 50 in an acceptable manner, with the exception of the open items listed below. With the resolution of these items, this QA requirements document can serve as an adequate framework for DOE/NV and its project participants to develope specific policies, plans, and procedures to implement the QA Program for the NNWSI Project.

The DOE and NRC staffs have discussed the open items and they are expected to be resolved in Revision 2 to the 88-9 QA Plan. With the implementation of the modifications to address these open items, the staff will find the 88-9 QA Plan fully acceptable.

5. OPEN ITEMS

1. The definition of "Corroborative Data" found in Appendix A of the 88-9 QA Plan should be consistent with the definition contained in NUREG-1298.

2. Section 6 of Appendix J in the 88-9 QA Plan should state that each individual member should sign the peer review report, to be consistent with NUREG-1297.

3. Paragraph 1.6.4.1 of Section III of the 88-9 QA Plan should contain provisions for precision and accuracy for initial entries in the records for experiments or research.

4. Appendix I of the 88-9 QA Plan should be consistent with Section 4 of NUREG-1318 for Q-List items and activities.

5. The control of non-conformances generated by surveillances should be addressed in greater detail, e.g., by indicating that Section XV of the 88-9 QA Plan "Control of Nonconforming Items," applies to surveillances.

6. The section on scientific investigations should be revised to better address changes to procedures and use of lab notebooks, as discussed in Section 3.3. of this SE.

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3. U. S. Nuclear Regulatory Commission, "Quality Assurance Program Requirements (Design and Construction)," Regulatory Guide 1.28, Rev.3 1985.

4. ANSI/ASME, NQA-3 (Draft), "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories," 1988.

5. U. S. Nuclear Regulatory Commission, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297, 1987.

6. U. S. Nuclear Regulatory Commission, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," NUREG-1298, 1987.

7. U. S. Nuclear Regulatory Commission, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to 10 CFR Part 60 Quality Assurance Requirements," NUREG-1318, 1988.

8. U. S. Nuclear Regulatory Commission, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," NUREG-0856, 1983.