

U.S. GEOLOGICAL SURVEY

QUALITY ASSURANCE PROGRAM PLAN

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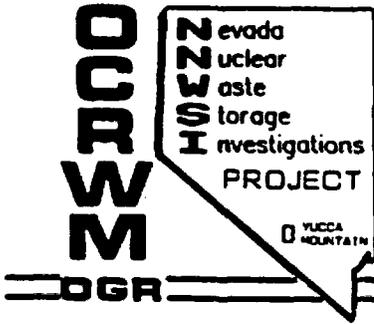
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United States Geological Survey
Department of the Interior
Nevada Nuclear Waste Storage Investigations
QUALITY ASSURANCE PROGRAM PLAN

Changes to this Quality Assurance Program Plan shall be distributed to holders of controlled copies who are responsible for entering changes in the assigned copy. This Manual is the property of the U. S. Geological Survey and shall be returned to the USGS Quality Assurance Manager when it is no longer needed or in the event of position reassignment.

U.S. GEOLOGICAL SURVEY
QUALITY ASSURANCE PROGRAM PLAN
FOR
NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS
Effective Date January 5, 1988

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QUALITY ASSURANCE PROGRAM PLAN

REVISION RECORD

Record for QAPP

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QUALITY ASSURANCE PROGRAM PLAN

TABLE OF CONTENTS

	<u>Page</u>
Signature Page	i
Revision Record	ii
Table of Contents	iii
Preface	x
Policy	xii
Introduction	1
 SECTION 1 - ORGANIZATION	
1.1	7
1.2	7
1.2.1	7
1.2.2	8
1.2.3	8
1.3	8
1.3.1	8
1.3.2	8
1.4	8
 SECTION 2 - QUALITY ASSURANCE PROGRAM	
2.1	10
2.1.1	10
2.1.2	10
2.1.3	10
2.1.4	11
2.1.4.1	11
2.1.4.2	11
2.1.4.3	11
2.1.5	11
2.1.5.1	11
2.1.5.2	11
2.1.6	11
2.1.7	12
2.2	12
2.2.1	12
2.2.2	12
2.2.3	13
2.2.4	13
2.2.5	13
2.2.5.1	13
2.2.5.2	13
2.2.5.3	14
2.2.5.4	16
2.3	17
2.3.1	17

2.3.2	Review and Approval of Subcontractor Quality Assurance Programs	17
2.4	Management Assessment	17
2.4.1	Frequency of Management Assessments	17
2.4.2	Performance of Management Assessments	17
2.5	Personnel Selection, Indoctrination, and Training Procedures	17
2.5.1	Position Description	18
2.5.2	Personnel Qualification Evaluation	18
2.5.3	Indoctrination	18
2.5.4	Training	18
2.5.5	Proficiency Evaluation	18
2.5.6	Records	18
SECTION 3 - SCIENTIFIC INVESTIGATION AND DESIGN CONTROL		
3.1	Scientific Investigation Control	20
3.1.1	Preparation of Plans	20
3.1.1.1	Responsibilities of the Principal Investigator	20
3.1.1.2	Planning Documents	20
3.1.2	Assignment of Quality Assurance Levels	20
3.1.2.1	Level Assignment	20
3.1.2.2	Conformance	20
3.1.3	Review and Approval Process	21
3.1.3.1	Responsibility	21
3.1.3.2	Waste Management Project Office Review	21
3.1.3.3	Peer Review	21
3.1.4	Use of Computer Programs	21
3.1.5	Use of Scientific Notebooks Versus Technical Implementing Procedures	21
3.1.5.1	Documentation	21
3.1.5.2	Scientific Notebooks	21
3.1.5.3	Technical Implementing Procedures and Supporting Documentation	22
3.1.5.4	Format for Documentation	22
3.1.6	Change Control	23
3.1.7	Interface Control	23
3.1.7.1	Coordination	23
3.1.7.2	Transmittal	23
3.1.8	Surveillance of Scientific Investigations and Experiments	23
3.1.8.1	Logistics of Surveillance	23
3.1.8.2	Surveillance Team	24
3.1.9	Reports, Conclusions, and Recommendations	24
3.1.10	Close-Out Verification	24
3.2	Design Control	24
3.2.1	Design Input	25
3.2.1.1	Identification, Review and Approval of Input	25
3.2.1.2	Changes to Design Input	25
3.2.2	Design Documents as Quality Assurance Records	25
3.3	Software Quality Assurance Requirements	25
3.3.1	Computer Software Documentation and Control	25
3.3.2	Documentation of Computer Software	25
3.3.3	Software Configuration Management	25
3.4	Peer Reviews	26

3.4.1	Applicability	26
3.4.2	Peer-Review Group Selection	26
3.4.3	Performance of Peer Reviews	26
3.4.4	Records of Peer Reviews	27

SECTION 4 - PROCUREMENT DOCUMENT CONTROL

4.1	General Requirements	28
4.2	Procured Services	28
4.3	Additional Requirements for Quality Assurance Level I Activities	28
4.3.1	Scope of Work	28
4.3.2	Technical Requirements	28
4.3.3	Quality Assurance Requirements	28
4.3.4	Rights of Access	29
4.3.5	Documentation Requirements	29
4.3.6	Nonconformance	29
4.3.7	Spare and Replacement Parts	29
4.4	Procurement-Document Review	29
4.5	Procurement-Document Changes	30
4.6	Distribution of Procurement Documents	30

SECTION 5 - INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

5.1	General	31
5.2	Reviews	31
5.3	Instructions for Scientific Notebooks	31
5.4	Distribution	31

SECTION 6 - DOCUMENT CONTROL

6.1	Document Preparation, Review, Approval, and Issuance	32
6.1.1	Methods for Control	32
6.1.2	Implementation of Document Control	32
6.2	Document Changes	32
6.3	Distribution of Documents	33

SECTION 7 - CONTROL OF PURCHASED ITEMS AND SERVICES

7.1	General Purchasing Requirements	34
7.1.1	Procurement Planning	34
7.1.1.1	Procurement Timing	34
7.1.1.2	Procurement Methods	34
7.1.2	Source Evaluation and Selection	35
7.1.2.1	Selection of Suppliers	35
7.1.2.2	Source Evaluation and Selection Measures	35
7.1.2.3	Measures for Evaluation and Selection of Procurement Sources	35
7.1.3	Bid Evaluation	35
7.1.3.1	Extent of Conformance	35
7.1.3.2	Resolution of Unacceptable Quality Assurance Conditions	35
7.1.4	Supplier-Performance Evaluation	36
7.1.4.1	Interface Measures	36
7.1.4.2	Verification Measures	36
7.1.5	Control of Documents Generated by Suppliers	37

7.1.6	Acceptance of Item or Service	37
7.1.6.1	Certificate of Conformance	37
7.1.6.2	Source Verification	38
7.1.6.3	Receiving Inspection	38
7.1.6.4	Post-Installation Testing	38
7.1.7	Acceptance of Services Only	38
7.1.8	Control of Supplier Nonconformances	38
7.1.8.1	Evaluation	38
7.1.8.2	Submittal	38
7.1.8.3	Disposition	39
7.1.8.4	Verification	39
7.1.8.5	Records Maintenance	39
7.2	Commercial-Grade Items	39
7.2.1	Source Evaluation and Selection	39
7.2.2	Purchase Order	39
7.2.3	Receipt of Commercial-Grade Item(s)	39
7.2.4	Commercial-Grade Items Requiring Calibration	40

SECTION 8 - IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA

8.1	General	41
8.2	Identification and Control of Items	41
8.2.1	Identification	41
8.2.1.1	Physical Identification	41
8.2.1.2	Markings	41
8.2.1.3	Specific Identification or Traceability	41
8.2.1.4	Shelf Life	41
8.2.2	Control	42
8.3	Identification and Control of Samples	42
8.3.1	Identification	42
8.3.1.1	Procedures	42
8.3.1.2	Storage	42
8.3.1.3	Transportation	42
8.3.1.4	Identification	42
8.3.2	Control of Samples	43
8.3.3	Curation	43
8.4	Identification and Control of Data	43
8.4.1	Identification	43
8.4.2	Multiple Organizations	43

SECTION 9 - CONTROL OF PROCESSES

9.1	General Requirements	44
9.2	Statement of Exclusion	44

SECTION 10 - INSPECTION

10.1	General Requirements	45
10.2	Statement of Exclusion	45

SECTION 11 - TEST CONTROL

11.1	General Requirements	46
11.2	Statement of Exclusion	46

SECTION 12 - CONTROL OF MEASURING AND TEST EQUIPMENT

12.1	Introduction	47
12.2	Requirements	47
12.2.1	Selection	47
12.2.2	Calibration	47
12.2.3	Control	47
12.2.4	Handling and Storage	48
12.2.5	Records	48
12.3	Commercial Devices	48

SECTION 13 - HANDLING, SHIPPING, AND STORAGE

13.1	General Requirements	49
13.1.1	Special Equipment and Protective Environments	49
13.1.2	Specific Required Procedures	49
13.1.3	Inspection and Testing of Special Tools and Equipment	49
13.1.4	Operators of Special Equipment	49
13.1.5	Marking and Labeling	49

SECTION 14 - INSPECTION, TEST, AND OPERATING STATUS

14.1	General Requirements	50
14.2	Statement of Exclusion	50

SECTION 15 - CONTROL OF NONCONFORMING ITEMS

15.1	Requirements Concerning Nonconforming Items	51
15.1.1	Identification	51
15.1.2	Nonconformance-Control Log	51
15.1.3	Segregation	51
15.1.4	Disposition	51
15.1.4.1	Responsibility and Authority	52
15.1.4.2	Dispositioning of NCR	52
15.1.4.3	WMPO Approval	53
15.1.4.4	Corrective Action	53
15.1.4.5	Interfaces	53
15.2	Partial Nonconformances	53
15.3	Repetitive Nonconformances	53
15.4	Unusual Occurrences	54
15.5	Trends	54
15.6	Distribution of Documents	54

SECTION 16 - CORRECTIVE ACTION

16.1	General	55
16.1.1	Significant Adverse Conditions	55
16.1.2	Follow-Up Action	55

16.1.3	Corrective Action	55
16.2	Distribution of Documents	55

SECTION 17 - QUALITY ASSURANCE RECORDS

17.1	General Records Requirements	56
17.2	USGS Records System	56
17.2.1	Records-System Management Plan	56
17.2.2	Preservation of Records	57
17.3	Records Collection, Identification, and Processing	57
17.3.1	Selection of Records	57
17.3.2	Quality of Records	57
17.3.3	Completion of Records	57
17.3.4	Validation of Records	57
17.3.5	Records Identification and Processing	57
17.3.6	Corrected Information in Records	58
17.3.7	Records Transfer	58
17.4	Records Storage, Preservation, and Safekeeping	58
17.4.1	Records Storage	58
17.4.1.1	Single Facility	59
17.4.1.2	Alternative Single Facilities	60
17.4.1.3	Dual Facilities	60
17.4.1.4	Record Retrieval From Storage Facilities	60
17.4.2	Preservation of Records	60
17.4.3	Records Safekeeping	61
17.4.3.1	Personnel Access	61
17.4.3.2	Custodial Duties	61
17.4.3.3	Requirements of Regulatory Agencies	61

SECTION 18 - AUDITS

18.1	General Audit Requirements	62
18.1.1	NNWSI Project Audits	62
18.1.1.1	WMPO Audits	62
18.1.1.2	USGS Audits	62
18.1.2	Audit Schedules	63
18.1.2.1	Internal-Audit Schedule	63
18.1.2.2	External-Audit Schedule	63
18.1.3	Audit Preparation	63
18.1.3.1	Audit Plan	63
18.1.3.2	Audit Personnel	63
18.1.3.3	Audit-Team Selection	64
18.1.4	Audit Performance	64
18.1.5	Audit Reporting	64
18.1.6	Response to Audit Findings	64
18.1.7	Follow-Up Action	64
18.1.8	Audit Records	65
18.2	General Surveillance Requirements	65
18.2.1	Surveillance Planning	65
18.2.2	Surveillance Personnel Selection	65
18.2.3	Surveillance Reporting	65

APPENDIX A - TERMS AND DEFINITIONS

APPENDIX B - DESIGN INPUTS

APPENDIX C - REQUIREMENTS FOR THE QUALIFICATION OF
INSPECTION AND TEST PERSONNEL

APPENDIX D - REQUIREMENTS FOR THE QUALIFICATION OF
NON-DESTRUCTIVE EXAMINATION PERSONNEL

APPENDIX E - LIST OF TYPICAL USGS QA RECORDS

APPENDIX F - REQUIREMENTS FOR THE QUALIFICATION OF
QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL

QUALITY ASSURANCE PROGRAM PLAN

PREFACE

This document is the fourth revision of the Nevada Nuclear Waste Storage Investigations (NNWSI) U.S. Geological Survey Quality Assurance Program Plan (QAPP).

This NNWSI-USGS QAPP is a requirements document that was developed from the QA requirements imposed on the USGS for NNWSI Project activities by the Waste Management Project Office, U.S. Department of Energy. Accordingly this document establishes the QA requirements that are applicable to the USGS and its supporting organizations.

This revision incorporates significant changes to the QA requirements from that of the QAPP, Rev. 3, and it reflects changes in the organization of the QA program documents. The previous versions of the QAPP incorporated Quality Management Procedures (QMP's) as an integral part of the document. In this QAPP all QA program requirements are now included. The QMP's hereafter will be a part of the USGS Management Procedures that specify program procedures and interfaces. Existing QMP's will remain in effect until new or revised documents are distributed. The changes made to this document are so extensive that line-by-line revision indicators are not used. Some of the significant changes in this revision are:

- o Section 1 has been modified to include requirements for the establishment of full-time, dedicated QA positions by each NNWSI Project participant, and to clarify requirements for the resolution of disputes involving quality.
- o Section 2 has been revised to establish requirements for the formulation of a "Q" List. In addition, requirements for application of graded Quality Assurance, overview of quality activities, and personnel selection, indoctrination, and training have been modified and expanded. The ability of the USGS to take exception to QA requirements for Level II items and activities, upon WMPO approval, has been included. Finally, requirements for the content and approval of the USGS QA Program have been clarified.
- o Section 3 has been modified to clarify the requirements for scientific-investigation control including the use of scientific notebooks in lieu of technical-implementation procedures. Requirements for surveillance of scientific-investigation activities have been added. Requirements for peer review have been clarified.
- o Sections 5 and 6 have been modified to include requirements for plans and to clarify the requirements for implementing procedures to identify the QA records generated.
- o Section 7 has been modified to allow the use of calibration procedures for acceptance of commercial-grade scientific instruments.

- o Section 8 has been revised to clarify and separate requirements for the identification and control of items, samples, and data. Additionally, the applicability of the requirements of this section to scientific investigations as opposed to engineered items has been clarified.
- o Sections 9 and 10 have been revised to indicate that the requirements of these sections apply to engineered items and not to scientific investigations.
- o Section 18 has been modified to include surveillance activities.
- o Various sections of this document have been revised to clarify and (or) modify distribution requirements for selected documents generated by the NNWSI-USGS.

QUALITY ASSURANCE PROGRAM PLAN

STATEMENT OF POLICY
QUALITY ASSURANCE PROGRAM PLAN

The U.S. Geological Survey (USGS) is dedicated to conducting high-quality research and investigative studies for the U.S. Department of Energy (DOE) as part of their high-level nuclear-waste-repository program.

To meet future licensing requirements of the Nuclear Regulatory Commission for repository sites selected by DOE, a Quality Assurance (QA) Program has been established by the USGS for research and investigations conducted for DOE at potential waste-repository sites. The QA Program is described in the USGS Quality Assurance Program Plan for the management of nuclear-waste investigations and research activities, and it has the full endorsement and support of the USGS management.

The Assistant Director for Engineering Geology has the overall responsibility for the USGS QA Program. The authority for development of the QA Program shall be assigned to a Quality Assurance Office within the Project organization. USGS managers and employees having responsibility for conducting high-level waste-repository investigations and research for DOE are responsible for the application and implementation of the quality assurance requirements for their activities as described in the QA Program Plan and associated procedures.

Changes to the Quality Assurance Program will be issued as necessary to reflect revisions or additions to legal requirements and to DOE or USGS standards. Suggested improvements should be submitted to the Quality Assurance Manager for evaluation.

To be effective, this Program must be understood, accepted, and fully implemented by each USGS employee holding responsibility for high-level waste-repository investigations and research activities conducted for DOE.

James F. Devine
Assistant Director for
Engineering Geology

December 15, 1987

Date

QUALITY ASSURANCE PROGRAM PLAN

INTRODUCTION

I.1 OVERVIEW

The U.S. Geological Survey (USGS) is one of the principal organizations participating in the Nevada Nuclear Waste Storage Investigations (NNWSI) Project conducting investigations and research on and adjacent to the Nevada Test Site (NTS). The specific responsibility of the USGS is for site hydrogeologic characterization including geologic, hydrologic, geophysics, and geochronologic investigations, and tectonic, volcanic, and natural seismic studies. The USGS acts as the lead technical participant for the site-characterization drilling activities and provides assistance to other Project participants in areas of specialized USGS expertise.

One requirement for participation in the NNWSI Project is that a Quality Assurance Program Plan (QAPP) be prepared to describe how the participant will satisfy the quality assurance requirements of the project, and to recognize the importance of both radiological and non-radiological health and safety related activities. The quality assurance activities of the NNWSI-USGS Project must be in conformance with the 18 criteria of NQA-1 and Federal regulations 10CFR60 and 10CFR50, Appendix B, as specified for NNWSI participants by the Project's Quality Assurance Plan NVO-196-17. This QAPP brings together the requirements that are needed for the USGS QA Program to be in compliance with the NNWSI Project QA Program Plan, NVO-196-17. The provisions of the QAPP and its implementing documents apply to all nuclear waste management activities performed by USGS participants and by contractors to the USGS who do not have a qualifying QAPP of their own.

I.2 PURPOSE

To delineate the organization of the Quality Assurance activities of the NNWSI-USGS Project in conformance with the 18 criteria of NQA-1 and Federal regulations 10CFR60 and 10CFR50, Appendix B, as specified for NNWSI participants by the Project's Quality Assurance Plan NVO-196-17.

I.3 SCOPE OF COMPLIANCE

The provisions of this QAPP and its implementing documents apply to all nuclear waste management activities performed by USGS participants and by contractors to the USGS who do not have a qualifying QAPP.

I.4 ORGANIZATIONAL DUTIES AND RESPONSIBILITIES

This section describes the organizational structure, functional responsibilities, levels of authority, and lines of communication of the U.S. Geological Survey (USGS) staff performing work on the NNWSI Project. The organization of the USGS with respect to the NNWSI-USGS Project and quality assurance is shown in Figure 1.

ORGANIZATION CHART OF NNWSI-USGS PROJECT

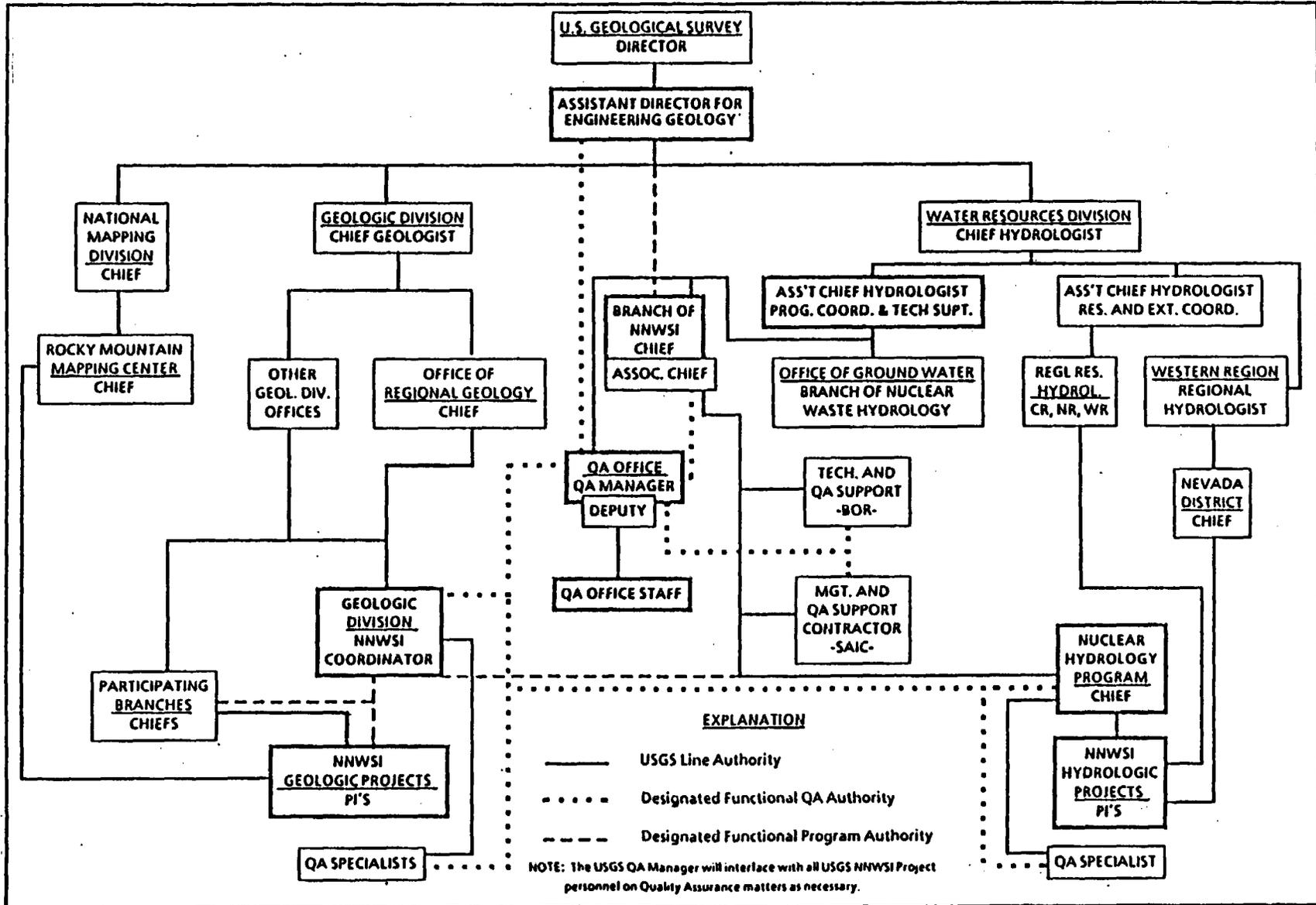


Figure 1

I.4.1 Assistant Director for Engineering Geology: The Office of the Assistant Director for Engineering Geology of the U.S. Geological Survey has the overall responsibility for management of the USGS commitment to the NNWSI Project. This management responsibility includes full responsibility for the QA Program associated with the Project, including resolution of conflicts and disputes involving quality arising from differences of opinion between QA personnel and others, in accordance with the organization chart (Figure 1).

I.4.2 Chief, Branch of NNWSI: The Chief, Branch of NNWSI, has programmatic and budgetary responsibility over USGS personnel assigned to the NNWSI Project. The Chief is the USGS Technical Project Officer (TPO) and represents the USGS at all Waste Management Project meetings. Within the USGS the Chief, Branch of NNWSI, reports administratively to the Assistant Chief Hydrologist for Program Coordination and Technical Support; reports functionally to the Assistant Director for Engineering Geology on policy matters; and interfaces with the Principal Investigators, through the Nuclear Hydrology Program Chief for hydrology tasks, and through the NNWSI Coordinator, Geologic Division, for all geologic-related tasks. The Chief, Branch of NNWSI, insures that USGS technical activities are accomplished in accordance with the quality assurance requirements of the USGS QA Program Plan. The Chief serves as a permanent member of the Review Board for corrective action and may serve as the Contracting Officer Representative. For use in the QAPP this position will hereafter be referred to as the Technical Project Officer (TPO).

I.4.3 Geologic Division NNWSI Coordinator: The Geologic Division NNWSI Coordinator, reporting administratively to the Chief, Office of Regional Geology, provides the coordination between the Chief, Branch of NNWSI, and the individual Geologic Division Branches working on the NNWSI Project. Matters concerning quality assurance in the Geologic Division are provided to the Coordinator's office for input and implementation.

I.4.4 Geologic Division Branch Chief(s): Various Branch Chiefs within the Geologic Division are responsible for the quality of work performed by Principal Investigators assigned to NNWSI activities. Branch Chiefs also may be responsible for assigning personnel to conduct the assigned tasks, and for the certification of the assignees. Branch Chiefs shall be responsible to assure that all NNWSI participants in their Branches perform their work in accordance with the QA documents, to fulfill the requirements set forth by Project management.

I.4.5 Nuclear Hydrology Program Chief: The Chief of the Nuclear Hydrology Program (NHP), reporting administratively and functionally to the Chief, Branch of NNWSI, provides the coordination between the Chief, Branch of NNWSI and the Water Resources Division personnel assigned to NNWSI. The NHP Chief also is responsible for coordinating with personnel assigned from the USGS Nevada District Office and the National Research Program for NNWSI hydrologic activities. Matters concerning quality assurance in the Nuclear Hydrology Program are provided to the NHP office for input and implementation. In addition, the NHP Chief shall certify all participants in the NHP, and assure

that they perform their work in a manner in accordance with the QA Documents, to fulfill the requirements set forth by Project management.

I.4.6 Quality Assurance Specialists: Staff positions exist within the Branch of NNWSI to assist with implementing the QA Program. Personnel filling these positions report in line either to their respective Division Chief or NNWSI Coordinator. In QA program matters, each QA Specialist functionally is directed by the USGS QA Office.

I.4.7 Principal Investigators and Other Contributing Investigators: Under the NNWSI Geologic and Hydrologic Projects, USGS Principal Investigators (PI) are responsible for carrying out the NNWSI tasks assigned to them, including the responsibility of satisfying all technical and quality assurance requirements specified in contracts, purchase documents, or management meetings. The PI may delegate tasks to contributing investigators as necessary, but the PI maintains ultimate responsibility for the task.

Contributing investigators are scientists with part- or full-time responsibilities, who lend their expertise to the conduct of various tasks, under the supervision of a Principal Investigator. Contributing investigators are responsible for working in a professional manner and in total compliance with the NNWSI-USGS QA Program and pertinent technical procedures.

The entire technical staff has the responsibility to:

- a) Establish the quality controls for their respective NNWSI-USGS programs, projects, and activities in compliance with USGS QA program requirements;
- b) Assure that appropriate technical procedures are developed and approved for their respective NNWSI-USGS programs, projects, and activities;
- c) Assure implementation of quality requirements and continued compliance therewith for their respective NNWSI-USGS programs, projects, and activities;
- d) Assure that NNWSI-USGS QA program requirements are included in appropriate requests for proposals, bids, contracts, subcontracts, and purchase orders; and
- e) Cooperate with surveillances and audits that are performed to verify compliance with QA requirements for the respective NNWSI-USGS programs, projects, and activities.

I.4.8 Quality Assurance Manager: The NNWSI-USGS QA Program is directed by the QA Manager, who reports administratively to the Assistant Chief Hydrologist for Program Coordination and Technical Support. The QA Manager reports functionally to, and has direct access to the Assistant Director for Engineering Geology concerning QA responsibilities related to policy and guidance. The USGS QA Manager interfaces with project personnel on QA matters as necessary, and is dedicated to QA for the NNWSI-USGS Project. As required, the QA Manager has authority to delegate, in writing, signature authority to qualified personnel. The basic responsibilities of the overall QA task are to insure that all NNWSI-USGS activities are conducted in accordance with quality and technical

requirements as specified by the DOE Nevada Operations/NNWSI WMPO Project QA Plan (NVO-196-17). In this capacity, the QA Manager has the responsibility to:

- a) Serve as a focal point in developing and implementing the USGS QA Program;
- b) Maintain liaison with the WMPO Project management to assure adequate implementation and compliance with the NNWSI QA Program;
- c) Provide and direct QA support (QA Office Staff) for the management and investigators of the NNWSI-USGS Project;
- d) Be a permanent member of the Corrective Action Review Board;
- e) Have authority to stop work that does not meet QA standards; and
- f) Resolve conflicts and disputes between QA personnel and others. Further resolution of conflicts on QA matters between the QA Manager and the Chief, Branch of NNWSI, shall be referred to the Assistant Director for Engineering Geology.

I.4.9 Quality Assurance Contractors(s): Parts of the NNWSI-USGS Project work may be contracted as needed. The USGS Management Support Contractor, operating under the USGS QA Program, is responsible to the QA Manager for all matters concerning quality, including USGS assigned QA tasks and similar QA related work for the U.S. Bureau of Reclamation (USBR) who also responds to the USGS QA Manager on QA matters.

I.4.10 Contracting Officers and Contracting Officer Representatives: Contracting officers and contracting officer representatives assure that the contractors under their jurisdiction are directed to maintain QA Programs that meet the requirements of the USGS QA Program.

I.4.11 Contractors: All contractors performing activities that support the NNWSI-USGS Project either shall comply with the requirements of the NNWSI-USGS QA Program Plan as specified by contract, or they shall perform under equivalent programs approved by the USGS.

I.5 IMPLEMENTATION OF QAPP

This USGS QAPP contains the policies and requirements that shall be carried out by the USGS throughout the life of the NNWSI Project.

The USGS QAPP identifies the systems, structures, components, and activities to be covered by the USGS QA Program. It also identifies the major organizations participating in the project and the designated functions of these organizations. The USGS QAPP provides control over activities that affect the quality of the identified structures, systems, and components to an extent consistent with their importance to safety. The activities that affect quality are 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 USGS QAPP also takes into account the need for special controls,

processes, test equipment, instruments and skills to attain the required quality, and the need for verification of quality by inspection, test, and/or peer review. The USGS QA Program provides for indoctrination and as necessary, training of personnel performing activities that affect quality to assure that suitable proficiency is achieved and maintained. The Waste Management Project Office (WMPO) will regularly assess the status and adequacy of the QAPPs of the U.S. Geological Survey and Support Contractors by means of surveillance and audit activities. The USGS and Support Contractors' management shall assess the adequacy and implementation of their QA Program Plans on an annual basis.

I.6 EXCEPTIONS TO REQUIREMENTS OF NVO-196-17, R5

The USGS is permitted by the NNWSI QA Program to exclude those portions of the NNWSI Project QA Program requirements that are not applicable to the work undertaken by the USGS for NNWSI. The exceptions to NVO-196-17, R5 requirements that are made in this QAPP are summarized hereafter:

I.6.1 Section 3 Scientific Investigation and Design Control: Because the USGS performs no hardware design functions, and has no responsibilities for repository design, those specific provisions pertaining to design control, exclusive of design inputs, are omitted from this QAPP.

I.6.2 Section 9. Control of Processes: The USGS scientific investigations are controlled by technical procedures and document controls as specified by other sections of this QAPP. Accordingly, controls in the sense of process control as specified by this section are not pertinent to the USGS NNWSI work, and the requirements of this section are omitted from this QAPP.

I.6.3 Section 10. Inspection: The elements of the USGS scientific investigations requiring "inspection" related to receiving inspection, technical and other reviews, and document compliance are covered by the QAPP in other sections. Accordingly the requirements of Section 10 are omitted from this QAPP.

I.6.4 Section 11. Test Control: For the USGS NNWSI activities, tests are made only in the sense of calibrations. Because the calibration requirements are met under Section 12, the requirements of Section 11 are omitted from this QAPP.

I.6.5 Section 13. Handling, Shipping and Storage: The USGS activities pertaining to handling, shipping, and storage, are restricted to identification and control of instruments. Because any pertinent requirements for an activity or its specified equipment are included in the technical procedures, all requirements pertaining to special handling tools, equipment, or materials are excluded from this QAPP.

I.6.6 Section 14. Inspection, Test, and Operating Status: Because provision for the control of status indicators pertinent to USGS activities are included in Sections 7, 12, and 15, and because the USGS performs no "tests" nor has any involvement with operations, as defined, the requirements of Section 14 are not necessary and have been omitted from this QAPP.

QUALITY ASSURANCE PROGRAM PLAN

**SECTION 1
ORGANIZATION**

1.1 QUALITY ASSURANCE RESPONSIBILITIES OF THE USGS

The U.S. Geological Survey (USGS) shall be responsible for the establishment and execution of a Quality Assurance Program Plan (QAPP). The USGS 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 the USGS shall retain the responsibility for the QA Program. The delegation of execution of the QA Program Plan requirements shall be documented. The organizational structure, lines of communication, lines of authority, and duties of persons and organizations performing activities, shall be clearly established and delineated in writing. These activities affecting quality include both the performance of functions that attain quality objectives and the QA functions. While the line organization is responsible for properly performing these activities, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.

1.2 QUALITY ASSURANCE FUNCTIONS

The QA functions are to assure that an appropriate QA program is established and executed effectively, and to verify that those functions have been performed correctly by checking, auditing, conducting surveillances, and inspections of activities that affect quality. 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 these 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 authority 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 they shall report to a management level at which this required authority and organizational freedoms are provided, including sufficient independence from cost and scheduling.

1.2.1 Dedicated Quality Assurance Positions: Full-time dedicated QA positions are to be established by the USGS. The person responsible for directing and managing the overall USGS QA program shall be identified and have appropriate organizational position, responsibility, and authority to exercise proper control over the QA program. This position shall be occupied by an individual with appropriate management and QA knowledge and experience. The position shall be at the same, or higher, organizational level as the highest line manager responsible for performing activities affecting quality, and it shall be sufficiently independent from cost and schedule applications to perform the QA functions. The person in this position shall have responsibility for approval of: (1) QAPPs, changes thereto, and interpretations thereof; and (2) implementation procedures and all changes thereto. This position shall have effective communication channels with other senior management positions. Personnel in QA positions shall

have the responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA program implementation by the Branch of NNWSI and its subordinate organizations. These personnel shall not be assigned duties that would prevent full attention to QA responsibilities, or that would conflict with the reporting and resolution of QA issues and problems.

1.2.2 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 Project Quality Manager (PQM), if the dispute cannot be resolved within the USGS-NNWSI.

1.2.3 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.

1.3 QUALITY ASSURANCE PROGRAM PLAN

The Quality Assurance Program Plan (QAPP) shall apply to all items and activities of the USGS Branch of NNWSI affecting quality. The organizational structure and the responsibility of assignments shall be clearly established to obtain the results described hereafter.

1.3.1 Achievement and Maintenance of Quality: Quality is achieved and maintained by those who have been assigned responsibility for performing work.

1.3.2 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.

1.4 MULTIPLE-ORGANIZATIONAL INTERFACES

If organizations other than the USGS are involved in the execution of activities affecting quality, then the responsibility and authority of that organization relative to the USGS shall be established clearly. 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 USGS, WMPO, and the NTS Support Contractors shall be described in the USGS QAPP. 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 used by all of the NNWSI Project participants while the USGS and any pertinent NTS Support Contractor

implementing procedures describe the methods of conducting inter-organizational interfaces.

The organizational structure for executing the QA program shall be described in the NNWSI-USGS QAPP. The USGS Technical Project Officer (TPO) is responsible to the WMPO Director to insure that the project activities for which the USGS is responsible are performed in accordance with a QAPP, and implementing procedures that are consistent with the NNWSI Project QA Plan, NVO 196-17.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 2
QUALITY ASSURANCE PROGRAM

2.1 EXTENT OF THE QUALITY ASSURANCE PROGRAM

The USGS Quality Assurance (QA) Program for the NNWSI Project consists of the NNWSI-USGS Quality Assurance Program Plan (QAPP), and the QA Program Plan of the NNWSI-U.S. Bureau of Reclamation. The NNWSI-USGS QA Office shall submit this QAPP to the Assistant Director for approval. Upon approval by the Assistant Director, the NNWSI-USGS QA Office shall submit the NNWSI-USGS QAPP to WMPO for approval. If the NNWSI-USGS QA Manager determines that the QAPP shall be issued for interim use, the transmittal record shall be appropriately marked. Final QA plans will include a signature block for approval by the Assistant Director for Engineering Geology and WMPO.

The USGS is to develop a Quality Assurance Program Plan that provides the description of the USGS QA program, and indicates the USGS commitment to the applicable NNWSI Project QA requirements. This Quality Assurance Program Plan (QAPP) includes consideration of the technical aspects of all activities affecting quality; it has been generated by the USGS QA organization, with assistance from the technical staff. This QAPP provides instructions to implement and apply the QA requirements to the technical activities of the NNWSI-USGS Project. This QAPP has been and will be planned, implemented, and maintained in accordance with and consistent with all of the applicable requirements of the WMPO NNWSI QA Plan, NVO 196-17.

2.1.1 Quality Assurance Criteria: The QA criteria, and specific requirements associated with these criteria, have been, and are, adapted to the NNWSI-USGS Project activities through this QA plan; they are addressed in the USGS QAPP. When a specific criterion is not applicable to the NNWSI-USGS activities, it shall be noted in the QAPP and recorded on the checklist provided by WMPO with justification of its exception.

2.1.2 Contents of the QAPP: The USGS Quality Assurance Program consists of the QAPP plus appropriate implementing procedures required to provide and implement control over activities affecting quality. The control will be consistent with the importance of the activity. These procedures shall be developed by qualified personnel; they shall be reviewed and approved by the NNWSI-USGS QA Office prior to implementation to assure that they meet all the requirements of this QAPP.

The QAPP will be submitted to the WMPO for review and approval prior to implementation and will include a checklist based on the WMPO NNWSI QAPP. The USGS QAPP shall be reviewed, comments shall be resolved, and approved by the WMPO prior to implementation.

2.1.3 QAPP Verification: The USGS shall assure that the QA requirements have been addressed adequately and implemented effectively. The USGS shall monitor its respective QAPP through internal audits to assess the adequacy of the NNWSI-USGS QA program and to assure its effective implementation. Additional verification is conducted by the WMPO, with support from the QA Support

Contractor, by the review and approval of the USGS QAPP, by monitoring operations, and by conducting surveillances and audits of activities.

2.1.4 Use of Data Not Generated Under Quality Assurance Controls: The USGS QA program for the NNWSI Project provides for the acceptance of primary data or primary data interpretations for use in licensing activities that were not generated under the controls of the NNWSI QA Plan. Specific methods for acceptance of this information are contained in the NNWSI-USGS Project Administrative Procedures Manual. These methods apply to the items listed hereafter.

2.1.4.1 DATA GENERATED PRIOR TO NNWSI PROJECT QAP, REV. 0: Primary data or primary data interpretations and reports that were generated by the NNWSI-USGS Project participants or their subcontractors, involved in siting the NNWSI Project Yucca Mountain Mined Geologic Disposal System (MGDS) prior to the NNWSI Project QAP, Rev. 0 implementation date (August, 1980).

2.1.4.2 DATA NOT GENERATED BY THE NNWSI PROJECT: Primary data or data interpretations from reports, books, files, and theses generated by non-NNWSI Project participants.

2.1.4.3 DATA FROM TECHNICAL JOURNALS: Primary data or data interpretations from a technical journal.

2.1.5 Method for Formulating the "Q" List

2.1.5.1 DEFINITION OF THE "Q" LIST: The "Q" List is a compilation of geologic repository structures, systems, components, and activities that have been determined to be important to safety or waste isolation or both; therefore, they are subject to the highest QA level (Quality Level I) of the formal NNWSI QA program.

2.1.5.2 DETERMINATION OF ITEMS TO BE INCLUDED ON THE "Q" LIST: The appropriate NNWSI Procedures for determining the items and activities to be placed on the Project "Q" List shall be obtained from the WMPO.

2.1.6 Approach to Quality Assurance: The NNWSI Project uses an approach to QA that recognizes the differences between items and activities that affect radiological health and safety, and those that do not. The approach is designed to insure that each item or activity is assigned a QA level that is consistent with its potential impact or importance, or both, pertaining to radiological health and safety, waste isolation, nonradiological health and safety, the U.S. Nuclear Regulatory Commission (NRC) licensing process, the operability and maintainability of the repository, its costs, and its schedules. The USGS, other Participating Organizations, or WMPO shall identify the appropriate QA 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. After being assigned, the QA level for a particular item or activity shall be applied by all NNWSI Project participants involved in the activity.

2.1.7 Application of Quality Assurance: This QAPP is written to comply with the requirements of NVO-196-17; it shall be established by the USGS at the earliest practicable time consistent with the schedule for accomplishing the activities. This QAPP assures that procedures required to implement the requirements of NVO-196-17 are documented, controlled, and mandated properly through a policy statement or equivalent document signed by a responsible official. The USGS QAPP shall be applied throughout the USGS participation in the NNWSI Project in accordance with established policies, procedures, and instructions. The QAPP applies to all items and activities affecting quality; it also identifies the major organizations participating in the project, and the designated functions of these organizations.

This QAPP provides control over activities that affect the quality of the identified structures, systems, and components, to an extent consistent with the importance to the activity. The activities that affect quality shall be accomplished under suitably controlled conditions, including 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 considers 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 processes. The program shall provide for indoctrination, and, as needed, training of personnel performing activities that affect quality, to assure that suitable proficiency is achieved and maintained.

The status and adequacy of the QA Programs of the USGS, the U.S. Bureau of Reclamation, and other supporting organizations are subject to assessment by WMPO by overview, surveillance, and audit activities.

2.2. APPLICATION OF GRADED QUALITY ASSURANCE

2.2.1. 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. In compliance with a WMPO-developed Project administrative procedure, the USGS will develop an administrative procedure for the application of graded QA (assignment of QA levels) consonant with the QA requirement specified herein. Certain NNWSI items and activities may be necessarily exempted from QA level assignment. Requests for exemptions shall be documented; they shall contain sufficient justification to support the exemption request. Such exemptions shall be submitted to the WMPO Project QA Manager for approval.

2.2.2 Purpose of a Graded Quality Assurance 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 applications to safety, waste isolation, and the achievement of U.S. Department of Energy (DOE) mission objectives. This grading will be accomplished by deliberate quality planning and selective application of QA requirements to the item or activity to be performed, with varying degrees of QA to be applied, depending on item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations.

2.2.3 Determination of the Degree to Which Application is Necessary: This determination involves identifying those items and activities whose failure could cause undue risks to the public and facility personnel, or extended interruption of facility operation with critical economic losses, or both, and insuring that these items and activities are covered by a relevant QA program. Alternatively, an item whose failure or malfunction could result only in operational inconvenience or negligible economic loss may deserve only a quality inspection by the purchaser upon delivery of the item. Between these two extremes, varying degrees of QA are needed to achieve the desired confidence in the quality of the completed line of activity.

2.2.4 Flexibility of Quality Assurance Level Selection: The graded method set forth here provides flexibility in the selection of the level of the quality assurance 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.

2.2.5 Requirements: The requirements specified in this section are to be used in applying the graded quality assurance to all NNWSI-USGS Project items and activities.

2.2.5.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QUALITY ASSURANCE REQUIREMENTS: The appropriate QA level for any item or activity shall be determined by the application of decision criteria provided by the NNWSI-USGS Administrative Procedure. The basis for the selection of the QA level and assigned QA requirements shall be documented. The assigned QA levels and QA requirements must be submitted to the WMPO for review, resolution of comments, and approval prior to implementation or use.

2.2.5.2 SELECTION OF SPECIFIC QUALITY ASSURANCE LEVELS: The graded QA level approach incorporates three QA levels (QA level), one of which 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.

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 that must meet the criteria that address long-term performance of the engineered and natural barriers to inhibit the release of radionuclides from the site to the accessible environment after permanent closure. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

QA Level II - are those activities and items related to the systems, structures, and components that require a level of QA sufficient to provide for reliability, maintainability, public and repository-worker nonradiological health and safety, repository-worker radiological health and safety, and other operational factors that would have an impact on DOE and WMFO concerns and the environment.

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

2.2.5.3 APPLICATION OF LEVELS

QA Level I - is the most stringent level of quality assurance. QA Level I 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 that are on the Q-List will provide the primary data input information base for the NRC to authorize construction of a geologic repository and to issue a license for the DOE to receive and possess source, special-nuclear, and by-product material (waste) at the geologic repository. QA Level I control and documentation must be applied to activities including data-collection investigation, analysis, design, construction, fabrication, operation, decommissioning, or sealing, when these activities are concerned specifically 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 use engineered systems, structures, and components to contain the waste and to insure the short-term safety. The repository also will use 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 the following guidelines:

- o Items and activities that could affect the preclosure radiological health and safety of the general public. Specifically, this statement 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.
- o Items and activities that will provide site-characterization data. Site-characterization 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 providing long-term waste containment and isolation. These items and activities include all tests, experiments, and research, that have significant impact to site-characterization, or that are an essential part of the data base that directly supports the final design of the repository and waste package, as well as the assessment of repository

performance. Also included are those activities (tests, experiments, and research) that are among several independent activities contributing to a single information base that is considered in formulating the repository design or performance assessment of the engineered or natural barriers.

- o Items and activities that could affect the retrievability of waste up to the time of repository closure.
- o Activities that are intended to provide the primary data that will be used to support public radiologic health and safety issues for a license application.
- o Items and activities that, having failed, could cause a failure of a QA Level I item, or irretrievable loss of QA Level I data.
- o The design phase that is conducted immediately prior to application for an NRC license, procurement, or construction, shall be assigned a QA Level I prior to execution. One of the purposes of this design phase shall be to define in detail those items that are to be procured and (or) constructed as a result of the design. As the design phase proceeds, each item shall be assigned a QA Level I, II or III, as applicable. After the QA level for the item is approved, design activities associated with the item shall be governed by the QA level assigned to the item.

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 to 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 use engineered systems, structures, and components, that 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 Geologic Repositories (OGR) milestones must be controlled appropriately. Therefore, QA Level II must be applied to activities and items according to the following guidelines:

- o Items and activities that are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and that could have a major impact on the non-radiological health and safety of the public and of a repository worker.
- o Items and activities that having failed, or that are performed inadequately, would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10CFR20.

- o Items and activities that involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components.
- o Design phases, that involve the comparative technical analysis of alternatives, methods, and equipment to determine which alternative, method, and equipment is preferred, shall be assigned a QA level of II prior to execution. Where a particular item can be identified during this phase that warrants a QA level assignment other than Level II, then a separate QA level assignment may be made for that item. After the QA level is approved, design activities associated with the item shall be governed by the QA level assigned to the item.
- o Where items and activities that, having failed, could result in a major cost overrun.
- o Where items and activities that, if failed, could result in a major schedule slippage.

QA Level II activities may have as much importance as QA Level I activities; however, except when used to support a QA 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 QA Level II program cannot be used subsequently to directly support QA Level I activities unless it can be substantiated that QA requirements equivalent to those which would have been applied to a QA Level I activity were implemented or that a technical justification process is applied.

QA Level III - is the least stringent level of quality assurance. QA Level III 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, and equipment which are felt to be worthy of more detailed study shall be assigned a QA Level III prior to execution. Those activities controlled in accordance with a QA Level III program cannot subsequently be used to directly support QA Level I or II 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 QA Plan may be used in the licensing process as background or corroborative information.

2.2.5.4 GENERAL: The requirements contained in this document apply to QA 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 USGS. Deviations within applicable criteria are permissible for Level II items

and activities, provided that adequate justification has been documented and approved by the WMPO.

2.3 QUALITY ASSURANCE ACTIVITIES

2.3.1 Overview: All QA activities of the USGS and other supporting organizations' QA activities that are under WMPO purview, are subject to WMPO overview. The USGS shall have similar overview responsibilities for the QA activities of its subcontractors. The overview includes the following, as appropriate:

- o Review and approval of their QAPPs.
- o Surveillance of participating NNWSI activities affecting quality to verify compliance with requirements.
- o Performance of quality audits to verify the adequacy and compliance of NNWSI programs.

2.3.2 Review and Approval of Subcontractor Quality Assurance Programs:

Procedures shall be established by the USGS for the review of subcontractor (U.S. Bureau of Reclamation) QA programs documentation for adequacy, completeness, and relevance. The procedures shall identify the types of documents to be submitted by the participant for review and approval, assign project responsibility for review, and identify the methods for documenting review and approval action. Reviews of subcontractor QA program documentation shall be recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance.

2.4 MANAGEMENT ASSESSMENT

2.4.1 Frequency of Management Assessments: Management assessments are to be conducted at least annually for determining: (1) Effectiveness of the system and management controls that are established to achieve and assure quality; and (2) adequacy of resources and personnel provided to the QA program. USGS Management is to verify that the USGS QA program is being implemented effectively, and that personnel are trained to the QA requirements of the program.

2.4.2 Performance of Management Assessments: The USGS shall develop 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 Director, WMPO, and the WMPO PQM.

2.5 PERSONNEL SELECTION, INDOCTRINATION, AND TRAINING PROCEDURES

The USGS 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 elsewhere in this document.

2.5.1 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.

2.5.2 Personnel Qualification Evaluation: Personnel selected shall have education and experience that satisfy the minimum requirements specified in the position description. Relevant education and experience shall be verified, and this verification shall be documented. The initial capabilities of an individual shall be based upon an evaluation of their education, experience, and training, and they shall be compared to requirements established for the position. Evaluations shall be documented by managers or supervisors responsible for the activities to be performed.

2.5.3 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, 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 by other instructional methods.

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

2.5.4 Training: Prior to assigning personnel to perform quality-affecting activities that are complex in nature (i.e., assignments where initial proficiency is deemed necessary to develop and demonstrate), training shall be conducted to gain required proficiency. The training (in-depth instruction) shall include the principles, techniques, and requirements of the activity. Such in-depth instruction may be produced by classroom sessions, hands-on workshops supplemented by classroom sessions, on-the-job training, other instructional methods, or combinations of these methods.

2.5.5 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 other routine employee-performance evaluations. Proficiency evaluations shall be performed by managers or supervisors, who have responsibility for the activities being performed or verified.

2.5.6 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 hereafter:

- o Personnel Qualification Evaluation Records - Records of the verification and evaluation of a candidate's education, experience, and training, compared to those established for the position.
- o Indoctrination Records - Records of indoctrination, including the objective and content of the indoctrination, date(s) of indoctrination, and other applicable information.
- o Training Records - Records of training, including the objective(s) and content of the training, name of the instructor, attendees, dates of attendance, and results of proficiency evaluations (where applicable), and other applicable information.
- o Proficiency Evaluation Records - Records of proficiency evaluation shall include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date(s) of evaluation, and activities covered by the evaluation.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 3
SCIENTIFIC INVESTIGATION AND DESIGN CONTROL

3.1 SCIENTIFIC-INVESTIGATION CONTROL

3.1.1 Preparation of Plans

3.1.1.1 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR: Prior to the start of any scientific investigation, the responsible Principal Investigator (PI) shall develop a Scientific Investigation Plan (SIP) for that investigation. The SIP shall contain or shall reference the following information:

Description of Work to be Performed - A description of the work to be performed in the scientific investigation, including a discussion of the overall purpose for the work. 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, also shall be provided. This description shall identify all factors and concerns that related to the planning or the performance of the scientific investigation.

Description of previous work - A description of any previous work, that will be used in support of the scientific investigation, including the identification of the QA levels or Quality Assurance (QA) controls under which that previous work was performed.

3.1.1.2 PLANNING DOCUMENTS: The scientific-investigation planning document shall contain a level of detail that would enable an independent reviewer to determine the appropriate QA level to be applied to the investigation.

3.1.2 Assignment of Quality Assurance Levels:

3.1.2.1 LEVEL ASSIGNMENT: After a SIP (as specified in Paragraph 3.1.1.1 of this section) has been developed, the QA levels for all of the items and activities associated with that work may be assigned. In some cases, QA levels may need to be assigned to the items and activities in a plan that was prepared earlier. Therefore, the QA level assignments are not an integral part of the plans although, normally, they would accompany those plans through the same review and approval process.

3.1.2.2 CONFORMANCE: Scientific investigation plans shall be prepared and QA levels shall be assigned in accordance with the methods specified in the NNWSI Project Administrative Procedures Manual.

3.1.3 Review and Approval Process

3.1.3.1 **RESPONSIBILITY:** The USGS shall conduct a technical review of the SIP. This review shall be performed by any qualified individual(s) other than those who developed the original plan. 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 by the supervisor with the concurrence of the USGS QA Manager. cursory reviews shall not satisfy the intent of this requirement. The results of this technical review, and the resolution of any comments by the reviewer or reviewers, shall be documented, and they shall become a part of the USGS QA records.

3.1.3.2 **WASTE MANAGEMENT PROJECT OFFICE REVIEW:** The WMPO Project Quality Manager and the appropriate WMPO Branch Chief shall review and approve the SIP prior to implementation. Upon receipt of the approved plan, the USGS shall proceed with its controlled distribution.

3.1.3.3 **PEER REVIEW:** A peer review of the SIP shall be conducted when the WMPO considers it is necessary.

3.1.4 **Use of Computer Programs:** Computer programs that are used for analysis shall be verified and controlled, as specified in the NNWSI Project Administrative Procedures Manual. 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"; see Section 3, Paragraph 3.0, in NUREG-0856 for additional Software QA Requirements.

3.1.5 Use of Scientific Notebooks Versus Technical Implementing Procedures

3.1.5.1 **DOCUMENTATION:** Two basic kinds of documentation can be used for the quality assurance, documentation, and control of scientific work: (1) A scientific notebook system; and (2) a technical implementing procedure system. The scientific-notebook system generally will be used by qualified individuals who largely are using professional judgment or trial-and-error methods, or both, in their work. Alternatively, the technical implementing procedure system generally will be used when workers are performing repetitive work, that does not include the use of professional judgment or trial-and-error methods in the performance of the work.

Detailed technical implementing procedures are required, when a strict sequence of actions cannot be deviated from, without endangering the validity of the results that will be obtained from the work. Notebooks 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.

3.1.5.2 **SCIENTIFIC NOTEBOOKS:** Scientific notebooks and other appropriate documents may be used to document scientific investigations and experiments, when the PI is performing the work personally or is supervising the work directly. In such cases, this documentation shall be

sufficient, to the extent that another qualified scientist can use the notebook to retrace the investigation and to confirm the results, or to repeat the experiment and to achieve the same results, without recourse to the PI.

3.1.5.3 TECHNICAL IMPLEMENTING PROCEDURES AND SUPPORTING DOCUMENTATION: Detailed technical implementing procedures with appropriate logbooks and other supporting documents, shall be used, whenever the work is repetitive and is to be performed by technicians not under the direct personal supervision of the PI. These technical implementing procedures shall be developed in accordance with the requirements given in Section 5 of this document.

3.1.5.4 FORMAT FOR DOCUMENTATION: Documentation of scientific work (that is, experiments and research) shall be performed by using bound logbooks or notebooks to provide written record of the experiment or research.

Initial Entries - Prior to initiation of an experiment, series of experiments, or research activity, the following entries, as a minimum, shall be made:

- o Title of the experiments or research;
- o Name of the qualified individual or individuals performing the experiment or research;
- o Description of the experiment's or research's objective(s);
- o List of equipment and materials to be employed during the experiment(s) or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material;
- o Calibration requirements; and
- o Dated signature of the individual or individuals making the initial entries.

In-process Entries - Entries to be made during the experiment(s) or research, daily or as appropriate, shall be sufficiently detailed so that another researcher could repeat the experiment or research; these entries shall include:

- o Date and name of individual making the entry;
- o Description of the experiment or research attempted, including detailed step-by-step process followed, either by reference to implementing procedure or by entry into a scientific notebook;
- o Description of any conditions that may have adversely affected the results of the experiment or research;.

- o Identification of samples collected or used, and any additional equipment and materials not included as part of the initial entries;
- o All data collected and a brief description of the results, including notation of any unexpected results;
- o Any deviations from the planned experiment or research; and
- o Any interim conclusions reached.

At the conclusion of the experiment(s) or research, the final results and a summary of the outcome of the experiment(s) or research shall be provided. This summary shall include a discussion of whether the experiment or research objectives, as outlined in the initial entries, were achieved; this discussion shall be accomplished either by inclusion of a completed report or entry of the information into the notebook. If the report is used, it shall become part of the notebook.

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.

3.1.6 Change Control: All changes in scientific-investigation plans shall go through the same review and approval process specified in Paragraph 3.1.3 of this section. The USGS shall be responsible for evaluating the effects of such changes on associated QA level assignments.

3.1.7 Interface Control

3.1.7.1 COORDINATION: Both internal and external scientific-investigation interfaces shall be identified, and scientific-investigation efforts shall be coordinated among Participating Organizations and within the USGS. Interface controls shall include the assignment of responsibility and the establishment of procedures among Participating Organizations and within the USGS for the review, approval, release, distribution, and revision of documents involving scientific-investigation interfaces. Interfaces between scientific investigations, or between a scientific investigation and any other Project activity, including design activities, shall be coordinated among Project Participants in accordance with administrative procedures established by the WMPO. Interfaces between the USGS and its suppliers shall be controlled in accordance with USGS procedures.

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

3.1.8 Surveillance of Scientific Investigations and Experiments

3.1.8.1 LOGISTICS OF SURVEILLANCE: The USGS QA Office shall perform surveillances of all scientific investigations, as 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 shall be performed in accordance with the requirements specified in Section 18 of this document.

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

3.1.9 Reports, Conclusions, and Recommendations: Technical review and approval of the results of scientific investigations shall be conducted according to USGS procedures. These procedures shall include the WMPO in the review and approval cycle of the final report.

3.1.10 Close-Out Verification: The USGS 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 verification will be completed, because a considerable period of time after the work is completed may lapse before the results of the investigation are used in the licensing process. Close-out verifications shall be performed by a team consisting of qualified technical personnel as well as QA personnel.

3.2 DESIGN CONTROL

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 analysis activities that are used to support design development and verification, including general plans and detailed implementing procedures for data collection and analyses and related information, such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) that integrate many other data and analyses of individual parameters.

The policy of the NNWSI Project indicates that a completed or final design of a facility or item evolves from a sequential order of design activities (or phases); each phase becomes more detailed than the preceding phase. 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. All Project design activities, although undertaken by different organizations, that may progress at different speeds are dependent on, and require an interface with each other to produce a unified facility design.

The USGS does not perform actual design, design analysis or design verification activities directly related to the NNWSI Repository design. In the sense of data collection and analysis activities, the design-related requirements as described above are specified and controlled through other criteria of this QAPP. However, the USGS on occasion provides design inputs. Therefore, the requirements of this section are excluded from this QAPP with the exception of design input and its related requirements.

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

3.2.1.1 IDENTIFICATION, REVIEW, AND APPROVAL OF INPUT: Applicable design input, such as criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards, shall be identified and documented, and their selection shall be reviewed and approved by the responsible design organization and 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.

3.2.1.2 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.

3.2.2 Design Documents as Quality Assurance Records: Design input documentation and approved changes shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section 17 of this document.

3.3 SOFTWARE QUALITY ASSURANCE REQUIREMENTS

3.3.1 Computer Software Documentation and Control: Computer software used to support a high-level nuclear waste repository license application shall be documented and controlled. Methods for this documentation and control are contained in the NNWSI Project Administrative Procedures Manual. 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."

3.3.2 Documentation of Computer Software: Documentation of computer software shall include the following, as a minimum:

- o Software summary;
- o Description of mathematical models and numerical methods;
- o User's manual;
- o Code assessment and support; and
- o Continuing documentation and code listings.

3.3.3 Software Configuration Management: The USGS shall institute a software configuration management program appropriate to the projects it conducts and shall provide documentation of this program to the Records Management System (RMS). The minimum requirements for this configuration management program shall be: (1) 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.

3.4 PEER REVIEWS

The WMPO retains the authority and responsibility to initiate peer reviews.

3.4.1 Applicability: The following paragraphs are applicable to all peer reviews, including those conducted by the WMPO, Participating Organizations and their contractors, NTS Support Contractors and their contractors, and other participating government agencies and their contractors. Peer reviews, as defined in the Glossary, are not to be confused with technical reviews. Peer reviews are required for activities that support a license application and involve use of data collection or analysis procedures and methods that are untried or beyond the state of the art or where detailed technical criteria and requirements do not exist or are being developed. Other instances where a peer review needs to be considered in lieu of a technical review include situations in which:

- o Analytical modeling techniques are (or will be) applied to a range of conditions outside of their normally accepted boundaries.
- o Data collection results are not predictable with a high degree of certainty.

3.4.2 Peer-Review Group Selection: The USGS shall document procedures that define the selection process for a peer-review group. The peer-review group shall be comprised of individuals who have qualifications at least equivalent to those required for performance of the original work and who are independent of performing the work being reviewed. The peer reviewer's qualifications shall be documented and verified by the organization requesting the peer review.

3.4.3 Performance of Peer Reviews: Peer Reviews shall address the following areas as applicable:

- o Validity of basic assumptions or functional requirements;
- o Appropriateness of the methodology;
- o Logic of the methodology;
- o Verification of calculations or computer software; and
- o Validity of interpretation of results.

Peer reviews shall be conducted in accordance with written procedures that shall address the following:

- o The review process and reviewer responsibilities;
- o Handling of comment resolution;
- o Reporting of minority positions;
- o Involvement of the QA organization;
- o Changes to previously peer-reviewed documents;
- o Re-review of revised documents;
- o Records of the review.

Previously peer-reviewed documents shall be reviewed again whenever the technical content or results presented in the documents significantly are revised. Justification for not providing re-review by a peer group shall be documented.

3.4.4 Records of Peer Reviews: Peer-review records shall include personnel qualifications of the reviewers, results of the review, and disposition or replies to reviewer comments. Peer-review records shall be retained in accordance with the retention requirements of the data or documents that they support.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 4
PROCUREMENT DOCUMENT CONTROL

4.1 GENERAL REQUIREMENTS

Measures shall be established to insure that applicable regulatory requirements, design or site-investigation bases, and other requirements that are necessary to assure adequate quality in scientific investigations are included or referenced in the documents for procurement of material, equipment, and services used on the Project. To the extent necessary, procurement documents of the USGS shall require subtier contractors to provide a Quality Assurance (QA) program that is consistent with the pertinent provisions of this QAPP, as required for the specified QA level.

4.2 PROCURED SERVICES

USGS initiated procurements for services shall be controlled through the use of the Federal Acquisition Regulations (FAR) and U.S. Geological Survey Manual. When the USGS procures services from contractors or requests services from national laboratories and supporting Federal agencies, the USGS shall prepare work agreements, memorandums of understanding, interagency agreements, management agreements, or other suitable documents.

4.3 ADDITIONAL REQUIREMENTS FOR QUALITY ASSURANCE LEVEL I ACTIVITIES

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

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

4.3.2 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.

4.3.3 Quality Assurance Requirements: Procurement documents shall require that the supplier have a documented QA program, that implements either part or all of the requirements of this document. Quality Assurance Program Plans (QAPPs) and documents of subcontractors for QA Level I purchases shall be reviewed and approved by the USGS QA Office or its delegate. Those documents that do not adequately define QA requirements, as judged by the USGS QA Office, 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.

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

4.3.4 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 QA personnel, or other QA authorized representatives. WMPO access to subtier contractor facilities shall be arranged by the USGS.

4.3.5 Documentation Requirements: The procurement documents at all tiers shall identify the documentation required to be submitted to the purchaser. The time of submittal also shall 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 17 of this QA Plan.

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

4.3.7 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; this evaluation shall be documented.

4.4 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:

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

4.5 PROCUREMENT-DOCUMENT CHANGES

Procurement document changes shall be subject to the same degree of control as was used 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:

- o Appropriate content shall be included in procurement documents as required by Paragraph 4.3 of this Section.
- o Additional or modified design or site-investigation criteria shall be determined.
- o 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, shall be included.

4.6 DISTRIBUTION OF PROCUREMENT DOCUMENTS

The USGS shall forward to the WMPO QA (QASC - Audits and Surveillance Branch Manager), one copy of purchase documents, and changes thereto, as issued, when purchases involve QA Level I items or services. Only those purchase documents that identify the vendor, describe the scope of work, and indicate when work is to start, are required to be submitted to WMPO QA.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 5
INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

5.1 GENERAL

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, and (or) plans or drawings, of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been accomplished satisfactorily. Each implementing procedure shall include a section that identifies the QA records that are generated during implementation of the procedure. These documents shall be controlled as required in Section 6 of this document.

5.2 REVIEWS

An independent technical and QA review of all USGS originated instructions, procedures, plans, and drawings shall be performed by the USGS.

5.3 INSTRUCTIONS FOR SCIENTIFIC NOTEBOOKS

The USGS shall prepare instructions for the control of scientific notebooks, plans, and other documentation, that will be used in scientific investigations. (See Section 3 of this document.)

5.4 DISTRIBUTION

The USGS shall maintain and provide the WMPO PQM and the QA Support Contractor (QASC) with controlled distribution of all implementing procedures, plans, and instructions used for QA Level I and II activities.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 6
DOCUMENT CONTROL

6.1 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

6.1.1 Methods for Control: The preparation, review, approval, and issuance of documents, such as instructions, procedures, and 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:

- o Documents that assure technical adequacy;
- o Documents containing or specifying quality requirements; and
- o Documents that prescribe activities affecting quality.

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

6.1.2 Implementation of Document Control: Implementation of document control shall provide for the following:

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

6.2 DOCUMENT CHANGES

Changes to documents, other than those defined below as minor changes, are considered major changes; these changes shall be reviewed and approved by the same organization(s) that performed the original review and approval, unless the USGS specifically designates another organization to do this review and approval.

The reviewing organization shall have access to pertinent background data or information, upon which to base their approval.

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 delineated clearly in the appropriate implementing procedure.

6.3 DISTRIBUTION OF DOCUMENTS

The document-control system shall assure that documents requiring verification are not released prior to verification; if these documents need to be released before verification, they need to be uniquely identified and controlled. A master list, or equivalent, used to identify the correct, current, and updated versions of documents shall be submitted to the WMPO and the QASC.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 7
CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 GENERAL PURCHASING REQUIREMENTS

Measures shall be established to insure 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 NNWSI Project Information Management System (IMS), and it 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 hereafter.

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

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

7.1.1.1 PROCUREMENT TIMING: To insure 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.

7.1.1.2 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 hereafter. Planning shall provide for the integration of:

- o Procurement document preparation, review, and change control;
- o Selection of procurement sources;
- o Purchaser control of supplier performance;
- o Verification (surveillance, inspection, or audit) activities by purchaser, including notification for hold-and-witness points;

- o Control of nonconformances;
- o Corrective action;
- o Acceptance of the item or service; and
- o QA records.

7.1.2 Source Evaluation and Selection

7.1.2.1 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.

7.1.2.2 SOURCE EVALUATION AND SELECTION MEASURES: Procurement-source evaluation and selection measures shall be implemented by the USGS and shall provide for identification of the USGS responsibilities for determining supplier capability.

7.1.2.3 MEASURES FOR EVALUATION AND SELECTION OF PROCUREMENT SOURCES: Measures for evaluation and selection of procurement sources, and the results thereof, shall be documented; they shall include one or more of the following items:

- o 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.
- o Supplier's current QA records, supported by documented qualitative and quantitative information, that can be evaluated objectively.
- o Supplier's technical and quality-assurance capability, as determined by a direct evaluation of his facilities and personnel and the implementation of his QA program.

7.1.3 Bid Evaluation

7.1.3.1 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:

- o Technical considerations;
- o QA requirements;
- o Supplier's personnel;
- o Supplier's production capabilities;
- o Supplier's past performance;
- o Alternates or replacement items; and
- o Exceptions to requirements and (or) specifications.

7.1.3.2 RESOLUTION OF UNACCEPTABLE QUALITY ASSURANCE CONDITIONS: Before the award of the contract, the purchaser shall resolve or obtain commitments to resolve unacceptable QA conditions resulting from the bid evaluation.

7.1.4 Supplier-Performance Evaluation

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

- o Documenting the understanding between purchaser and supplier of the provisions and specifications of the procurement documents;
- o Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement-document requirements;
- o Reviewing supplier documents that are generated or processed during activities fulfilling procurement-document requirements;
- o 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; and
- o Establishing methods of document-information exchange between purchaser and supplier.

7.1.4.2 VERIFICATION MEASURES: 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 the USGS uses another Participating Organization or NTS support contractor for NNWSI activities, for which they are responsible, the user organization shall conduct surveillances 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 shall be coordinated with the WMPO.

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 USGS verification activities shall not relieve the supplier of responsibilities for verification of quality achievement. 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; they shall be controlled in accordance with Section 17 of this Quality Assurance Plan. The purchaser shall insure that this documentation is evaluated to determine the supplier's QA program effectiveness.

7.1.5 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 insure that the submittal of these documents is accomplished in accordance with the procurement-document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.

7.1.6 Acceptance of Item or Service: 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 hereafter:

7.1.6.1 CERTIFICATE OF CONFORMANCE: When a certificate of conformance is used, the following minimum criteria shall be met:

- o The certificate shall identify the purchased material or equipment, such as by the purchase-order number.
- o The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, or other specifications. This requirement 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, with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.
- o The certificate shall identify any procurement requirements that have not been met, with an explanation and the means by which to resolve the nonconformances.
- o 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.
- o The certificate system, including the procedures to be followed in filling out a certificate(s) and the administrative procedures for the review and approval of these certificates, shall be described in the purchaser's or supplier's QA program.
- o 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 during independent inspection(s) or test(s) of the items. Such

verification shall be conducted by the purchaser at intervals commensurate with the supplier's past quality performance.

7.1.6.2 SOURCE VERIFICATION: If source verification is used, 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.

7.1.6.3 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, 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.

7.1.6.4 POST-INSTALLATION TESTING: When post-installation testing is used, post-installation test requirements and acceptance documentation shall be established mutually by both the USGS and the supplier.

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

- o Technical verification of data produced;
- o Surveillance, audit, or both, of the activity; or
- o Review of objective evidence for conformance to the procurement-document requirements, such as certifications, stress reports, etc.

7.1.8 Control of Supplier Nonconformances: The USGS and supplier shall establish and document methods for disposition of items and services that do not meet procurement-document requirements. These methods shall include the following provisions:

7.1.8.1 EVALUATION: Evaluation of nonconforming items.

7.1.8.2 SUBMITTAL: Submittal of nonconformance notice to the USGS by supplier, as directed by the USGS. These submittals shall include the disposition (e.g., use as-is or repair) and technical justification, that are recommended by the supplier. Approval of the recommended disposition shall be in accordance with documented procedures. Nonconformances to the

procurement requirements or USGS approved documents, that are the result of one or more of the items listed hereafter, shall be submitted to the USGS.

- o Technical or material requirement is violated.
- o Requirement in supplier documents, that has been approved by the USGS, is violated.
- o Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.
- o The item does not conform to the original requirement, even though the item can be restored to a condition, so that the capability of the item to function is unimpaired.

7.1.8.3 DISPOSITION: USGS disposition of supplier recommendation.

7.1.8.4 VERIFICATION: Verification of the implementation of the disposition.

7.1.8.5 RECORDS MAINTENANCE: Maintenance of records of nonconformances that are submitted by the supplier.

7.2 COMMERCIAL-GRADE ITEMS

Commercial-grade items to be used as an integral part of a scientific investigation shall be identified in an approved SIP or technical procedure. An alternate commercial-grade item may be supplied, if the cognizant organization provides verification that the alternate commercial-grade item will perform the intended function, and that it will meet the requirements applicable to both the replaced item and its application. Commercial-grade items shall be controlled by the use of the following requirements:

7.2.1 Source Evaluation and Selection: Source evaluation and selection shall be in accordance with Paragraph 7.1.2, if that evaluation and selection is determined necessary by the purchaser, based on the complexity of the item and its importance to safety.

7.2.2 Purchase Order: Commercial-grade items shall be identified in the purchase order by the manufacturer's published product description (for example, the catalog number) in accordance with Section 4.

7.2.3 Receipt of Commercial-Grade Item(s): After receipt of a commercial-grade item, the purchaser shall determine that the following conditions have been met:

- o Damage was not sustained during shipment.
- o The item received was the item ordered.
- o Inspection, testing, or both, is accomplished by the USGS, in accordance with written procedures, to insure conformance with the manufacturer's published requirements.

- o Documentation, as applicable to the item, was received and is acceptable.

7.2.4 Commercial-Grade Items Requiring Calibration: Commercial-grade items requiring calibration may be controlled in accordance with the requirements of Section 12.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 8
IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA

8.1 GENERAL

This section provides the requirements for the identification and control of items, samples, and data. The section consists of three separate parts: (1) The requirements for items are stated in Para. 8.2; (2) the requirements for samples are stated in Para. 8.3; and (3) the requirements for data resulting from scientific investigations are stated in Para. 8.4. Para 8.2 applies to activities related to the engineered items and does not apply to scientific investigations. Para. 8.3 and Para. 8.4 apply to scientific-investigation activities and do not apply to engineered items.

8.2 IDENTIFICATION AND CONTROL OF ITEMS

8.2.1 Identification: Items shall be identified to assure that only correct and accepted items are used or installed. Identification shall be maintained either on the item, their containers, or in documents traceable to the item, from receipt until installed. Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of the items, up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document.

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

8.2.1.2 MARKINGS: Identification markings, when used, shall be applied, using materials and methods that provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings shall be transferred to each part of an identified item, when it is subdivided, and they shall not be obliterated or hidden by surface treatment or coatings, unless other means of identification are substituted.

8.2.1.3 SPECIFIC IDENTIFICATION OR TRACEABILITY: When specified by codes, standards, or specifications, that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part or serial number; or specified inspections, tests, or other records) the program shall be designed to provide such identification and traceability control.

8.2.1.4 SHELF LIFE: Where specified, items having limited calendar or operating life or cycles shall be identified and controlled, to preclude use of items whose shelf life or operating life has expired.

8.2.2 Control: Provisions shall be made for the control of item identification consistent with the planned duration and condition of storage, such as: (1) Provisions for maintenance or replacement of markings and identification records resulting from damage during handling or aging; (2) protection of identification on items subject to excessive deterioration resulting from environmental exposure; and (3) provisions for updating existing facility records.

8.3 IDENTIFICATION AND CONTROL OF SAMPLES

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

8.3.1. Identification: Physical identification shall be used to the maximum extent possible. Where physical identification cannot be placed on the sample, appropriate alternative identification methods shall be described and used. All identification methods shall provide methods whereby identification of samples can be traced to the appropriate documentation, such as drawings specifications, drilling logs, test records, inspection documents, and nonconformance reports. Samples shall be identified by placing the identification directly on the sample, on its container, or on records traceable thereto. If placing the identification on the sample is impractical, methods shall be described and implemented to assure that samples are not mixed with like samples, and that the correct identification of samples is verified and documented prior to release for use.

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

8.3.1.2 STORAGE: Storage methods shall be developed and implemented to insure that samples are maintained in predetermined physical conditions, commensurate with their intended purpose. Samples intended for storage shall receive appropriate treatment to assure that they do not degrade during storage. Sample treatment and storage requirements shall be defined in the appropriate technical procedure(s).

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

8.3.1.4 IDENTIFICATION: Measures shall be taken to maintain sample identification in storage. These measures shall be consistent with the planned duration and conditions of storage, and they shall describe actions to be taken where samples may have a maximum life expectancy while

in storage. Physical segregation of samples to preclude mixing with like samples shall be used to the maximum degree practical.

8.3.2 Control of Samples: Controls shall be developed and implemented to assure that sample identification is verified and maintained when handled, transported, or transferred from one organization's responsibility to another. Where samples are controlled by more than one organization, procedures describing the organizational responsibilities shall be developed and implemented.

8.3.3 Curation: The WMPO has assumed responsibility to develop and implement an Administrative Procedure (AP) describing the ultimate curation of all types of samples, including liquids, gases and solids. That AP, as a minimum, is to address the transportation, handling, storage, retrievability of samples, and the generation and retention of records. All records generated as a result of testing of samples shall be handled in accordance with Section 17.

8.4 IDENTIFICATION AND CONTROL OF DATA

Data generated from a NNWSI scientific investigation shall be identified to assist in the determination of their correct use. Identification of such data shall be provided in all documents, information systems, or both, in which such data appear. The identification of NNWSI Project data shall include a reference to the origin of the data (task, test, experiment, report, publication, etc.) and an indication of the QA Level assigned to the activity that produced the data.

8.4.1 Identification: Control measures shall be established and implemented to assure that NNWSI Project data are identified properly. These measures shall include verification of the identification of such data prior to release for use.

8.4.2 Multiple Organizations: Where data are the results of the efforts of more than one organization, procedures describing the organizational responsibilities for that data shall be developed and implemented. The documentation resulting from the scientific investigation involving more than one organization shall be annotated to show which organization produced what part of the data.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 9
CONTROL OF PROCESSES

9.1 GENERAL REQUIREMENTS

The requirements of this section apply to engineered items and scientific investigations for process control. The requirements for special processes apply to engineered items only. Measures shall be established, if necessary, to insure that processes that affect quality of items or services are controlled either by instruction, procedures, or other appropriate means.

9.2 STATEMENT OF EXCLUSION

The activities associated with the USGS scientific investigation do not include processes that need to be controlled in the sense of this criterion. Those activities requiring control are governed by technical procedures and other portions of this QAPP. Accordingly, this section of the QAPP has been excluded as noted in the introduction.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 10
INSPECTION

10.1 GENERAL REQUIREMENTS

Measures shall be established by the USGS to provide inspections required to verify conformance of an item or activity to specified requirements if necessary. These measures shall provide for: (1) Inspections to be performed in accordance with written procedures by qualified personnel, who did not perform the work being evaluated; (2) criteria for determining when inspections are required, or how and when inspections are to be performed; (3) sampling methodology, if used; (4) identification of mandatory hold points; and (5) identification of inspections requiring special expertise. Results of all inspection activities shall be documented by the inspecting organization. The requirements of this section apply to engineered items and do not apply to scientific-investigation activities.

10.2 STATEMENT OF EXCLUSION

The activities associated with the USGS scientific investigation do not require verification of conformance against standards or specified requirements, as specified in Criterion 10. As a result, the provisions of Criterion 10 have been removed from this QAPP. Those elements of the USGS scientific investigation requiring "inspection" related activity, such as receiving inspection, technical and other reviews, and document compliance are covered by the QAPP under other appropriate criteria.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 11
TEST CONTROL

11.1 GENERAL REQUIREMENTS

Tests required to verify conformance of an item to specified requirements, and to demonstrate that items will perform satisfactorily in service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. The test procedures shall be implemented by trained and appropriately qualified personnel.

11.2 STATEMENT OF EXCLUSION

By definition, a test means to measure against a known standard. In the USGS-NNWSI Scientific Investigation Program, such tests are made only in the sense of calibrations. Because the calibrations requirements are met under Criterion 12, the requirements of Criterion 11 are excluded in this USGS-NNWSI QAPP.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 12
CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 INTRODUCTION

Measures shall be established to insure that tools, gages, instruments, and other measuring and test equipment used in activities that affect quality are controlled, calibrated, and adjusted properly at specified periods to maintain accuracy within necessary limits.

The USGS control program for measuring and test equipment shall include all measuring and test equipment or systems used to calibrate, measure, gage, test, or inspect; either to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known. The USGS-NNWSI QA Office and Chief of Branch of NNWSI shall be responsible for the establishment, implementation, and assurance that the calibration program is effective.

12.2 REQUIREMENTS

Measuring and test equipment are devices or systems used to calibrate, measure, gage, test, or inspect, either to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known. Specific requirements for control of measuring and test equipment are:

12.2.1 Selection: Selection of measuring and test equipment shall be controlled to assure that such equipment is of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements. The type, range, accuracy, and tolerance of a measuring device shall be specified in test and inspection documents. Each device shall have a unique identification number. This number shall be recorded on the data sheet, log, etc., with the measurement taken, to insure traceability to the measurement of the device that was used to take the measurement.

12.2.2 Calibration: Measuring and test equipment shall be calibrated against certified equipment having known valid relations to the National Bureau of Standards, or to other nationally recognized standards; this equipment shall be calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the basis for calibration shall be documented.

12.2.3 Control: The method and interval of calibration for each item shall be defined, based on the type of equipment, stability, characteristics, required accuracy, intended use, and other conditions that affect measurement control. Measuring and test equipment must be labeled, tagged, or otherwise documented, in a fashion that indicates the due date of the next calibration, to provide traceability to calibration data. If measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous results obtained, and of the acceptability of items previously inspected

and tested, or data gathered since the last calibration. Devices that are out of calibration shall be tagged or segregated, and they shall not be used until they have been recalibrated. If any measuring or test equipment consistently is found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed, when the accuracy of equipment is suspect.

12.2.4 Handling and Storage: Measuring and test equipment shall be handled properly and stored to maintain accuracy.

12.2.5 Records: Records shall be maintained, and equipment shall be suitably marked to indicate calibration status.

12.3 COMMERCIAL DEVICES: Calibration and control measures are not required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 13
HANDLING, SHIPPING, AND STORAGE

13.1 GENERAL REQUIREMENTS

Measures shall be established to control the packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration. Handling, storage, and shipping of items shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures, specified for use in conducting the activity.

13.1.1 Special Equipment and Protective Environments: When required for particular items, special equipment (for example, containers, shock absorbers, and accelerometers) and special protective environments (for example, an inert gas atmosphere, specific moisture-content levels, and temperature levels) shall be specified and provided, and their existence shall be verified.

13.1.2 Specific Required Procedures: Specific procedures for handling, storage, packaging, shipping, and preservation shall be used, when they are required for critical, sensitive, perishable, or especially expensive articles.

13.1.3 Inspection and Testing of Special Tools and Equipment: Special handling tools and equipment shall be used and controlled as necessary to insure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures, and at specified time intervals, to verify that the tools and equipment are maintained adequately.

13.1.4 Operators of Special Equipment: Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

13.1.5 Marking and Labeling: Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary, to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 14
INSPECTION, TEST, AND OPERATING STATUS

14.1 GENERAL REQUIREMENTS

The requirements of this section apply to engineered items and do not apply to scientific investigations.

14.2 STATEMENT OF EXCLUSION

Because the USGS is not producing engineered items in their NNWSI scientific investigation, the requirements of this Criterion are omitted from this QAPP.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 15
CONTROL OF NONCONFORMING ITEMS

15.1 REQUIREMENTS CONCERNING NONCONFORMING ITEMS

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 USGS personnel involved in Nevada Nuclear Waste Storage Investigations (NNWSI) Project activities are responsible for reporting nonconformances, in accordance with their established nonconformance-control procedures. Nonconformance-control procedures of the USGS shall include provisions for processing WMPO-initiated nonconformance reports. These procedures shall be consistent with the minimum requirements listed hereafter.

15.1.1 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. If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified. 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 (such as USGS-6, etc). If tags are used, they shall be securely attached to avoid loss during handling.

15.1.2. Nonconformance-Control Log: The USGS shall maintain a nonconformance-control log to track nonconforming items. This log shall contain the following information:

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

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

15.1.4 Disposition: 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. Nonconformance documentation shall be distributed to all affected organizations.

15.1.4.1 RESPONSIBILITY AND AUTHORITY: Responsibility and authority for the evaluation and disposition of nonconforming items shall be defined and documented in an implementing procedure. Those personnel assigned signature approval of the disposition shall be identified. QA responsibilities relating to nonconformances shall be described. 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.

15.1.4.2 DISPOSITIONING OF NCR: The person or organization assigned the responsibility of dispositioning the NCR shall insure the following:

- o Nonconformance documentation adequately identifies and describes the nonconformance.
- o 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.
- o 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.
- o Technical details for correction of the nonconforming condition are adequate for the recommended disposition.
- o If continuance has been requested, justification for the activity to continue has been documented and approved by the WMPO.
- o The disposition complies with existing design documents, test plans or procedures, reports, and regulatory requirements.
- o 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 also shall be cross-referenced on the NCR.
- o Disposition has identified and documented the correction as repair, rework, use-as-is, or reject/scrap.
- o Disposition has identified the people or organization responsible to implement the disposition.
- o The cause of the nonconforming condition has been described.
- o Action needed to preclude recurrence has been documented, if appropriate.

15.1.4.3 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. NVO-196-17 Rev. 5 specifies that "the appropriate WMPO Branch Chief and the WMPO PQM shall approve NCR dispositions involving "repair" or "use-as-is" determinations and conditional release recommendations".

15.1.4.4 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.

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

15.2 PARTIAL NONCONFORMANCES

Work on the nonconforming item shall be stopped, until completion of the action specified in the Nonconformance Report disposition. If only a specific part 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 WMPO shall approve such continuance. Requests for conditional releases on nonconforming items shall include documented justification that the following conditions are met:

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

15.3 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 it shall be processed in accordance with corrective-action procedures developed by the USGS.

15.4 UNUSUAL OCCURRENCES

The USGS shall develop a procedure for reporting unusual occurrences. This procedure shall meet the requirements of U.S. Department of Energy (DOE/NV) Order 5000.3 as supplemented or modified by the cognizant DOE field office. Nonconformance Reports shall be evaluated by the USGS to determine if further processing as an unusual occurrence is required per DOE/NV Order 5000.3. Reports of unusual occurrences shall be submitted to the cognizant DOE field offices for further processing. Copies also shall be provided to the WMPO QA Support Contractor (QASC) Manager.

15.5 TRENDS

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

15.6 DISTRIBUTION OF DOCUMENTS

Copies of nonconformance reports for items shall be sent to the WMPO and the QASC by the USGS upon issuance and upon closure. The original nonconformance reports shall be sent to the WMPO for approval, as required by Para. 15.1.4.3 of this section.

QUALITY ASSURANCE PROGRAM PLAN

**SECTION 16
CORRECTIVE ACTION**

16.1 GENERAL

The USGS shall establish a corrective action system for identifying or determining the cause of, and providing corrective action for, significant or recurring conditions adverse to quality, including, but not limited to, breakdown of the USGS QA Program and repetitive nonconformances. This system shall insure that significant conditions, that are adverse or potentially adverse to quality, are identified promptly and corrected as soon as practical. A significant condition adverse to quality is a condition that, if not corrected, could have a serious effect on safety or operability. Significant conditions include, but are not limited to, breakdowns in the QA program and repetitive nonconformances.

16.1.1 Significant Adverse Conditions: The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.

16.1.2 Follow-up Action: 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 in a timely manner.

16.1.3 Corrective Action: Corrective-action reports (CAR) periodically shall be analyzed by the QA Office to show quality trends. Results shall be reported to upper management for review and assessment. The USGS shall be responsible for evaluating CARs, to determine if further processing is required as an unusual occurrence, as in U.S. DOE/NV Order 5000.3, as supplemented or modified by the cognizant DOE on site office.

16.2 DISTRIBUTION OF DOCUMENTS

Copies of CARs shall be sent to the WMPO QASC by the USGS upon issuance and closure.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 17 QUALITY ASSURANCE RECORDS

17.1 GENERAL RECORDS REQUIREMENTS

Records that furnish documentary evidence of quality shall be specified, prepared, and maintained in accordance with NNWSI Administrative Procedures, that shall meet the requirements of this section; a requirement is included that all documents be legible, identifiable, and retrievable. A document is not considered a Quality Assurance (QA) Record until it satisfies the definition given hereafter. The term records, as used throughout this section, is to be interpreted as QA Records. QA Records include: (1) Individual documents that have been executed, completed, and approved, and that furnish evidence of the quality and completeness of data (including raw data), and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of QA 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: (1) Will either receive no more entries, or whose revision normally would consist of the reissue of the document; and (2) is signed and dated by the originator, and, as applicable, by other personnel authorized to approve the document. Records shall be distributed, handled, and controlled in accordance with written procedures.

17.2 USGS RECORDS SYSTEM

A record system or systems shall be established by the USGS at the earliest practicable time, consistent with the schedule for accomplishing work activities. The record system shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation prepared in accordance with Section 5 of this document. The records-management activities to be performed by the USGS, during the processing of QA records, are detailed in the NNWSI Project Administrative Procedures Manual and the corresponding USGS procedure(s).

17.2.1 Records-System Management Plan: In accordance with the WMPO NNWSI Project Information Management System plan, the USGS records-system management plan shall:

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

- o Comply with requirements established by WMPO concerning record types and retention, that shall include duration, location, and assigned responsibility.

17.2.2 Preservation of Records: The procedure defining implementation of the record system for the USGS shall identify measures to be implemented for preservation and safekeeping of the records before storage, and for prevention of delays between record completion and storage at the Project Record Center. For purposes of record retention, all NNWSI Project records are classified as lifetime records, and they are required to be retained for the life of the project.

17.3 RECORDS COLLECTION, IDENTIFICATION, AND PROCESSING

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

17.3.1 Selection of 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: (1) Operating logs; (2) results of reviews, inspections, tests, and audits; and (3) monitoring of work performance. 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.

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

17.3.3 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.

17.3.4 Validation of Records: 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. The USGS shall maintain a list that contains the signatures and initials of the personnel authorized to authenticate records.

17.3.5 Records Identification and Processing: 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, that 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 be designated so that it does

not repeat any other system in the NNWSI Project. The USGS records-identification system shall be submitted to WMPO for review and approval to insure consistency with the project records 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.

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

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

- o A method for designating the required records.
- o A method for identifying the records received.
- o Procedures for receipt and inspection of incoming records.

17.4 RECORDS STORAGE, PRESERVATION, AND SAFEKEEPING

Before the records are stored, a written storage procedure shall be prepared, and responsibility shall be assigned for enforcing the requirements of that procedure. As a minimum, this procedure shall include the following:

- o A description of the storage facility.
- o The filing system to be used.
- o The method for verifying that the records received are legible and are in agreement with the transmittal document.
- o The method of verifying that the records are those designated.
- o The rules governing access to and control of the files.
- o The method for maintaining control of and accountability for records removed from the storage facility.
- o A method for filing supplemental information and disposing of superseded records.

17.4.1 Records Storage: Records shall be stored in permanent or temporary facilities constructed and maintained in a manner that minimizes the risk of

damage or destruction from natural disasters, such as winds, floods, or fires; from environmental conditions, such as high and low temperatures and humidity; and from infestation of insects, mold, or rodents. The records shall be stored in a predetermined location or locations, that meets the requirements of applicable standards, codes, and regulatory agencies. The following requirements apply to both permanent and temporary record-storage facilities.

Records shall be controlled from the time they are complete, until the time they are stored in a permanent storage facility. Temporary storage, preservation, safekeeping, and retrievability of completed records shall be in accordance with the requirements applicable to the permanent storage of records. The use of dual-storage facilities is an acceptable alternative to a single fire-rated, environmentally controlled facility. The two satisfactory methods of providing storage facilities are: (1) Single; and (2) dual; these methods are detailed in the following sections.

17.4.1.1 SINGLE FACILITY: Design and construction of a single record-storage facility shall meet the following criteria:

- o It shall have reinforced concrete, concrete block, masonry, or equal construction.
- o It shall have a floor and roof with drainage control; if a floor drain is provided, then a check valve (or equivalent device) shall be included.
- o It shall have doors, structures, frames, and hardware, that shall be designed to comply with the requirements of a minimum two-hour fire rating.
- o Sealant shall be applied over walls as a moisture or condensate barrier.
- o Surface sealant shall be placed on the floor to provide a hard-wearing surface to minimize concrete dusting.
- o It shall have foundation sealant and provisions for drainage.
- o It shall have forced-air circulation with a filtration system.
- o It shall have a fire-protection system.
- o 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.
- o 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.

- o If the facility is located within a building or structure, then the environment and construction of that building can provide a portion of, or all of, these criteria.

17.4.1.2 ALTERNATIVE SINGLE FACILITIES: The following are acceptable alternatives to the criteria for a single facility:

- o Two-hour fire-rated vault that meets National Fire Protection Association (NFPA) 232-1975.
- o Two-hour fire-rated Class B file containers that meet the requirements of NFPA 232-1975.
- o 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.
 - Prohibit work in the file room that is not associated directly with record storage or retrieval.
 - Prohibit smoking, eating, or drinking in the file room.
 - Two-hour fire-rated dampers or doors in all boundary penetrations.

17.4.1.3 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 for single facilities or single-alternative facilities, but they shall meet the other requirements of this document.

17.4.1.4 RECORD RETRIEVAL FROM STORAGE FACILITIES: 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).

17.4.2 Preservation of Records: Records shall be stored in a manner approved by the USGS. To preclude deterioration of the records, the following requirements shall apply:

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

17.4.3 Records Safekeeping: Measures shall be established to preclude the entry of unauthorized personnel in the storage area. These measures shall guard against larceny and vandalism. Measures also 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 that a record has been damaged, to a degree that it is no longer complete or legible. Access controls shall be defined and maintained.

17.4.3.1 PERSONNEL ACCESS: A list shall be maintained that designates those personnel, who shall have access to the files. Records maintained by the USGS at their facility or other location (on an interim or other basis) shall be accessible to the WMPO or its designated alternate. Records that are accumulated at various locations, prior to transfer, shall be made accessible to the WMPO either directly or through the procuring organization.

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

17.4.3.3 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.

QUALITY ASSURANCE PROGRAM PLAN

SECTION 18
AUDITS

18.1 GENERAL AUDIT REQUIREMENTS

All NNWSI Project activities shall 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. The USGS shall include in their QAPP a system of planned, periodic audits to provide an objective evaluation of quality-related practices, procedures, instructions, activities, and items, including the review of documents and records, to insure that the QA program is effective and implemented properly. 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 addressed appropriately, and to identify quality trends. The audited entity shall describe, in a formal report, the corrective action to be taken to address any findings; and the report shall be submitted to the auditing organization and the USGS management. Follow-up action, including verification of corrective action or reaudit of specific areas, shall be performed.

18.1.1 NNWSI Project Audits: WMPO assumes responsibility for the NNWSI Project audit program to be executed at the project level, and the USGS and other participating organizations and NTS support contractors shall execute the NNWSI Audits at the activity level.

18.1.1.1 WMPO AUDITS: The USGS is subject to audits by WMPO, according to an annual WMPO plan, to verify the effectiveness and adequacy of the implementation of all elements of the USGS QAPP. Audits, in addition to the WMPO planned and scheduled audits, may be conducted when a unique need arises, or when an audit is requested by the USGS.

The WMPO audits eliminate the need for participating organizations or NTS support contractors to conduct audits of each other. Representatives of the USGS may be invited to participate in a WMPO audit, when the audited organization's activities are of mutual interest.

18.1.1.2 USGS AUDITS: The USGS shall conduct internal audits covering their entire QAPP on an annual basis, and external audits (direct subcontractor) of activities under its direct control. The audits shall be scheduled, planned, conducted, and reported as described in the following sections. External and internal audit schedules, dates, and changes thereto, will be sent to the WMPO QA (QASC Audit and Surveillance Branch 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.

The USGS shall evaluate audit findings to determine if further processing, as an unusual occurrence, is required per DOE/NV Order 5000.3, as supplemented or modified by the cognizant DOE field office.

18.1.2 Audit Schedules: 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. The audit schedule shall be evaluated periodically and revised as necessary to insure that coverage is maintained current. Revisions of the audit schedule shall be documented. The evaluation should include an assessment of the effectiveness of the program based on: (1) Previous audit results and corrective actions; (2) nonconformance reports; and (3) information from other sources such as the American Society of Mechanical Engineers (ASME), Nuclear Regulatory Commission (NRC), and so forth. Regularly scheduled audits shall be supplemented by additional audits of specific subjects to provide adequate coverage when necessary.

18.1.2.1 INTERNAL-AUDIT SCHEDULES: Elements of the USGS QAPP shall be audited at least annually. The scope of the audit shall be established by considering the results of any previous audits, the nature and frequency of identified deficiencies, and any significant changes in personnel, in organization, or in the QA program.

18.1.2.2 EXTERNAL-AUDIT SCHEDULES: 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 activities are less than four months in duration shall be documented and approved by the QA Manager.

18.1.3 Audit Preparation: Preparation for an audit shall include the items listed hereafter:

18.1.3.1 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, schedules, and written procedures or checklists.

18.1.3.2 AUDIT 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 audit, 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 effective. Appendix F defines the requirements for the qualification of QA audit personnel.

18.1.3.3 **AUDIT-TEAM SELECTION:** An audit team shall be identified before the beginning of each audit. This team shall contain one or more auditors, with one 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 insure that the audit team is prepared before the audit begins.

18.1.4 **Audit Performance:** Audits shall be performed in accordance with written procedures using checklists, as early in the life of the activity as practical; they 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 they 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 shall be reviewed with the audited entity at a closing meeting.

18.1.5 **Audit Reporting:** The audit report shall be signed by the audit-team leader and issued within 30 calendar days; the report shall include the following information, as appropriate:

- o Description of the audit scope.
- o Identification of the auditors.
- o Identification of persons contacted during audit activities.
- o Summary of audit results, including a statement of the effectiveness of the QA program elements that were audited.
- o Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

18.1.6 **Response to Audit Findings:** Management of the audited entity or activity shall investigate adverse audit findings; schedule corrective action, including measures to prevent recurrence; and, within 30 calendar days of receipt of the audit report, notify the appropriate office in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization.

18.1.7 **Follow-up Action:** Follow-up action shall be taken to determine whether or not corrective action has been accomplished as scheduled, and this corrective action shall be verified by the auditing organization. An analysis of audit results shall be performed to identify quality trends.

18.1.8 Audit Records: As a minimum, audit records shall include the following:

- o Identification of the entity or activities, or items audited and the individual(s) contacted during the audit(s).
- o Description of any deficiencies, nonconformances, and potential quality problems identified.
- o Audit plans, audit reports, written replies, the record of completion of corrective action, and the close-out of the audit.
- o Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer. Records for each Lead Auditor shall be maintained and updated annually.

18.2 GENERAL SURVEILLANCE REQUIREMENTS

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 USGS, other Participating Organizations, and the NTS Support Contractors; and they 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 significance, 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:

18.2.1 Surveillance Planning: Surveillances are to be performed to written checklists or surveillance plans whenever practical. This documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of results, identification, and qualification of personnel, and accuracy of the equipment necessary to perform the surveillance.

18.2.2 Surveillance Personnel Selection: Surveillance personnel shall not report directly to the immediate supervisors who are responsible for the work that is the subject of the surveillance.

18.2.3 Surveillance Reporting: As a minimum, surveillance records shall identify the following:

- o Item or activity.
- o Date of surveillance.
- o Name of individual performing the surveillance.

- o Identification of the organization(s), activities, or items under surveillance, including the name or names of personnel contacted.
- o Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance.
- o Surveillance criteria.
- o Equipment used during the surveillance.
- o Results.
- o Acceptance statement.

QUALITY ASSURANCE PROGRAM PLAN

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

ACTIVITY: Any time consuming effort (operation, task, function, or service) 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 to meet QA requirements. The control methods are those which govern Project-wide systems and are implemented by all Project participants.

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 implementation.

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

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

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

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

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

- 1) The item is not subject to design or specification requirements that are unique to nuclear facilities;
- 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 nuclear facilities.

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

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

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

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

CONTROLLED AREA: The surface location, which is to be marked by suitable monuments, that extends horizontally no more than 10 kilometers in any direction from the outer boundary of the underground facility and the underlying subsurface, which is an area that has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure. The controlled area is also known as the site.

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

CORROBORATIVE DATA: Information that may or may not have been acquired and controlled in a manner consistent with Quality Assurance Level I requirements and may be used as background, or corroborative support to primary data.

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

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

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

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

DEVIATION: A departure from specified requirements.

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

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

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

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

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

IMPORTANT TO WASTE ISOLATION: The barriers that must meet the criteria that address long-term performance of the engineered and natural barriers to prevent the release of radionuclides from the site to the accessible environment.

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, service, structure, subassembly, subsystem, system, unit, data, 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 so that conformance to specified requirements can be verified.

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.

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. The QAPPs of the WMPO, Participating Organizations and NTS Support Contractors shall be consistent with this document.

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

NTS: Nevada Test Site

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

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

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

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

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

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.

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 structures, systems, components, and activities that have been determined to be important to safety, waste isolation, or both, and are thereby subject to the highest Quality Assurance Level (Quality Assurance Level I) of the formal QA Plan.

QMP - Quality Management Procedure: An implementing procedure which identifies the control methods to meet Project QA requirements utilized by WMPO, WMPO matrix support, and QASC personnel.

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

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

QUALITY ASSURANCE: All those planned and systematic actions that are necessary to provide adequate confidence that the geologic repository and its subsystems or subcomponents will perform satisfactorily in service. Quality Assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system that provide a means by which to control the quality of the material, structure, component, or system to predetermined requirements.

QUALITY ASSURANCE 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 long-term performance of the engineered and natural barriers to inhibit the release of radionuclides from the site to the accessible environment after permanent closure. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

QUALITY ASSURANCE LEVEL II: 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 the instructions to implement and apply the QA requirements to activities.

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

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

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

REPOSITORY: See Geologic Repository Operations Area.

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

REWORK: The process 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.

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.

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

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

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

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

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

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

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

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

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

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

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.

WORK BREAKDOWN STRUCTURE (WBS) DICTIONARY: A product oriented framework for organizing and defining work to be accomplished.

QUALITY ASSURANCE PROGRAM PLAN

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. Codes, standards, and regulatory requirements including the applicable issue, agenda, or both.
3. Loads such as seismic, wind, thermal, and dynamic.
4. 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.
5. Interface requirements including definition of the functional and physical interfaces involving structures, systems, and components.
6. Material requirements including such items as compatibility, protective coating, and corrosion resistance.
7. Mechanical requirements such as vibration, stress, shock, and reaction forces.
8. Hydraulic requirements such as pump net positive suction heads (NPSH), allowable pressure drops, and allowable fluid velocities.
9. Chemistry requirements such as provisions for sampling and limitations on water chemistry.
10. Layout and arrangement requirements.
11. 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 spare, range of measurement, and location of indication are included.
12. Access and administrative control requirements for repository security.
13. Handling, storage, cleaning, and shipping requirements.
14. Materials, processes, parts, and equipment suitable for application.
15. Quality Control and Quality Assurance requirements.

16. Reliability requirements of structures, systems, and components, including their interactions, which may impair functions that are important to safety.
17. Other requirements to prevent undue risk to the health and safety of the public.

QUALITY ASSURANCE PROGRAM PLAN

APPENDIX C
REQUIREMENTS FOR THE QUALIFICATION OF INSPECTION AND TEST PERSONNEL

Not Applicable

QUALITY ASSURANCE PROGRAM PLAN

**APPENDIX D
REQUIREMENTS FOR THE QUALIFICATION OF
NONDESTRUCTIVE EXAMINATION PERSONNEL**

Not Applicable

QUALITY ASSURANCE PROGRAM PLAN

APPENDIX E
LIST OF TYPICAL USGS QA RECORDS

The following is a list of typical QA records. The nomenclature of these may vary but some element of the item may apply. The NNWSI Project retention period is defined as lifetime. QA records will be submitted to the Project Records Center by the USGS Records Center.

1.0 SITE CHARACTERIZATION

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

- o Environmental Impact Statement.
- o Environmental Report.

2.0 PROCUREMENT RECORDS

- o Procurement specifications.
- o Purchase orders including amendments.

3.0 GENERAL

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

QUALITY ASSURANCE PROGRAM PLAN

APPENDIX F
REQUIREMENTS FOR THE QUALIFICATION OF QUALITY ASSURANCE
PROGRAM AUDIT PERSONNEL

1.0 GENERAL

This Appendix provides requirements for the qualification of Lead Auditors. A Lead Auditor organizes and directs audits, reports audit findings, and evaluates corrective action. This Appendix also provides amplified requirements for the qualifications of individuals, henceforth referred to as Auditors, who participate in an audit, such as technical specialists, management representatives, and auditors-in-training.

1.1 QUALIFICATION OF AUDITORS

The USGS 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 NNWSI-USGS QAPP and the USGS 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 USGS.

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:

- o Knowledge and understanding of the NNWSI-USGS QAPP document, 10 CFR 60 Subpart G, and other nuclear and/or DOE related codes, standards, regulations, and regulatory guides, as applicable to the NNWSI Project.
- o General structure of Quality Assurance programs and applicable elements as defined in the NNWSI-USGS QAPP document.
- o Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.
- o Audit planning in the functions related to quality for the following activities as they relate to earth science and other types of scientific investigations: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility.
- o On-the-job training to include applicable elements of the audit program.

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 the comprehension of and ability to apply the body of knowledge identified in the Training Section above. The test may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section 1.4 of this Appendix.

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 the Training Section, reexamination in accordance with the Qualification Examination, 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 USGS. The USGS shall select and assign personnel who are independent of any direct responsibility for the performance of the activities that they will audit. Prior to commencing the audit, the Lead Auditor shall 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 is the responsibility of the USGS. The USGS may delegate this activity to an independent certifying agency, but shall retain responsibility for conformance to the NNWSI-USGS QAPP for the examination and its administration. Integrity of the examination shall be maintained by the USGS or the 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 USGS.

1.5 CERTIFICATION OF QUALIFICATION

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

- o Employer's name.
- o Lead Auditor's name.
- o Date of certification or recertification.

- o Basis of qualification (i.e., education, experience, communication skills, training, examination, etc.).
- o Signature of employer's designated representative who is responsible for such certification.