

U.S. GEOLOGICAL SURVEY  
QUALITY ASSURANCE PROGRAM PLAN  
FOR THE  
YUCCA MOUNTAIN PROJECT

Effective Date \_\_\_\_\_

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QUALITY ASSURANCE PROGRAM PLAN

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REVISION RECORD

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Record for QAPP

<u>QAPP Number</u>	<u>Effective Date</u>
NWM-USGS-QAPP-01, R0	11/01/80
NWM-USGS-QAPP-01, R1	07/15/83
NNWSI-USGS-QAPP-01, R2	08/24/85
NNWSI-USGS-QAPP-01, R3	10/27/86
NNWSI-USGS-QAPP-01, R4	01/05/88
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QUALITY ASSURANCE PROGRAM PLAN

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## QUALITY ASSURANCE PROGRAM PLAN

### PREFACE

This document is the fifth revision of the Yucca Mountain Project (YMP) U.S. Geological Survey (USGS) Quality Assurance Program Plan (QAPP).

This YMP-USGS QAPP is a requirements document that was developed from the quality assurance (QA) requirements imposed on the USGS for YMP activities by the Yucca Mountain Project Office (YMPO), U.S. Department of Energy (DOE). Accordingly, this document establishes the QA requirements that are applicable to the USGS and its supporting organizations.

This revision incorporates changes to YMP-USGS QA requirements developed since the issuance of NNWSI-USGS-QAPP-01, Revision 4. Changes may include additions to or deletions of past requirements. Other than minor and/or editorial changes, line-by-line revision indicators (change bars) are used in this document to note the location of changes. In addition, the major or most significant changes are described below:

- o Nevada Nuclear Waste Storage Investigations (NNWSI) was changed to Yucca Mountain Project (YMP) except as used for historical reference.
- o Waste Management Project Office (WMPO) was changed to Yucca Mountain Project Office (YMPO).
- o References to Office of Geologic Repositories (OGR) were changed to Office of Civilian Radioactive Waste Management (OCRWM).
- o The Statement of Policy has been revised to better reflect the Director's support of the YMP-USGS Quality Assurance Program.
- o The Introduction has been updated to show current USGS organization for implementation of the YMP-USGS responsibilities.
- o Section 1 was revised to allow the individual with overall responsibility for the QA Program to have other responsibilities provided that "full-time", dedicated personnel have been assigned to adequately fulfill QA responsibilities.
- o Section 2 was revised to establish requirements for regular QA Program status reporting and readiness reviews.
- o Section 2 was revised to add a requirement for non-technical implementing procedure submittal to YMPO for review and approval prior to implementation.
- o Section 2 was revised to clarify the term "primary data". Deletions were made since Appendix G was added to expand requirements for qualification of existing data.
- o Section 2 was revised to provide commitment to meet the guidance of NUREG-1298 and NUREG-1318.

- o Section 3 was revised to clarify and expand the requirements for scientific investigation planning documents, including OCRWM review of Study Plans.
- o Section 3 was revised to include requirements for scientific investigation data interpretation and analysis.
- o Section 3 was revised to expand the requirements for technical implementing procedures.
- o Section 3 was revised to include requirements for the verification of scientific investigations.
- o Section 3 was revised to revise and expand the requirements for software quality assurance.
- o Section 3 was revised to clarify design input requirements.
- o Section 3 was revised to commit to the requirements of NUREG-1297 (Feb., 1988) for peer review. Accordingly, peer review requirements were deleted from this section.
- o Section 7 was revised to clarify the USGS exclusion from YMP/88-9, Section X and XI requirements.
- o Section 15 was revised to remove the requirement for the USGS to process nonconformance reports initiated by YMPO.
- o Section 17 was revised to eliminate provisions for superceded records disposal. All records will be retained.
- o Section 18 was revised to require the documentation and monitoring of potential quality problems.
- o Section 18 was revised to add requirements for the evaluation of suppliers.
- o Section 18 was revised to require "root cause" determination for adverse audit findings.
- o Appendix A was revised to update the Project glossary.
- o Appendix F was revised to include site characterization to the list of activities related to audit planning.
- o Appendix G was added to delineate the requirements for qualification of existing data not generated under the control of the YMP-USGS QAPP.
- o Appendix H was added to delineate computer software requirements.
- o Appendix I was added to delineate requirements for identification of items and activities subject to quality assurance requirements.
- o Appendix J was added to delineate peer review requirements.
- o Appendix K was added to delineate SCP Study Plan requirements.

QUALITY ASSURANCE PROGRAM

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STATEMENT OF POLICY  
QUALITY ASSURANCE PROGRAM PLAN

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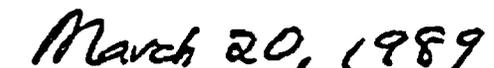
The U.S. Geological Survey is committed to the achievement of quality in the earth sciences. It is the policy of the Geological Survey that all products produced as a result of its activities meet the highest standards for scientific work.

To fulfill this commitment for activities supporting the DOE Yucca Mountain Project (YMP), the Geological Survey has established organizational responsibilities, including a Technical Project Officer and a Quality Assurance Manager, to ensure that quality is integrated into all Yucca Mountain Project activities.

The achievement of quality is the responsibility of all personnel assigned to this project. Quality shall be accorded top priority in situations where choices between cost and schedule or quality are necessary. Activities and actions that provide the highest standards of quality accomplishment, such as training, recognition of performance, identification of problems, and verification of solutions, must be supported at all levels in the YMP-USGS program.

Accordingly, the Geological Survey has prepared this Quality Assurance Program Plan. The requirements described herein establish the framework of a quality program that is intended to meet our quality commitment.

  
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Dallas L. Peck, Director  
U.S. Geological Survey

  
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Date

Danny

PARTICIPANT PROCEDURES REQUIRED FOR FOOQAP PER 88-9 REV 2

4/314

MILESTONE LEGEND:

1-TITLE II DESIGN, 2-LONG LEAD PROC, 3-SITE PREP, 4-FOOQAP

PROCEDURE	REV	TITLE	APQ REF	MILE STONE	ISSUE DATE	NEED DATE
** USGS QMP-01.01	1	ORGANIZATION PROCEDURE		3	04/10/89	04/10/89
QMP-02.01	2	MANAGEMENT ASSESSMENT OF THE YMP-USGS QUALITY ASSURANCE PROGRAM		4	02/17/89	04/10/89
QMP-02.02	2	PERSONNEL QUALIFICATION AND TRAINING PROGRAM		1	02/27/89	03/01/89
QMP-02.05	2	QUALIFICATION OF AUDIT AND SURVEILLANCE PERSONNEL		2	10/25/88	04/03/89
QMP-02.06	1	CONTROL OF READINESS REVIEW	5.130	3	02/01/89	04/10/89
QMP-02.07	0	DEVELOPMENT AND CONDUCT OF TRAINING		1	03/14/89	03/01/89
QMP-02.08	0	CONTRACTOR PERSONNEL QUALIFICATION AND TRAINING		-	03/14/89	/ /
QMP-03.02	2	USGS QA LEVELS ASSIGNMENT (QALA) ON HOLD	5.40	3	04/10/89	04/10/89
QMP-03.03	1	SCIENTIFIC AND ENGINEERING SOFTWARE		4	03/14/89	04/10/89
QMP-03.04	2	TECHNICAL REVIEW OF YMP-USGS PUBLICATIONS	1.40	4	02/17/89	04/10/89
QMP-03.05	2	WORK REQUEST FOR NTS CONTRACTOR SERVICES (CRITERIA 5.100 LETTER)		3	04/10/89	04/10/89
QMP-03.06	0	SCIENTIFIC INVESTIGATION PLAN		3	04/10/89	04/10/89
QMP-03.07	1	TECHNICAL REVIEW PROCEDURE		3	11/04/88	04/10/89
QMP-03.09	0	PREPARATION OF DRAFT STUDY PLANS	1.100	3	04/10/89	04/10/89
QMP-03.10	0	CLOSE-OUT VERIFICATION FOR SCIENTIFIC INVESTIGATIONS		4	03/06/89	04/10/89
QMP-03.11	0	PEER REVIEW		3	04/10/89	04/10/89
QMP-03.12	0	QUALITY ACTIVITIES LIST IDENTIFICATION	6.110	1	03/14/89	03/01/89
QMP-03.13	0	DESIGN INPUT		1	03/16/89	03/01/89
QMP-03.14	0	SOFTWARE CONFIGURATION MANAGEMENT-SYSTEM		-	03/14/89	/ /
QMP-03.15	0	APPLICATION OF GRADED QUALITY ASSURANCE		-	03/14/89	/ /
QMP-04.01	2	PROCUREMENT DOCUMENT CONTROL		2	01/30/89	04/03/89
QMP-04.02	0	ACQUISITION OF INTERNAL SERVICES		3	03/06/89	04/10/89
QMP-05.01	2	PREPARATION OF TECHNICAL PROCEDURES		3	04/10/89	04/10/89
QMP-05.02	1	PREPARATION AND CONTROL OF DRAWINGS AND SKETCHES		3	11/04/88	04/10/89
QMP-05.03	3	DEVELOPMENT & MAINTENANCE OF MANAGEMENT PROCEDURES		1	02/17/89	03/01/89
QMP-05.04	1	PREPARATION AND CONTROL OF THE USGS QA PROGRAM PLAN		1	02/17/89	03/01/89
QMP-05.05	0	PREPARATION & ISSUANCE OF TENTATIVE TECHNICAL PROCEDURES (REPLACES QMP-11.01)		3	04/10/89	04/10/89
QMP-06.01	2	DOCUMENT CONTROL	1.50	1	11/04/88	03/01/89
QMP-07.01	1	SUPPLIER EVALUATION, SELECTION AND CONTROL		2	11/04/88	04/03/89
QMP-08.01	2	IDENTIFICATION AND CONTROL OF SAMPLES	6.2,6.3,6.60	4	02/01/88	04/10/89
QMP-08.03	0	CONTROL OF DATA	5.2, 5.30	1	11/04/88	03/01/89
QMP-12.01	2	INSTRUMENT CALIBRATION	5.110	2	10/25/88	04/03/89

PARTICIPANT PROCEDURES REQUIRED FOR FOOQAP PER 88-9 REV 2

MILESTONE LEGEND:  
1-TITLE II DESIGN, 2-LONG LEAD PROC, 3-SITE PREP, 4-FOQAP

PROCEDURE	REV	TITLE	APQ REF	MILE STONE	ISSUE DATE	NEED DATE
GMP-13.01	0	HANDLING, STORAGE, AND SHIPPING OF INSTRUMENTS		2	10/01/88	04/03/89
GMP-15.01	2	CONTROL OF NONCONFORMING ITEMS		2	10/25/88	04/03/89
GMP-16.01	2	CONTROL FOR CORRECTIVE ACTION REPORTS		1	10/11/88	03/01/89
GMP-16.02	0	CONTROL OF STOP WORK ORDERS		1	11/04/88	03/01/89
GMP-16.03	0	TREND ANALYSIS		4	10/11/88	04/10/89
GMP-17.01	3	YMP-USGS RECORDS MANAGEMENT	1.70	2	04/10/89	04/03/89
GMP-17.02	1	ACCEPTANCE OF DATA NOT DEVELOPED UNDER THE YMP QA PLAN	5.90	4	/ /	04/10/89
GMP-18.01	2	AUDITS		2	11/04/88	04/03/89
GMP-18.02	0	SURVEILLANCE		2	11/04/88	04/03/89

## QUALITY ASSURANCE PROGRAM PLAN

### INTRODUCTION

#### I.1 OVERVIEW

The U.S. Geological Survey (USGS) is one of the principal organizations participating in the Yucca Mountain Project (YMP) of the DOE's nuclear waste repository program, 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 YMP is that a Quality Assurance Program Plan (QAPP) be prepared to describe how the USGS will satisfy the quality assurance (QA), technical, and other quality-affecting requirements of the Project and to recognize the importance of both radiological and non-radiological health and safety related activities. The establishment and maintenance of requirements and the implementing procedures necessary to fulfill those requirements constitutes the QA Program. YMP-USGS activities affecting quality must be in conformance with the 18 criteria of ANSI-AMSE NQA-1 and Federal regulations 10CFR60, Subpart G and 10CFR50, Appendix B, as specified for YMP Participants by the Project's Quality Assurance Plan (QAP), YMP/88-9. This QAPP establishes the USGS requirements needed for the YMP-USGS QA Program to be in compliance with YMP/88-9.

#### I.2 PURPOSE

To delineate the QA Program requirements governing quality-affecting activities of the YMP-USGS in conformance with the 18 criteria of NQA-1 and Federal regulations 10CFR60 and 10CFR50, Appendix B, as specified for YMP Participants by the Project's QAP, YMP/88-9.

#### I.3 SCOPE OF COMPLIANCE

The provisions of this QAPP and its implementing documents apply to all nuclear waste management quality-affecting activities performed by the USGS and to YMP-USGS contractors not working to their own USGS-approved QA program.

#### I.4 ORGANIZATIONAL DUTIES AND RESPONSIBILITIES

The organizational structure, program responsibilities, levels of authority, and lines of communication of the USGS staff performing work on the YMP are described below. All organization and authority presented herein is YMP-USGS Project-specific and represents program relationships established to implement Project activities. The organization of the USGS with respect to the YMP-USGS and QA is shown in Figure 1.

# YMP-USGS ORGANIZATION CHART

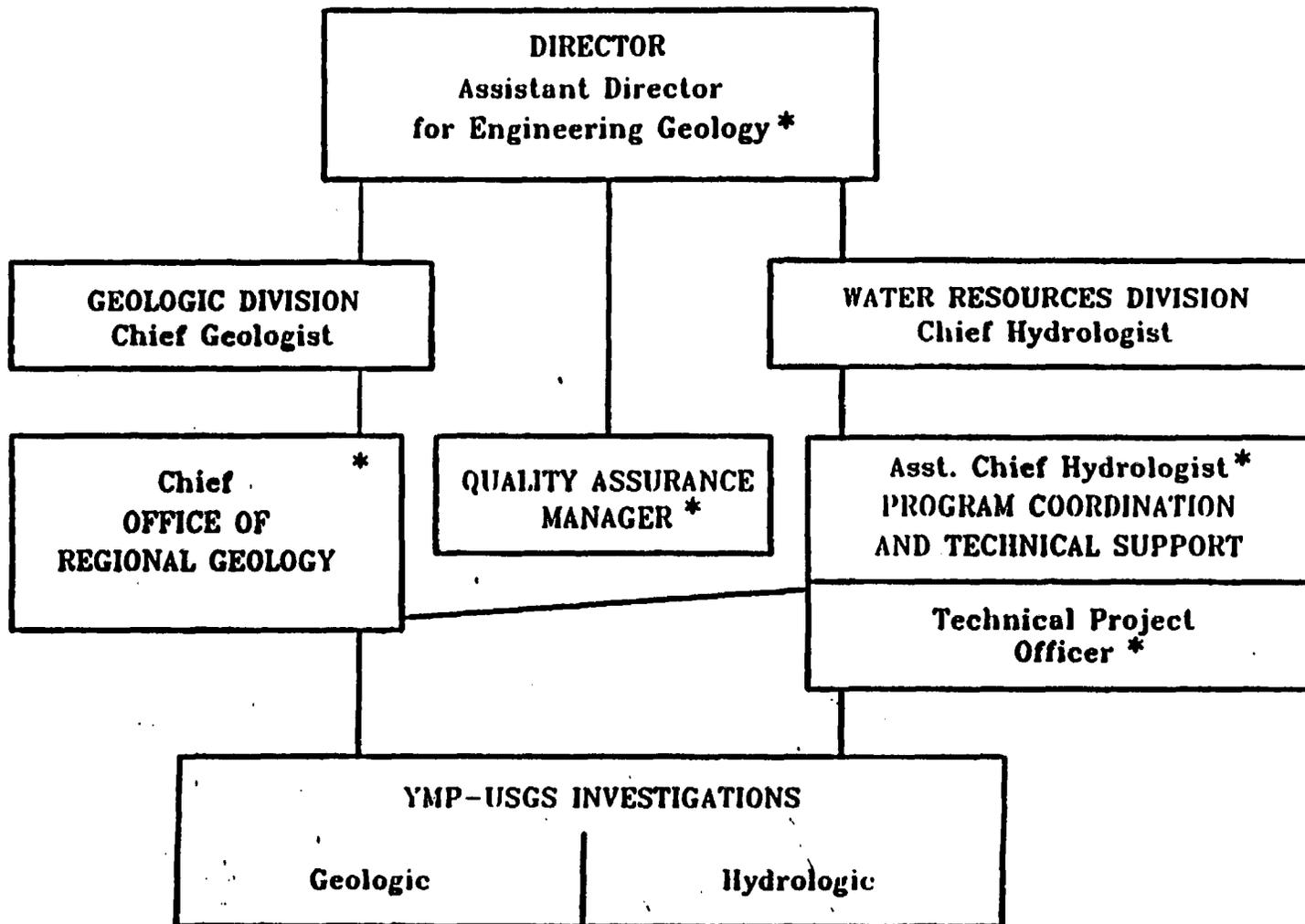


Figure 1. YMP-USGS Organizational Chart. The YMP-USGS TPO and QA Manager have access to all YMP-USGS personnel for QA, budget, and program purposes as applicable. Asterisk denotes approval authority for YMP-USGS governing documents.

I.4.1 USGS Director's Office: The Director is responsible for direction of the YMP-USGS. This management function includes responsibility for the YMP-USGS QA Program, including final USGS resolution of conflicts and disputes involving quality arising from differences of opinion between QA Office personnel and technical/administrative personnel. The Director may delegate approval authority of YMP-USGS governing documents to the Assistant Director for Engineering Geology.

I.4.2 YMP-USGS Technical Project Officer: The Technical Project Officer (TPO) reporting to the Assistant Chief Hydrologist for Program Coordination and Technical Support has YMP-USGS programmatic and budgetary responsibility for technical and administrative USGS and contractor personnel assigned to the YMP, including responsibility for the implementation of the YMP-USGS QA Program. The TPO's directional authority for scientific studies and personnel is described in Paras. I.4.4 and I.4.5.

I.4.3 YMP-USGS Quality Assurance Manager: The development and verification of the YMP-USGS QA Program is directed by the QA Manager. The QA Manager is independent of programmatic or budgetary constraints imposed by the TPO and reports to the Assistant Director for Engineering Geology for QA matters. The YMP-USGS QA Manager interfaces with the TPO and technical personnel on QA matters, as necessary, and is dedicated to QA for the YMP-USGS. The basic responsibilities of the overall QA organization task are development of the QA Program, verification that YMP-USGS activities are conducted in accordance with governing documents, and implementation of specific QA Office requirements. In this capacity, the QA Manager has the responsibility to:

- a) Serve as a focal point in developing and verifying the YMP-USGS QA Program;
- b) Maintain liaison with Yucca Mountain Project Office (YMPO) management to assure adequate compliance with the YMP QA Program;
- c) Provide and direct QA support (QA Office Staff) for the YMP-USGS;
- d) Have review and approval authority as outlined in the QAPP and implementing procedures;
- 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 TPO shall be referred to the Director's Office, and, if necessary, the YMPO Project Quality Manager (PQM).

I.4.4 YMP-USGS Geologic Studies: YMP-USGS quality-affecting geologic activities are performed by USGS Geologic Division Principal Investigators and staff. The YMP-USGS TPO coordinates and oversees QA Program implementation through the Chief Office of Regional Geology. Geologic personnel are responsible for the performance of assigned YMP-USGS tasks, including satisfying all technical, QA, or other quality-affecting requirements specified in YMP-USGS plans, procedures, contracts, purchase documents, or management directives.

I.4.5 YMP-USGS Hydrologic Studies: YMP-USGS quality-affecting hydrologic activities are performed by USGS Water Resources Division Principal Investigators

and staff. The YMP-USGS TPO coordinates and oversees QA Program implementation. Hydrologic personnel are responsible for the performance of assigned YMP-USGS tasks, including satisfying all technical, QA or other quality-affecting requirements specified in YMP-USGS plans, procedures, contracts, purchase documents, or management directives.

**1.4.6 YMP-USGS Governing Documents Approval:** The QAPP, the Software QA Plan, the Records Management Plan, and all Quality Management Procedures shall receive review and approval by signature of the following YMP-USGS management personnel: USGS Director's Office, Assistant Director for Engineering Geology; USGS Water Resources Division, Assistant Chief Hydrologist for Program Coordination and Technical Support; USGS Geologic Division, Chief, Office of Regional Geology; YMP-USGS Technical Program Office, YMP-USGS TPO; YMP-USGS QA Office, YMP-USGS QA Manager.

## 1.5 IMPLEMENTATION OF QAPP

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

The QAPP identifies the systems, structures, components, and activities to be covered by the YMP-USGS QA Program. The YMP-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 QAPP also takes into account the need for special controls, instruments and skills to attain the required quality, and the need for verification of quality. The YMP-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.

## 1.6 EXCEPTIONS TO REQUIREMENTS OF YMP/88-9

The USGS is permitted by the YMP QA Program to exclude those portions of the YMP QA Program requirements that are not applicable to the work undertaken by the USGS for YMP. The exceptions to YMP/88-9 requirements made in this QAPP are summarized hereafter:

**1.6.1 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.

**1.6.2 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 YMP-USGS work, and the requirements of this section are omitted from this QAPP.

**1.6.3 Section 10. Inspection:** The YMP-USGS does not include inspections in the 10CFR50, Appendix B, Criterion 10 definition of the term. The elements of the

USGS scientific investigations requiring "inspection" related to receiving acceptance, 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 YMP-USGS 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: YMP-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 technical procedures, 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 YMP-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.

I.6.7 Appendix C. Requirements for the Qualification of Inspection and Test Personnel: See I.6.3 and I.6.4 above.

I.6.8 Appendix D. Requirements for the Qualification of Nondestructive Examination Personnel: The USGS has no YMP responsibilities for nondestructive examinations, therefore, the requirements of Appendix D are excluded from this QAPP.

I.6.9 Appendix I. Requirements for the Identification of Items and Activities Subject to Quality Assurance Requirements: Because the USGS has no responsibilities for "Items" as pertaining to the Q-List or for submission of YMP Documents, Sections 3.0 and 5.0, respectively, of this Appendix 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, including 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. Delegation of execution of the QAPP 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 additional QA organization functions. While the line organization, under the programmatic direction of the TPO, is responsible for properly performing technical/administrative activities, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls. The organizational responsibilities for QA Program development/verification and implementation are detailed in the Introduction to this QAPP and in YMP-USGS Quality Management Procedures.

#### 1.2 QUALITY ASSURANCE ORGANIZATION FUNCTIONS

The QA organization (Office) functions are those of assuring that an appropriate QA program is established, executed effectively, and of verifying that requirements have been performed correctly by checking, auditing, conducting surveillances, and otherwise monitoring activities that affect quality. The persons performing QA Office 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:** The person responsible for directing and managing the overall Yucca Mountain Project (YMP) USGS QA Program shall be identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA Program. This person shall have appropriate management and QA knowledge and experience, be at the same or higher organizational level as the highest line manager responsible for performing activities affecting quality, and be sufficiently independent from cost and schedule to independently perform QA functions. The person in this position shall have responsibility for approval of (1) QAPPs, changes thereto, and interpretations thereof and (2) implementing procedures and all changes thereto. This position

shall have effective communication channels with other senior management positions.

Personnel in QA positions shall have the responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA Program implementation by the USGS and its subordinate organizations. Full-time, dedicated QA positions shall be established by the USGS for the YMP-USGS. The management position that retains authority and responsibility for the QA Program as well as personnel considered to be "full-time dedicated" shall not be assigned duties that would prevent full attention to YMP-USGS QA responsibilities or that would conflict with the reporting and resolution of QA issues and problems related to the YMP-USGS.

**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 Yucca Mountain Project Office (YMPO) Project Quality Manager (PQM), if the dispute cannot be resolved within the YMP-USGS.

**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. YMP-USGS organizational QA responsibilities shall be described in the QAPP or its implementing procedures, as applicable.

### 1.3 QUALITY ASSURANCE PROGRAM PLAN

The QAPP shall apply to YMP-USGS quality-affecting items, activities, and personnel. 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, YMPO, and the NTS Support Contractors shall be described in the USGS QAPP. From an overall YMP standpoint, these interfaces are

exchanges of technical requirements of work to be performed and liaison until completion of work. The YMP Administrative Procedures (APs) provide the implementing interface controls used by all of the YMP 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 QAPP and the YMP-USGS Quality Management Procedures. The USGS Technical Project Officer (TPO) is responsible to the Project Manager, YMPO to insure that the Project activities for which the USGS is responsible are performed in accordance with the QAPP, and implementing procedures that are consistent with the YMP QA Plan, YMP/88-9.

**QUALITY ASSURANCE PROGRAM PLAN**

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**SECTION 2  
QUALITY ASSURANCE PROGRAM**

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**2.1 EXTENT OF THE QUALITY ASSURANCE PROGRAM**

The USGS QA Program for the YMP consists of the YMP-USGS QAPP, QA program plans of contractors, as applicable, and all implementing technical and QA procedures. The YMP-USGS QA Office shall submit this QAPP to the Assistant Director for Engineering Geology for approval. Upon approval by the Assistant Director, the YMP-USGS QA Office shall submit the YMP-USGS QAPP to YMPO for approval. If the YMP-USGS QA Manager determines that the QAPP shall be issued for interim use, the transmittal record shall so indicate. Final QAPPs shall include a signature block for approval by the Yucca Mountain Project Quality Manager.

The USGS is required to develop a QAPP that provides the description of the YMP-USGS QA Program and indicates the USGS commitment to the applicable YMP QA requirements. This 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 YMP. This QAPP has been and will be planned, implemented, and maintained in accordance with and consistent with all of the applicable requirements of the YMP QA Plan, YMP/88-9. YMP-USGS management above the level of the QA organization shall regularly receive reports from the USGS QA Manager as to the scope, status, adequacy, compliance, etc. of the QA Program. A formal assessment shall be made at least annually per Para. 2.4. In addition, management shall perform readiness reviews, as deemed appropriate. Readiness reviews shall apply to major scheduled/ planned activities which could affect quality. Readiness reviews shall be used in verifying that specified prerequisites and programmatic requirements have been identified prior to starting a major activity.

**2.1.1 Quality Assurance Criteria:** The QA criteria and specific requirements associated with these criteria (as interpreted by the YMP QA Plan, YMP/88-9), have been, and are, adapted to the YMP-USGS activities through this QAPP. When a specific criterion is not applicable to the YMP-USGS activities, it shall be noted in the QAPP and recorded on the checklist provided by YMPO with justification of its exception.

**2.1.2 Contents of the QAPP:** The YMP-USGS QA 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 YMP-USGS QA Office prior to implementation to assure that they meet all the requirements of this QAPP.

The QAPP shall be submitted to the YMPO for review prior to implementation and shall include a checklist based on the YMP QA Plan, YMP/88-9 which identifies how and where each 88-9 requirement is met or excluded.

**2.1.3 QAPP Verification:** The USGS shall assure that the QA requirements have been addressed adequately and implemented effectively. The USGS shall monitor the

QAPP implementation through internal audits to assess the adequacy of the YMP-USGS QA Program and to assure its effective implementation. Additional verification is conducted by the YMPO, 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 YMP provides for the acceptance of existing data for use in licensing activities that were not generated under the controls of a QA program which meets the requirements of 10CFR60, Subpart G. Specific methods for acceptance of this information are contained in Appendix G of this QAPP. Once accepted, this data is classified as "primary data" for licensing purposes.

2.1.5 Methodology for Formulating the "Q" List and Quality Activities List: The YMP QA Plan requires that the USGS shall prepare the appropriate procedures for determining the items and activities to be placed on the Project's Q-List and Quality Activities List. These procedures shall meet the guidelines of NUREG-1318 "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements" as are contained in Appendix I to this QAPP.

2.1.6 Approach to Quality Assurance: The YMP uses an approach to QA that recognizes the differences between items and activities that affect radiological health and safety, and waste isolation, and those that do not. The approach is designed to 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 requirements, the operability and maintainability of the repository, its costs, and its schedules. The USGS, other Participating Organizations, or YMPO 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 YMP Participants involved in the activity.

2.1.7 Application of Quality Assurance: This QAPP is written to comply with the requirements of YMP/88-9 and 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 YMP/88-9 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 YMP 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 YMP-USGS 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 QA

Program considers the need for special controls, processes, equipment, tools, and skills to attain the required quality, and the need for verification of quality. 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 and its contractors, as applicable, are subject to assessment by YMPO 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. The preparation of administrative and management planning documents shall not require QA level assignments, except for Project level documents which are specifically required by the Nuclear Waste Policy Act of 1982 (as amended), or are required for licensing. In addition, procurement of administrative items (i.e., office supplies) do not require QA level assignments. In compliance with YMPO-developed administrative procedures, the USGS shall develop an implementing procedure for the application of graded QA consonant with the QA requirement specified herein. Certain YMP 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 YMPO PQM 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 an acceptance 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 quality assurance requirements to be applied to an item or activity that is commensurate with the relative importance of the role or function assigned to the item or activity.

**2.2.5 Requirements:** The requirements specified in this section shall be used in applying the graded quality assurance to all YMP-USGS 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 YMP-USGS implementing 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 YMPO 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, one of which will be assigned to each technical task that affects the quality of the YMP. 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 post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

**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 YMPO 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 site characterization, scientific investigation, facility and equipment design, procurement, construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities 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 ensure 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 where:

- 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 primary data which will be relied on for performance assessment of the repository system. These data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research which have a significant impact to site-characterization or are an essential part of the data base that directly support the final design of the repository and waste package performance.
- o Activities that could adversely impact the waste isolation capabilities of the engineered and natural barriers.
- o Items that are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system.
- 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 involves the preparation of detailed design documents (such as drawings, specifications, and analyses) will be assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationships. As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities shall be governed by the QA level assigned to the item.

QA Level II - is the second highest level of quality assurance. QA Level II controls and documentation shall be applied to YMP activities and items that are specifically concerned with nonradiological operation of the exploratory-shaft facilities and repository, and the radiological safety of the repository worker. The high-level waste (HLW) repository will 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 Civilian Radioactive Waste Management (OCRWM) milestones must be controlled appropriately. Therefore, QA Level II must be applied to activities and items according to the following guidelines where:

- 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 could affect the retrievability of waste up to the time of repository closure.
- 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 Items and activities that, having failed, could result in a major cost overrun.
- o 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 in accordance with YMPO requirement YMP AP 5.9Q "Acceptance of Data and Data Interpretations Not Developed Under the YMP QA Program".

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 that 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 YMP 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.

### 2.3 QUALITY ASSURANCE ACTIVITIES

2.3.1 Overview: The USGS shall perform overview of the QA activities of all organizations (including subcontractors doing supportive work) under its purview. Overview is to include the following as appropriate:

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

2.3.2 Review and Approval of Subcontractor Quality Assurance Programs: Procedures shall be established by the USGS for the review of subcontractor QA programs documentation for adequacy, completeness, and relevance. The procedures shall identify the types of documents to be submitted by the subcontractor for review and approval, assign 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 Project Manager, YMPO, and the YMPO PQM. Management above or outside the QA organization shall be responsible for the management assessment activity.

## **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. These requirements will be based on the Office of Personnel Management approved USGS personnel system. All requirements shall be consistent with the Privacy Act of 1974 (P.L.93-579). The requirements shall establish position descriptions, 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) shall be certified in accordance with the detailed requirements specified in Appendix F of this QAPP.

**2.5.1 Position Description:** Minimum education and experience requirements shall be established and documented 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 accordance with quality management procedures. Relevant education and experience shall be verified and 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 (including changes thereto), as a minimum, as they relate to the work to be accomplished. Indoctrination may be accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or by other instructional methods.

- o QAPP
- 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, training, if needed, 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. The instruction may be either internal or external, as necessary.

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 be maintained in accordance with Federal regulations and 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 SCIENTIFIC INVESTIGATION PLANNING DOCUMENTS: All scientific investigations require the development, review, and approval of planning documents prior to work initiation. Scientific investigations categorized as site characterization activities as defined in the Nuclear Waste Policy Act (as amended) shall utilize Study Plans as the principal scientific investigation planning documents. Scientific investigation planning documents shall contain a level of detail that would enable an independent reviewer to determine the appropriate QA Level for the investigation. All scientific investigation planning documents require YMPO approval prior to implementation with Study Plans additionally requiring OCRWM approval.

A Scientific Investigation Plan (SIP) may be used as the planning document to continue ongoing monitoring activities that were authorized to proceed prior to December 1988, and for prototype activities until Study Plans are approved. SIPs also may be referenced in Study Plans as an integral part of the principal planning document when their use is determined to be a practical method of accomplishing an intended goal or presenting equivalent information with a minimum of reorganization.

3.1.1.2 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR: Prior to the start of any scientific investigation, the Principal Investigator (PI) shall develop a scientific investigation planning document for that investigation. If an interim planning document (e.g., SIP) is utilized to initiate the start of work, the completion of the principal planning document (Study Plan) shall be accomplished at the earliest practical and reasonable time thereafter. Planning documents shall contain or reference the following information:

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

Description of Previous Work - A description of any previous work, to be used in support of the scientific investigation, including the identifica-

tion of the QA levels or QA controls under which that previous work was performed. Note: This requirement does not apply to Study Plans.

3.1.2 Planning Documents - The scientific investigation planning document shall contain a level of detail which would enable an independent reviewer to determine the appropriate QA Level to be applied to the investigation. For site characterization activities, the purpose and key milestones of Study Plans is described in the SCP. The format and content of Study Plans shall meet the requirements of Appendix K of this QAPP.

3.1.3 Assignment of Quality Assurance Levels:

3.1.3.1 LEVEL ASSIGNMENT: Once a scientific investigation planning document (as specified in Para. 3.1.1.1 of this section) has been developed, QA levels for all 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 planning document that was prepared earlier. Therefore, the QA level assignments are not an integral part of the planning documents, although, normally they would accompany those documents through the same review and approval process.

3.1.3.2 CONFORMANCE: Scientific investigation planning documents shall be prepared and QA levels assigned in accordance with the methods specified in the YMP Management Procedures Manual.

3.1.4 Review and Approval Process

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

3.1.4.2 YUCCA MOUNTAIN PROJECT OFFICE REVIEW: The YMPO PQM and the appropriate YMPO Branch Chief review and approve the scientific investigation planning document prior to implementation. Study Plans are also reviewed and approved by OCRWM prior to implementation.

3.1.4.3 PEER REVIEW: A peer review of the scientific investigation planning document shall be conducted when the YMPO considers it is necessary.

3.1.5 Scientific Investigation Data Interpretation and Analysis:

3.1.5.1 INTERPRETATION/ANALYSIS DOCUMENTS: Study Plans or other comparable scientific investigation planning documents shall be used for planning the interpretation and analysis of data. Changes are controlled as changes to Study Plans or other scientific investigation planning documents and through the use of internal reviews. Interpretation/analysis shall be performed and documented in sufficient detail as to purpose, method, as-

sumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer and date.

**3.1.5.2 DOCUMENTATION OF INTERPRETATION/ANALYSIS:** Documentation of interpretation/analysis shall include the following:

- o Definition of the objective of the interpretation/analysis.
- o Definition of input and their sources.
- o A listing of applicable references.
- o Results of literature searches or other background data.
- o Identification of assumptions.
- o Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the basis of application to the specific problem.
- o Signatures and dates of review and approval by appropriate personnel.

**3.1.6 Use of Computer Programs:** Computer programs that are used to support a licensee application shall be documented and controlled as specified elsewhere in this section and in Appendix H of this QAPP. The documentation and control measures shall be consistent with guidance contained in NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management".

**3.1.7 Use of Scientific Notebooks and Technical Implementing Procedures:**

**3.1.7.1 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, trial and error methods, or developing the methodology by which an activity will be accomplished. When the scientific notebook system is used, the Study Plan or scientific investigation planning document shall be the controlling document used to perform the activity since it describes the proposed approach or general procedure for accomplishing the work. Alternatively, the technical implementing procedure system 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. Modifications may be made to these procedures as detailed in Para. 3.1.7.2. 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.

3.1.7.2 TECHNICAL IMPLEMENTING PROCEDURES: Detailed technical implementing procedures, with appropriate logbooks and other supporting documents, shall be used whenever the work is repetitive. These technical implementing procedures shall be developed in accordance with the requirements given in Section 5 and reviewed in accordance with this section of the QAPP. Modifications may be made to the technical aspects of technical implementing procedures by the individual utilizing the procedure. If the change or modification is not within the scope of the Study Plan or scientific investigation planning document, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer. Requirements and acceptance or rejection criteria, including required levels of precision and accuracy, shall be provided or approved by the organization responsible for the scientific investigation, unless otherwise designated.

Technical procedures utilized for scientific investigations shall provide for the following as appropriate:

- o Requirements, objectives, methods and characteristics to be tested or observed.
- o Acceptance limits, if applicable, contained in applicable documents, including precision and accuracy.
- o Prerequisites such as calibrated instrumentation, adequate and appropriate equipment and instrumentation, suitable and controlled environmental conditions, and provisions for data collection and storage. For activities of long duration, specific provisions shall be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions are to be designed to ensure validity of data throughout the scientific investigation.
- o Mandatory verification points.
- o Acceptance and rejection criteria, including required levels of precision and accuracy (Note: "Accept/reject criteria" means those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output that, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject" criteria" are simply the conditions and methods stated in the procedure.)
- o Methods of documenting or recording data and results, including precision and accuracy.

- o Methods of data reduction.
- o Provision for ensuring that prerequisites have been met.
- o Special training or qualification requirements for personnel performing the scientific investigation.
- o Personnel responsibilities.

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

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

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

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

**3.1.7.3 SCIENTIFIC NOTEBOOKS:** Scientific notebooks and other appropriate documents may be used to document scientific investigations and experiments. 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.

**3.1.7.4 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** - Where appropriate, and 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 or objectives and the proposed approach or procedure for achieving these objectives. This may be accomplished by reference to the appro-

appropriate Study Plan or other scientific investigation planning document which controls the work;

- 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;
- o Dated signature of the individual or individuals making the initial entries;
- o Special training or qualification requirements;
- o Documentation of suitable and controlled environmental conditions, if applicable;
- o Required levels of precision and accuracy shall be identified; and
- o The potential sources of uncertainty and error in scientific investigations which must be controlled and measured to assure the investigations are well controlled shall be identified.

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

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 Provisions for assuring prerequisites have been met;
- 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 unaccepted results;
- o Any deviations from the planned experiment or research; and
- o Any interim conclusions reached, as appropriate.

**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.

**Final Results** - Final results and a summary of the outcome of the experiment or research shall be documented (e.g. in a technical report). This shall include a discussion of whether the experiment's objectives as outlined in the initial entries (Para. 3.1.7.4) were achieved. This documentation shall become part of the QA records of the activity.

**3.1.8 Change Control**: All changes in scientific investigation planning documents shall go through the same review and approval process specified in Para. 3.1.4 of this section. The USGS shall be responsible for evaluating the effects of such changes on associated QA level assignments.

**3.1.9 Interface Control**:

**3.1.9.1 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 YMPO. Interfaces between the USGS and its suppliers shall be controlled in accordance with USGS procedures. Ongoing field or laboratory scientific investigations shall be identified to preclude inadvertent interruption and to ensure operational compatibility. Such identification shall be clearly evident at the location at which the scientific investigation is being performed. Field investigations shall identify the location of the investigation.

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

**3.1.10 Verification of Scientific Investigations**:

**3.1.10.1 VERIFICATION PLANNING**: Planning for verification activities shall be accomplished and documented via verification procedures, instructions, or checklists. Verification procedures, instructions, or checklists shall provide for following:

- o Identification of characteristics and activities to be verified.

- o A description of the method of verification.
- o Identification of the individuals or groups responsible for performing the verification.
- o Acceptance and rejection criteria.
- o Identification of required procedures, drawings, and specifications (including revisions).
- o Recording identification of the verifier and the results of the verification.

**3.1.10.2 VERIFICATION HOLD POINTS:** Mandatory verification hold-points shall be established as necessary. When such hold points are established, work may not proceed without the specific consent of the responsible representative. These hold points shall be indicated in appropriate documents controlling the activity. Consent to waive any specified hold point shall be documented before work can be continued beyond the designated hold point.

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

**3.1.11 Surveillance of Scientific Investigations and Experiments:**

**3.1.11.1 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.

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

**3.1.12 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 YMPO in the review and approval cycle of the final report.

3.1.13 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. The data collection activities result from scientific investigations and produce design input. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) that integrate many other data and analyses of individual parameters.

The policy of the YMP 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 YMP 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 YMP requirements for 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 QA requirements. The design input shall be specified and approved on a timely basis and to the level of detail necessary to

permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

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.

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

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 perform QA Level I and II analyses to support a license application for a mined geologic repository shall be controlled to insure that the software is developed, acquired, and maintained in an orderly, systematic, and traceable manner. The USGS shall develop a software QA program that provides for the application of the requirements in this section based on the nature, complexity, importance, and intended application of that software to site characterization. The USGS software QA program shall be based on the concept of the software lifecycle as described in Appendix H to this QAPP. Software acquired from sources external to the USGS shall be controlled. All available documentation from the software supplier shall be obtained. It is recognized that source code is generally not available for acquired software, and controls on this software are restricted to unique version identification and user documentation. Supplemental, detailed requirements for the development, maintenance, and security of computer software will be identified in a Software Quality Assurance Plan. Specific elements of control include:

3.3.1.1 **DESCRIPTION:** The USGS shall prepare a software QA plan that describes the software development, test, and configuration management system and submit it to the YMPO for review and approval. The description shall:

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

- o Identify the required documentation to be prepared, reviewed, and maintained during software design, implementation, test, and use.
- o Identify the software configuration-management methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software.
- o Specify the process to be used for verification and validation of the software developed or acquired for and applied to site-characterization activities supporting geologic repository design and performance analyses.
- o Identify the procedure for reporting and documenting software defects and deficiencies, including the sources, evaluating impacts of defects and deficiencies on previous calculations, and determining appropriate corrective action.

3.3.1.2 CONFIGURATION MANAGEMENT: Software shall be placed under configuration management as each baseline is identified. Software baseline elements shall be uniquely identified to assure positive control of all revisions; the identification of each software configuration item shall be directly related to the associated documentation.

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

3.3.1.4 SOFTWARE DOCUMENTATION: Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. This requirement may be met in part by existing documentation that is properly referenced and related to the NUREG-0856 requirements.

3.3.1.5 SOFTWARE TESTING: Testing of software, including new or modified software, shall be performed for those inputs and conditions necessary to exercise the software over its range of applicability, to identify boundary conditions, and to provide a suitable benchmark or sample problem for installation. The goal of testing is to develop a set of test cases that have highest probability of detecting the most errors in order to identify under what conditions the software does not perform properly.

3.3.1.6 SOFTWARE VERIFICATION AND VALIDATION: Verification and validation of computer software shall be performed prior to the use of such software to perform technical calculations in support of site-characterization, performance assessment analyses, and the design, analysis, and operation of repository structures, systems, and components. In those cases where this requirement cannot be met, the portion or portions of software which have not been verified and validated shall be identified and controlled. In all cases, the verification and validation of software shall be completed prior

to relying on the software to support the license application. Verification and validation procedures shall assure that the software adequately and correctly performs all numerical and logical operations, that the functional requirements and capabilities are implemented properly in the software design, and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

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

**3.3.1.8 SOFTWARE IMPLEMENTING PROCEDURES:** Methods for determining the applicability of requirements and managing interfaces involving software documentation, configuration management, change, qualification, verification, and validation, shall be described in the YMP-USGS Software Quality Assurance Plan and implementing procedures.

**3.3.2 Documentation of Computer Software:** Documentation of software intended for scientific and engineering applications shall include the following as a minimum:

- o Software functional requirements specification;
- o Software design and related change documentation;
- o Description of mathematical models and numerical methods;
- o Software verification and validation documentation;
- o User documentation;
- o Code assessment and support;
- o Continuing documentation and code listings; and
- o Software summary.

This documentation is considered to be a QA record and is subject to the requirements of Section 17 of this QAPP. Appendix H to this QAPP provides detailed requirements on the documentation of computer software used on the YMP-USGS.

**3.3.3 Software Configuration Management System:** The USGS shall institute a software configuration management system and shall provide documentation of this system to the Records Management System (RMS). The minimum requirements for the configuration management system shall be: (1) inclusion of a unique identification, including software version numbers whenever feasible, in the output and listings of the software; (2) source code listings of the software, if available; and (3) a traceable chronology of software versions, including descriptions of the changes

| made between versions that will permit the history of the development or acquisition of software and the testing of software to be reconstructed.

#### 3.4 PEER REVIEWS

| The USGS shall institute a peer review process, when applicable, to provide additional confidence in the work being reviewed. Peer review shall meet the requirements of NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories" (Feb. 1988). These requirements are contained in Appendix J of this QAPP.

#### 3.5 TECHNICAL REVIEWS

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

QUALITY ASSURANCE PROGRAM PLAN

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SECTION 4  
PROCUREMENT DOCUMENT CONTROL

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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 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. 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. YMPO 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 QAPP.

#### 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 Para. 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 SAIC/T&MSS Project QA Department (QA Verification  
| Division Manager), one copy of purchase documents, and changes thereto, as issued,  
| when purchases involve QA Level I items or services. Only those purchase docu-  
| ments that identify the vendor, describe the scope of work, and indicate when work  
| is to start, are required to be submitted to SAIC/T&MSS Project QA Department.

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, or drawings, of a type appropriate to the circumstances, except as noted in Para. 5.3 of this section. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been accomplished satisfactorily. Instructions and procedures shall include a section which identifies the QA records which are generated during implementation of the document. If plans are used in lieu of procedures, then these plans shall also include or reference appropriate acceptance criteria and identify the QA records which are generated. These documents, including drawings, shall be controlled as required in Section 6 of this document.

**5.2 REVIEWS**

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

**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. When scientific notebooks are used to document scientific investigations, the requirements of Section 3 shall prevail over the requirements of this section. Scientific notebooks shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section 17 of this document.

**5.4 DISTRIBUTION**

The USGS shall maintain and provide the YMPO PQM and the SAIC/T&MSS Project QA Department Manager with controlled distribution of all implementing procedures, plans, and instructions used for QA Level I and II activities.

QUALITY ASSURANCE PROGRAM PLAN

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SECTION 6  
DOCUMENT CONTROL

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

The document control system shall be documented. 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 technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements, 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 as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated by the organization responsible for the document. The reviewing organization shall have access to pertinent background data or information upon which to base their approval and, if applicable, shall specifically consider whether or not the activities being changed are repeatable, have the

| potential to impact the waste isolation capability of the site or interfere with  
| other site characterization activities.

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 or, if they must be released before verification, they are uniquely identified as such and controlled in accordance with Para. 6.1.2 of this section. A master list or equivalent used to identify the correct, current and updated versions of documents shall be submitted to the YMPO PQM and the SAIC/T&MSS Project QA Department Manger.

**QUALITY ASSURANCE PROGRAM PLAN**

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**SECTION 7  
CONTROL OF PURCHASED ITEMS AND SERVICES**

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**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 YMP 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 capability as determined by a direct evaluation of the supplier's facilities, personnel and QA program implementation.

### 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 utilizes another Participating Organization or NTS Support Contractor for YMP activities for which they are responsible, the user organization shall initiate a request to YMPO to conduct a YMPO surveillance of the organization performing the work. The surveillance shall be conducted to determine that the item or activity is being produced or performed in accordance with the user organization's requirements. These surveillances may utilize USGS personnel as technical advisors.

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, audits, receiving acceptances, 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 QA 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 docu-

mented 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 acceptance or post-installation test (calibration) at the facility site, or a combination thereof. Note: Inspection and Testing as defined in 10CFR50, Appendix B Criteria 10 and 11 requirements are exempted from the USGS QA Program per Paras. I.6.3, I.6.4, 10.2, and 11.2 of this document. Items and services may be "inspected" and "tested" as part of acceptance functions, but only in the context of other criteria (e.g. calibration). 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 evaluation 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 acceptance functions 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 ACCEPTANCE: When receiving acceptance 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 acceptance shall be performed in accordance with established procedures to verify, by objective evidence, such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving acceptance shall be coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving acceptance. Personnel selected to receipt acceptance activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities. When required, personnel shall also be indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are applicable.

7.1.6.4 POST-INSTALLATION TESTING (CALIBRATION): When post-installation testing is used as part of the calibration system, 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: Provisions for evaluation of nonconforming items.

7.1.8.2 **SUBMITTAL:** Provisions for submittal of nonconformance notice to the USGS by supplier as directed by the USGS. These submittals shall include supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to the procurement requirements or USGS approved documents, which consist of one or more of the items listed below shall be submitted to the USGS. Approval of the recommended disposition shall be in accordance with documented procedures.

- 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:** Provisions for USGS disposition of supplier recommendation.

7.1.8.4 **VERIFICATION:** Provisions for verification of the implementation of the disposition.

7.1.8.5 **RECORDS MAINTENANCE:** Provisions for 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 scientific investigation planning document 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 Para. 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 (as related to calibration) is accomplished by  
| the USGS in accordance with written procedures to insure conformance with  
| requirements. Commercial-grade items purchased for the YMP-USGS may re-  
| quire inspection and/or testing from a calibration standpoint only.
  
- | o Documentation, as applicable to the item, was received and is acceptable.

7.2.4 Commercial-Grade Items Requiring Calibration: Commercial-grade items re-  
| quiring calibration may be accepted 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. The identification shall be verified prior to installation or use. 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 YMPO 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 YMP-USGS 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 YMP 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 YMP-USGS 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

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SECTION 9  
CONTROL OF PROCESSES

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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

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**SECTION 10  
INSPECTION**

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**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 activities, such as receiving acceptance, technical and other reviews, and document compliance are covered by the QAPP under other appropriate criteria.

QUALITY ASSURANCE PROGRAM PLAN

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SECTION 11  
TEST CONTROL

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

11.2 STATEMENT OF EXCLUSION

By definition, a test means to measure against a known standard. In the USGS-YMP 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-YMP QAPP.

QUALITY ASSURANCE PROGRAM PLAN

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SECTION 12  
CONTROL OF MEASURING AND TEST EQUIPMENT

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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 shall describe 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, and accuracy, to accomplish the function of determining conformance to specified tolerance requirements. The type, range, accuracy, and tolerance of a measuring device shall be specified in calibration procedures. Each device shall have a unique identification. This identification 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 Institute of Standards and Technology, 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. Calibrating standards shall have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of the acceptance is documented and authorized by responsible management. The management authorized to perform this function shall be identified.

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, precision, intended use, degree of usage, and other conditions that affect measurement control. Measuring and test equipment must be labeled, tagged, or otherwise documented, in a fashion 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 suitably marked to  
| indicate calibration status. Calibration records shall identify the calibration  
| procedure (including revision) utilized to perform the calibration.

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

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SECTION 13  
HANDLING, SHIPPING, AND STORAGE

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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**

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**SECTION 14  
INSPECTION, TEST, AND OPERATING STATUS**

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**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 YMP scientific investigations, the requirements of this Criterion are omitted from this QAPP.

QUALITY ASSURANCE PROGRAM PLAN

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SECTION 15  
CONTROL OF NONCONFORMING ITEMS

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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 YMP activities are responsible for reporting nonconformances in accordance with established nonconformance-control procedures. 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, disposition, and close-out 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 appropriate YMPO Branch Chief and the YMPO PQM.
- 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.

15.1.4.3 YMPO APPROVAL: In those cases where the responsible organization proposes a disposition of "repair", YMPO approves the proposed disposition prior to implementation. In the case of a proposed disposition of "use-as-is", the NCR shall be forwarded to YMPO for approval, after all actions necessary to support technical justification of the disposition have been completed. The appropriate YMPO Branch Chief and the YMPO PQM 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 YMP Participants shall be described clearly.

## 15.2 CONDITIONAL RELEASE

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

## 15.4 TRENDS

Nonconformance reports shall be periodically analyzed 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.

## 15.5 DISTRIBUTION OF DOCUMENTS

Copies of nonconformance reports for items shall be sent to the YMPO PQM and the SAIC/T&MSS Project QA Department (QA Engineering Division Manager) by the USGS upon issuance and upon closure. The original nonconformance reports shall be sent to the YMPO for approval, as required by Para. 15.1.4.3.

## 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.

**16.1.1 Significant Adverse Conditions:** For significant conditions adverse to quality the identification, cause, and corrective action taken to preclude recurrence shall be documented and reported to immediate and upper levels of management for review and assessment. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability. Significant conditions include, but are not limited to breakdowns in the QA Program and repetitive nonconformances. Upon discovering or receiving notification that a significant condition adverse to quality or unusual occurrence exists, the USGS shall ensure that:

- o Immediate actions have been taken to remedy the specific condition(s).
- o Causative factors have been determined.
- o Controls have been reviewed, implemented, monitored and revised, if necessary.
- o Affected managers at all levels have been notified of adverse condition(s) and of lessons to be learned to improve conditions or avoid similar occurrences.

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

**16.1.3 Corrective Action:** Corrective Action Reports (CARs) shall be periodically analyzed by the QA Office to show quality trends. Results shall be reported to upper management for review and assessment.

#### 16.2 DISTRIBUTION OF DOCUMENTS

Copies of Corrective Action Reports (CARs) shall be sent to the SAIC/T&MSS Project QA Department (QA Engineering Division Manager) 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 YMP Administrative Procedures, that shall meet the requirements of this section; a requirement is included that all documents be legible, identifiable, and retrievable. A document or other item is not considered a 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. All YMP-USGS records (including superceded records) shall be retained and dispositioned as described elsewhere in this section.

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 YMP Management Procedures Manual and the corresponding USGS procedure(s).

17.2.1 Records-System Management Plan: In accordance with the YMPO YMP 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 YMP-USGS Participants, including the QA organization.

- o Comply with requirements established by YMPO 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 YMP 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 YMPO. 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 YMP-USGS Management 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 YMP. The USGS records identification system shall be submitted to YMPO 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.
- o A method for submittal of completed records to the storage facility without unnecessary delay.

#### 17.4 RECORDS STORAGE, PRESERVATION, AND SAFEKEEPING

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

- 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.

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 infes-

tation 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 YMPO or its designated alternate. Records that are accumulated at various locations, prior to transfer, shall be made accessible to the YMPO 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 YMP activities shall be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall QA Program and to determine their effectiveness. This QAPP includes 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. All deficiencies, nonconformances, and potential quality problems identified during an audit are to be documented and monitored until verification of effective corrective action is made. 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 YMP-USGS management. Follow-up action, including verification of corrective action or reaudit of specific areas, shall be performed.

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

**18.1.1.1 YMPO AUDITS:** The USGS is subject to audits by YMPO, according to an annual YMPO plan, to verify the effectiveness and adequacy of the implementation of all elements of the USGS QAPP. Audits, in addition to planned and scheduled audits, may be conducted when a unique need arises or when an audit is requested by the USGS. The YMPO 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 YMPO audit, when the audited organization's activities are of mutual interest.

**18.1.1.2 USGS AUDITS:** The USGS shall conduct internal audits covering the entire QAPP on an annual basis, and external audits (subcontractor and supplier) 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 SAIC/T&MSS Project QA Department (QA Verification Division Manager). Audit schedules shall identify the date of the audit, the activities to be audited, and the requirements to which the activities are to be audited.

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

**18.1.2.1 INTERNAL-AUDIT SCHEDULE:** Applicable elements of the USGS QAPP shall be audited at least annually or at least once during the life of the activity, whichever timeframe is shorter. The scope of the audit shall be established by considering the results of any previous audits, the nature and frequency of identified deficiencies, and any significant changes in personnel, organization, or the QA Program.

**18.1.2.2 EXTERNAL-AUDIT SCHEDULE:** 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. A copy of the documented justification shall be provided to the YMPO PQM.

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

**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 of this QAPP 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 identify the technical specialists, if any, who will participate in the audit and include this information in the audit plan. Audit team members selected to participate in audits for technical consideration purposes shall have appropriate technical expertise or experience in the work being audited. Multidisciplinary audit teams shall be employed when activities to be audited involve more than a single technical area. The audit-team leader shall 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 organization or activity shall investigate adverse audit findings; determine root cause, 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 shall be verified by the auditing organization. An analysis of audit results shall be performed by the QA organization to identify quality trends. The results of this analysis shall be reported to responsible management for review, assessment, and appropriate action.

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 USGS. Records for each Lead Auditor shall be maintained and updated annually.

## 18.2 GENERAL SURVEILLANCE REQUIREMENTS

The YMP 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 YMPO, 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 YMP. 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. The documentation shall identify characteristics, methods, and acceptance criteria and shall provide for recording objective evidence of results and accuracy of the equipment necessary to perform surveillance. The specification of acceptance criteria related to surveillances may be as simple as "to verify proper implementation of procedures" or "to verify conformance to requirements".

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 surveilled, including the name or names of personnel contacted.
- o Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance. Nonconformances shall be handled in accordance with the requirements of Section 15 or 16, as applicable.
- o Surveillance criteria.
- o Equipment used during the surveillance.
- o Results.
- o Acceptance statement.

QUALITY ASSURANCE PROGRAM PLAN

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APPENDIX A  
TERMS AND DEFINITIONS

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**ACCEPTANCE CRITERIA:** Specified limits defined in codes, standards, or other requirement documents placed on characteristics of an item, process, or service.

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

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

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

**AMP - Administrative Management Procedure:** A USGS document that specifies methods to be used by the YMP-USGS to implement requirements of 1) the YMP Administrative Procedures, 2) the YMP Plans, 3) the YMPO directives, or 4) the USGS Branch of YMP policies, but which does not specify methods to be used to implement requirements of the YMP-USGS QAPP.

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

**AUDIT:** A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, codes, standards, instructions, drawings, and other applicable requirements, and the effectiveness implementation.

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

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

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

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

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

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

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

- 1) The item is not subject to design or specification requirements that are unique to Mined Geologic Disposal Systems;
- 2) The item is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description, i.e., catalog.
- 3) The item is used in applications other than Mined Geologic Disposal Systems.

**COMPUTER CODE:** A sequence of instructions suitable for processing by a computer (ANSI/IEEE Std 729-1983).

**COMPUTER MODEL VALIDATION:** Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (NUREG-0856). Usually accomplished by comparing model results to (1) physical data, or (2) a verified or validated model designed to perform the same type of analysis (e.g., benchmarking with a validated model). Peer review may be used for model validation if it is the only available means for validating a model.

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

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

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

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

| **CONSEQUENCE ANALYSIS:** A method by which the consequences of an event are calcu-  
| lated and expressed in some quantitative way, e.g., money loss, deaths, or quanti-  
| ties of radionuclides released to the accessible environment.

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

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

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

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

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

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

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

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

**DESIGN:** The act of developing designs for construction or of analyzing the performance of repository engineered structures, systems, components, and natural barriers. Design documentation includes, but is not limited to, drawings, specifications, test plans, design reports, test reports, system design descriptions,

configuration status listings, design manuals, and manuals describing computer programs used for design or performance analysis.

**DESIGN INPUT:** Those criteria, parameters, bases, or other 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 QA record until it satisfies the definition of a QA record as defined in this Appendix.

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

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

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

| **EXISTING DATA:** Data developed prior to the implementation of a 10CFR60, Subpart G  
| QA program by DOE and its contractors, or data developed outside the DOE repository program, such as by oil companies, national laboratories, universities, or  
| data published in technical or scientific publications. Existing data does not  
| include information which is accepted by the scientific and engineering community  
| as established facts (e.g., engineering handbooks, density tables, gravitational  
| laws, etc.).

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

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

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

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

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

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

**IMPORTANT TO WASTE ISOLATION:** The barriers that must meet the criteria that address long-term performance of the engineered and natural barriers to prevent the release of radionuclides from the site to the accessible environment (i.e. for achieving the postclosure performance objectives in 10CFR60 Subpart E).

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

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

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

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

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

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

**LIFETIME RECORDS:** QA records that furnish evidence of the quality and completeness of data, items, and activities affecting quality. All YMP 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 YMP. Hardware and geologic specimens include but are not limited to test apparatus or equipment, special nuclear material, cores, geologic samples, water and gas samples, etc.

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

**MODEL:** A representation of a process or system (NUREG-0856).

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

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

**NTS:** Nevada Test Site

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

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

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

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

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

**PARTICIPATING ORGANIZATION:** Government agencies external to the DOE, national laboratories, and other organizations which participate directly in YMP activities.

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

| **PEER REVIEW:** A documented, critical review performed by peers who are independent  
| of the work being reviewed. The peer's independence from the work being reviewed  
| means that the peer (a) was not involved as a participant, supervisor, technical  
| reviewer, or advisor in the work being performed, and (b) to the extent practical,  
| has sufficient freedom from funding considerations to assure the work is impar-  
| tially reviewed. A peer review is an in-depth critique of assumptions, calcula-  
| tions, extrapolations, alternate interpretations, methodology, and acceptance  
| criteria employed, and of conclusions drawn in the original work. Peer reviews  
| confirm the adequacy of work. In contrast to peer review, the term "technical  
| review" refers to a review to verify compliance to predetermined requirements;  
| industry standards; or common scientific, engineering, and industry practice.

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

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

| **PERFORMANCE ALLOCATION:** The process of deriving subsystem and component perfor-  
| mance goals from performance objectives. A systematic process of assigning  
| confidence levels with their desired, associated performance goals for the mined  
| geologic disposal systems, subsystems, and components.

| **PERFORMANCE ASSESSMENT:** The process of quantitatively evaluating component and  
| system behavior, relative to containment and isolation of radioactive waste, to  
| determine compliance with the numerical criteria associated with 10CFR60.

**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.

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

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

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

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

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

| **Q-LIST:** A list of geologic repository engineered structures, systems, and com-  
| ponents that have been determined to be important to safety, waste isolation, or  
| both, and a list of activities that will provide site characterization data which  
| will be used to assess the performance of natural barriers or activities whose  
| undertaking could adversely affect the performance of the natural barriers. The

| Items and activities on this list are subject to the highest quality assurance  
| level (QA Level I) of the formal QAPP.

| QMP - Quality Management Procedure: A USGS document that specifies the methods to  
| be used to implement the requirements of the YMP-USGS-QAPP.

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

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

| QUALIFIED DATA: Data initially collected under a 10CFR60, Subpart G quality  
| assurance program or existing data qualified in accordance with Appendix G of this  
| QAPP.

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

| QUALITY ACTIVITIES LIST: A list of those major activities conducted during site  
| characterization, construction, operation, or closure that relate to natural  
| barriers important to waste isolation. These activities, which must be covered  
| under the 10CFR60, Subpart G QA program, include data gathering, performance  
| assessments, and those activities that could affect a natural barrier's ability to  
| isolate waste.

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

QUALITY ASSURANCE 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, sys-  
tems, 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 non-radiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE and YMPO concerns, and the environment.

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

| **QUALITY ASSURANCE PROGRAM PLAN (QAPP):** The document that describes an organization's quality assurance program, the applicable QA requirements, and defines how compliance with QA criteria will be accomplished.

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

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

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

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

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

**REPOSITORY:** See Geologic Repository Operations Area.

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

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

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

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

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

| **SCIENTIFIC NOTEBOOK:** A document which may be used to provide a written record of  
| the results of scientific investigations and experiments when the work involves a  
| high degree of professional judgement or trial and error methods, or both.

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

**SITE:** 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 10CFR60. 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.

| **SOFTWARE:** Computer programs (codes), procedures, rules and possibly associated  
| documentation and data pertaining to the operation of a computer system (ANSI/IEEE  
| Std 729-1983).

**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 YMPO, to a participating organization, or to an NTS Support Contractor for YMP 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 YMP 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.

**VALIDATION (QA RECORDS):** The act of reviewing a document package to ensure it is complete, authenticated reproducibly, and microfilmable.

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

**WAIVER:** Documented authorization to depart from specified requirements.

**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.

**YMP PARTICIPANTS:** An all inclusive term used to describe (generically) the various organizations involved in the YMP. This term includes the YMPO, Participating Organizations, and NTS Support Contractors. These organizations are required to have a YMPO-approved QAPP for the conduct of their activities.

**YMP PERSONNEL:** All DOE Participating Organizations, and NTS Support Contractor personnel involved in YMP activities.

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

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

YUCCA MOUNTAIN PROJECT OFFICE (YMPO): The organization to which the DOE, Nevada Operations Office (DOE/NV), has assigned the responsibility of administering and coordinating the activities of various Participating Organizations and NTS Support Contractors associated with the YMP.

**QUALITY ASSURANCE PROGRAM PLAN**

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**APPENDIX B  
DESIGN INPUTS**

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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**

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

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Not Applicable - See Para. I.6

**QUALITY ASSURANCE PROGRAM PLAN**

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

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Not Applicable - See Para. 1.6

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**APPENDIX E  
LIST OF TYPICAL USGS QA RECORDS**

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The following is a list of typical QA records. The nomenclature of these may vary but some element of the item may apply. The YMP 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

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

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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 QA programs. Personnel selected for QA 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 YMP-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 YMP-USGS QAPP document, 10CFR60 Subpart G, and other nuclear and/or DOE related codes, standards, regulations, and regulatory guides, as applicable to the YMP.
- o General structure of QA programs and applicable elements as defined in the YMP-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: site characterization (scientific investigations), design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility.
- o On-the-job training to include applicable elements of the audit program.

1.2.3 Audit Participation: The prospective Lead Auditor shall have participated in a minimum of five QA 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 QA 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 Para. 1.2.2 of this Appendix. The test may be oral, written, practical, or any combination of the three types. If any portion of the examination is oral, written documentation of the oral questions/content shall be maintained. The development and administration of the examination shall be in accordance with Para. 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 QA 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 QA 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 YMP-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.

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APPENDIX G  
REQUIREMENTS FOR THE QUALIFICATION OF EXISTING DATA NOT GENERATED  
UNDER A QA PROGRAM MEETING THE REQUIREMENTS OF 10CFR60, SUBPART G

1.0 GENERAL

This Appendix provides the requirements for the qualification of existing data that will be needed to support a license application and which have not been initially generated under a QA program meeting the requirements of 10CFR60, Subpart G.

2.0 METHODS FOR QUALIFICATION OF EXISTING DATA

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

- a. Execution of the peer review process in accordance with the requirements of Appendix J of this QAPP.
- b. Use of corroborating data which is defined as existing data used to support or substantiate other existing data. Inferences drawn to corroborate the existing data shall be clearly identified, justified, and documented. The level and confidence associated with corroborating data is related to the quality of the program under which it was developed and the number of independent data sets. The amount of corroborating data needed shall be dealt with on a case-by-case basis in the documented reviews for qualification.
- c. Use of confirmatory testing which is defined as testing conducted under a 10CFR60, Subpart G QA program which investigates the properties of interest (e.g., physical, chemical, geologic mechanical) of an existing data base. One example of confirmatory testing is testing conducted under the same environmental conditions and with similar or the same procedures, test material, and equipment as the original test which generated the existing data. Another type of confirmatory testing is testing conducted by different test methods and equipment but which still investigates the same parameter of interest. The amount of confirmatory testing required shall be dealt with on a case-by-case basis in the documented reviews for qualification.
- d. Demonstrating that the existing data was collected under a QA program which is equivalent to a 10CFR60, Subpart G QA Program.

3.0 SELECTION AND DOCUMENTATION OF QUALIFICATION METHODOLOGY

3.1 When the methods indicated in Paras. 2.1b, 2.1c, and 2.1d are utilized to qualify existing data, a technical review shall be conducted to support the quality of the data. Additional confidence/credibility can be achieved when a combination of methods is used.

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

Attributes which shall be considered in the qualification process are:

- a. Qualifications of personnel or organizations generating the data are comparable to qualification requirements of personnel generating similar data under the approved 10CFR60, Subpart G QA program.
- b. The technical adequacy of equipment and procedures used to collect and analyze the data.
- c. The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).
- d. The environmental conditions under which the data were obtained if germane to the quality of data.
- e. The quality and reliability of the measurement control program under which the data were generated.
- f. The extent to which conditions under which the data were generated by partially meeting Subpart G.
- g. Prior uses of the data and associated verification processes.
- h. Prior peer or other professional reviews of the data and their results.
- i. Extent and reliability of the documentation associated with the data.
- j. Extent and quality of corroborating data or confirmatory testing results.
- k. The degree to which independent audits of the process that generated the data were conducted.
- l. The importance of the data to showing that the proposed repository design meets the performance objectives of 10CFR60, Subpart E.
- m. Replication of test results.

**Note:** Additional guidance related to this subject can be found in NUREG-1298 "Qualification of Existing Data for High-Level Nuclear Waste Repositories" (February, 1988).

QUALITY ASSURANCE PROGRAM PLAN

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APPENDIX H  
REQUIREMENTS FOR COMPUTER SOFTWARE USED TO SUPPORT  
THE YUCCA MOUNTAIN PROJECT

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1.0 OBJECTIVES

The purpose of this Appendix is to establish requirements for the development, management, control, and documentation of software used by the USGS to support QA Level I and II activities as part of the YMP. These requirements are intended to ensure software quality and to satisfy existing regulations and guidelines issued by the NRC.

This Appendix supplements Section 3 of this QAPP and shall be used in conjunction with that section as applicable.

2.0 APPLICABILITY

The requirements set forth in this Appendix apply to computer software used to produce or manipulate data that is used directly for site-characterization and performance-assessment QA Level I and II analyses. The USGS and USGS contractors involved in the development, acquisition, or maintenance of computer software shall establish written procedures that assure the requirements of this Appendix are implemented in a consistent and systematic manner. The extent to which these requirements apply shall be defined and described by a Software Quality Assurance Plan to be prepared by the USGS and is related to the nature, complexity, importance, and intended application of the software.

3.0 TERMS AND DEFINITIONS

Terms and definitions for YMP-USGS software are contained in Appendix A of this QAPP or, as specific to this Appendix, are defined below:

Defect: Condition adverse to quality; reference to any of the following: errors, failures, malfunctions, deficiencies, and nonconformances.

Functional Requirement: The capabilities, performance, design constraints, attributes (e.g., correctness, reliability, efficiency, etc.) and external interfaces of a software product.

Lifecycle: See Software Lifecycle.

Software Lifecycle: A set of discrete activities occurring in a given order during the development and use of software and software systems (ANSI/IEEE Std 729-1983).

Software Product: See Software (Appendix A).

#### 4.0 SOFTWARE QUALITY ASSURANCE PLAN

The USGS shall prepare a Software Quality Assurance Plan to describe the software development, acquisition, and applications undertaken by the USGS. Individual Software Quality Assurance Plan may be prepared for specific software products or may be prepared as a generic document to be applied to a set of software products controlled within the USGS. The Software Quality Assurance Plan shall identify the:

- o Responsibilities of the USGS for the management and control of software
- o Software products to which the Software Quality Assurance Plan applies
- o Criteria for meeting the requirements set forth in this Appendix to the applicable software
- o Software lifecycle model used
- o Software verification and validation methodologies
- o Software configuration-management system
- o Required documentation
- o Software documentation and testing review procedures
- o Defect reporting and corrective actions

The USGS shall describe the specific software lifecycle controls that are appropriate and applicable to software developed by, existing within, and acquired by the USGS. A generic lifecycle that presents the conceptual lifecycle management steps is described in Para. 4.1.

#### 4.1 SOFTWARE LIFECYCLE

The USGS shall adhere to a software lifecycle model that requires that software development, acquisition, and maintenance proceed in a traceable, organized, and structured manner. The relative emphasis placed on the phases of the software lifecycle depend on the nature, complexity, importance, and intended application of the software. All phases of the software lifecycle shall be performed under the same quality assurance level.

The following lifecycle elements shall apply as appropriate for the specific lifecycle model defined, interpreted, and described in the USGS Software Quality Assurance Plan.

**4.1.1 CONCEPTS EXPLORATION PHASE:** During this phase of the lifecycle development of software, the problem to be addressed by the software will be defined. For scientific and engineering software (SES), the physical concepts or hypotheses appropriate to the problem and its solution will be identified; the concepts and hypothesis will be formulated mathematically; analytic or numerical solution methodologies and algorithms will be derived, developed, or selected from existing, available techniques; and input-data and input-parameter needs will be

identified. For data-acquisition or data-processing software, the logic and methodologies pertaining to data storage manipulations, transfers, conversions, controls and database structures and management will be devised. The principal purpose of this phase will be to evaluate the feasibility that a well-defined set of lifecycle-based software requirements can be identified for the problem under investigation and that software can be designed to solve the problem based on these functional requirements. Documentation produced during this phase will support the software lifecycle requirements and design phases for developing SES and data-acquisition software for application to site-characterization and performance-assessment activities and tasks.

**4.1.2 LIFECYCLE REQUIREMENTS PHASE:** During this phase, functional requirements that pertain to the capabilities, performance, design constraints, attributes, and external interfaces of the completed software are specified, documented, and reviewed. These requirements include the following elements:

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

**4.1.3 LIFECYCLE SOFTWARE DESIGN PHASE:** During the lifecycle software design phase, a software design based on the functional requirements of the software is developed, documented, and systematically reviewed. The software design specifies the overall structure (control and data flow), and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). Detailed software design issues may necessitate the modification of the software functional requirements documentation.

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

- o Planning for software design-based test cases.
- o Review and analysis of the software design.
- o Verification of the software design.

**4.1.4 LIFECYCLE IMPLEMENTATION PHASE:** During this phase, the software design is translated into a programming language and the implemented software is debugged. The software design should be complete at this stage; consequently, only minor, if any, software design issues should require resolution during this phase.

Verification activities during this phase shall consist of:

- o Possible modification of test cases as a result of software design changes made during coding.

- o Examination of source code listings to assure adherence to coding standards and conventions.

**4.1.5 LIFECYCLE TESTING PHASE:** The testing phase consists of verifying that the software design has been properly implemented in a computer code and that the functional requirements are properly implemented in the software design. Software verification (Para. 5.1) will be essentially completed during this phase. The verification activities include:

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

**4.1.6 LIFECYCLE INSTALLATION AND CHECKOUT PHASE:** During this phase, the software may become part of a complex software system incorporating other software components, hardware, and production data. The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating databases, and verifying that all software components, modules, and units have been included and properly implemented.

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

**4.1.7 LIFECYCLE OPERATIONS AND MAINTENANCE PHASE:** During the operations and maintenance phase, the software has been approved and baselined for operational use. Maintenance activity shall consist of the identification and correction of latent errors (corrective maintenance), response to new or revised requirements (perfective maintenance), or adaptation of the software to changes in the software environment (adaptive maintenance). Software modifications shall be approved, documented, tested, and controlled in accordance with software configuration management requirements. All users of a corrected or modified software product shall be notified of the new software configuration.

## **5.0 SOFTWARE VERIFICATION AND MODEL VALIDATION**

Software verification and model validation activities will be performed as described in the USGS Software Quality Assurance Plan.

### **5.1 SOFTWARE VERIFICATION**

Verification activities by the USGS shall employ methods such as inspections, analyses, demonstrations, and tests to assure that the software adequately and correctly performs all intended functions and that the software does not perform any function that, either by itself or in combination with other functions, can degrade the entire system.

Verification activities shall be performed according to written procedures relative to specific hardware configurations. The extent of verification activity

shall be determined by the type and complexity of the software. The results of verification shall be documented in accordance with Para. 7.0 and reviewed in accordance with Para. 8.0 of this Appendix.

## 5.2 MODEL VALIDATION

Model validation activities shall be performed according to written procedures to demonstrate that physical and mathematical models embodied in computer software are adequate representations of the process or system for which they are intended. Model validation shall be accomplished by comparing software results against verified and traceable data obtained from laboratory experiments, field experiments or observations, or in-situ testing. Specific sets of data used in the validation process shall be identified, and the justification for use of these data shall be documented. When data are not available from the sources mentioned above, alternative approaches may be used and shall be documented. Alternative approaches, for example, may include peer review and comparing model results with the results of similar analyses performed with verified software. The results of model validation, including an evaluation of the degree of validity of the model, shall be documented according to Para. 7.0 and reviewed according to Para. 8.0 of this Appendix.

## 6.0 SOFTWARE CONFIGURATION MANAGEMENT

A software configuration management system shall be established to provide unique identification of software and to ensure adequate control of all software baseline changes.

### 6.1 CONFIGURATION IDENTIFICATION

Baselined software configuration items shall be identified for baselining at the appropriate phase of the software lifecycle. Software configuration items include the computer code and supporting documents. Approved changes to a baselined item shall be added to the baseline as updates. A baseline plus updates shall specify the most recent software configuration. A labeling system for configuration items shall be implemented that:

- o Uniquely identifies each software configuration item or version.
- o Identifies changes to software configuration items by using revision identifiers.
- o Facilitates placement of the software configuration item in a relationship with other configuration items.

### 6.2 CONFIGURATION CHANGE CONTROL

Changes to software configuration items shall be formally controlled and documented. This documentation shall contain a description of the change, the identification of the originating organization, the rationale for the change, and the identification of affected baselines and software configuration items. Assurance shall be provided that only authorized changes are made to software baselines and software configuration items as detailed in the YMP-USGS Software Quality

| Assurance Plan.

### 6.3 CONFIGURATION STATUS ACCOUNTING

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

### 7.0 DOCUMENTATION

Documentation is required as defined by the USGS Software Quality Assurance Plan. The following is acceptable documentation of computer software to be used for the YMP. Additional documentation also may be identified in the USGS Software Quality Assurance Plan.

#### 7.1 SOFTWARE LIFECYCLE DOCUMENTATION

The following describes appropriate software lifecycle documentation.

**7.1.1 SOFTWARE LIFECYCLE REQUIREMENTS SPECIFICATION:** Software lifecycle requirements documentation shall outline the functional requirements that the software must fulfill. A specific capability of software should be called a functional requirement only if its achievement can be verified by a prescribed method. The functional requirements shall address the following as are appropriate to the intended software application:

- o Functionality - the functions the software are to perform.
- o Performance - the time-related issues of software operation such as speed, recovery time, response time, etc.
- o Software design constraints imposed on implementation - any elements that will restrict software design options.
- o Attributes - non-time-related issues of software operation such as portability, correctness, security, maintainability, etc.
- o External Interfaces - interactions with other participants, hardware, and other software.

**7.1.2 SOFTWARE LIFECYCLE DESIGN DOCUMENTATION:** Software design documentation shall address the following as appropriate to the intended application of the software:

- o A description of the major components of the software design as they relate to the functional requirements specified by the software lifecycle requirements documentation.
- o A technical description of the software with respect to control flow, data flow, control logic, and data structure.

- o A description of the allowable and tolerable ranges for inputs and outputs.
- o The software design described in a manner that is easily traceable to the software functional requirements.
- o A preliminary description of planned software lifecycle testing and verification activities.

**7.1.3 SOFTWARE LIFECYCLE IMPLEMENTATION DOCUMENTATION:** Software implementation documentation shall address the following as applicable:

- o Source code listings.
- o Revised functional requirements documentation produced as a result of detailed software design considerations.
- o Revised software design documentation produced as a result of detailed design considerations.

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

**7.1.4 SOFTWARE LIFECYCLE TESTING DOCUMENTATION:** Lifecycle testing activities shall be documented. Software testing documentation should include a plan that describes the tasks and criteria for accomplishing the testing and verification of the software in this phase. The documentation also should specify the hardware and system software configuration(s) for which the software is designed. In those cases where testing is used to ensure that functional requirements are met in the software design, test documentation shall provide traceability from the functional requirements to the software design as implemented in the code. This documentation should also include a report on the results of the execution of the lifecycle testing and verification activities. This report should include the results of all reviews, audits and tests, and a summary of the status of the software.

## **7.2 MANDATORY DOCUMENTATION**

The following mandatory documentation (consistent with NUREG-0856) shall be provided to meet the requirements of Para. 3.3.2 of this QAPP, as applicable and appropriate:

- o Software Summary
- o Mathematical and Numerical Models
- o User's Manual
- o Code Assessment and Support
- o Continuing Documentation and Code Listings

## 8.0 REVIEWS

Documentation produced during software development, acquisition, implementation, testing, and use will be subject to appropriate reviews as described in the USGS Software Quality Assurance Plan.

### 8.1 SOFTWARE LIFECYCLE REVIEWS

Reviews of software lifecycle activities shall be performed for each lifecycle phase completed. The procedures used for reviews should identify the reviewers and their responsibilities.

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

The following reviews shall be performed as applicable:

**8.1.1 SOFTWARE LIFECYCLE REQUIREMENTS REVIEW:** The review of software requirements is performed upon completion of the software requirements documentation. This review shall assure that the functional requirements of the software are complete, verifiable and consistent. The review assures that there is sufficient detail available to facilitate definition of the software design or acquisition.

**8.1.2 SOFTWARE LIFECYCLE DESIGN REVIEW:** The software design review is performed upon completion of the software design documentation. This review evaluates the technical adequacy of the software design approach and assures that the software design satisfies all of the functional requirements specified in the software requirements documentation. The complexity of the software design may require the performance of multiple software design reviews.

**8.1.3 SOFTWARE LIFECYCLE IMPLEMENTATION REVIEW:** The software implementation review is an evaluation of the completed software lifecycle requirements, software design, and implementation processes.

**8.1.4 SOFTWARE LIFECYCLE TESTING REVIEW:** The software testing review is an evaluation of the adequacy of completed software lifecycle testing and verification activities.

### 8.2 MANDATORY REVIEWS

Mandatory documents (consistent with Para. 7.2 of this Appendix) shall be reviewed in accordance with review procedures to be established within the USGS Software Quality Assurance Plan.

The adequacy of verification activities and of model-validation activities shall be reviewed in accordance with procedures to be established within the USGS Software Quality Assurance Plan.

## 9.0 DEFECT REPORTING AND CORRECTIVE ACTION

Formal procedures shall be established by the USGS for reporting software defects and for taking appropriate corrective action. The defect reporting system shall be integrated within the configuration management system to assure formal acknowledgement or resolution of defects.

Software defect procedures shall assure that, as a minimum:

- o Defects are documented and evaluated for possible corrective action.
- o Defects are assessed for impact on previous applications.
- o Corrections are reviewed and approved before changes to software configuration items are entered into baselines.
- o All preventive and corrective actions taken shall provide for appropriate notification of organizations to which controlled copies of the software have been distributed.

## 10.0 MEDIA CONTROL AND SECURITY

Physical media on which software is stored shall be physically protected to prevent their inadvertent damage, degradation, or loss.

## 11.0 SOFTWARE ACQUISITION, PROCUREMENT, AND TRANSFER

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

Requests by the USGS for the acquisition or procurement of software shall include appropriate criteria to enable the software received to comply, to the extent possible, with the requirements of this QAPP. Any requirements not satisfied by the acquired software, shall be completed by the USGS by entering the acquired software into the appropriate phase of the applicable software lifecycle. Any software acquisition that cannot meet the requirements of this QAPP will be justified and documented prior to distribution among the users of this software within the USGS.

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

## 12.0 SOFTWARE APPLICATIONS

The USGS shall establish procedures for controlling the application of software that perform technical calculations in support of site-characterization and performance-assessment analyses. These software applications shall be reviewed and approved to assure that the software selected is applicable to the problem being solved and that all input data and assumptions are valid and traceable.

The USGS shall establish procedures for documenting software applications that perform technical calculations to ensure that these applications and the results of these applications can be independently reproduced.

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

QUALITY ASSURANCE PROGRAM PLAN

APPENDIX I  
REQUIREMENTS FOR THE IDENTIFICATION OF ITEMS  
AND ACTIVITIES TO QUALITY ASSURANCE REQUIREMENTS

1.0 GENERAL

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

2.0 QUALITY ASSURANCE CRITERIA FOR LICENSING

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

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

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

2.2 CRITERIA FOR NON-Q-LIST ITEMS

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

II requirements shall be applied. Additional guidance related to this subject can be found in NUREG-1318, (April, 1988), paragraph 5.1(b).

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

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

### 3.0 IDENTIFICATION OF ITEMS IMPORTANT TO SAFETY

This section concerning items important to safety has been excluded from this QAPP because the YMP-USGS does not include these items.

### 4.0 IDENTIFICATION OF ITEMS AND ACTIVITIES IMPORTANT TO WASTE ISOLATION

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

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

The items and activities important to waste isolation shall include:

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

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

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

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

#### 5.0 SUBMITTAL REQUIREMENTS

Because this section concerns the license application and site characterization plans, neither of which is the responsibility of the USGS, its contents as provided in YMP/88-9, are excluded from this QAPP.

#### 6.0 GRADED APPLICATION OF QA MEASURES

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

- o The impact of malfunction or failure of the item, or the impact of erroneous data associated with data collection activities, on safety or waste isolation.
- o The complexity of design or fabrication of an item, or design and implementation of a test, or the uniqueness of an item of test.
- o The special controls and surveillance needed over processes, tests, and equipment.

- o The degree to which functional compliance can be demonstrated by inspection or test.
- o The quality history and degree of standardization of the item or test.

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

QUALITY ASSURANCE PROGRAM PLAN

APPENDIX J  
REQUIREMENTS FOR PEER REVIEW

1.0 GENERAL

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

2.0 APPLICABILITY OF PEER REVIEW

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

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

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

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

3.0 STRUCTURE OF PEER REVIEW GROUP

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

- a. The complexity of the work to be reviewed.
- b. Its importance to establishing that safety or waste isolation performance goals are met.
- c. The number of technical disciplines involved.
- d. The degree to which uncertainties in the data or technical approach exist.
- e. The extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.

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

#### 4.0 ACCEPTABILITY OF PEERS

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

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

#### 5.0 PEER REVIEW PROCESS

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

5.2 The peer review group shall evaluate and report on:

- a. Validity of assumption.
- b. Alternate interpretations.
- c. Uncertainty of results and consequences if incorrect.

- d. Appropriateness and limitations of methodology and procedures.
- e. Adequacy of application.
- f. Accuracy of calculations.
- g. Adequacy of requirements and criteria.
- h. Validity of conclusions.

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

#### 6.0 PEER REVIEW REPORT

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

- a. A clear description of the work or issue that was peer reviewed.
- b. Conclusions reached by the peer review process.
- c. Individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate.
- d. Listing of the peers and the technical qualification and evidence of independence for each peer, including potential technical and/or organizational partiality.

Note: Additional guidance related to this subject can be found in NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories" (February, 1988).

**QUALITY ASSURANCE PROGRAM PLAN**

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**APPENDIX K  
FORMAT AND CONTENT REQUIREMENTS FOR SCP STUDY PLANS**

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**1.0 PURPOSE AND OBJECTIVES OF STUDIES:**

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

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

**2.0 RATIONALE FOR SELECTED STUDY:**

**2.1 Provide the rationale and justification for the selected tests and analyses (including standard tests). Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitations of the various options; and**

**2.2 Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). This rationale should also identify reasonable alternatives; summarize reasons for not selecting these alternatives, and reference if available, reports which evaluate alternatives considered.**

**2.3 Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. Factors to be considered include:**

- a) Potential impacts on the site from testing;**
- b) Whether the study needs to simulate repository conditions;**
- c) Required accuracy and precision of parameters to be measured with test instrumentation;**
- d) Limits of analytical methods that will use the information from the tests;**
- e) Capability of analytical methods to support the study;**
- f) Time required versus time available to complete the study;**

- g) The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field;
- h) Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and
- i) Interrelationships involving significant interference among tests and ESF design and construction, as appropriate (refer to Section 8.4 of the SCP or its references for specific ESF design information).

### 3.0 DESCRIPTION OF TESTS AND ANALYSES:

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

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

- h) Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests, and
- i) Relationship of the test to the set performance goals and confidence levels.

### 3.2 For each type of analysis:

- a) State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;
- b) Describe the methods of analysis including any analytical expressions and numerical models that will be employed;
- c) Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of QA that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA level I. Reference the applicable QA requirements.
- d) Identify the data input requirements of the analysis;
- e) Describe the expected output and accuracy of this analysis; and
- f) Describe the representativeness of the analytical approach (e.g., with respect to spatial variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.

### 4.0 APPLICATION OF RESULTS:

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

4.2 For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) that will use the information produced from the studies described above, and refer to any use of the results for model validation;

4.3 For design uses, refer to, or describe, where the information from the study described above will be used in construction equipment design and development, and engineering system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals); and

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

5.0 SCHEDULE AND MILESTONES:

5.1 Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities;

5.2 Describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study; and

5.3 Dates for activities or milestones including durations and interrelationships, for the study plans will be provided. These should reference the master schedules provided in Section 8.5 of the SCP.

NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT NRC REQUIREMENTS MATRIX

N-QA-059  
10/80

PREPARED BY STEVEN P. NOLAN

PARTICIPANT CONTRACTOR United States Geological Survey

REQUIREMENT

WHERE LOCATED IN REV. 5  
OF PARTICIPANT QAPP

COMMENTS

I. ORGANIZATION

The organization elements responsible for the QA program are acceptable to the NRC staff if:

- |  |                           |
|--|---------------------------|
| <p>1. The responsibility for the overall program is retained and exercised by the DOE at a level which is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization shall verify the proper performance of work through implementation of appropriate QA controls.</p> | <p>1.1</p>                |
| <p>2. DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.</p>  | <p>1.1</p>                |
| <p>3. DOE describes how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOE headquarters and from the field office should be addressed.</p>   | <p>NA</p>                 |
| <p>4. DOE evaluates the performance of work delegated to other organizations. This shall include audits of the prime contractor's QA program and audits of the representative subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.</p>  | <p>1.2, 2.3.2</p>         |
| <p>5. Qualified individual(s) or organization elements are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities.</p>  | <p>1.1</p>                |
| <p>6. Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors, to assure direction of the QA program.</p>   | <p>1.1</p>                |
| <p>7. Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program and the lines of responsibility</p>  | <p>Fig 1 Introduction</p> |

NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS PROJECT NRC REQUIREMENTS MATRIX

14-0A-059  
10/88

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REQUIREMENT	WHERE LOCATED IN REV. <u>5</u> OF PARTICIPANT QAPP	COMMENTS
<p>8. The QA organization is involved in the aspects of the high level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation as defined in 10 CFR Part 60.2.</p>	<p>1.2</p>	
<p>9. DOE and its prime contractor describe the QA responsibilities of each of the organizational elements noted on the organization charts.</p>	<p>1.1, 1.2, 1.2.3, 1.4</p>	
<p>10. DOE and its prime contractor identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience has the following characteristics:</p> <ul style="list-style-type: none"> <li>a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.</li> <li>b. Has effective communication channels with other senior management positions.</li> <li>c. Has responsibility for approval of QA manuals, changes thereto, and interpretations thereof.</li> <li>d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters.</li> </ul>	<p>1.2.1, 1.2</p>	
<p>11. Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization. Certain exceptions for design (item 3.7) inspections (item 10.2) and test data evaluation (item 11.3) are outlined in these sections.</p>	<p>1.2.1</p>	
<p>12. Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:</p>	<p>1.2.3</p>	

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REQUIREMENT	WHERE LOCATED IN REV. <u>5</u> OF PARTICIPANT QAPP	COMMENTS
<p>a. Identify quality problems.                      b. Initiate, recommend, or provide solutions through designated channels.                      c. Verify implementation of solutions.                      d. Stop unsatisfactory work.</p> <p>The persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.</p>		
<p>13. Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.</p>	1.2, 1.2.2.	
<p>14. Policies regarding the implementation of the QA program are documented and made mandatory.</p>	1.3	
<p>15. The persons responsible for directing and managing the overall QA program are identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. These individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented.</p>	1.2.1	

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14-0A-059  
10/88

PREPARED BY STEVEN P. ABLAN

PARTICIPANT CONTRACTOR United States Geological Survey

REQUIREMENT

WHERE LOCATED IN REV. 5  
OF PARTICIPANT OAPP

COMMENTS

II. QUALITY ASSURANCE PROGRAM

Activities related to the QA program are acceptable to the NRC staff if:

1. The QA program includes all items and activities important to safety and waste isolation as defined in 10 CFR 60.2. The items and activities covered by the QA program are identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR 60.2. These terms are defined as numerical performance objectives and standards. The rationale should include systems analyses that are used to determine what specific items and activities are covered.

2.1.1

2. The QA program includes a commitment that all development, control and/or use of computer programs will be conducted in accordance with the QA program. Requirements for the content of documentation of computer codes is provided by NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."

2.1  
See Section 3

3. Provisions are established to assure that technical and QA procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document consistent with QA program requirements and are properly documented and signed by a responsible official.

2.1

4. The QA organization reviews and documents concurrence with the quality-related procedures relative to QA requirements.

2.1.3

5. The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific items and activities.

2.1

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REQUIREMENT	WHERE LOCATED IN REV. <u>5</u> OF PARTICIPANT QAPP	COMMENTS
<p>This effort involves applying a defined graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR 60.2 and affects such disciplines as design, data analysis (such as performance assessment), procurement, document control, inspections, tests, special processes, records, audits, and other described in 10 CFR 50, Appendix B.</p>		
<p>6. Existing or proposed QA procedures and detailed technical procedures are identified and documented reflecting that each criterion of 10 CFR 50, Appendix B, appropriate to specific items and activities, will be met.</p>	<p>2.1.1, 2.1.2</p>	
<p>7. A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR 50, Appendix B. These measures should include:</p> <ul style="list-style-type: none"> <li>A. Frequent contact with program status through reports, meetings, and/ or audits.</li> <li>B. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.</li> </ul>	<p>2.4.1, 2.4.2</p>	
<p>8. Indoctrination, training, and qualification programs are established such that:</p> <ul style="list-style-type: none"> <li>a. Personnel responsible for performing quality-related activities are instructed to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.</li> <li>b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.</li> <li>c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.</li> </ul>	<p>2.5.3, 2.5.4 2.5.5, 2.5.6</p> <p style="text-align: center;">↓</p>	

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REQUIREMENT	WHERE LOCATED IN REV. <u>5</u> OF PARTICIPANT QAPP	COMMENTS
<p>d. Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retaining and/or replacement. A system of annual appraisal and evaluation can satisfy this criterion.</p>	<p>2.5.5</p>	
<p>e. Qualified personnel are certified in accordance with applicable codes and standards.</p>	<p>2.5</p>	<p>↓</p>

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III. DESIGN CONTROL

Activities related to design control are acceptable to the NRC staff if:

1. The definitions of design, design information, and design activities used in the design control program are as defined in this section. The term design refers to specifications, drawings, design criteria, and components performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed 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) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR 60 and the Atomic Energy Act of 1954.
2. The design control program is implemented at the time of submission of the Site Characterization Plan and includes design and design activities: It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents. Performance requirements are specified for repository system components to support: (a) identification of which items are important to waste isolation; (b) establishment of a graded QA approach; and (c) establishment of data gathering and analysis needs.
3. Organizational responsibilities are described for preparing, reviewing, approving, verifying, and validating design and design information documents.
4. Errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected.

SECTION III  
PARA 3.2  
" 3.2.1.1

SECTION II

PARA 3.2.1.1  
" 3.1.3.2  
PARA 3.2.1.1  
" 3.1.13

PARA 2.1.6  
2.1.7  
2.2.1  
2.2.2  
2.2.3  
2.2.4  
2.2.5 et al..

NOTE:  
Per the YMP-USGS-QAPP-DI, REV. 5 page 4/68, the USGS performs no hardware design functions AND HAS NO RESPONSIBILITY FOR REPOSITORY DESIGN, and are not a part of the USGS-QAPP.

PARA 3.1.13

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	<u>Section III</u>	
5. Interface controls among organizations or groups involved in design development and other design activities are described.	DARA 3.2.1.3 " 3.1.9	
6. Procedures require that design drawings, specifications, criteria, and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.	PARA 3.2.1.1	
7. Procedures are established and described for verification of designs and design activities, the verifier of which is qualified and not directly responsible for the design (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification provided:	PARA 3.1.13 " 3.1.10.3 " 3.1.4	
a. The supervisor is the only technically qualified individual.	PARA 3.1.10.3 " 3.1.4	
b. The need is individually documented and approved in advance with concurrence of the quality assurance manager.		
It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities.	PARA 3.1.10.3	
8. For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required.	PARA 3.1.4.3 " 3.4	

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<p>9. The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in the procedures.</p>	<p><u>SECTION III</u> PARA 3.1.7</p>	
<p>10. Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system should be in place at the earliest practicable time. These changes should be analyzed to assure that change is required. Associated changes to procedures and training should be considered, and changes should be communicated to all affected groups or individuals.</p>	<p>PARA 3.1.8 2.2.1.2</p>	

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IV. PROCUREMENT DOCUMENT CONTROL

Activities related to procurement document control are acceptable to the NRC staff if:

SECTION 4

1. Procedures are established for the review of procurement documents by QA personnel to determine that applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. Procurement documents should require contractors, subcontractors and consultants to provide an acceptable quality assurance program.
2. Organizational responsibilities are described for: (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations, and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

PARA 4.1  
" 4.3.2  
" 4.3.3

PARA 4.4 / 4.1  
" 7.1.1  
" 7.1  
" 7.1.2  
" 7.1.3  
" 7.1.4

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V. INSTRUCTIONS, PROCEDURES, AND DRAWINGS		
<p>Activities related to instructions, procedures, and drawings are acceptable to the NRC staff if:</p>	<p><u>SECTION 5</u></p>	
<p>1. Organizational responsibilities are described for assuring that quality related activities are (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents. These documents should be verified and approved as described under verification in Section III of this document.</p>	<p>PARA 5.2/S.1</p>	
<p>2. Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality related activities have been satisfactorily accomplished.</p>	<p>PARA 5.1</p>	

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VI. DOCUMENT CONTROL		
<p>Activities related to document control are acceptable to the NRC staff if:</p>		
1. The scope of the document control program is described, and the types of controlled documents are identified.	<u>SECTION 6</u>  <u>PARA 6.1.1</u>	
2. Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these documents with respect to quality related aspects.	6.1.1 6.1.2	
3. Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.	6.1.2	
4. Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner.	6.1.2	
5. A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.	6.1.2	
6. When documents which require verification are released prior to verification, they are so identified and controlled.	6.3	

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VII. CONTROL OF PURCHASED ITEMS AND SERVICES		
<p>Activities related to control of purchased materials, equipment, and services are acceptable to the NRC staff if:</p>	<p><u>SECTION III</u></p>	
<p>1. Organizational responsibilities are described for the control of purchased material, equipment, and services.</p>	<p>PARA 7.1.1</p>	
<p>2. Procedures governing procurement of items and services, including appropriate QA organization participation, provide for (a) evaluation and selection of supplier's; (b) verification of supplier's activities; and (c) receiving inspections.</p>	<p>PARA 7.1.1</p>	
<p>3. The organization providing materials, equipment, or services furnishes the following records to the purchaser:</p>	<p>PARA 7.1.4.1</p>	
<p>a. Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met.</p>	<p>↓</p>	
<p>b. Documentation identifying any procurement requirements that have not been met.</p>		
<p>c. A description of these nonconformances from the procurement requirements dispositioned "accept as is" or repair."</p>	<p>PARA 7.1.8.2</p>	
<p>The procedure for review and acceptance of these documents should be described in the purchaser's QA program.</p>	<p>7.1.4.1 / 7.1.8.2</p>	
<p>4. Supplier certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.</p>	<p>PARA 7.1.6.1</p>	

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<p>5. In developing quality assurance requirements for data collection test equipment and other equipment, consideration should be given to whether proper performance of a test can be determined during or after testing (i.e., whether failure or malfunction of test equipment can be detected). Where no specific QA controls are found to be necessary, special quality/performance verification requirements shall be established and described in procedures governing the use of the equipment.</p>	<p><u>SECTION 8</u> <u>PARA 8.4</u></p> <p><u>SECTION 12</u> <u>12.2.3</u></p>	

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VIII. IDENTIFICATION AND CONTROL OF ITEMS

Activities related to sample identification and control are acceptable to the NRC staff if:

1. Controls are established and described to identify and control samples. The description should include organizational responsibilities.
2. Procedures are established which assure that identification is maintained either on the samples or their containers, or on records traceable thereto.
3. Identification of samples can be traced to the appropriate documentation such as drawings, specifications, purchase orders, drilling logs, test records, inspection documents, and nonconformance reports.
4. Correct identification of samples is verified and documented prior to release for use or analysis.

SECTION 8

PARA 8.3

PARA 8.3.1

PARA 8.3.1

PARA 8.3.1

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IX. CONTROL OF PROCESSES		
<p>Activities related to control of special processes are acceptable to the NRC staff if:</p>		<p><i>USES TABLE EXCEPTION, SEE PAGE 62 OF 62 ; I.6.2</i></p> 
<p>1. The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, is provided.</p>		
<p>2. Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.</p>		
<p>3. Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to help assure they are satisfactorily performed.</p>		
<p>4. Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.</p>		
<p>5. Qualification records of procedures, equipment, and personnel associated with special processes are established and maintained.</p>		

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X. INSPECTION

Activities

1. The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions.
2. Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained.
3. A qualification program for inspectors is established and documented, and the qualifications and certifications of inspectors are kept current.
4. Inspection procedures, instructions, or checklists provide for the following:
  - a. Identification of characteristics and activities to be inspected.
  - b. A description of the method of inspection.
  - c. Identification of the individuals or groups responsible for performing the inspection operation.
  - d. Acceptance and rejection criteria.
  - e. Identification of required procedures, drawings, and specifications and revisions.
  - f. Recording inspector or data recorder and the results of the inspection operation.

USGS TAKES EXCEPTION, SEE  
PAGE 6 OF 68, I.63



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<p>g. Specifying necessary measuring and test equipment including accuracy requirements.</p> <p>5. Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.</p> <p>6. Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.</p>		<p><i>USGS TAKES EXCEPTION, SEE PAGE 6 of 68, I.6.3</i></p>

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XI. TEST CONTROL

Activities related to test control are acceptable to the NRC staff if:

1. The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for: (a) determining when a test is required or how and when testing activities are performed, and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.
2. Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.7, 3.8, and 3.9.
3. The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified.
4. Test procedures or instructions provide the following:
  - a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy.
  - b. Instruction for performing the test.
  - c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.
  - d. Mandatory inspection hold points (as required).
  - e. Acceptance and rejection criteria, including required levels of precision and accuracy.

*USGS THIS EXCEPTION SEE  
PAGE 6 OF GR, PARA 2.6.4*



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<p>f. Methods of data analysis.</p> <p>g. Methods of documenting or recording test data and results. only required for</p> <p>h. Provisions for assuring test prerequisites have been met.</p> <p>5. Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3.</p>		<p><i>USGS TAKES EXCEPTION. SEE PAGE 6 OF GR; PARA I.6.4</i></p> 

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XII. CONTROL OF MEASURING AND TEST EQUIPMENT		
Activities related to control of measuring and test equipment are acceptable to the NRC staff if:		
1. The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established.	<u>SECTION 12</u> PARA 12.1	
2. QA and other organization's responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.	PARA 12.1	
3. Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.	PARA 12.2.1 12.2.2 12.2.5	
4. Measuring and test equipment is labeled, tagged, or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data.	PARA 12.2.3	
5. Measuring and test equipment is calibrated at specified intervals based on required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions which could affect measurement.	PARA 12.2.3	
6. Calibration standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document acceptability of the calibration standard used.	PARA 12.2.2	
7. When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.	PARA 12.2.3	

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XIII. HANDLING, STORAGE, AND SHIPPING

Activities related to sample handling, storage, and shipping are acceptable to the NRC staff if:

1. Sampling, handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.
2. Procedures are established and described to control sample handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

SECTION 8  
PARA 8.5 et al.

SECTION 8  
PARA 8.3.1  
8.3.2  
8.3.4B

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XIV. INSPECTION, TEST, AND OPERATING STATUS

Activities related to inspection, test, and operating status are acceptable to the NRC staff if:

1. Procedures are established to indicate by the use of markings the status of inspections and tests on individual items.

*USGS DOES EXCEPTION TO THIS AS IT APPLIES TO ENGINEERED SYSTEMS. See page 6 of 68, Part I.6.6.*

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XV. CONTROL OF NONCONFORMING ITEMS		
Activities related to nonconformances are acceptable to the NRC staff if:		
1. Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities. Procedures identify individuals authorized to dispose of and close out nonconformances	SECTION 15 PARA 15.1, 15.2 15.1.4.1	
2. QA responsibilities related to nonconformance control are described.	SECTION 15 PARA 15.1.4.1	
3. Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition.	SECTION 15 PARA 15.1.4.2	states that responsibilities and authority to be defined and documented in an implementing procedure.
4. Nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances, and the significant results are reported to upper management for review and assessment.	SECTION 15 PARA 15.4.	

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XVI. CORRECTION ACTION		
Activities related to corrective action are acceptable to the NRC staff if:		
1. Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.	<i>Section 16 Para 16.1 Section 2 Para 2.2.2</i>	
2. Corrective action is documented and initiated following a nonconformance to preclude recurrence. The QA organization is involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied.	<i>Section 16 Para 16.1.2 Para 16.1.1</i>	
3. Follow-up action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.	<i>Section 16 Para 16.1.2</i>	
4. Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.	<i>Section 16 Para 16.1</i>	

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XVII. QUALITY ASSURANCE RECORDS		
Activities related to QA records are acceptable to the NRC staff if:		
1. The scope of the records program is described. QA records include geotechnical samples and data; results of reviews; inspection; tests; audits and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, design review reports; peer review reports; nonconformance reports; and corrective action reports.	SECTION 17 PARA 17.1	
2. QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.		
3. Inspection and test records contain the following where applicable:		→ PAGE 6 OF 62 OF THE USGS-QAPP-01, REV. 5, SECTION 2.6 HAS THREE EXCEPTION TO THESE CRITERIA AS THEY ARE NOT APPLICABLE TO THEIR SCOPE OF WORK
a. A description of the type of observation. b. The date and results of the inspection or test. c. Information related to conditions adverse to quality. d. Inspector or data recorder identification. e. Evidence as to the acceptability of the results. f. Action taken to resolve any discrepancies noted.		
4. Suitable facilities for the storage of records are described and utilized.	SECTION 17 PARA 17.4; 17.4.1; 17.4.1.1; 17.4.1.2; 17.4.1.3	

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<b>XVIII. AUDITS</b>		
Activities related to audits are acceptable to the NRC staff if:		
1. Internal and external audits to assure that procedures and activities comply with the overall QA program are performed by DOE and its contractors. DOE should perform audits of the prime contractor and representative subcontractors, consultants, vendors, and laboratories to assess the effectiveness of the prime contractor's audit program.	SECTION 18 PARA 18.1; 18.2	
2. An audit plan is prepared identifying audits, their frequencies, and schedules. Audits are regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA.	SECTION 18 PARA 18.1; 18.1.2; 18.1.2;	
3. Audits include an objective evaluation of the quality-related practices, procedures, instructions, activities, and items and the review of documents and records to ensure that the QA program is effective and properly implemented.	SECTION 18 PARA 18.1; 18.1.4;	
4. Audit data are analyzed by the QA organization and the results are reported to responsible management for review, assessment, and appropriate action.	SECTION 18 PARA 18.1; 18.1.6	
5. Audits are performed in accordance with preestablished written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.	SECTION 18 PARA 18.1; 18.1.2; 18.1.4;	
6. A tracking system for audit findings is established to help assure that all findings are appropriately addressed and to trend audit findings.	SECTION 18 PARA 18.1; 18.1.7	
7. The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and/or responsible management.	SECTION 18 PARA 18.1; 18.1.6	
8. In the resolution of findings, the root cause of each finding is also identified and corrective action for it described.	SECTION 18 PARA 18.1.6	

**QA COMPLIANCE REVIEW CHECKLIST**

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 Organization USGS QA Document's Title, No., Revision YMP-USGS-QAPP-01, R 5, Draft 4  
 Date Received 12-16-88 *Ymp- 1.9.89* Reviewed By SAIC-GOLDEN *Ymp-9A Stammf. Nels* Date Review Completed 12-28-88  
 Review Comments:  Yes  No Date Comments Returned to Org 12-30-88 Comments Resolved By \_\_\_\_\_

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

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<p>implementation of the solutions; and to assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. (9) This includes the ability to stop (or cause to be stopped) unsatisfactory work through established channels. (10) Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected and shall report to a management level at which this required authority and organizational freedom are provided, including sufficient independence from cost and schedule.</p> <p>2.1 DEDICATED QA POSITIONS</p> <p>(11) The person responsible for directing and managing the overall NNWSI Project Participant QA program shall be identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. (12) This person shall have appropriate management and QA knowledge and experience and shall be at the same or higher organization level as the highest line manager responsible for performing activities affecting quality and sufficiently independent from cost and schedule.</p> <p>(13) Personnel in this position shall have responsibility for approval of (1) QAPPs, changes thereto, and interpretations thereof and (2) implementing procedures and all changes thereto. (14) This position shall have effective communication channels with other senior management positions. (15) Personnel in this position shall have the responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA program implementation by that organization and its subordinate organizations. (16) Full-time dedicated QA positions are to be established by the Waste Management Project Office (WMPO), Participating Organizations, and the Nevada Test Site (NTS)</p>	9 ✓	1.2					
	10 ✓	1.2					
	11 ✓	1.2.1					
	12 ✓	1.2.1					
	13 ✓	1.2.1					
	14 ✓	1.2.1					
	15 ✓	1.2.1					
	16 ✓	1.2.1					

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<p>Support Contractors. (17)The management position that retains overall authority and responsibility for the QA Programs as well as personnel considered to be "full-time dedicated" shall not be assigned duties that would prevent full attention to NWSI Project QA responsibilities or that would conflict with the reporting and resolution of QA issues and problems related to the NWSI Project.</p>	17 ✓	1.2.1						
<b>2.2 AUTHORITY</b>								
(18)Authority for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and others shall be identified.	18 ✓	1.2.2						
(19)This authority shall include the ability of QA personnel to elevate the resolution of disputes to progressively higher organization levels through established channels including the WFO PDM, if the dispute cannot be resolved within the organization.	19 ✓	1.2.2						
<b>2.3 ORGANIZATIONAL STRUCTURE</b>								
(20)Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations at which the activities are to be performed, the organizational structure for executing the QA program may take various forms provided that the persons and organizations assigned the QA functions have the required authority and organizational freedom.	20 ✓	1.2.3						
(21)The QA responsibilities of all organizational elements depicted on organization charts shall be described.	21 ✓	1.2.3						

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<b>3.0 QUALITY ASSURANCE PROGRAM PLAN</b>								
(22)A Quality Assurance Program Plan (QAPP) shall apply to all items and activities of an organization affecting quality. (23)The organizational structure and the responsibility of assignments shall be clearly established such that certain results, as described below, are obtained.	22 ✓	1.3						
	23 ✓	1.3						
<b>3.1 ACHIEVEMENT AND MAINTENANCE OF QUALITY</b>								
(24)Quality is achieved and maintained by those who have been assigned responsibility for performing work.	24 ✓	1.3.						
<b>3.2 VERIFICATION</b>								
(25)Quality achievement is verified by persons or organizations not directly responsible for performing the work. (26)Verification of conformance to established requirements (acceptance) is accomplished by individuals or groups within the QA organization unless specifically exempted elsewhere in this document.	25 ✓	1.3.2						
	26 ✓	1.3.2						
<b>4.0 MULTIPLE ORGANIZATIONS</b>								
(27)If more than one organization is involved in the execution of activities affecting quality, then the responsibility and authority of each organization shall be established clearly and documented.	27 ✓	1.4						

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<b>4.1 DOCUMENTATION OF INTERFACES</b>								
<p>(28)The external interfaces between organizations and the internal interfaces between organizational units and changes thereto shall be documented. (29)All interface responsibilities shall be defined and documented. (30)Interfaces between the WFO, the Participating Organizations, and the NTS Support Contractors shall be described in the OAPs of the respective organizations. (31)From an overall NWWSI Project standpoint, these interfaces are exchanges of technical requirements of work to be performed and liaison until completion of work. (32)The NWWSI Project Administrative Procedures (APs) provide the implementing interface controls utilized by all of the NWWSI Project participants while Participating Organization and NTS Support Contractor implementing procedures describe the methods of conducting inter-organizational interfaces.</p> <p>(33)The organizational structure for executing the QA programs varies from organization to organization, and each one shall be described in the individual organization's OAP. (34)The Technical Project Officer of the respective Participating Organizations and the respective NTS Support Contractors are responsible to the WFO Project Manager to ensure that the Project activities for which they are responsible are performed to a OAP and implementing procedures that are consistent with this OAP.</p>	28 ✓	1.4						
	29 ✓	1.4						
	30 ✓	1.4						
	31 ✓	1.4						
	32 ✓	1.4						
	33 ✓	1.4						
	34 ✓	1.4						

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SECTION II								
QUALITY ASSURANCE PROGRAM								
1.0 EXTENT OF THE QUALITY ASSURANCE PROGRAM								
<p>(1)The Quality Assurance (QA) Program for the NWSI Project consists of the NWSI Quality Assurance Plan (QAP), the QA Program Plans of the Waste Management Project Office (WPO), the Participating Organizations, and the Nevada Test Site (NTS) Support Contractors, and the QA and technical procedures required to implement these documents. (2)The NWSI Project Office will submit this QAP and the WPO QAPP to the OCSRM Director, Office of Quality Assurance for approval. (3)Pending receipt of this approval, QA plans may be issued by WPO for interim use. (4)When any QA plan is issued for interim use, the transmittal record shall be appropriately marked to indicate that it is for interim use. (5)Final QA plans will include a signature block for approval by the Director, Office of Quality Assurance.</p> <p>(6)Each NWSI Project Participant shall develop a Quality Assurance Program Plan which shall provide the description of the organization's QA program and indicate the commitment to the applicable NWSI Project QA requirements given herein. (7)Each Quality Assurance Program Plan (QAPP) shall include consideration of the technical aspects of the activities affecting quality and shall be generated by the respective QA organization with assistance from the technical staff. (8)The QAPP shall provide instruction to implement and apply the QA requirements to the technical activities of the NWSI Project. (9)It shall be planned, implemented, and maintained in accordance with this document and be consistent with and address all of the applicable requirements of this NWSI QA Plan. (10)Management above or outside of the QA organization</p>	1	2.1						
	2	2.1						
	3	NA						
	4	2.1						
	5	2.1						
	6	2.1						
	7	2.1						
	8	2.1						
	9	2.1						
	10	2.1						

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<p>shall regularly receive information as to the scope, status, adequacy, compliance, etc. of the QA Program. (11)Management shall perform readiness reviews, as deemed appropriate. (12)Readiness reviews shall apply to major scheduled/planned activities which could effect quality. (13)Readiness reviews shall be used in verifying that specified prerequisites and programmatic requirements have been identified prior to starting a major activity.</p> <p>(14)The hierarchy of criteria applicable to the Project are shown in Figure 1 of the Introduction of this document. (15)With the exception of the CFR, where deviations between the requirements of the higher-tier documents referenced in that Figure and this QAP exist, the requirements of this document shall prevail.</p> <p align="center"><b>1.1 QA CRITERIA</b></p> <p>(16)The QA Criteria and specific requirements associated with these criteria have been adapted to the NWWSI Project activities through this QA plan and shall be addressed in the QAPPs of the NWPO, the Participating Organizations, and NTS Support Contractors. (17)When a specific criteria is not applicable to an organization's activities, it shall be noted in the QAPP and recorded on the checklist required in paragraph 1.2 below with justification of its exception.</p> <p align="center"><b>1.2 CONTENTS OF THE QAPP</b></p> <p>(18)The Quality Assurance Program of each organization shall consist of the QAPP plus appropriate implementing procedures required to provide and implement control over activities affecting quality. (19)The control shall be consistent with the importance of the activity. (20)These procedures shall be developed by qualified personnel and be reviewed and approved by the cognizant QA organization prior to implementation to assure that they meet all the requirements of their QAPP.</p>	11 ✓	2.1	<p align="center">SPW 1-23-89</p>					
	12 ✓	2.1						
	13 ✓	2.1						
		14 ✓	NA					
		15 ✓	NA					
		16 ✓	2.1.1	<p align="center">SPW 1-23-89</p>				
		17 ✓	2.1.1					
		18 ✓	2.1.2					
		19 ✓	2.1.2					
		20 ✓	2.1.2	<p align="center">SPW 1-23-89</p>				

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<p>(21)The QAPP of each Participating Organization and NTS Support Contractor shall be submitted to the WFO for review prior to implementation and shall include a checklist based on this NWSI QAP which identifies how and where each requirement of this document is addressed. (22)The WFO is also required to complete a checklist based on NWSI/88-9 (formerly NVO-196-17) for the preparation of the WFO QAPP. (23)The QAPP of each Project Participating Organization and NTS Support Contractor shall be reviewed, comments resolved, and the document approved by the WFO within a timely manner.</p>	21	2.1.2					
	22	NA					
	23	NA					
<p>1.3 QAPP VERIFICATION</p>							
<p>(24)Assurance that the QA requirements have been adequately addressed and effectively implemented will be provided by the WFO with support from the SAIC/TSMSS Project QA Department during the review and approval of each organization's QAPP, monitoring and surveillance operations, and audits of activities. (25)The Participating Organizations' and NTS Support Contractors' management shall also monitor their respective QAPPs through internal audits to assess the adequacy of their program and assure its effective implementation.</p>	24	2.1.3					
	25	2.1.3					
<p>1.4 USE OF DATA NOT GENERATED UNDER QA CONTROLS</p>							
<p>(26)The QA program for the NWSI Project provides for the acceptance of existing data for use in licensing activities that were not generated under the controls of a QA Program which meets the requirements of 10 CFR 60, Subpart G. (27)Specific methods for acceptance of this information are contained in NWSI Project Administrative Procedure 5.9Q. (28)This procedure shall meet the requirements of NUREG - 1298 "Qualification of Existing Data for High-Level Nuclear Waste Repositories" (February, 1986). (29)These requirements are contained in Appendix G to this QA Plan. (30)Once accepted, this existing data is classified as "primary data" for licensing purposes.</p>	26	2.1.4					
	27	2.1.4					
	28	NA					
	29	2.1.4					
	30	2.1.4					

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<p><b>1.5 METROLOGY FOR FORMULATING THE "Q" LIST AND QUALITY ACTIVITIES LIST</b></p> <p>(31)The WFO shall prepare the appropriate NWWSI AP or APs for determining the items and activities to be placed on the Project Q-List and Quality Activities List. (32)Procedure(s) shall meet the requirements of NUREG - 1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements" (April, 1988). These requirements are contained in Appendix I to this QA Plan.</p>	31 ✓	2.1.5						
	32 ✓	2.1.5						
<p><b>1.6 APPROACH TO QA</b></p> <p>(33)The NWWSI Project uses an approach to QA that recognizes the differences between items and activities that affect radiological health and safety and waste isolation and those that do not. (34)The approach is designed to ensure that each item or activity is assigned a QA level that is consistent with its potential impact or importance, or both, in terms of radiological health and safety, waste isolation, nonradiological health and safety, the U.S. Nuclear Regulatory Commission (NRC) licensing requirements, the operability and maintainability of the repository, costs, and schedules. (35)The Participating Organizations or WFO shall identify the appropriate quality assurance levels for all items and activities that affect quality associated with site characterization, facility and equipment construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. (36)Once assigned, the QA level for a particular item or activity shall be applied by all NWWSI Project participants involved in the activity.</p>	33 ✓	2.1.6						
	34 ✓	2.1.6						
	35 ✓	2.1.6						
	36 ✓	2.1.6						

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1.7 APPLICATION OF QA								
(37)A QAPP that complies with the requirements of this document, NNWSI/88-9 (formerly NVO-196-17), shall be established by each NNWSI Participant at the earliest practicable time consistent with the schedule for accomplishing the activities.	37 ✓	2.1.7						
(38)Each QAPP shall assure that procedures required to implement the requirements of this document are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official.	38 ✓	2.1.7						
(39)The QAPP shall be applied throughout the life of the NNWSI Project in accordance with the established policies, procedures, and instructions.	39 ✓	2.1.7						
(40)The QAPP shall apply to all items and activities affecting quality. It also shall identify the major organizations participating in the project and the designated functions of these organizations.	40 ✓	2.1.7						
(41)The QAPP shall provide control over activities that affect the quality of the identified structures, systems, and components to an extent consistent with their importance.	41 ✓	2.1.7						
(42)The activities that affect quality shall be accomplished under suitably controlled conditions.	42 ✓	2.1.7						
(43)Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that all prerequisites for the given activity have been satisfied.	43 ✓	2.1.7						
(44)The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection, test, peer review, or a combination of these.	44 ✓	2.1.7						
(45)The program shall provide for indoctrination and, as necessary, training of personnel performing activities that affect quality to assure that suitable proficiency is achieved and maintained.	45 ✓	2.1.7						
(46)The WFO shall regularly assess the status and adequacy of the QA Programs of the Participating Organizations and NTS Support Contractors by means of overview, surveillance, and audit activities.	46 ✓	2.1.7						

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<b>2.0 APPLICATION OF GRADED QUALITY ASSURANCE</b>								
<b>2.1 SCOPE</b>								
<b>2.1.1 EXTENT OF APPLICATION</b>								
<p>(47)The requirements of this section are applicable (as defined herein) to all items and activities that affect quality during geologic repository site characterization, facility and equipment design, procurement and construction, facility operation, performance confirmation, permanent closure, decommissioning, and dismantling of surface facilities. (48)The preparation of administrative and management planning documents shall not require QA level assignments, except for project level documents which are specifically required by the Nuclear Waste Policy Act of 1982 (as amended), or are required for licensing. In addition, procurement of administrative items (i.e., office supplies) do not require QA level assignments. (49)The WFO shall develop a Project administrative procedure for the application of graded QA. (50)The procedure shall be in consonance with the QA requirements specified herein. (51)It may be necessary to exempt certain NWSI items and activities from QA Level assignment. (52)Requests for exemptions shall be documented and shall contain sufficient justification to support the exemption request. Such exemptions shall be approved by the WFO PCM.</p>	47 ✓	2.2.						
		48 ✓	2.2.					
		49 ✓	2.2.					
		50 ✓	2.2.					
		51 ✓	2.2.					
		52 ✓	2.2.					
<b>2.1.2 PURPOSE OF A GRADED QA PROGRAM</b>								
<p>(53)The purpose of a graded QA program is to select the QA requirements and measures to be applied to items and activities in the Repository Program consistent with their importance to safety, waste isolation, and the achievement of U.S. Department of Energy (DOE) mission objectives. (54)This will be accomplished by deliberate quality planning and selective application of QA requirements on the item or activity to be performed, with varying degrees of QA applied depending on item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations.</p>	53 ✓	2.2.2						
		54 ✓	2.2.2					

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<b>2.1.3 DETERMINATION OF THE DEGREE TO WHICH APPLICATION IS NECESSARY</b>								
(55) This approach involves (1) identifying those items and activities whose failure could cause undue risks to the public and facility personnel or extended interruption of facility operation with critical economic losses, or both, and (2) ensuring that these items and activities are covered by a commensurate QA program.	55	2.2.3						
(56) Alternatively, an item whose failure or malfunction could result only in operational inconvenience or negligible economic loss may deserve only a quality inspection by the purchaser upon the delivery of the item.	56	2.2.3						
(57) Between these two extremes, there are varying degrees of QA to achieve the desired confidence in the quality of the completed line of activity.	57	2.2.3						
<b>2.1.4 FLEXIBILITY OF QA REQUIREMENT SELECTION</b>								
(58) The graded approach set forth here provides flexibility in the selection of the quality assurance requirements to be applied to an item or activity that is commensurate with the relative importance of the role or function assigned to the item or activity.	58	2.2.4						
<b>2.2 REQUIREMENTS</b>								
(59) The requirements specified in this section are to be used to apply the graded quality philosophy to all NWSI Project items and activities.	59	2.2.5						
<b>2.2.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QA REQUIREMENTS</b>								
(60) The appropriate Quality Assurance Level for any item or activity shall be determined by the application of decision criteria as provided by the NWSI Administrative Procedures.	60	2.2.5.1						
(61) The basis for the selection of the Quality	61	2.2.5.1						

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<p>Assurance Level and assigned QA requirements shall be documented. (62)The assigned Quality Assurance Levels and QA requirements must be submitted to the WFO for review, resolution of comments, and approval prior to implementation or use. This review and approval shall be performed by the WFO PCM and appropriate WFO Branch Chiefs.</p> <p>2.2.2 SELECTION OF SPECIFIC QA LEVELS</p> <p>(63)This approach incorporates three quality assurance levels (QA level) of which one will be assigned to each technical task that affects the quality of the NWWSI Project. (64)The definition, application, and assignment to each of the three QA levels are described in the following discussion.</p> <p>2.2.2.1 (65)QA Level I - are those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public.</p> <p>(66)Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. (67)Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. (68)The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.</p>	<p>62 ✓</p> <p>63 ✓</p> <p>64 ✓</p> <p>65 ✓</p> <p>66 ✓</p> <p>67 ✓</p> <p>68 ✓</p>	<p>2.2.5.1</p> <p>2.2.5.2</p> <p>2.2.5.2</p> <p>2.2.5.2</p> <p>2.2.5.2</p> <p>2.2.5.2</p> <p>2.2.5.2</p>	<p>sp 1-23-87</p>					

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2.2.2.2 QA Level II -(69)are those activities and items related to the systems, structures, and components which require a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE and WFO concerns, and the environment.	69	2.2.5.2						
2.2.2.3 QA Level III -(70)are those activities and items not classified as QA Levels I or II.	70	2.2.5.2						
2.2.3 APPLICATION OF LEVELS	71	2.2.5.3						
2.2.3.1 QA LEVEL I								
QA Level I is the most stringent level of quality assurance. (72)It is to be applied to those items and activities that may affect the ability of the repository to meet the preclosure and postclosure performance objectives specified by the NRC and the U.S. Environmental Protection Agency (EPA) for protecting public health and safety from radiological hazards. (73)QA Level I activities which are on the Q-List will provide the primary data input to the basis for the NRC to authorize construction and to issue a license for the DOE to receive and possess source, special nuclear, and byproduct material (waste) at the geologic repository. (74)QA Level I control and documentation must be applied to activities, including site characterization, scientific investigation, facility and equipment design, procurement, and construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities when they are specifically concerned with the protection of the public's health and safety with respect to a radiological hazard.	72	2.2.5.3						
	73	2.2.5.3						
	74	2.2.5.3						

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<p>(75) To keep radionuclides out of man's environment, a high level radioactive waste repository will utilize engineered systems, structures, and components to contain the waste and ensure the short-term safety. (76) The repository also will utilize the natural barriers to afford long-term isolation. (77) Within this context, QA Level I must be applied for near-term safety as well as long term isolation as per the following:</p> <ul style="list-style-type: none"> <li>o Where items and activities could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, or result in, an accident that could result in a radiation dose, either to the whole body or to any organ, of 0.5 rem or greater, either at or beyond the nearest boundary of the unrestricted area, at any time until the permanent closure of the repository. ✓</li> <li>o Where items and activities will provide primary data which will be relied on for performance assessment of the repository system. This data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research which have a significant impact to site-characterization or are an essential part of the data base that directly support the final design of the repository and waste package performance. ✓</li> <li>o Where activities could adversely impact the waste isolation capabilities of the engineered and natural barriers. ✓</li> <li>o Where items are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system. ✓</li> </ul>	75 ✓	2.2.5.3						
	76 ✓	2.2.5.3						
	77	2.2.5.3						

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<ul style="list-style-type: none"> <li>Where items and activities that, having failed, could cause a failure of a QA level I item, or irretrievable loss of QA level I data.</li> <li>The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) will be assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationships. As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities shall be governed by the QA level assigned to the item.</li> </ul>								
<p>2.2.3.2 QA LEVEL II</p> <p>(78)QA Level II is the second highest level of quality assurance. (79)QA Level II controls and documentation shall be applied to the NNWSI Project activities, and items that are specifically concerned with nonradiological operation of the exploratory shaft facilities and repository, and the radiological safety of the repository worker. (80)The high-level waste (HLW) repository will utilize engineered systems, structures, and components which must be designed, constructed, fabricated, tested, and operated to meet the performance objectives during the operational phase and to minimize the nonradiological hazard to the public and repository worker and the radiological hazard to the repository worker. (81)Additionally, activities that have a major impact on project costs or schedules that could delay the achievement of DOE/Office of Civilian Radioactive Waste Management (OCRWM) milestones must be appropriately controlled.</p>	<p>SPH 1-23-89</p> <p>78</p> <p>79</p> <p>80</p> <p>81</p> <p>SPH 1-23-89</p>	<p>2.2.5.3</p> <p>2.2.5.3</p> <p>2.2.5.3</p> <p>2.2.5.3</p>						

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<p>(82) Therefore, Quality Assurance Level II must be applied to activities and items as follows:</p> <ul style="list-style-type: none"> <li>Where items and activities that are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and could have a major impact on the non-radiological health and safety of the public and repository worker.</li> <li>Where items and activities which having failed or which are performed inadequately would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10CFR20.</li> <li>Where items and activities could affect the retrievability of waste up to the time of repository closure.</li> <li>Where items and activities that involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components.</li> <li>The design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/method/equipment is preferred, shall be assigned a QA Level of II prior to execution. Where a particular item can be identified and defined during this phase, a separate QA Level assignment may be made for that item. Once the QA Level for such an item is identified and approved, design procurement and construction activities shall be governed by the QA Level assigned to the item.</li> </ul>	82	<p>SPJ 1-25-89</p> <p>2.2.5.3</p>						

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(89) In some cases, data or data interpretations generated as a result of activities controlled in accordance with QA Level II or III programs, or activities performed prior to the complete implementation of the NWSI Project Quality Assurance Plan may be used in the licensing process as background or corroborative information.	89	2.2.3.3						
2.2.4 GENERAL								
(90) The requirements contained in this document apply to Quality Assurance Levels I and II items and activities unless otherwise noted herein. (91) The requirements imposed for QA Level III items and activities are those managerial, administrative, scientific, engineering, commercial, and laboratory practices that are commonly used by the organizations participating in the NWSI Project.	90	2.2.5.4						
	91	2.2.5.4						
3.0 QA ACTIVITIES								
3.1 OVERVIEW								
(92) Each NWSI Project Participant shall perform overview of the QA activities of all organizations (including subcontractors doing supportive work) under their purview. (93) Overview is to include the following as appropriate:	92	2.3.1						
o The review and approval of QAPPs	93	2.3.1						
o Surveillance of activities affecting quality to verify compliance with requirements.								
o Performance of quality audits to verify the adequacy and compliance of QA programs.								

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<b>3.2 REVIEW AND APPROVAL OF QA PROGRAMS</b>								
(94) Procedures are to be established by each NNWSI Project Participant for the review of QA program documentation of those organizations under their purview for adequacy, completeness and relevance.	94	2.3.2						
(95) The procedures shall identify the types of documents to be submitted for review and approval, assign responsibility for review, and identify the methods for documenting review and approval action.	95	2.3.2						
(96) Reviews of QA program documentation shall be recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance.	96	2.3.2						
<b>4.0 MANAGEMENT ASSESSMENT</b>								
<b>4.1 FREQUENCY OF MANAGEMENT ASSESSMENTS</b>								
(97) Management assessments are to be conducted at least annually for determining (1) the effectiveness of the system and management controls that are established to achieve and assure quality, and (2) the adequacy of resources and personnel provided to the QA program.	97	2.4.1						
(98) Management is to verify that the QA program is being effectively implemented and that personnel are trained to the QA requirements of the program.	98	2.4.1						
<b>4.2 PERFORMANCE OF MANAGEMENT ASSESSMENTS</b>								
(99) Management assessments are to be performed by the WFO and each NNWSI Project Participant.	99	2.4.2						
(100) Each organization is to develop its internal procedures for planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results	100	2.4.2						

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<p>and the tracking of recommendations. (101)Copies of all management assessments are to be provided to the Project Manager, WFO and the WFO PGM. (102)The Project Manager, WFO will make appropriate submittals of management assessment reports to OCRM. (103)Management above or outside the QA organization shall be responsible for the management assessment activity.</p>	101 ✓	2.4.2						
	102	NA						
	103 ✓	2.4.2						
<p>5.0 PERSONNEL SELECTION, INDOCTRINATION, AND TRAINING PROCEDURES</p> <p>5.1 ESTABLISHMENT OF REQUIREMENTS</p>								
<p>(104)All NNWSI Project participants shall establish requirements for the selection, indoctrination, and training of personnel performing or verifying activities that affect quality. (105)The requirements shall establish position descriptions that set forth minimum personnel qualifications and provide for appropriate indoctrination or training or both, prior to initiation of activities that affect quality. (106)In addition to the following requirements for indoctrination and training, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, nondestructive examiners, etc.) shall be certified in accordance with the detailed requirements specified in Appendix C, D, or F, as applicable.</p>	104 ✓	2.5						
	105 ✓	2.5						
	106 ✓	2.5						
<p>5.1.1 POSITION DESCRIPTION</p> <p>(107)Minimum education and experience requirements shall be established and documented in position descriptions for each position involved in the performance of activities that affect quality.</p>	107 ✓	2.5.1						

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<b>5.1.2 PERSONNEL QUALIFICATION EVALUATION</b>								
(108) Personnel selected shall have education and experience commensurate with the minimum requirements specified in the position description.	108 ✓	2.5.2						
(109) Relevant education and experience shall be verified. (110) This verification shall be documented. (111) The initial capabilities of an individual shall be based upon an evaluation of their education, experience, and training and compared to those established for the position.	109 ✓	2.5.2						
(112) Evaluations shall be documented by managers or supervisors responsible for the activities to be performed.	110 ✓	2.5.2						
	111 ✓	2.5.2						
	112 ✓	2.5.2						
<b>5.1.3 INDOCTRINATION</b>								
(113) Prior to assigning personnel to perform activities affecting quality, they shall be indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the work to be accomplished.	113 ✓	2.5.3						
(114) Indoctrination may be accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or other instructional methods.	114 ✓	2.5.3						
o QAPP's ✓								
o Implementing Procedures and Work Instructions (applicable to the individual's responsibilities).								
o Regulations								
o Project level Documents								

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5.1.4 TRAINING

(115) Prior to assigning personnel to perform quality affecting activities training, if needed, shall be conducted to gain the required proficiency. (116) The training (in-depth instruction) shall include the principles, techniques, and requirements of the activity. (117) Such in-depth instruction may be internal or external classroom sessions, classroom sessions supplemented by hands-on workshops, on-the-job training, other instructional methods, or combinations thereof.

115 ✓ 2.5.4  
116 ✓ 2.5.4  
117 ✓ 2.5.4

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5.1.5 PROFICIENCY EVALUATION

(118) After the initial personnel qualification evaluation, the job proficiency of personnel who perform activities affecting quality shall be evaluated and documented at least annually. (119) Proficiency evaluations may be performed in conjunction with periodic or day-to-day employee performance evaluations. (120) Proficiency evaluations shall be performed by managers or supervisors who have responsibility for the activities being performed or verified.

118 ✓ 2.5.5  
119 ✓ 2.5.5  
120 ✓ 2.5.5

5.1.6 RECORDS

(121) Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations shall be retained as lifetime QA records. (122) These records shall include, as a minimum, the items listed below.

121 ✓ 2.5.6  
122 ✓ 2.5.6

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<p><b>5.1.6.1 Personnel Qualification Evaluation Records</b></p> <p>(123)Records of the verification and evaluation of a candidate's education, experience, and training, compared to those required for the position.</p>	123	2.5.6						
<p><b>5.1.6.2 Indoctrination Records</b></p> <p>(124)Records of indoctrination which include the objective and content of the indoctrination, date or dates of indoctrination, and other applicable information.</p>	124	2.5.6						
<p><b>5.1.6.3 Training Records</b></p> <p>(125)Records of training which include the objective(s) and content of the training, name of the instructor, attendees, dates of attendance, and result of proficiency evaluations (where applicable), and other applicable information.</p>	125	2.5.6						
<p><b>5.1.6.4 Proficiency Evaluation Records</b></p> <p>(126)Records of proficiency evaluation shall include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.</p>	126	2.5.6						

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9	3.1.1.2						
10	3.1.1.2						
11	3.1.2						
12	3.1.2						
13	3.1.2						
14	3.1.3.1						
15	3.1.3.1						

performed shall also be provided. (8) This discussion shall identify all of the factors and concerns that are important for the planning or the performance of the scientific investigation including identification, explanation, and justification for areas where scientific notebooks are to be used.

**1.1.1.2 Description of previous work**

(9) A description of any previous work which will be used in support of the scientific investigation, including the identification of the Quality Assurance Levels, or Quality Assurance (QA) controls, under which that previous work was performed. (10) Note: This requirement does not apply to study plans.

**1.1.2 PLANNING DOCUMENTS**

(11) The scientific investigation planning document shall contain a level of detail which would enable an independent reviewer to determine the appropriate QA Level to be applied to the investigation. (12) For Site Characterization activities, the purpose and key milestones of study plans is described in the SCP. (13) The format and content of study plans shall meet the requirements of Appendix K of this QA Plan.

**1.2 ASSIGNMENT OF QUALITY ASSURANCE LEVELS**

**1.2.1 ASSIGNMENT**

(14) Once a scientific investigation planning document, as specified in Paragraph 1.1.1 of this section has been developed, the Quality Assurance Levels for all of the items and activities which are associated with that work, may be assigned. (15) It may be necessary in some cases to assign Quality Assurance Levels to the items and activities within a plan that was prepared earlier.

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

16 ✓

3.1.3.1

1.2.2 CONFORMANCE

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

17 ✓

3.1.3.2

1.3 REVIEW AND APPROVAL PROCESS

1.3.1 RESPONSIBILITY

(18) The responsible Participating Organization shall conduct a technical review of the scientific investigation planning document. (19) This review shall be performed by any qualified individual(s) other than those who developed the original planning document. (20) In exceptional cases, the originator's immediate supervisor can perform the review if the supervisor is the only technically qualified individual, and if the need is individually documented and approved in advance with the concurrence of the QA manager of the originating organization. (21) The results of this technical review, and the resolution of any comments by the reviewer or reviewers, shall be documented, and shall become a part of the QA records.

18 ✓

3.1.4.1

19 ✓

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<b>1.3.2 WASTE MANAGEMENT PROJECT OFFICE REVIEW</b>								
(22) The WFO Project Quality Manager and the appropriate WFO Branch Chief shall review and approve the scientific investigation planning document prior to implementation. (23) The WFO PQM shall return the planning document to the responsible organization's TPO upon completion of the WFO review and approval cycle. (24) Study plans shall also be reviewed and approved by OCRM prior to implementation.	22 ✓	3.1.4.2						
	23	NA						
	24 ✓	3.1.4.2						
<b>1.3.3 PEER REVIEW</b>								
(25) A peer review of the scientific investigation planning document will be conducted when deemed necessary by the WFO.	25 ✓	3.1.4.3						
<b>1.4 SCIENTIFIC INVESTIGATION DATA INTERPRETATION AND ANALYSIS</b>								
<b>1.4.1 INTERPRETATION/ANALYSIS DOCUMENTS</b>								
(26) Interpretation/analysis shall be performed in a planned, controlled, and documented manner. (27) Interpretation/analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. (28) These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer and date.	26 ✓	3.1.5.1						
	27 ✓	3.1.5.1						
	28 ✓	3.1.5.1						

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<p>1.4.2 DOCUMENTATION OF INTERPRETATION/ANALYSIS</p> <p>(29) Documentation of interpretation/analysis shall include the following:</p> <ul style="list-style-type: none"> <li>o Definition of the objective of the interpretation/analysis.</li> <li>o Definition of input and their sources.</li> <li>o A listing of applicable references.</li> <li>o Results of literature searches or other background data.</li> <li>o Identification of assumptions.</li> <li>o Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem.</li> <li>o Signatures and dates of review and approval by appropriate personnel.</li> </ul>	29	3.1, 5.2						
<p>1.5 USE OF COMPUTER PROGRAMS</p> <p>(30) Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subsection 3.0 and Appendix H of this QA Plan. (31) 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."</p>	30	3.1.6						
	31	3.1.6						

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<p>1.6 THE USE OF SCIENTIFIC NOTEBOOKS VERSUS THE USE OF TECHNICAL IMPLEMENTING PROCEDURES</p> <p>1.6.1 DOCUMENTATION</p> <p>(32)There are two methods which can be used for the quality assurance, documentation and control of scientific work. (33)These are the scientific notebook system and the technical implementing procedure system.</p> <p>(34)The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgment, trial and error methods, or developing the methodology by which an activity will be accomplished. (35)When the scientific notebook system is used, the study plan or scientific investigation planning document shall be the controlling document used to perform the activity since it describes the proposed approach or general procedure for accomplishing the work. (36)Alternatively, the technical implementing procedure system will generally be used when qualified personnel are performing repetitive work which does not include the use of a high-degree of professional judgment or trial and error methods in the performance of the work. (37)Detailed technical implementing procedures are required when it is not possible to deviate from a prescribed sequence of actions, without endangering the validity of the results that will be obtained from the work. (38)Modifications may be made to these procedures as detailed in Para. 1.6.2. (39)Logbooks or appropriate forms or both are used, particularly in repetitive work, to document the performance of the work according to the technical implementing procedure, and to maintain absolute control over all other aspects of the work.</p>	<p>32-</p> <p>33✓</p> <p>34-</p> <p>35-</p> <p>36-</p> <p>37-</p> <p>38✓</p> <p>39✓</p>	<p>SP 1.24.89</p> <p>3.1.7.1</p> <p>3.1.7.1</p> <p>3.1.7.1</p> <p>3.1.7.1</p> <p>3.1.7.1</p> <p>3.1.7.1</p> <p>3.1.7.1</p> <p>3.1.7.1</p> <p>SP 1.24.89</p>						

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<p>1.6.2 TECHNICAL IMPLEMENTING PROCEDURES</p> <p>(40) Detailed technical implementing procedures together with appropriate logbooks and other supporting documents, shall be used whenever the work is repetitive. (41) Such technical implementing procedures shall be developed in accordance with the requirements given in Section V of this document and reviewed for compliance with the requirements of this section of the QA Plan. (42) Modifications may be made to the technical aspects of technical implementing procedures by the individual utilizing the procedure. (43) If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer.</p> <p>(44) Requirements and acceptance or rejection criteria, including required levels of precision and accuracy, shall be provided or approved by the organization responsible for the scientific investigation, unless otherwise designated.</p> <p>(45) Technical procedures utilized for scientific investigations shall provide for the following as appropriate:</p> <ul style="list-style-type: none"> <li>o Requirements, objectives, methods and characteristics to be tested or observed.</li> <li>o Acceptance limits, if applicable, contained in applicable documents, including precision and accuracy.</li> </ul>	<p>SPD 1-24-89</p> <p>40 - 3.1.7.2</p> <p>41 - 3.1.7.2</p> <p>42 - 3.1.7.2</p> <p>43 - 3.1.7.2</p> <p>SPD 1-24-89</p> <p>44 - 3.1.7.2</p> <p>45 - 3.1.7.2</p> <p>SPD 3-29-89</p>							

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

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<ul style="list-style-type: none"> <li>o Special training or qualification requirements for personnel performing the scientific investigation. ✓</li> <li>o Personnel responsibilities. ✓</li> </ul>								
1.6.2.1 (46) Procedures shall be complete to the extent that another qualified individual may, at a later date, reproduce the results.	46 ✓	3.1.7.2						
1.6.2.2 (47) The potential sources of uncertainty and error in technical implementation procedures which must be controlled and measured to assure that scientific investigations are well controlled shall be identified.	47 ✓	3.1.7.2						
(48) Parameters that need to be measured and/or controlled to minimize such uncertainties or error, and to ensure adequate control, shall be addressed explicitly in test procedures.	48 ✓	3.1.7.2						
1.6.2.3 (49) For instrumentation and/or equipment used in data collection consideration shall be given to whether failure or malfunction of the instrumentation during scientific investigation will be detectable, either during data collection or by examination of the data.	49 ✓	3.1.7.2						
(50) Where ability to detect such failure or malfunction is questionable, procedures will include any special provisions for equipment/instrumentation configuration, installation, and use that can further reduce risk of undetectable failure or malfunction.	50 ✓	3.1.7.2						
1.6.2.4 (51) Any procedural deviations or nonconformances, encountered during activities shall be documented, reported, and evaluated for significance.	51 ✓	3.1.7.2						

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<p><b>1.6.3 SCIENTIFIC NOTEBOOKS</b></p> <p>(52) Scientific notebooks along with other appropriate documents may be used to document scientific investigations and experiments. (53) In such cases, this documentation shall be sufficient such that another qualified scientist can use the notebook to retrace the investigation and confirm the results, or repeat the experiment and achieve the same results without recourse to the PI.</p>	52 ✓	3.1.7.3						
	53 ✓	3.1.7.3						
<p><b>1.6.4 FORMAT FOR DOCUMENTATION</b></p> <p>(54) Documentation of scientific work i.e. experiments and research shall be performed using bound logbooks or notebooks to provide written record of the experiment or research.</p>	54 ✓	3.1.7.4						
<p><b>1.6.4.1 Initial Entries</b></p> <p>(55) Where appropriate, and prior to initiation of the experiment or research, the following entries, as a minimum, shall be made ✓</p> <ul style="list-style-type: none"> <li>o Title of the experiment or research. ✓</li> <li>o Name of the qualified individual or individuals performing the experiment or research. ✓</li> <li>o Description of the experiment's objective or objectives and the proposed approach or procedure for achieving these objectives. This may be accomplished by reference to the appropriate study plan or other scientific investigation planning document which controls the work. ✓</li> </ul>	55	3.1.7.4						

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<ul style="list-style-type: none"> <li>o Equipment and materials to be employed during the experiment or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material. ✓</li> <li>o Calibration requirements. ✓</li> <li>o Dated signature of the individual or individuals making the initial entries. ✓</li> <li>o Special training or qualification requirements. ✓</li> <li>o Documentation of suitable and controlled environmental conditions, if applicable. ✓</li> <li>o Required levels of precision and accuracy shall be identified. ✓</li> <li>o The potential sources of uncertainty and error in scientific investigations which must be controlled and measured to assure the investigations are well controlled shall be identified. ✓</li> </ul> <p>(56)The initial entries described above are considered to be a "general" procedure and shall be entered into the scientific notebook prior to beginning an investigation. (57)Modifications may be made by the individual performing the investigation. (58)If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site, or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer.</p>	<p style="text-align: center;">SPJ 1-24-89</p> <p style="text-align: center;">56- 3.1.7.4</p> <p style="text-align: center;">57- 3.1.7.4</p> <p style="text-align: center;">58- 3.1.7.4</p> <p style="text-align: center;">SPJ 1-24-89</p>						

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<p>1.6.4.2 In-process Entries</p> <p>(59) Entries to be made during the experiment or research, daily or as appropriate, shall be sufficiently detailed so that another competent experimenter/researcher could repeat the experiment or research, and shall include:</p> <ul style="list-style-type: none"> <li>o Date and name of individual making the entry. ✓</li> <li>o Provisions for assuring prerequisites have been met. ✓</li> <li>o Description of the experiment or research attempted, including detailed step-by-step process followed; either by reference to implementing procedure or by actual entry into the notebook. ✓</li> <li>o Description of any conditions which may adversely affect the results of the experiment or research. ✓</li> <li>o Identification of samples used and any additional equipment and materials not included as part of the initial entries prescribed by Paragraph 1.6.4.1 of this section. ✓</li> <li>o All data taken and a brief description of the results, to include notation of any unaccepted results. ✓</li> <li>o Any deviations from the planned experiment or research. ✓</li> <li>o Any interim conclusions reached, as appropriate. ✓</li> </ul>	59	3.1.7.4						

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<p>1.6.4.3 Final Entries</p> <p>(60)The final entries in the record shall have, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer.</p>	60	3.1.7.4						
<p>1.6.4.4 Final Results</p> <p>(61)Final results and a summary of the outcome of the experiment or research shall be documented (e.g. in a technical report). (62)This shall include a discussion of whether the experiment's objectives as outlined in the initial entries (Paragraph 1.6.4.1) were achieved. (63)This documentation shall become part of the QA records of the activity.</p>	61- 62- 63-	3.1.7.4 3.1.7.4 3.1.7.4						
<p>1.7 CHANGE CONTROL</p> <p>(64)All changes in scientific investigation planning documents shall go through the same review and approval process as specified in Paragraph 1.3 of this section. (65)The Participating Organization shall be responsible for evaluating the impacts of such changes on the associated Quality Assurance level assignments.</p>	64- 65-	3.1.8 3.1.8						
<p>1.8 INTERFACE CONTROL</p> <p>1.8.1 COORDINATION</p> <p>(66)Internal and external scientific investigation interfaces shall be identified and scientific investigation efforts shall be coordinated among and within Participating Organizations. (67)Interface controls shall include the assignment of responsibility and the establishment of procedures among and</p>	66- 67-	3.1.9.1 3.1.9.1						

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<p>within Participating Organizations for the review, approval, release, distribution and revision of documents involving scientific investigation interfaces. (68)Interfaces within a participating organization shall be coordinated according to procedures developed by that participating organization. (69)Interfaces between scientific investigations, or between a scientific investigation and any other Project activity including design activities, shall be coordinated among Project participants in accordance with administrative procedures established by the WFO. (70)Interfaces between Participating Organizations and their suppliers shall be controlled in accordance with procedures established by the Participating Organization. (71)Ongoing field or laboratory scientific investigations shall be identified to preclude inadvertent interruption and to ensure operational competability. (72)Such identification shall be clearly evident at the location at which the scientific investigation is being performed. (73)Field investigations shall identify the location of the investigation.</p> <p><b>1.8.2 TRANSMITTAL</b></p> <p>(74)The method of transmittal of information or items, including samples of natural or man-made materials, across interfaces shall be documented.</p> <p align="center"><b>1.9 VERIFICATION OF SCIENTIFIC INVESTIGATIONS</b></p> <p><b>1.9.1 VERIFICATION PLANNING</b></p> <p>(75)Planning for verification activities shall be accomplished and documented via verification procedures, instructions, or checklists. (76)Verification procedures, instructions, or checklists shall provide for following:</p> <ul style="list-style-type: none"> <li>o Identification of characteristics and activities to be verified.</li> </ul>	68	3.1.9.1						
	69	3.1.9.1						
	70	3.1.9.1						
	71	3.1.9.1						
	72	3.1.9.1						
	73	3.1.9.1						
	74	3.1.9.2						
	75	3.1.10.1						
	76	3.1.10.1						

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processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. (83)When these persons or organizations who perform the verification activities are not part of the formal QA organization (i.e., part of line management), then the quality assurance organization shall overview and monitor the verification activity.

**1.10 SURVEILLANCE OF SCIENTIFIC INVESTIGATIONS AND EXPERIMENTS**

**1.10.1 LOGISTICS OF SURVEILLANCE**

(84)The QA organization within the Participating Organization shall perform surveillances of all scientific investigations, as may be deemed appropriate for the purposes and the complexity of the work. (85)The QA surveillance team for a scientific investigation shall consist of one or more qualified technical individuals and one or more QA personnel. (86)The timing and the number of surveillances shall be determined by the QA surveillance team that is formed for this work. (87)Surveillances will be performed in accordance with the requirements specified in Section XVIII of this document.

**1.10.2 SURVEILLANCE TEAM**

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

**1.11 REPORTS, CONCLUSIONS, AND RECOMMENDATIONS**

(89)The Participating Organization shall have implementing procedures for the technical review and approval of the results of scientific investigations. (90)These procedures shall include the WFO in the review and approval cycle of the Final report.

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85- 3.1.11.1				
86- 3.1.11.1				
87- 3.1.11.1				
88- 3.1.11.2				
89- 3.1.12				
90- 3.1.12				

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<b>1.12 CLOSE-OUT VERIFICATION</b>								
(91)The Participating Organization shall perform a close-out verification upon the completion of any scientific investigation to assure that the QA records for that investigation are adequate and complete. (92)This will be done because it may be a considerable period of time after the work is completed and before the investigation is used in the licensing process. (93)Close-out verifications shall be performed by a team consisting of qualified technical personnel as well as QA personnel.	91	3.1.13						
	92	3.1.13						
	93	3.1.13						
<b>2.0 DESIGN CONTROL</b>								
<b>2.1 GENERAL</b>								
<b>2.1.1 DEFINITION</b>								
(94)The design shall be defined, controlled, and verified. (95)The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. (96)Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. (97)This includes general plans and detailed implementing procedures for data collection and analyses and related information such as test results and analysis. (98)The data collection activities result from scientific investigations and produce design input. (99)Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters.	94	NA						
	95	3.2						
	96	3.2						
	97	3.2						
	98	3.2						
	99	3.2						

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<p>(100) It is the policy of the NWSI Project that a completed or final design of a facility or item evolves from a sequential order of design activities (or phases) wherein each phase becomes more detailed in nature than the preceding phase. (101) It is recognized that the number and length of design phases required to produce a completed or final design of any particular item or facility may vary, among organizations responsible for design, according to the timeliness and availability of pertinent information and the complexity of the item or facility. (102) It is also recognized that all Project design activities, although undertaken by different organizations, which may progress at different rates, are dependant on and require an interface with each other to produce a unified facility design.</p>	100	3.2						
	101	3.2						
	102	3.2						
<p>2.1.2 QUALITY ASSURANCE LEVEL ASSIGNMENT</p> <p>(103) All design phases shall be assigned a Quality Assurance Level prior to execution in accordance with the methods specified in the NWSI Project Administrative Procedures Manual.</p>	103	NA						
<p>2.1.3 QUALIFICATION OF PERSONNEL</p> <p>(104) Personnel performing design work shall be indoctrinated, trained, and qualified in accordance with the requirements of Section II of this document. (105) Instructions, procedures and drawings for design work shall be in accordance with the requirements of Section V of this document.</p>	104	NA						
	105	NA						

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<p><b>2.1.4 PEER REVIEW</b></p> <p>(106) For design activities including design output documents which involve use of untried or beyond state-of-the-art testing and analysis procedures and methods, or where detailed technical criteria and requirements do not exist or are being developed, a peer review shall be conducted. (107) The peer review shall meet the requirements of Paragraph 4.0 of this section of the NWSI Project Quality Assurance Plan (QAP).</p>	106	NA						
	107	NA						
<p><b>2.2 DESIGN INPUT</b></p> <p><b>2.2.1 IDENTIFICATION, REVIEW AND APPROVAL OF INPUT</b></p> <p>(108) Applicable design input, such as site characterization data, criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards, shall be identified, documented, and their selection reviewed and approved by the responsible design organization and the responsible QA organization. (109) The purpose of the QA review is to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements. (110) The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.</p>	108	3.2.1.1						
	109	3.2.1.1						
	110	3.2.1.1						

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<p>2.2.2 CHANGES TO DESIGN INPUT</p> <p>(111) Changes to approved design input, including the reason for the changes, shall be identified, documented, approved, and controlled by the responsible design organization.</p>	111	3.2	1.2					
<p>2.2.3 CONSIDERATIONS FOR DESIGN INPUT</p> <p>(112) Considerations for design inputs as they apply to specific items or systems are contained in Appendix B of this document.</p>	112	3.2	1					
<p>2.3 DESIGN ANALYSIS</p> <p>2.3.1 DESIGN ANALYSIS DOCUMENTS</p> <p>(113) Design analyses shall be performed in a planned, controlled, and documented manner. (114) Design analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, design input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. (115) These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject (including structure, system, or component) originator, reviewer, and date.</p>	113 114	NA						
<p>2.3.2 DOCUMENTATION OF DESIGN ANALYSES</p> <p>(116) Documentation of design analysis shall include the following:</p> <ul style="list-style-type: none"> <li>o Definition of the objective of the analysis.</li> <li>o Definition of design input and their sources.</li> </ul>	116	NA						

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<ul style="list-style-type: none"> <li>o A listing of applicable references.</li> <li>o Results of literature searches or other background data.</li> <li>o Identification of assumptions and indication of those which require verification as the design proceeds.</li> <li>o Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem.</li> <li>o Signatures and dates of review and approval by appropriate personnel including QA Personnel. The purpose of the QA review is to assure that the documentation is prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.</li> </ul>								
<p><b>2.3.3 USE OF COMPUTER PROGRAMS</b></p> <p>(117) Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subparagraph 3.0 and Appendix H of this QA Plan.</p>	117	NA						
<p align="center"><b>2.4 DESIGN VERIFICATION</b></p> <p><b>2.4.1 IDENTIFICATION AND DOCUMENTATION</b></p> <p>(118) Design control measures shall be applied to verify the adequacy of design and verification shall be performed in a timely manner. (119) The responsible design organization shall identify and document the verification method used, the results of the verification, and the verifier.</p>	118	NA						
	119	NA						

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<b>2.4.2 TIMING OF VERIFICATION</b>								
(120) Verification of the adequacy of design shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities.	120	NA						
(121) In those cases, where this timing can not be met, the portion or portions of design which have not been verified shall be identified and controlled.	121	NA						
(122) In all cases, the verification shall be completed prior to relying on the component, system, or structure to perform its function.	122	NA						
<b>2.4.3 EXTENT OF VERIFICATION</b>								
(123) The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs.	123	NA						
(124) Where the design has been subjected to a verification process in accordance with Paragraph 2.4 of this section, the verification process need not be duplicated for identical designs.	124	NA						
(125) However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application.	125	NA						
(126) Known problems affecting the standardized or previously proven designs and their effects on other features shall be considered.	126	NA						
(127) The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.	127	NA						
<b>2.4.4 CHANGES TO VERIFIED DESIGNS</b>								
(128) Changes to previously verified designs shall require verification including evaluation of the effects of those changes on the overall design.	128	NA						

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

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<p><b>2.4.6.1 Design Reviews</b></p> <p>(135) Design reviews are detailed critical reviews to provide assurance that the design is correct and satisfactory. (136) At a minimum, the items below shall be considered during the review and the results of such deliberations shall be documented.</p> <ul style="list-style-type: none"> <li>o Were the design inputs correctly selected?</li> <li>o Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent re-verifications when the detailed design activities are completed?</li> <li>o Was an appropriate design method used?</li> <li>o Were the design inputs correctly incorporated into the design?</li> <li>o Is the design output reasonable compared to design inputs?</li> <li>o Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?</li> <li>o Are computer programs used for analysis identified and verified in accordance with the methods specified in paragraph 3.0 of this Section.</li> </ul>	135 136	NA NA						

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

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

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	<b>2.6 DESIGN INTERFACE CONTROL</b>							
<b>2.6.1 IDENTIFICATION AND RESPONSIBILITY</b>								
(154) Internal and external design interfaces shall be identified and controlled and design efforts shall be coordinated among and within responsible design organizations. (155) Interface controls shall include the assignment of responsibility and the establishment of procedures among and within responsible design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.	154	NA						
	155	NA						
<b>2.6.2 INFORMATION TRANSMITTED ACROSS INTERFACES</b>								
(156) Design information transmitted across interfaces shall be documented and controlled. (157) Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. (158) Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.	156	SPN 12/4/89 3.2/1.3						
	157	3.2/1.3						
	158	3.2/1.3						
	159	SPN 12/4/89						
<b>2.7 DESIGN OUTPUT REQUIREMENTS</b>								
<b>2.7.1 DESIGN OUTPUT DOCUMENTS</b>								
Design output documents shall:								
2.7.1.1 (160) Relate to the design input by documentation in sufficient detail to permit design verification.	160	NA						

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	<p>2.7.1.2 (161) Identify assemblies or components or both that are part of the item being designed. (162) When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection or testing or both, to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.</p> <p>2.7.1.3 (163) Show evidence that the required review and approval cycle has been achieved prior to release for procurement, construction, or release to another organization for use in other design activities. (164) As a minimum, the review and approval cycle shall include the participation of the technical and QA elements of both the responsible design organization and the WFO. (165) The purpose of the QA review is to assure that the documents are prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.</p> <p>2.8 DESIGN DOCUMENTS AS QA RECORDS</p> <p>(166) Design documentation, including design inputs, analyses, drawings, specifications, approved changes thereto, evidence of design verification and records confirming interface control shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section XVII of this document.</p>	161 162	NA NA					
	163 164 165	NA NA NA						
	166	NA						

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<p>3.0 SOFTWARE QUALITY ASSURANCE REQUIREMENTS</p> <p>3.1 COMPUTER SOFTWARE DOCUMENTATION AND CONTROL</p> <p>(167) For a geologic repository, computer software used to perform analysis in support of the license application shall be controlled to the same level of requirements as software used to perform direct design analysis.</p> <p>(168) Auxiliary software used to support primary analysis software shall be controlled at a level commensurate with the complexity of that software.</p> <p>(169) Where commercial auxiliary software is used, all available documentation from the software supplier shall be obtained. (170) It is recognized that source code is generally not available and controls are limited to unique version identification and user-related manuals.</p> <p>(171) Supplemental, detailed requirements for the development, maintenance, and security of computer software based on the life cycle model are contained in Appendix B to this QA Plan.</p> <p>3.1.1 (172) Each organization participating in the NWSI Project shall prepare a description of their software design, test and configuration management system, and submit it to the next higher program organizational level for review and approval. (173) The description shall:</p> <ul style="list-style-type: none"> <li>Provide criteria for application of the requirements of this section based on the complexity and importance of the software used to perform analysis in support of the design of a geologic repository.</li> <li>Indicate the methods to be used to develop computer program requirements, to translate those requirements into a detailed design, and to implement that design in executable code.</li> </ul>	167	3.3.1	Because USGS is not directly involved with repository-design issues, sentence was rephrased to be applicable to all USGS QA Level I and II activities that invoke software.					
	168	NA	USGS does not define "auxiliary software".					
	169	3.3.1	USGS replaced the term "commercial auxiliary software" with the generic term "software acquired from sources external to the USGS".					
	170	3.3.1						
	171	3.3.1						
	172	3.3.1.1						
	173	3.3.1.1	USGS introduces "functional requirements" that are to be implemented in "software design" in order to avoid possible confusion between "QA requirements", for example, and between "repository design"					

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All sections of USGS-QAPP, RS software QA were reviewed 1-26-89, 22 Comments were resolved on 3/30/89 via meetings and discussions. See DRS sheets by K. Schwartz, transcribed 1-26-89. The following pages were reviewed for compliance and accepted 3/30/89, p. 53-57 and p. 205-222. K. Schwartz transcribed 3/30/89

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<ul style="list-style-type: none"> <li>• Relate the types of documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use.</li> <li>• Identify the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software.</li> <li>• Specify the process to be used for verification and validation of the software developed or applied to geologic repository design analysis.</li> <li>• Identify the procedure for reporting and documenting software discrepancies, including sources, evaluating aspects of discrepancies on previous calculations, and determining appropriate corrective action.</li> </ul>								
<p>3.1.2 (174)Software shall be placed under configuration management as each baseline element is approved. (175)Software baseline elements shall be uniquely identified to assure positive control of all revisions; the identification of each code version shall be directly related to the associated documentation.</p>	174	3.3.1.2				<p>USGS replaces the term "discrepancy" with the term "defect" in order to be consistent throughout Subsection 3.3 and Appendix H.</p>		
	175	3.3.1.2						
<p>3.1.3 (176)Changes to software shall be systematically evaluated, coordinated, and approved to assure that the impact of a change is carefully assessed prior to updating the baseline, required action is documented, and the information concerning approved changes is transmitted to all affected organizations.</p>	176	3.3.1.3						
<p>(177)Changes to computer software shall be subject to the same level of approval, verification, and validation as the original software.</p>	176	3.3.1.3						
	177	3.3.1.3						
						See p53		X

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<p>3.1.4 (178) Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. (179) This requirement may be met in part by existing documentation if properly referenced and related to the NUREG-0856 requirements.</p>	178	3.3.1.4				<p align="center">See p. 53</p>		
<p>3.1.4 (179) This requirement may be met in part by existing documentation if properly referenced and related to the NUREG-0856 requirements.</p>	179	3.3.1.4						
<p>3.1.5 (180) Testing of software, including new or modified software, shall be performed for those inputs and conditions necessary to exercise the software, identify boundary conditions and to provide a suitable benchmark or sample problem for installation. (181) The goal of testing is to develop a set of test cases that have highest probability of detecting the most errors in order to identify under what conditions the software does not perform properly.</p>	180	3.3.1.5						
<p>3.1.5 (181) The goal of testing is to develop a set of test cases that have highest probability of detecting the most errors in order to identify under what conditions the software does not perform properly.</p>	181	3.3.1.5						
<p>3.1.6 (182) Verification and validation of computer software shall be performed prior to the use of such software to perform technical calculations in support of site-characterization, performance assessment analyses, and the design, analysis, and operation of repository structures, systems, and components. (183) In those cases where this requirement cannot be met, the portion or portions of software which have not been verified and validated shall be identified and controlled. (184) In all cases, the verification and validation of software shall be completed prior to relying on the software to support the license application.</p>	182	3.3.1.6						
<p>3.1.6 (183) In those cases where this requirement cannot be met, the portion or portions of software which have not been verified and validated shall be identified and controlled. (184) In all cases, the verification and validation of software shall be completed prior to relying on the software to support the license application.</p>	183	3.3.1.6						
<p>3.1.6 (184) In all cases, the verification and validation of software shall be completed prior to relying on the software to support the license application.</p>	184	3.3.1.6						
<p>3.1.7 (185) Verification and validation procedures shall assure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.</p>	185	3.3.1.6						

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<p>3.1.8 (186)Existing software shall be qualified for use. (187)This qualification shall be based on the ability of the software to provide acceptable results for specific applications and compliance with the requirements of this section. (188)Software that has not been developed in accordance with this QA Plan may be qualified for use provided the software is verified and validated, a software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this section.</p> <p>3.1.9 (189)Methods for determining the applicability of requirements and managing interfaces involving the documentation, configuration management, change, qualification, verification, and validation of software, shall be described in each organizations software QA Plan and procedures.</p> <p>3.2 DOCUMENTATION OF COMPUTER SOFTWARE</p> <p>(190)Documentation of scientific and engineering software shall include the following, as a minimum:</p> <ul style="list-style-type: none"> <li>o Software requirements specification;</li> <li>o Software design and change documentation;</li> <li>o Description of mathematical models and numerical methods;</li> <li>o Software verification and validation documentation;</li> <li>o User documentation;</li> <li>o Code assessment and support;</li> </ul>	186 187 188	3.3.1.7 3.3.1.7 3.3.1.7				See p. 53		X
	189	3.3.1.8						
	190	3.3.2						

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<ul style="list-style-type: none"> <li>• Continuing documentation and code listings; and</li> <li>• Software summary.</li> </ul> <p>(191) This documentation is considered to be a QA Record and is subject to the requirements of Section XVII of this QA Plan. (192) Appendix H to this QA Plan provides detailed requirements on the content of the documentation for this software and other computer software used on the NWWSI Project.</p>	191	3.3.2				See p. 53 ↓		
	192	3.3.2						
<p><b>3.3 SOFTWARE CONFIGURATION MANAGEMENT</b></p> <p>(193) All Participating Organizations and WTS Support Contractors shall institute a software configuration management program appropriate to the projects they conduct and shall provide documentation of this program to the Records Management System (RMS). (194) The minimum requirements for this configuration management program shall be: (1) the inclusion of a unique identification, including software version numbers whenever feasible, in the output; (2) listings of the software; and (3) a brief chronology of the software versions, including descriptions of the changes made between versions.</p>	193	3.3.3	USGS replaced word "program" with word "system" to avoid possible confusion with the term "computer program".					
	194	3.3.3	USGS enlarged the concept of a traceable chronology to include software acquisition and testing.					
<p><b>4.0 PEER REVIEWS</b></p> <p>(195) All Participating Organizations and WTS Support Contractors shall institute a peer review process, when applicable, to provide adequate confidence in the work being reviewed. (196) Peer reviews shall meet the requirements of NWREG-1297 "Peer Review for High-Level Nuclear Waste Repositories" (Feb. 1988). These requirements are contained in Appendix J to this QA Plan.</p>	195	3.4						
	196	3.4						

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

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<p><b>SECTION IV</b></p> <p><b>PROCUREMENT DOCUMENT CONTROL</b></p> <p><b>1.0 REQUIREMENTS</b></p> <p><b>1.1 MEASURES TO ASSURE ADEQUATE QUALITY</b></p> <p>(1) Measures shall be established to ensure that applicable regulatory requirements, design or site investigation bases, and other requirements that are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services utilized on the Nevada Nuclear Waste Storage Investigations (NWSI) Project. (2) To the extent necessary, procurement documents of Participating Organizations and Nevada Test Site (NTS) Support Contractors, shall require sub-tier contractors to provide a Quality Assurance (QA) program that is consistent with the pertinent provisions of this NWSI Quality Assurance Plan as required for the specified Quality Assurance Level.</p> <p><b>1.2 WFO PROCURED SERVICES</b></p> <p>(3) Waste Management Project Office (WFO) initiated procurements for services shall be controlled through the use of the Federal Acquisition Regulations (FAR) and Department of Energy Acquisition Regulations (DEAR). (4) When the WFO procures services from contractors or requests services from national laboratories and supporting Federal agencies, the WFO shall prepare work agreements, memos of understanding, interagency agreements, management agreements, or other suitable documents.</p>	<p>1 -</p> <p>2 -</p> <p>3 -</p> <p>4 -</p>	<p>4.1</p> <p>4.1</p> <p>NA</p> <p>4.2</p>						

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	<p align="center"><b>2.0 ADDITIONAL REQUIREMENTS FOR QA LEVEL I ACTIVITIES</b></p> <p align="center"><b>2.1 CONTENT OF PROCUREMENT DOCUMENTS</b></p> <p>(5) Procurement documents issued at all tiers of procurement shall include provisions for the items listed below, as deemed necessary by the purchaser:</p> <p><b>2.1.1 SCOPE OF WORK</b></p> <p>(6) A statement of the scope of the work to be performed by the supplier shall be in the procurement documents.</p> <p><b>2.1.2 TECHNICAL REQUIREMENTS</b></p> <p>(7) Technical requirements shall be specified in the procurement documents.                      (8) Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. (9) The procurement documents shall provide for identification of test, inspection, and acceptance requirements of the purchaser for monitoring and evaluating the supplier's performance.</p> <p><b>2.1.3 QA REQUIREMENTS</b></p> <p>2.1.3.1 (10) Procurement documents shall require that the supplier have a documented QA program that implements either portions or all of the requirements of this document. (11) Quality Assurance Program Plans (QAPPs) and documents of subcontractors for Quality Assurance Level I purchases shall be reviewed and approved by the procuring Project participant. (12) Those which do not adequately define QA requirements, as judged by the QA representative of the Project participant, shall be corrected prior to initiation of activities</p>							
	5	4.3						
	6	4.1.1						
	7	4.3.2						
	8	4.3.2						
	9	4.3.2						
	10	4.3.3						
	11	4.3.3						
	12	4.3.3						

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	<p>specified by the purchase order or contract. (13)The extent of the program required shall depend upon the type and use of the item or service being procured. (14)The procurement documents shall require the supplier to incorporate appropriate QA program requirements in subtier procurement documents.</p> <p>2.1.3.2 (15)In developing QA requirements for test and other equipment, consideration should be given to whether proper performance of that equipment can be determined during or after its use (i.e., whether failure or malfunction of the equipment can be detected).</p> <p>2.1.4 RIGHTS OF ACCESS</p> <p>(16)At each tier of procurement, the procurement documents shall provide for access to the suppliers' facilities and records for inspection or audit by the purchaser, appropriate WFO personnel, or other WFO authorized representatives. (17)WFO access to subtier contractor facilities shall be arranged by the contracting organization.</p> <p>2.1.5 DOCUMENTATION REQUIREMENTS</p> <p>(18)The procurement documents at all tiers shall identify the documentation required to be submitted to the purchaser. (19)The time of submittal shall also be established. (20)If the purchaser requires the supplier to maintain specific QA records, then the retention times and disposition requirements shall be specified in accordance with Section XVII of this QA Plan.</p> <p>2.1.6 NONCONFORMANCE</p> <p>(21)The procurement documents shall prescribe the purchaser's requirements for reporting and approving disposition of nonconformances.</p>	<p>13 ✓</p> <p>14 ✓</p> <p>15 ✓</p> <p>16 ✓</p> <p>17 ✓</p> <p>18 ✓</p> <p>19 ✓</p> <p>20 ✓</p> <p>21 ✓</p>	<p>SPD 1-14-89</p> <p>4.3.3</p> <p>4.3.3</p> <p>4.3.3</p> <p>4.3.4</p> <p>4.3.4</p> <p>4.3.5</p> <p>4.3.5</p> <p>4.3.5</p> <p>4.3.6</p> <p>SPD 1-14-89</p>					



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<p>2.3 PROCUREMENT DOCUMENT CHANGES</p> <p>(32) Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. (33) Changes that are made as a result of the bid evaluation or precontract negotiations shall be incorporated into the procurement documents. (34) The review of such changes and their effects shall be completed and documented prior to contract award. (35) Review of changes shall include the following considerations:</p> <ul style="list-style-type: none"> <li>o Appropriate content shall be included in procurement documents as required by Paragraph 2.1 of this Section. ✓</li> <li>o Additional or modified design or site investigation criteria shall be determined. ✓</li> <li>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.</li> </ul> <p>2.4 DISTRIBUTION OF PROCUREMENT DOCUMENTS</p> <p>(36) Participating Organizations and NTS Support Contractors shall forward to the SAIC/T&amp;MSS Project QA Department (QA Verification Division Manager), a copy of purchase documents, and changes thereto, as issued, when purchases involve Quality Assurance Level I items or services. (37) Only those purchase documents which identify the vendor, describe the scope of work, and detail when work is to start are required to be submitted to the SAIC/T&amp;MSS Project QA Department.</p>								
	32 ✓							
	33 ✓							
	34 ✓							
	35 ✓							
	36 ✓							
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**SECTION V**

**INSTRUCTIONS, PROCEDURES, PLANS AND DRAWINGS**

**1.0 GENERAL**

(1)Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings, of a type appropriate to the circumstances except as noted in paragraph 3.0 of this Section. (2)These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. (3)Instructions and procedures shall include a section which identifies the QA records which are generated during implementation of the document. (4)If plans are used in lieu of procedures, then these plans shall also include or reference appropriate acceptance criteria and identify the QA records which are generated. (5)These documents, including drawings, shall be controlled as required in Section VI of this document.

**2.0 REVIEWS**

(6)An independent review of all instructions, procedures, plans and drawings shall be performed by the originating organization to assure technical adequacy and inclusion of appropriate quality requirements. (7)If applicable, this review shall consider whether the activities are not repeatable, have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities.

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2 - 5.1  
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<p align="center"><b>3.0 INSTRUCTIONS FOR SCIENTIFIC NOTEBOOKS</b></p> <p>(8)The Participating Organizations shall prepare instructions for the control of scientific notebooks, plans and the other documentation that will be used in scientific investigations. (9)When scientific notebooks are used to document scientific investigations, the requirements of Section III, paragraph 1.6 shall prevail over the requirements of this Section. (10)Scientific notebooks shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section XVII of this document.</p>	<p align="center">SA 1-24-89</p> <p>8 ✓ 5.3</p> <p>9 ✓ 5.3</p> <p>10 ✓ 5.3</p>							
<p align="center"><b>4.0 DISTRIBUTION</b></p> <p>(11)Each Participating Organization and Nevada Test Site (NTS) Support Contractor shall maintain and provide the NNPO POM and the SAIC/TMSS Project Quality Assurance Department Manager with controlled distribution of all implementing procedures, plans and instructions used for QA Level I and II activities.</p>	<p>11 ✓ 5.4</p> <p align="center">↓ JP 1-24-89</p>							

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<p><b>SECTION VI</b></p> <p><b>DOCUMENT CONTROL</b></p> <p><b>1.0 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE</b></p> <p><b>1.1 METHODS</b></p> <p>(1) The preparation, review, approval, and issuance of documents such as instructions, procedures, plans and drawings, including changes thereto, shall be controlled through the implementation of methods that assure that only correct documents are used. (2) Document control shall be applied to the following:</p> <ul style="list-style-type: none"> <li>o Documents containing or specifying quality requirements. ✓</li> <li>o Documents that prescribe activities affecting quality. ✓</li> </ul> <p>(3) The document control system shall be documented, and the QA organization shall provide the appropriate review, resolution of comments, and concurrence with respect to quality-related aspects of the documents.</p> <p><b>1.2 IMPLEMENTATION</b></p> <p>(4) Implementation of document control shall provide for the following:</p> <ul style="list-style-type: none"> <li>o Identification of documents to be controlled. ✓</li> </ul>	<p>SPD 12/88</p>							
	1-	6.1.1						
	2-	6.1.1						
	3-	6.1.1						
	4-	6.1.2						
		<p>✓ SPD 12/88</p>						

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<ul style="list-style-type: none"> <li>o Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.</li> <li>o Review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements, prior to approval and issuance.</li> <li>o A method for the removal or marking of obsolete or superseded documents to prevent inadvertent use.</li> <li>o A method for assuring that the correct and applicable documents are available at the location where they are to be used.</li> <li>o A master list or equivalent to identify the correct and updated revisions of documents.</li> <li>o Coordination of interface documents.</li> </ul> <p style="text-align: center;">2.0 DOCUMENT CHANGES</p> <p style="text-align: center;">2.1 MAJOR CHANGES</p> <p>(5) Changes to documents, other than those defined below as minor changes are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated by the organization responsible for the document. (6) The reviewing organization shall have access to pertinent background data or information upon which to base their approval and, if applicable, shall specifically consider whether the changes are not repeatable, have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities.</p>	<p style="text-align: center;">5</p> <p style="text-align: center;">6</p>	<p style="text-align: center;">6.2</p> <p style="text-align: center;">6.2</p>	<p style="text-align: center;">500 1-24-89</p> <p style="text-align: center;">VSPW 1-24-89</p>					

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<p align="center"><b>2.2 MINOR CHANGES</b></p> <p>(7) Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. (8) To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.</p>	7 -	6.2					
	8 -	6.2					
<p align="center"><b>3.0 DISTRIBUTION OF DOCUMENTS</b></p> <p align="center"><b>3.1 DOCUMENT CONTROL SYSTEM</b></p> <p>(9) The document control system shall assure that documents requiring verification are not released prior to verification or, if they must be released before verification, they are uniquely identified, as such and controlled in accordance with Paragraph 1.2 of this section. A master list or equivalent used to identify the correct, current and updated versions of documents shall be submitted to the WFO PCM and the SAIC/T&amp;MS Project Quality Assurance Department Manager.</p>	9 -	6.3					

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

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organization participation shall be provided for evaluation and selection of suppliers, verification of suppliers activities and receiving inspections.

(8) 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.

1.1.2 PROCUREMENT TIMING

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

1.1.3 PROCUREMENT METHODS

(10) Planning shall result in the documented identification of the methods to be used in procurement activities, the sequence of actions and milestones that indicate the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. (11) Planning shall provide for the integration of the following:

- o Procurement document preparation, review, and change control.
- o Selection of procurement sources.
- o Purchaser control of supplier performance.

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10-7.1.1.2

11-7.1.1.2  
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<ul style="list-style-type: none"> <li>o Verification (surveillance, inspection, or audit) activities by purchaser, including notification for hold-and-witness points.</li> <li>o Control of nonconformances.</li> <li>o Corrective action. ✓</li> <li>o Acceptance of item or service. ✓</li> <li>o QA records. ✓</li> </ul>								
1.2 SOURCE EVALUATION AND SELECTION								
1.2.1 SELECTION OF SUPPLIERS								
(12) The selection of suppliers shall be based on evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents before the award of contract.	12	7.1.2.1						
1.2.2 SOURCE EVALUATION AND SELECTION MEASURES								
(13) Procurement source evaluation and selection measures shall be implemented by the purchaser and shall provide for identification of the purchaser's organizational responsibilities for determining supplier capability.	13	7.1.2.2						

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**1.2.3 MEASURES FOR EVALUATION AND SELECTION OF PROCUREMENT SOURCES**

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

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

**1.3 BID EVALUATION**

**1.3.1 EXTENT OF CONFORMANCE**

(15) Bid evaluation shall determine the extent of conformance to the procurement documents. (16) This evaluation shall be performed by individuals or organizations designated to evaluate the following subjects, as applicable to the type of procurement:

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- o Technical considerations. ✓
- o QA requirements. ✓

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<ul style="list-style-type: none"> <li>o Supplier's personnel. ✓</li> <li>o Supplier's production capabilities. ✓</li> <li>o Supplier's past performance. ✓</li> <li>o Alternates. ✓</li> <li>o Exceptions. ✓</li> </ul>								
<p><b>1.3.2 RESOLUTION OF UNACCEPTABLE QUALITY ASSURANCE CONDITIONS</b></p> <p>(17) Before the award of the contract, the purchaser shall resolve or obtain commitments to resolve unacceptable quality assurance conditions resulting from the bid evaluation.</p>	17	7.1.3.2						
<p><b>1.4 SUPPLIER PERFORMANCE EVALUATION</b></p> <p><b>1.4.1 INTERFACE MEASURES</b></p> <p>(18) The purchaser of items and services shall establish measures to interface with the supplier. (19) The measures shall include the following:</p> <ul style="list-style-type: none"> <li>o Documentation of the understanding between purchaser and supplier of the provisions and specifications of the procurement documents. ✓</li> <li>o Requiring the supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements. ✓</li> </ul>	18 19	7.1.4.1 7.1.4.1						

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<ul style="list-style-type: none"> <li>o Reviewing supplier documents that are generated or processed during activities fulfilling procurement document requirements. ✓</li> <li>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. ✓</li> <li>o Establishing methods of document information exchange between purchaser and supplier. ✓</li> </ul>								
<p>1.4.2 VERIFICATION MEASURES</p> <p>1.4.2.1 EXTENT OF VERIFICATION</p> <p>(20) The purchaser of items and services shall establish measures to verify supplier's performance, as deemed necessary by the purchaser. The measures shall establish the extent of source surveillance and inspection activities.</p>	20	7.1.4.2						
<p>NOTE: (21) When a Participating Organization, or Nevada Test Site (NTS) Support Contractor, utilizes another Participating Organization or NTS Support Contractor for NWSI activities for which they are responsible, the user organization shall initiate a request to WFO to conduct a WFO surveillance of the organization performing the work. The surveillance shall be conducted to determine that the item or activity is being produced or performed in accordance with the user organization's requirements. These surveillances may utilize NTS Support Contractor or Participating Organization personnel as technical advisors.</p>	21	7.1.4.2						

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<p>(22)The extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance. (23)Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the suppliers' activities. (24)These verification activities shall be conducted as early as practicable. (25)However, the purchaser's verification activities shall not relieve the supplier of their responsibilities for verification of quality achievement.</p>	22	7.1	4.2					
	23	7.1	4.2					
	24	7.1	4.2					
	25	7.1	4.2					
<p>1.4.2.2 Record of Verification Activities</p>								
<p>(26)Activities performed to verify conformance to requirements of procurement documents shall be recorded. (27)Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be documented. (28)These completed documents shall be considered QA records and shall be controlled in accordance with Section XVII of this Quality Assurance Plan (QAP). (29)The purchaser shall ensure that this documentation is evaluated to determine the supplier's QA program effectiveness.</p>	26	7.1	4.2					
	27	7.1	4.2					
	28	7.1	4.2					
	29	7.1	4.2					
<p>1.5 CONTROL OF DOCUMENTS GENERATED BY SUPPLIERS</p>								
<p>(30)Documents that are generated by suppliers shall be controlled, handled, and approved in accordance with documented procedures. (31)Means shall be implemented to assure that the submittal of these documents is accomplished in accordance with the procurement document requirements. (32)These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.</p>	30	7.1	5					
	31	7.1	5					
	32	7.1	5					

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- o The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means by which to resolve the nonconformances. ✓
- 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 and the administrative procedures for the review and approval of the 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 independent inspection or test of the items. Such verification shall be conducted by the purchaser at intervals commensurate with the supplier's past quality performance. ✓

1.6.1.2 Source verification

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

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	<p><b>1.6.1.3 Receiving inspection</b></p> <p>(40)When receiving inspection is used, purchased items shall be inspected as necessary to verify their conformance to specified requirements, by taking into account source verification and audit documentation and the demonstrated quality performance of the supplier. (41)Receiving inspection shall be performed in accordance with established procedures and inspection instructions to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. (42)Receiving inspection shall be coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection. (43)Receiving inspections associated with engineered items shall be planned, performed, and documented in accordance with the requirements specified in Section X, Para. 2.1, 4.0, 4.1, 6.1, 9.0 and 9.1 of this document. (44)Personnel selected to receipt inspection activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities. (45)When required, personnel shall also be indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are applicable.</p> <p><b>1.6.1.4 Post-Installation testing</b></p> <p>(46)When post-installation testing is used, post-installation test requirements and acceptance documentation shall be established mutually by both the purchaser and the supplier.</p>							
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	40	7.1.6.3						
	41	7.1.6.3						
	42	7.1.6.3						
	43	NA						
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	44	7.1.6.3						
	45	7.1.6.3						
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	46	7.1.6.4						
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<p align="center"><b>1.7 ACCEPTANCE OF SERVICES ONLY</b></p>							
<p><b>1.7.1 PROCUREMENT OF SERVICES ONLY</b></p>							
<p>(47) In certain cases involving procurement of services only, such as third party inspections, engineering, and consulting; and installation, repair, overhaul, or maintenance work, the purchaser shall accept the service by any or any combination of the following methods:</p> <ul style="list-style-type: none"> <li>o Technical verification of data produced. ✓</li> <li>o Surveillance, audit, or both, with regard to the activity ✓</li> <li>o Review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc. ✓</li> </ul>	47	7.1.7					
<p align="center"><b>1.8 CONTROL OF SUPPLIER NONCONFORMANCES</b></p>							
<p><b>1.8.1 METHODS</b></p>							
<p>(48) The purchaser and supplier shall establish and document methods for disposition of items and services that do not meet procurement document requirements. These methods shall include the following provisions:</p>	48	7.1.8					
<p><b>1.8.1.1 Evaluation</b></p>							
<p>(49) Provisions for evaluation of nonconforming items. ✓</p>	49	7.1.8.1					

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<p><b>1.8.1.2 Submittal</b></p> <p>(50)Provisions for submittal of nonconformance notice to purchaser by supplier as directed by the purchaser. (51)These submittals shall include supplier recommended disposition (e.g., use as-is or repair) and technical justification. (52)Nonconformances to the procurement requirements or purchaser approved documents, which consist of one or more of the items listed below shall be submitted to the purchaser. (53)Approval of the recommended disposition shall be in accordance with documented procedures:</p> <ul style="list-style-type: none"> <li>o Technical or material requirement is violated. ✓</li> <li>o Requirement in supplier documents, which has been approved by the purchaser, is violated. ✓</li> <li>o Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework. ✓</li> <li>o The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired. ✓</li> </ul>	<p>50 ✓</p> <p>51 ✓</p> <p>52 ✓</p> <p>53 ✓</p>	<p>7.1.3.2</p> <p>7.1.3.2</p> <p>7.1.3.2</p> <p>7.1.3.2</p>	<p>SPW 1-21-89</p>					
<p><b>1.8.1.3 Disposition</b></p> <p>(54)Provisions for purchaser disposition of supplier recommendation. ✓</p>	<p>54</p>	<p>7.1.3.3</p>						
<p><b>1.8.1.4 Verification</b></p> <p>(55)Provisions for verification of the implementation of the disposition. ✓</p>	<p>55</p>	<p>7.1.3.4</p>	<p>SPW 1-21-89</p>					

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**1.8.1.5 Records maintenance**

(56) Provisions for maintenance of records of nonconformances that are submitted by the Supplier.

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**2.0 COMMERCIAL-GRADE ITEMS**

**2.1 ALTERNATIVES**

(57) If a design requires commercial-grade items, then the following requirements are an acceptable alternative to other requirements of this section, except as noted in Paragraph 2.1.2 below and the requirements of Section IV of this QAP. (58) If a scientific investigation requires commercial-grade items they may be controlled by the use of the following requirements (except Paragraph 2.1.1) and Section IV of this QAP.

57 NA  
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**2.1.1 IDENTIFICATION OF COMMERCIAL-GRADE ITEMS**

(59) Where the commercial-grade item is to be used as an integral part of the designed facility, it shall be identified in an approved design or design out-put document. (60) An alternate commercial-grade item may be supplied if the cognizant organization provides verification that the alternate commercial-grade item will perform the intended function and will meet the requirements applicable to both the replaced item and its application.

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**2.1.2 SOURCE EVALUATION AND SELECTION**

(61) Source evaluation and selection shall be in accordance with Paragraph 1.2, if it is determined necessary by the purchaser based on the complexity of the item and importance to safety.

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<p>2.1.3 PURCHASE ORDER</p> <p>(62) Commercial-grade items shall be identified in the purchase order by the manufacturer's published product description (e.g., the catalog number).</p>	62	7.2.2						
<p>2.1.4 RECEIPT OF COMMERCIAL-GRADE ITEM</p> <p>(63) After receipt of a commercial-grade item, the purchaser shall determine that the following conditions have been met:</p> <ul style="list-style-type: none"> <li>o Damage was not sustained during shipment. ✓</li> <li>o The item received was the item ordered. ✓</li> <li>o Inspection, testing, or both, is accomplished by the purchaser, in accordance with written procedures, to ensure conformance with the manufacturer's published requirements. If applicable, acceptance of the item may be accomplished via the calibration program in accordance with the requirements of Section XII of this QA Plan.</li> <li>o Documentation, as applicable to the item, was received and is acceptable.</li> </ul>	63	7.2.3						

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	SECTION VIII							
IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES AND DATA								
INTRODUCTION								
<p>This section provides the requirements for the identification and control of items, samples and data and consists of three separate parts. (1)The requirements for items are stated in part A; in part B for samples; and, part C for data resulting from scientific investigations. (2)Part A applies to activities related to the engineered items and does not apply to scientific investigations. (3)Parts B and C apply to scientific investigation activities and do not apply to engineered items.</p>								
PART A - IDENTIFICATION AND CONTROL OF ITEMS								
1.0 IDENTIFICATION								
<p>(4)Items shall be identified to assure that only correct and accepted items are used or installed. (5)The identification shall be verified prior to installation or use. (6)Identification shall be maintained either on the item, their containers, or in documents traceable to the item from receipt until installed.</p>								
1.1 GENERAL								
<p>(7)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. (8)This identification shall relate an item to an</p>								

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1.1.1 (9) Physical identification shall be used to the maximum extent possible. ✓ (10) Where physical identification on the item is either impracticable or insufficient, physical separation, procedural control, or other appropriate means shall be employed.	9-8.2.1.1 10-8.2.1.1							
1.1.2 (11) Identification markings, when used, shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. (12) Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.	11-8.2.1.2 12-8.2.1.2							
1.1.3 (13) When specified by codes, standards or specification that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part or serial number; or specified inspection, test or other records) the program shall be designed to provide such identification and traceability control.	13-8.2.1.3							
1.1.4 (14) Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.	14-8.2.1.4							
2.0 CONTROL  (15) Provisions shall be made for the control of item identification consistent with the planned duration and condition of storage, such as: (1) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; (2) protection of identification on items subject to excessive deterioration due to environmental exposure; (3) provisions for updating existing facility records.	15-8.2.2							

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**PART B - IDENTIFICATION AND CONTROL OF SAMPLES**

(16) Procedures shall be developed and implemented to assure that samples are identified and controlled in a manner consistent with their intended use.

(17) Such procedures shall define the responsibilities (including interface between organizations) for collection, identification, handling, storage, transportation and the generation of records.

**1.0 IDENTIFICATION**

(18) Physical identification shall be used to the maximum extent possible.

(19) Where physical identification cannot be placed on the sample, appropriate alternative identification methods shall be described and used. (20) All identification methods shall provide methods whereby identification of samples can be traced to the appropriate documentation such as drawings, specifications, drilling logs, test records, inspection documents, and nonconformance reports.

**1.1 GENERAL**

(21) Samples shall be identified by placing the identification directly on the sample, on their container or on records traceable thereto. (22) If it is impractical to place the identification on the sample, methods shall be described and implemented to assure that samples are not mixed with like samples and that the correct identification of samples is verified and documented prior to release for use.

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1.1.1 (23) Procedures shall be developed and implemented to assure that sample collection methods, techniques and related equipment produce the intended sample. (24) Sample handling methods shall be developed, documented and utilized to assure that all samples meet the technical objectives dictated by the scientific investigation, for which the samples are collected.

1.1.2 (25) Storage methodology shall be developed and implemented to assure that samples are maintained in predetermined physical conditions commensurate with their intended purpose. (26) Samples intended for long term storage shall receive appropriate treatment to assure that they do not degrade during storage. (27) Long term is not defined herein and shall be defined by the responsible organization depending on the sensitivity of the sample to storage conditions.

1.1.3 (28) Transportation methods shall be described and effected by procedures prescribing appropriate containers, handling and any other environmental or safety considerations for the sample(s). (29) Where multiple organizations are involved, appropriate procedures shall define responsibilities and documentation methods to be used.

1.1.4 (30) Controls shall be developed and implemented to assure that sample identification is verified and maintained when handled, transported or transferred from one organization's responsibility to another.

1.1.5 (31) Measures shall be taken to maintain sample identification while in storage. (32) These measures shall be consistent with the planned duration and conditions of storage and shall describe actions to be taken where samples may have a maximum life expectancy while in storage. (33) Physical segregation of samples to preclude mixing with like samples shall be used to the maximum degree practical.

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23 8.3.1.1  
24 8.3.1.1  
25 8.3.1.2  
26 8.3.1.2  
27 8.3.1.2  
28 8.3.1.3  
29 8.3.1.3  
30 8.3.2  
31 8.3.1.4  
32 8.3.1.4  
33 8.3.1.4

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35	8.3.3						
36	8.3.3						
37	8.3.3						
PART C - IDENTIFICATION AND CONTROL OF DATA							
1.0 IDENTIFICATION							
38	8.4						
39	8.4						
1.1 GENERAL							
40	8.4						
41	8.4.1						
42	8.4.1						

1.1.6 (34) Where samples are controlled by more than one organization, procedures describing the organizational responsibilities shall be developed and implemented.

1.1.7 (35) The WFO will develop and implement an Administrative Procedure (AP) describing the ultimate curation of all types of samples including liquids, gases and solids. (36) The AP will, as a minimum, address the transportation, handling, storage, retrievability of samples and the generation and retention of records. (37) All records generated as a result of testing of samples shall be handled in accordance with Section XVII.

(38) Data generated from a Nevada Nuclear Waste Storage Investigation (NWSI) scientific investigation shall be identified to assist in the determination of its correct use. (39) Identification of such data shall be provided in all documents, information systems, or both, in which such data appear.

(40) The identification of NWSI Project data shall include a reference to the origin of the data (task, test, experiment, report, publication, etc.) and an indication of the Quality Assurance Level assigned to the activity which produced the data.

1.1.1 (41) Control measures shall be established and implemented to assure that NWSI Project data are properly identified. (42) These measures shall include verification of the identification of such data prior to release for use.

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

**2.2.1 RESPONSIBILITY**

(7) It is the responsibility of the Participating Organization and Nevada Test Site (NTS) Support Contractor that is performing the work to identify which portions of its activities involve the use of special processes. (8) A special process is a process in which the results are highly dependent on either the control of the process or the operator's skill, or both, and in which the specified quality cannot be readily determined by inspection or testing of the item.

7

N/A

8

N/A

**2.2.2 QUALIFICATION REQUIREMENTS**

(9) The necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in the procedures or instructions either for processes that are not covered by existing codes and standards or for processes where the quality requirements for an item or test exceed those of existing codes or standards.

9

N/A

**2.2.3 CONDITIONS**

(10) Conditions necessary for accomplishment of the special process shall be included in procedures or instructions. (11) These conditions shall include proper equipment, controlled parameters of the special process and calibration requirements.

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

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

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

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 N/A  
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<p><b>SECTION X</b></p> <p><b>INSPECTION</b></p> <p><b>1.0 GENERAL REQUIREMENTS</b></p> <p>(1) Measures shall be established by or for the Participating Organizations and Nevada Test Site (NTS) Support Contractors to provide inspections required to verify conformance of an item or activity to specified requirements.</p> <p>(2) These measures shall provide for: (1) inspections to be performed in accordance with written procedures by qualified personnel who did not perform the work being evaluated; (2) criteria for determining when inspections are required or how and when inspections are to be performed; (3) sampling methodology, if used; (4) the identification of mandatory hold points; and (5) identification of inspections requiring special expertise. (3) The results of all inspection activities shall be documented by the inspecting organization. (4) The requirements of this section apply to engineered items and do not apply to scientific investigation activities.</p> <p><b>2.0 PERSONNEL</b></p> <p><b>2.1 REPORTING INDEPENDENCE OF PERSONNEL</b></p> <p>(5) Inspections shall be performed by personnel who do not report directly to the immediate supervisor(s) who is/are responsible for performing the activity being inspected. (6) If these personnel are not part of the formal QA organization, they shall have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further</p>	<p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p>	<p>10.1</p> <p>10.1</p> <p>10.1</p> <p>10.1</p> <p>N/A</p> <p>N/A</p>	<p><i>SPW</i> <i>1-27-89</i></p>					

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processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. (7)When these persons or organizations who perform the inspection activities are not part of the formal QA organization (i.e., part of line management), then the quality assurance organization shall overview and monitor the inspection activity.

**2.2 QUALIFICATION**

(8)Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspections or tests. (9)The qualification of personnel performing inspection and test activities shall be certified in writing. (10)Personnel selected to perform inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities. (11)Personnel shall also be indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are to be employed.

**3.0 INSPECTION HOLD POINTS**

(12)Mandatory inspection or witness hold-points shall be established as necessary. (13)When such hold or witness points are established, work may not proceed without the specific consent of the responsible representative. (14)These hold or witness points shall be indicated in appropriate documents controlling the activity. (15)Consent to waive any specified hold or witness point shall be documented before work can be continued beyond the designated hold or witness point.

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7	N/A							
8	N/A							
9	N/A							
10	N/A							
11	N/A							
12	N/A							
13	N/A							
14	N/A							
15	N/A							

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

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

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

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**8.0 QUALIFICATION REQUIREMENTS**

Appendix C of this document defines the requirements for the qualification of inspection and test personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptance. Appendix D defines the requirements for qualification of nondestructive examination personnel.

**9.0 RECORDS**

(33) The following are the requirements for inspection records which shall be retained in accordance with Section XVII of this QAP.

**9.1 INSPECTION RECORDS**

(34) As a minimum, inspection records shall identify the following:

- o Item or activity.
- o The date of the inspection.
- o Name of individual performing the inspection.
- o Name or names of personnel contacted during the inspection.
- o A description of the type of observation (method of inspection).

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

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**3.0 TEST PROCEDURES**

**3.1 TEST INSTRUCTIONS, PROCEDURES AND DRAWINGS**

(8) Instructions, procedures, and drawings for tests shall be prepared in accordance with the requirements of Section V of this document. (9) Test procedures or instructions shall contain criteria for determining when a test is required and how the test is performed.

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N/A

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**3.2 TEST PREREQUISITES**

(10) Test procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. (11) Prerequisites shall include the following, as applicable: (1) calibrated instrumentation, (2) appropriate equipment, (3) completeness of item to be tested, (4) trained or appropriately qualified personnel, (5) condition of test equipment and the item to be tested, (6) suitable and controlled environmental conditions, and (7) provisions for data acquisition and storage.

10

N/A

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N/A

**3.3 REVIEW OF PROCEDURES**

(12) Test plans and procedures shall be reviewed in accordance with the verification requirements defined in Paragraph 2.4 of Section III of this document. (13) They shall prescribe mandatory inspection hold points (as required), methods of documenting test data and results, and methods of data analysis.

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N/A

13

N/A



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

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2.0 PURPOSE OF EQUIPMENT

(5) Measuring and test equipment are devices or systems used to calibrate, measure, gage, test, or inspect either to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known.

(6) Specific requirements for control of measuring and test equipment are listed below:

2.1 SELECTION

(7) Selection of measuring and test equipment shall be controlled to assure that such equipment is of proper type, range, and accuracy, to accomplish the function of determining conformance to specified tolerance requirements.

The type, range, and accuracy of a measuring device shall be documented in test and inspection documents. (8) Each device shall have a unique identification number. (9) This number shall be recorded on the data sheet, log, etc., along with the measurement taken, to ensure traceability to the measurement of the device that was used to take the measurement.

2.2 CALIBRATION

(10) Measuring and test equipment shall be calibrated against certified equipment having known valid relationships to the National Bureau of Standards or other nationally recognized standards and shall be calibrated, adjusted, and maintained at prescribed intervals. (11) If no nationally recognized standards exist, the basis for calibration shall be documented.

(12) Calibrating standards shall have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. (13) The management authorized to perform this function shall be identified.

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5- 12.2  
6- 12.2  
7- 12.2.1  
8- 12.2.1  
9- 12.2.1  
SPW  
1-21-89  
10- 12.2.2  
11- 12.2.2  
12- 12.2.2  
13- 12.2.2  
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<b>2.3 CONTROL</b>								
(14)The method and interval of calibration for each item shall be defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. (15)Measuring and test equipment must be labeled, tagged, or otherwise documented in a fashion which indicates the due date of the next calibration and to provide traceability to calibration data. (16)If measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous results obtained and of the acceptability of items previously inspected, tested or data gathered since the last calibration. (17)Devices that are out of calibration shall be tagged or segregated and shall not be used until they have been recalibrated. (18)If any measuring or test equipment is found to be out of calibration consistently, then it shall be repaired or replaced. (19)A calibration shall be performed when the accuracy of equipment is suspect.	14- 15- 16- 17- 18- 19-	SPW 1.2.89 12.2.3 12.2.3 12.2.3 12.2.3 12.2.3 12.2.3						
<b>2.4 COMMERCIAL DEVICES</b>								
(20)Calibration and control measures are not required for rulers, tape measure, levels, and other such devices, if normal commercial equipment provides adequate accuracy.	20-	12.3						
<b>2.5 HANDLING AND STORAGE</b>								
(21)Measuring and test equipment shall be handled properly and stored to maintain accuracy.	21-	12.2.4 SPW 1.2.89						

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<p>2.6 RECORDS</p> <p>(22)Records shall be maintained and equipment shall be marked suitably to indicate calibration status. (23)Calibration records shall identify the calibration procedure (including revision) utilized to perform the calibration.</p>	22	SPW 12.2.5						
	23	12.2.5 12/88						

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SECTION XIII

HANDLING, SHIPPING, AND STORAGE

1.0 GENERAL REQUIREMENTS

(1) Measures shall be established to control the packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration. (2) 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. Specific requirements are listed below.

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1.1 SPECIAL EQUIPMENT AND PROTECTIVE ENVIRONMENTS

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

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1.2 SPECIFIC PROCEDURES

(4) When they are required for critical, sensitive, perishable, or exceptionally expensive articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

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<p align="center"><b>1.3 INSPECTION AND TESTING OF SPECIAL TOOLS AND EQUIPMENT</b></p> <p>(5) Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling. (6) Special handling tools and equipment shall be inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are maintained adequately.</p>	<p align="center">5 ✓</p>	<p align="center">13.1.3</p>						
	<p align="center">6 ✓</p>	<p align="center">13.1.3</p>						
<p align="center"><b>1.4 OPERATORS OF SPECIAL EQUIPMENT</b></p> <p>(7) Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.</p>	<p align="center">7 ✓</p>	<p align="center">13.1.4</p>						
<p align="center"><b>1.5 MARKING AND LABELING</b></p> <p>(8) Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.</p>	<p align="center">8 ✓</p>	<p align="center">13.1.5</p>						

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<p><b>1.1.2 EXCEPTIONS</b></p> <p>(9) If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.</p>	9	15.1						
<p><b>1.1.3 CONDITIONAL RELEASE</b></p> <p>(10) Work on the nonconforming item shall be stopped until completion of the action specified in the Nonconformance Report (NCR) disposition. (11) If only a specific portion of the item is in nonconformance, then that specific area shall be identified and work may proceed on the remaining areas. (12) If work on a nonconforming item must be continued (conditional release) prior to implementation of the disposition, the Waste Management Project Office (WMPO) shall approve such continuance. (13) Requests for conditional releases on nonconforming items shall include documented justification that the following conditions are met:</p> <ul style="list-style-type: none"> <li>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. ✓</li> <li>o The nonconforming item remains accessible for inspection. ✓</li> <li>o The nonconforming item is evaluated and limitation(s) for use of the equipment or system is established. —</li> <li>o Traceability and identification of the nonconforming item are maintained. ✓</li> </ul>	10 11 12 13	15.2 15.2 15.2 15.2						

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<b>1.2 LOGGING</b>								
<b>1.2.1 NONCONFORMANCE CONTROL LOG</b>								
(14) Each NWSI Project participant shall maintain a nonconformance control log to track nonconforming items. (15) This log shall contain the following information:	14	15						
o The nonconformance report 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 (open or closed) ✓								
<b>1.3 SEGREGATION</b>								
<b>1.3.1 HOLD AREA</b>								
(16) When practical, nonconforming items shall be segregated by placing them in a clearly identified and designated hold area until they are dispositioned properly.	16	15						
<b>1.3.2 ALTERNATIVE</b>								
(17) When segregation is impractical or impossible because of physical conditions, such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.	17	15						

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<b>1.4 DISPOSITION</b>								
<b>1.4.1 NONCONFORMANCE CHARACTERISTICS</b>								
(18) Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. (19) Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel. (20) Distribution of nonconformance documentation shall be to all affected organizations.	18	15.1.4						
	19	15.1.4						
	20	15.1.4						
<b>1.4.2 RESPONSIBILITY AND AUTHORITY</b>								
(21) The responsibility and authority for the evaluation, disposition, and close-out of nonconforming items shall be defined and documented. (22) Those personnel assigned signature approval of the disposition shall be identified. Quality Assurance (QA) responsibilities relating to nonconformances shall be described.	21	15.1.4.1						
	22	15.1.4.1						
<b>1.4.3 PERSONNEL</b>								
(23) Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area that they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.	23	15.1.4.1						

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<p><b>1.4.4 DISPOSITIONING OF NCR</b></p> <p>(24) The person or organization assigned the responsibility of dispositioning the NCR shall ensure the following:</p> <ul style="list-style-type: none"> <li>o Nonconformance documentation adequately identifies and describes the nonconformance.</li> <li>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.</li> <li>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.</li> <li>o The technical details for correction of the nonconforming condition are adequate for the recommended disposition.</li> <li>o If continuance has been requested, justification for the activity to continue has been documented and approved by the appropriate WFO Branch Chief and the WFO PGM.</li> <li>o The disposition complies with existing design documents, test plans or procedures, reports, and regulatory requirements.</li> <li>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 shall also be cross referenced on the NCR.</li> </ul>	24	15.1	4.2					

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<ul style="list-style-type: none"> <li>Disposition has identified and documented the correction as repair, rework, use-as-is, or reject/scrap.</li> <li>Disposition has identified the people or organization responsible to implement the disposition.</li> </ul>								
<p>1.4.5 WFO APPROVAL</p> <p>(25) In those cases where the responsible organization proposes a disposition of "repair", WFO shall approve the proposed disposition prior to implementation. (26) In the case of a proposed disposition of "use-as-is", the NCR shall be forwarded to WFO for approval after all actions necessary to support technical justification of the disposition have been completed. (27) The appropriate WFO Branch Chief and the WFO PCM shall approve NCR dispositions involving "repair" or "use-as-is" determinations and conditional release recommendations.</p>	25 ✓	15.1.4.3						
	26 ✓	15.1.4.3						
	27 ✓	15.1.4.3						
<p>1.4.6 CORRECTIVE ACTION</p> <p>(28) The action taken to correct the nonconforming item shall be verified and documented. (29) Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria, unless the nonconforming item disposition has established alternate acceptance criteria.</p>	28 ✓	15.1.4.4						
	29 ✓	15.1.4.4						
<p>1.4.7 INTERFACES</p> <p>(30) Internal interfaces between organizational units and external interfaces between NWSI Project participants shall be clearly described.</p>	30 ✓	15.1.4.5						

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<p align="center"><b>2.0 REPETITIVE NONCONFORMANCES</b></p> <p>(31)When repetitive or recurring nonconforming conditions are identified, an evaluation shall be made as to whether or not further programmatic corrective action is warranted to preclude repetition. (32)This corrective action shall be beyond the scope of the action taken for the disposition on the existing NCRs and shall be processed in accordance with corrective action procedures developed by each NWSI Project participant.</p>	31	15.3						
	32	15.3						
<p align="center"><b>3.0 TRENDING</b></p> <p>(33)Nonconformance reports shall be periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances. (34)Results shall be reported to upper management for review and assessment.</p>	33	15.4						
	34	15.4						
<p align="center"><b>4.0 DISTRIBUTION OF DOCUMENTS</b></p> <p>(35)Copies of nonconformance reports for items shall be sent to the WFO PCM and the SAIC/TMSS Project QA Department (QA Engineering Division Manager) by the originating organization upon issuance and upon closure. (36)The original nonconformance reports shall be sent to the WFO for approval as required by Paragraph 1.4.5 of this section.</p>	35	15.5						
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SECTION XVI

CORRECTIVE ACTION

1.0 GENERAL

(1) A corrective action system is to be defined in the Quality Assurance Program Plan (QAPP) of each Nevada Nuclear Waste Storage Investigations (NWSI) Project Participant and NTS Support Contractor. (2) This system shall ensure that conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as practical.

1.1 SIGNIFICANT ADVERSE CONDITIONS

(3) For significant conditions adverse to quality the identification, cause, and corrective action taken to preclude recurrence shall be documented and reported to immediate management and upper levels of management for review and assessment. (4) A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability. (5) Significant conditions include, but are not limited to breakdowns in the Quality Assurance program and repetitive nonconformances. (6) Upon discovering or receiving notification that a significant condition adverse to quality or unusual occurrence exists, each NWSI Project Participant shall ensure that:

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

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<ul style="list-style-type: none"> <li>o Controls have been reviewed, implemented, monitored and revised, if necessary.</li> <li>o Affected managers at all levels have been notified of adverse condition(s) and of lessons to be learned to improve conditions or avoid similar occurrences.</li> </ul>								
<b>1.2 FOLLOW-UP ACTION</b>								
(7)The QA organization shall document concurrence of the adequacy of proposed corrective actions to assure that QA requirements will be satisfied.	7	16.1.2						
(8)Follow-up action shall be taken by the QA organization to verify proper implementation of this corrective action and to close out the corrective action.	8	16.1.2						
(9)The organization responsible for implementing the corrective action shall assure that the corrective action is completed in a timely manner.	9	16.1.2						
<b>1.3 CORRECTIVE ACTION</b>								
(10)Corrective action reports shall be periodically analyzed by the QA organization to show quality trends. (11)Results shall be reported to upper management for review and assessment.	10	16.1.3						
	11	16.1.3						
<b>2.0 DISTRIBUTION OF DOCUMENTS</b>								
(12)Copies of corrective action reports shall be sent to the SAIC/TMSS Project QA Department (QA Engineering Division Manager) by the originating organization upon issuance and closure. (13)Those that document significant conditions adverse to quality shall be reported to the appropriate OCMW Associate Director.	12	16.2						
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SECTION XVII								
QUALITY ASSURANCE RECORDS								
1.0 GENERAL REQUIREMENTS								
(1) Records that furnish documentary evidence of quality shall be specified, prepared, and maintained in accordance with NWSI Administrative Procedures which shall meet the requirements of this Section. (2) This shall include the requirements that all documents be legible, identifiable, and retrievable.	1-17.							
	2-17.							
1.1 DEFINITION								
(3) A document or other item is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined below. (4) The term records, used throughout this Section is to be interpreted as Quality Assurance Records. (5) Quality Assurance Records include	3-17.1							
(1) individual documents that have been executed, completed, and approved and that furnish evidence of the quality and completeness of data (including raw data), and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents, such as plans, correspondence, documentation of telecons, specifications, technical data, books, maps, papers, photographs, and data sheets; (5) magnetic media; and (6) other materials that provide data and document quality, regardless of the physical form or characteristic. (6) A completed record is a document that will either receive no more entries or	4-17.1							
	5-17.1							

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<p>whose revision would normally consist of the reissue of the document; and is signed and dated by the originator and, as applicable, by personnel authorized to approve the document. (7)Records shall be distributed, handled and controlled in accordance with written procedures. (8)All records (including superseded records) shall be retained for the NNWSI Project.</p> <p style="text-align: center;">1.2 ESTABLISHING A RECORD SYSTEM</p> <p>(9)A record system or systems shall be established by each NNWSI Project participant at the earliest practicable time consistent with the schedule for accomplishing work activities.</p> <p>1.2.1 RECORDS MANAGEMENT</p> <p>(10)The record system shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation prepared in accordance with Section V of this document. (11)The records management activities to be performed by the NNWSI Project Participating Organizations, Nevada Test Site (NTS) Support Contractors, and the Waste Management Project Office (WMPO) when processing QA records are detailed in the NNWSI Project Administrative Procedures Manual.</p> <p>(12)The WMPO shall prepare a NNWSI Project Information Management System Plan and shall submit the plan to OCRM for review and approval. (13)The records management plan shall:</p> <ul style="list-style-type: none"> <li>o Identify the types of records to be generated, purchased, or maintained, including all records referenced in pertinent final reports and other documents.</li> </ul>	<p style="text-align: right;">SPW 1-25-89</p> <p>7- 17.1</p> <p>8- 17.1 17.2.2 SPW</p> <p>9- 17.2</p> <p>10- 17.2</p> <p>11- 17.2</p> <p>12- 17.2.1</p> <p>13- 17.2.1</p> <p style="text-align: right;">SPW 1-25-89</p>							

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<ul style="list-style-type: none"> <li>o Identify the methods to be used to comply with all applicable records requirements, including those to be used to control in-process records.</li> <li>o Identify and define the responsibilities of pertinent organizations, including the QA organization.</li> </ul>								
<p>(14) Consistent with applicable regulatory requirements, the WFO shall establish requirements concerning record types and retention that shall include duration, location, and assigned responsibility.</p> <p><b>1.2.2 MINIMUM RECORDS</b></p> <p>(15) Sufficient records shall be specified, prepared, and maintained to furnish documented evidence of activities that affect quality. (16) The records shall include at least the following: operating logs, the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. (17) Also, the records shall include closely related data such as qualifications of personnel, procedures, and equipment. A list of typical QA records is contained in Appendix E.</p> <p><b>1.2.3 CONTROL OF RECORDS</b></p> <p>(18) Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition of QA records shall be established and documented.</p>	<p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p>	<p>17.2.1</p> <p>17.3.1</p> <p>17.3.1</p> <p>17.3.1</p> <p>17.3</p>						

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<p><b>1.3 PRESERVATION OF RECORDS</b></p> <p>(19) The procedure that defines the implementation of the record system for each organization shall identify measures to be implemented for the preservation and safe-keeping of the records before storage and for the prevention of delays between record completion and storage at the Project Record Center.</p>	19	17.2.2						
<p><b>1.4 RETENTION CLASSIFICATION</b></p> <p>(20) For purposes of record retention, all NWSI Project records are classified as lifetime records and are required to be retained for the life of the Project.</p>	20	17.2.2						
<p><b>2.0 GENERATION OF RECORDS</b></p>								
<p><b>2.1 RECORDS SPECIFICATION</b></p> <p>(21) The applicable design specifications, procurement documents, implementing procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for the NPO.</p>	21	17.3						
<p><b>2.1.1 QUALITY OF RECORDS</b></p> <p>(22) Documents that are designated to become records shall be legible, identifiable, accurate, complete, reproducible, microfilmable, and appropriate to the work accomplished.</p>	22	17.3.2						

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**2.1.2 COMPLETION OF RECORDS**

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

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**3.0 VALIDATION OF RECORDS**

**3.1 METHODS OF VALIDATION**

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

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**3.2 AUTHENTICATION LIST**

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

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**4.0 RECEIPT OF RECORDS**





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<p align="center"><b>6.1 STORAGE LOCATION</b></p> <p>(42)The records shall be stored in a predetermined location or locations that meets the requirements of applicable standards, codes, and regulatory agencies.</p>	42	17.4.1						
<p align="center"><b>6.2 STORAGE PROCEDURE</b></p> <p>(43)Before the records are stored, a written storage procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure. (44)As a minimum, this procedure shall include the following:</p> <ul style="list-style-type: none"> <li>o A description of the storage facility.</li> <li>o The filing system to be used.</li> <li>o The method for verifying that the records received are legible and are in agreement with the transmittal document.</li> <li>o The method of verifying that the records are those designated (see Paragraph 4.1 of this section).</li> <li>o The rules governing access to and control of the files.</li> <li>o The method for maintaining control of and accountability for records removed from the storage facility.</li> <li>o A method for filing supplemental information (see Paragraph 9.0 of this section).</li> </ul>	43 44	17.4 17.4						

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<p>7.0 PRESERVATION</p> <p>(45)Records shall be stored in a manner approved by the organization or organizations responsible for storage. (46)In order to preclude deterioration of the records, the following requirements shall apply:</p> <ul style="list-style-type: none"> <li>o Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure.</li> <li>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.</li> <li>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.</li> </ul>	45	17.4.2						
	46	17.4.2						
<p>8.0 SAFEKEEPING</p> <p>8.1 MEASURES TO PRECLUDE ENTRY</p> <p>(47)Measures shall be established to preclude the entry of unauthorized personnel in the storage area. (48)These measures shall guard against larceny and vandalism.</p>	47	17.4.3						
	48	17.4.3						

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**8.2 REPLACEMENT, RESTORATION, OR SUBSTITUTION**

(49) Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records. These measures shall be accomplished within 90 days following determination that either a record has been lost or a record has been damaged to a degree that it is no longer complete or legible.

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59 17.4.3

**9.0 CORRECTED INFORMATION IN RECORDS**

**9.1 METHOD**

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

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**9.2 IDENTIFICATION**

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

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**10.0 STORAGE FACILITY**

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

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<p>10.1 CONSTRUCTION AND MAINTENANCE OF FACILITY</p> <p>(53) Records shall be stored in facilities constructed and maintained in a manner that minimizes the risk of damage or destruction from natural disasters, such as winds, floods, or fires; environmental conditions such as high and low temperatures and humidity; and infestation of insects, mold, or rodents.</p>	53	17.4.1						
<p>10.2 METHODS</p> <p>(54) The two satisfactory methods of providing storage facilities are (1) single and (2) dual; these are detailed in the following sections.</p> <p>10.2.1 SINGLE FACILITY</p> <p>(55) Design and construction of a single record storage facility shall meet the following criteria:</p> <ul style="list-style-type: none"> <li>o It shall have reinforced concrete, concrete block, masonry, or equal construction.</li> <li>o It shall have a floor and roof with drainage control and if a floor drain is provided, then a check valve (or equivalent device) shall be included.</li> <li>o It shall have doors, structures and frames, and hardware that shall be designed to comply with the requirements of a minimum two hour fire rating.</li> </ul>	54 55	17.4.1 17.4.1.1						

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<ul style="list-style-type: none"> <li>o Sealant shall be applied over walls as a moisture or condensate barrier.</li> <li>o Surface sealant shall be placed on the floor to provide a hard wearing surface to minimize concrete dusting.</li> <li>o It shall have foundation sealant and provisions for drainage.</li> <li>o It shall have forced-air circulation with a filtration system.</li> <li>o It shall have a fire protection system.</li> <li>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 dampened to comply with the minimum two-hour fire protection rating.</li> <li>o The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing.</li> <li>o If the facility is located within a building or structure, then the environment and construction of that building can provide a portion or all of these criteria.</li> </ul>	<p>SPW 1.25-89</p> <p style="text-align: center;">↓</p> <p>SPW 1.25-89</p>							

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10.2.2 ALTERNATE SINGLE FACILITIES

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

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- 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.
  - Work that is not associated directly with record storage or retrieval shall be prohibited in the file room.
  - Smoking, eating, or drinking shall be prohibited in the file room.
  - Two-hour fire rated dampers or doors in all boundary penetrations.

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<p>10.2.3 DUAL FACILITIES</p> <p>(57)IF storage at dual facilities for each record is provided, then the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. (58)Neither facility is required to satisfy the requirements of Paragraphs 10.2.1 or 10.2.2 but shall meet the other requirements of this document.</p> <p>11.0 RETRIEVAL</p> <p>11.1 PROVISIONS</p> <p>(59)Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type. (60)Final reports shall contain a listing, by unique number or other designation, that enables prompt retrieval of all documents used to compile or evaluate the report. (61)This listing shall include, as a minimum, all referenced documents, peer review or other review documents, computer codes, data sheets, procedures, and test plans. (62)All documents referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineers handbook, etc., shall be retrievable from the Records Management System (RMS).</p> <p>11.2 PERSONNEL</p> <p>(63)A list shall be maintained that designates those personnel who shall have access to the files.</p>	<p>SPJ 1-25-89</p> <p>57</p> <p>58</p> <p>59</p> <p>60</p> <p>61</p> <p>62</p> <p>63</p> <p>SPJ 1-25-89</p>	<p>17.4.1.3</p> <p>17.4.1.3</p> <p>17.4.1.4</p> <p>17.4.1.4</p> <p>17.4.1.4</p> <p>17.4.1.4</p> <p>17.4.3.1</p>						

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<p><b>11.3 ACCESSIBILITY</b></p> <p>(64) Records maintained by a Participating Organization or Nevada Test Site (NTS) Support Contractor at their facility or other location (on an interim or other basis) shall be accessible to the WFO or its designated alternate.</p>	64	17.4.3.1						
<p><b>12.0 DISPOSITION</b></p> <p><b>12.1 ACCESSIBILITY AT VARIOUS LOCATIONS</b></p> <p>(65) Records that are accumulated at various locations, prior to transfer, shall be made accessible to the WFO either directly or through the procuring organization.</p>	65	17.4.3.1						
<p><b>12.2 CUSTODIAN</b></p> <p>(66) The custodian shall inventory the submittals, acknowledge receipt, and process these records in accordance with this document or the procedures implementing this document.</p>	66	17.4.3.2						
<p><b>12.3 REQUIREMENTS OF REGULATORY AGENCIES</b></p> <p>(67) Various regulatory agencies have requirements concerning records that are within the scope of this document. (68) The most stringent requirements shall be used to determine final dispositions.</p>	67	17.4.3.3						
	68	17.4.3.3						

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SECTION XVIII

AUDITS

1.0 GENERAL REQUIREMENTS

(1) All Nevada Nuclear Waste Storage Investigations (NWSI) Project activities will be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall Quality Assurance (QA) program and to determine their effectiveness. (2) Each NWSI Project participant shall include in their Quality Assurance Program Plan (QAPP) a system of planned, periodic audits to provide an objective evaluation of the quality-related practices, procedures, instructions, activities, and items including the review of documents and records to assure that the QA program is effective and properly implemented. (3) 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. (4) Audit results shall be documented, reported to, and reviewed by responsible management. (5) Tracking systems shall be instituted for audit findings to assure that all findings are appropriately addressed and to identify quality trends. (6) All deficiencies, nonconformances, and potential quality problems identified during the audit are to be documented and monitored until verification of effective corrective action is made. (7) The audited organization shall describe in a formal report the corrective action to be taken to address findings, and shall submit the report to the auditing organization and their own responsible management.

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

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1.1 MWSI PROJECT AUDITS

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

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1.1.1 WPFO AUDITS

(10) The SAIC/T&MS Project QA Department shall develop a schedule defining the WPFO audits planned for each fiscal year. (11) This schedule shall be approved and issued by the WPFO as an annual planning document. (12) As a minimum, WPFO shall audit all MWSI Project participants annually. (13) The audits shall cover the entire scope of the participants' QAPP. (14) Additional audits may be conducted when a unique need arises or when an audit is requested by a Participating Organization or NTS Support Contractor. (15) Participating Organizations and NTS Support Contractors shall be audited to verify the effectiveness and adequacy of implementation of all elements of their respective QAPPs and this QA Plan. (16) These audits will eliminate the need for Participating Organizations or NTS Support Contractors to conduct audits of each other. (17) Representatives of the Participating Organizations, or NTS Support Contractors, or both may be invited to participate in a WPFO audit when the audited organization's activities are of mutual interest. (18) Copies of audit documents for the WPFO audits shall be sent to the audited organization. (19) The WPFO shall also conduct internal audits, which cover the complete WPFO QAPP and this QAP, on an annual basis.

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<b>1.1.2 PARTICIPATING ORGANIZATION AND NTS SUPPORT CONTRACTOR AUDITS</b>								
(20) Each Participating Organization and NTS Support Contractor shall conduct internal (covering their entire QAPP, on an annual basis) and external (direct subcontractor) audits of activities under its direct control, but they will not conduct audits of each other. (21) These audits will be scheduled, planned, conducted, and reported as described in their respective QAPPs and this Quality Assurance Plan (QAP). (22) External and internal audit schedules, dates, and changes thereto, shall be sent to the SAIC/TSMS Project QA Department (QA Verification Division Manager). (23) Audit schedules shall identify the date of the audit, the activities to be audited, and the requirements to which the activities are to be audited.	20	18.1.1.2						
	21	18.1.1.2						
	22	18.1.1.2						
	23	18.1.1.2						
<b>1.2 SCHEDULING</b>								
(24) Internal and external QA audits, shall be scheduled in a manner that shall provide coverage and coordination with ongoing QA program activities. (25) Audits shall be scheduled at a frequency commensurate with the status and importance of the activity and shall be initiated early enough to assure effective QA. (26) Each NWSI Project Participant shall perform or arrange for annual evaluations of suppliers. (27) This evaluation shall be documented and shall take into account, where applicable, (1) review of supplier furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions; (2) results of previous source verifications, audits, and receiving inspections; (3) operating experience of identical or similar products furnished by the same supplier; and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.	24	18.1.2						
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1.2.1 INTERNAL AUDITS

(28) Applicable elements of an organization's QAPP shall be audited at least annually or at least once during the life of the activity, whichever is shorter. (29) The scope of the audit shall be established by: considering the results of any previous audits, the nature and frequency of identified deficiencies, and any significant changes in personnel, organization, or in the QA program.

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1.2.2 EXTERNAL AUDITS

(30) Elements of an external organization's QA program shall be audited at least annually or once during the life of the activity, whichever is the shorter period, with the following exception: (31) If the activity is less than four months in duration, an audit is not required to be performed unless an audit is necessary due to the complexity or importance of the activity being performed.

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(32) The justification for not performing audits of vendors whose activities are less than four months in duration shall be documented and approved by the responsible QA Manager prior to implementation of the activity. (33) A copy of the documented justification shall be provided to the Yucca Mountain Project Office POM.

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1.2.3 JOINT AUDITS

(34) If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier.

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(35) The scope of this audit shall satisfy the needs of all of the purchasers,

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<p>and the audit report shall be distributed to all the purchasers for whom the audit was conducted. (36)Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.</p> <p align="center"><b>1.3 PREPARATION</b></p> <p>Preparation for an audit shall include the items listed below.</p> <p><b>1.3.1 AUDIT PLAN</b></p> <p>(37)The auditing organization shall develop and document an audit plan for each audit. (38)This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.</p> <p><b>1.3.2 PERSONNEL</b></p> <p>(39)The auditing organization shall select and assign auditors who are independent of any direct responsibility for the performance of the activities that they are to audit. (40)If the audit is to be an internal one, then the personnel who have direct responsibility for performing the activities to be audited shall not be involved in the selection of the audit team. (41)Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. Appendix F defines the requirements for the qualification of QA audit personnel.</p>	<p align="center">36</p>	<p align="center">18.1.2.3</p>	<p align="center">SpJ 1.25-89</p>					
	<p align="center">37</p>	<p align="center">18.1.3.1</p>						
	<p align="center">38</p>	<p align="center">18.1.3.1</p>						
	<p align="center">39</p>	<p align="center">18.1.3.2</p>						
	<p align="center">40</p>	<p align="center">18.1.3.2</p>						
	<p align="center">41</p>	<p align="center">18.1.3.2</p>	<p align="center">SpJ 1.25-89</p>					

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**1.3.3 SELECTION OF AUDIT TEAM**

(42) An audit team shall be identified before the beginning of each audit.  
 (43) This team shall contain one or more auditors and shall have an individual qualified as a lead auditor who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates the responses.  
 (44) The audit team leader shall identify the technical specialists, if any, who will participate in the audit and include this information in the audit plan.  
 (45) Audit team members selected to participate in audits for technical consideration purposes shall have appropriate technical expertise or experience in the work being audited.  
 (46) Multidisciplinary audit teams shall be employed when activities to be audited involve more than a single technical area.  
 (47) The audit team leader shall ensure that the audit team is prepared before the audit begins.

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**1.4 PERFORMANCE**

(48) Audits shall be performed in accordance with written procedures using checklists as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity.  
 (49) Elements that have been selected for audit shall be evaluated against specified requirements including a review of corrective actions taken on deficiencies in the area being audited that were identified during previous audits.  
 (50) Objective evidence shall be examined to the depth necessary to determine if these elements are adequate for effective control and to determine whether or not they are being implemented effectively.  
 (51) The audit results shall be documented by audit personnel and shall be reviewed by management having responsibility for the area audited.  
 (52) Conditions that require prompt corrective action shall be reported immediately to the management of the audited organization.  
 (53) Audit findings will be reviewed with the audited organizations at a closing meeting.

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1.5 REPORTING

(54) The audit report shall be signed by the audit team leader and should be issued within 30 calendar days. (55) This report shall include the following information, as appropriate:

- 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.

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1.6 RESPONSE

(56) Management of the audited organization or activity shall investigate adverse audit findings; determine root cause; schedule corrective action, including measures to prevent recurrence; and, within thirty calendar days of receipt of the audit report, notify the appropriate organizations in writing of action taken or planned. (57) The adequacy of audit responses shall be evaluated by or for the auditing organization.

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<b>1.7 FOLLOW-UP ACTION</b>								
(58) Follow-up action shall be taken to determine whether or not corrective action has been accomplished as scheduled and shall be verified by the auditing organization. (59) An analysis of audit results shall be performed by the QA organization to identify quality trends. (60) The results of the analysis shall be reported to responsible management for review, assessment, and appropriate action.	58	18.1.7						
	59	18.1.7						
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<b>1.8 RECORDS</b>								
<b>1.8.1 AUDITS</b>								
(61) As a minimum, audit records shall include the following:	61	18.1.8						
o Identification of the organization(s), 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, and the record of completion of corrective action, and close-out of the audit.								
<b>1.8.2 PERSONNEL RECORDS</b>								
(62) Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer. Records for each Lead Auditor shall be maintained and updated annually.	62	18.1.8						

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<b>2.0 SURVEILLANCES</b>								
<p>(63)The NWSI Project audit program shall be supplemented by independent surveillance activities. (64)The purpose of a surveillance is to monitor or observe items or activities to verify conformance to specified requirements. (65)These surveillances shall be conducted by the NFO, the Participating Organizations and the NTS Support Contractors, and shall be either scheduled or implemented on a random basis.</p>	63	18.2						
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<p>(66)Measures for the surveillance of site investigation activities shall be established and executed in accordance with procedures prepared by the organization performing the activity. (67)Surveillances shall be scheduled and conducted based on the activity's relative impact or importance, or both, to the NWSI Project. (68)All deficiencies, nonconformances, and potential quality problems identified during surveillances are to be documented and monitored until verification of effective corrective action is made. Specific requirements applicable to surveillance activities are as follows:</p>	67	18.2						
	68	18.2						
<b>2.1 PLANNING</b>								
<p>(69)Surveillances are to be performed to written checklists or surveillance plans whenever practical. (70)The documentation shall identify characteristics, methods, and acceptance criteria, shall provide for recording objective evidence of results, and accuracy of the equipment necessary to perform surveillance. (71)The specification of acceptance criteria related to surveillances may be as simple as "to verify proper implementation of procedures" or "to verify conformance to requirements".</p>	69	18.2.1						
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	<p><b>2.2 REPORTING INDEPENDENCE</b></p> <p>(72) Surveillance personnel shall not report directly to the immediate supervisors who are responsible for the work being surveilled.</p> <p><b>2.3 RECORDS</b></p> <p>(73) As a minimum, surveillance records shall identify the following:</p> <ul style="list-style-type: none"> <li>o Item or activity.</li> <li>o Date of surveillance.</li> <li>o Name of individual performing the surveillance.</li> <li>o Identification of the organization(s), activities, or items surveilled, including the name or names of personnel contacted.</li> <li>o Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance. Nonconformances shall be handled in accordance with the requirements of Section XV or XVI, as applicable.</li> <li>o Surveillance criteria.</li> <li>o Equipment used during the surveillance.</li> <li>o Results.</li> <li>o Acceptance statement.</li> </ul>	<p>72</p> <p>73</p>	<p>18.2.2</p> <p>18.2.3</p>	<p>SPW 1.25.09</p> <p>SPW 1.25.09</p>				

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APPENDIX A

TERMS AND DEFINITIONS

✓ACCEPTANCE CRITERIA: Specified limits defined in codes, standards, or other requirement documents placed on characteristics of an item, process, or service.

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

✓ACTIVITIES THAT AFFECT QUALITY: Deeds, actions, work, or performance of a specific function or task. The NWSI QA Program applies to activities affecting the quality of all systems, structures, and components important to safety, and to the design and characterization of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation. The QA Level I requirements of this QA Program apply to all activities affecting the quality of structures, systems, and components important to safety and engineered barriers important to waste isolation. These activities include: designing (including such activities as safety analyses, laboratory testing of waste package materials to characterize their performance, and performance assessments), purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying. These types of activities do not need to be identified as part of the Q-list nor do they require QA

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level assignment. However, activities related to natural barriers important to waste isolation shall be identified and listed on a Q-list. These activities include: performance assessments, site characterization testing, and activities that may impact the waste isolation capability of the natural barrier. Examples are site characterization activities such as exploratory shaft construction, borehole drilling, and other activities that could physically or chemically alter properties of the natural barriers in an adverse way.

**ACTIVITY:** Any time consuming effort (operation, task, function, or service) which influences or affects the achievement or verification of the objectives of the NWSI Project as depicted in the NBS Dictionary.

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

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

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

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

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

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

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

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<p><b>CERTIFICATION:</b> The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.</p> <p><b>CHARACTERISTIC:</b> Any property or attribute of an item, process, or service that is distinct, describable, and measurable.</p> <p><b>COMMERCIAL GRADE ITEM:</b> An item satisfying all of the following requirements:</p> <ol style="list-style-type: none"> <li>1) The item is not subject to design or specification requirements that are unique to Mined Geologic Disposal Systems;</li> <li>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.</li> <li>3) The item is used in applications other than Mined Geologic Disposal Systems.</li> </ol> <p><b>COMPUTER MODEL VALIDATION:</b> Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (NUREG-0856). Usually accomplished by comparing code results to (1) physical data, or (2) a verified or validated code designed to perform the same type of analysis (e.g., benchmarking with a validated code). Peer review may be used for code validation if it is the only available means for validating a code.</p>	<p>SPN 1.25.89</p>							

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**COMPUTER CODE VERIFICATION:** Assurance that a computer code correctly performs the operations specified in a numerical model (NUREG-0856). Usually accomplished by comparing code results to (1) a hand calculation, (2) an analytical solution or approximation, or (3) a verified code designed to perform the same type of analysis (benchmarking).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**DEVIATION:** A departure from specified requirements.

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

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

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

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

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

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

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

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

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

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

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

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

**IMPORTANT TO WASTE ISOLATION:** The barriers that must meet the criteria that address long-term performance of the engineered and natural barriers to prevent the release of radionuclides from the site to the accessible environment (i.e. for achieving the postclosure performance objectives in 10CFR60, Subpart E).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**NTS:** Nevada Test Site

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

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

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

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<p><b>OVERVIEW:</b> An analysis and assessment by management of the scope, status, adequacy and effectiveness of Program quality achievement and assurance activities. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate.</p> <p><b>OWNER:</b> The person, group, company, agency, or corporation that has or will have title to the repository.</p> <p><b>PARTICIPATING ORGANIZATION:</b> This term applies to the following: (1) the government agencies external to the DOE, (2) national laboratories, and (3) organizations participating directly in NWSI Project activities.</p> <p><b>PEER:</b> A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work.</p> <p><b>PEER REVIEW:</b> A documented critical review performed by personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Peer reviews are in-depth, critical reviews and evaluations of documents, material or data that require interpretation or judgment to verify or validate assumptions, plans, results or conclusions or when the conclusions, material or data contained in a report go beyond the existing state of the art.</p> <p>A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work. In contrast to peer review, the term "technical review" refers to a review to verify compliance to predetermined requirements; industry standards; or common scientific, engineering, and industry practice.</p>	<p>SPN 1-25-89</p>							
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**PEER REVIEW GROUP:** A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed and should vary in size based on the subject matter and importance of the subject matter to safety or waste isolation.

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

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

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

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

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

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

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

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

**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.

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

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

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

**QUALIFICATION TESTING:** Demonstration that an item meets design requirements.

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

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

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

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

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

**QUALITY ASSURANCE LEVEL I:** those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public. Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

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**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 WFO concerns, and the environment.

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

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

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

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

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

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

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<p><b>REPAIR:</b> The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.</p> <p><b>REPOSITORY:</b> See Geologic Repository Operations Area.</p> <p><b>RETRIEVAL:</b> The act of intentionally removing radioactive waste from the underground location at which the waste had been emplaced previously for disposal.</p> <p><b>REWORK:</b> The process by which a nonconforming item or activity is made to conform to the original requirements by completion or correction utilizing existing approved procedures.</p> <p><b>RIGHT OF ACCESS:</b> The right of a purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or Quality Assurance audit.</p> <p><b>SCENARIO:</b> An account or sequence of a projected course of action or event.</p> <p><b>SCIENTIFIC INVESTIGATION:</b> Any research, experiment, test, study, or activity that is performed for the purpose of investigating the natural barriers or the man-made aspects of the geologic repository, including the overall design of the facilities and the waste package. This will include, but will not be restricted to, all geologic, tectonic, seismologic, hydrologic, climatologic, geochemical, chemical, geophysical, physical, geomechanical, mechanical, meteorological, metallurgical, environmental, socioeconomic, and transportation studies of activities which are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation and/or closure of the geologic repository.</p>	<p>304 1.25.89</p>							
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✓ **SCIENTIFIC NOTEBOOK:** A document which may be used to provide a written record of the results of scientific investigations and experiments when the work involves a high degree of professional judgment or trial and error methods, or both. These notebooks may be used in lieu of a technical procedure.

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

✓ **SITE:** Location of the controlled area.

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

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

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

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**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.

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**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 NWWSI Project.

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

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

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**APPENDIX B**

**DESIGN INPUTS**

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

1. Basic functions of each structure, system, and component.
2. Performance requirements such as capacity rating and system output.
3. Codes, standards, and regulatory requirements including the applicable issue, agenda, or both.
4. Design conditions such as pressure, temperature, fluid chemistry, and voltage.
5. Loads such as seismic, wind, thermal, and dynamic.
6. Environmental conditions anticipated during storage, construction, and operation such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, nuclear radiation, electromagnetic radiation, and duration of exposure.
7. Interface requirements including definition of the functional and physical interfaces involving structures, systems, and components.

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<p>(11) 3.1 LEVEL I EDUCATION AND EXPERIENCE REQUIREMENTS</p> <ul style="list-style-type: none"> <li>o Two years of related experience in equivalent inspection or testing activities; or</li> <li>o High school graduation and six months of related experience in equivalent inspection or testing activities; or</li> <li>o Completion of college level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspection or testing activities.</li> </ul>	11	NA						
<p>(12) 3.2 LEVEL II EDUCATION AND EXPERIENCE REQUIREMENTS</p> <ul style="list-style-type: none"> <li>o One year of satisfactory performance as a Level I in the corresponding inspection or test category or class; or</li> <li>o High school graduation plus three years of related experience in equivalent inspection or testing activities; or</li> <li>o Completion of college work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspection or testing activities; or</li> <li>o Graduation from a four-year college plus six months of related experience in equivalent inspection activities or testing activities.</li> </ul>	12	NA						

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<p>(13) 3.3 LEVEL III EDUCATION AND EXPERIENCE REQUIREMENTS</p> <ul style="list-style-type: none"> <li>o Six years satisfactory performance as a Level II in the corresponding inspection or test category or class; or</li> <li>o High school graduation plus ten years of related experience in equivalent inspection or testing activities; or high school graduation plus eight years of experience in equivalent inspection of testing activities with at least two years associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with relevant Quality Assurance aspects of a nuclear facility; or</li> <li>o Completion of college level work leading to an associate degree and seven years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or</li> <li>o Graduation from a four-year college plus five years related experience in equivalent inspection or testing activities with a least two years of this experience associated with nuclear facilities or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility.</li> </ul>	13	NA						

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<b>4.0 CERTIFICATION</b>								
<b>4.1 QUALIFICATION REQUIREMENTS</b>								
(14)The responsible organization shall designate those inspection and test activities that require qualified inspection and test personnel and the minimum qualification requirements for such personnel. (15)Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the established requirements are permitted to perform inspection and test activities. (16)If a single inspection or test requires implementation by a team or a group, then personnel who do not meet the requirements of this section may be used in data-taking assignments or in repository or equipment operation, provided they are supervised or overseen by a qualified individual.	14	NA						
	15	NA						
	16	NA						
<b>4.2 PERSONNEL SELECTION</b>								
(17)Personnel selected to perform inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.	17	NA						
<b>4.3 INDOCTRINATION</b>								
(18)Provisions shall be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards, elements of the Quality Assurance Program Plan, and procedures that are to be employed.	18	NA						

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**4.4 TRAINING**

(19)The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspection and tests. (20)On-the-job training shall be included also in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests. (21)Training shall also be provided with regard to those changes to the QAPP and implementing procedures that affect previous training.

19 NA  
20 NA  
21 NA

**4.5 DETERMINATION OF INITIAL CAPABILITY**

(22)The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration in accordance with the organization's personnel qualification procedure.

22 NA

**4.6 EVALUATION OF PERFORMANCE**

(23)The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed three years. (24)Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability. (25)If during this evaluation, or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with qualification requirements specified for the job, then that person shall be removed from that activity until such time as the required capability has been demonstrated. (26)Any person who has not performed inspection or testing activities in his qualified area for a period of one year shall be reevaluated and a redetermination of their capability made in accordance with the organization qualification procedure.

23 NA  
24 NA  
25 NA  
26 NA

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**4.7 CERTIFICATION OF QUALIFICATION**

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

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NA

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

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<p align="center"><b>4.8 PHYSICAL</b></p> <p>(28) The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examinations.</p>	28	NA						

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	<b>APPENDIX D</b>							
<b>REQUIREMENTS FOR THE QUALIFICATIONS OF NON-DESTRUCTIVE EXAMINATION PERSONNEL</b>								
(1) This Appendix provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), and leak-testing (LT), which is hereinafter referred to as nondestructive examination (NDE), to verify conformance to specified requirements.	1	NA						
1.0 CERTIFICATION								
1.1 APPLICABLE DOCUMENTS								
(2) The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 edition, and its applicable supplements shall apply as requirements to NDE personnel covered by this section.	2	NA						
1.2 PROGRAM								
(3) The responsible organization shall establish written procedures for the control and administration of NDE personnel training, examination, and certification.	3	NA						



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	NA						

**1.4 PHYSICAL**

(4) The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examinations.

4

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**APPENDIX E**

**LIST OF TYPICAL QA RECORDS**

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

**1.0 SITE CHARACTERIZATION**

- 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 site testing.
- o Technical specifications.
- o Sample extraction location maps.
- o Site Characterization Report.

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- o Environmental Assessment.
- o Peer review documentation.
- o Test plans and procedures, and results thereof.
- o Data reduction, evaluations, analyses, and reports for:
  - Geomorphology.
  - Stratigraphy.
  - Tectonics.
  - Seismicity.
  - Geoen지니어ing.
  - Hydrology.
  - Geochemistry.
  - Climatology and Meteorology.
- o Environmental Impact Statement.
- o Environmental Report.

2.0 DESIGN RECORDS

- o Applicable codes and standards used in design.
- o Design drawings.
- o Design calculations and records of checks.
- o Approved design change requests.

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<ul style="list-style-type: none"> <li>o Design deviations.</li> <li>o Design reports.</li> <li>o Design verification data.</li> <li>o Design specifications and amendments.</li> <li>o Safety analysis report.</li> <li>o Stress reports for code items.</li> <li>o Systems descriptions.</li> <li>o Systems process and instrumentation diagrams.</li> <li>o Technical analysis, evaluations, and reports.</li> </ul> <p style="text-align: center;">3.0 PROCUREMENT RECORDS</p> <ul style="list-style-type: none"> <li>o Procurement specifications.</li> <li>o Purchase order including amendments.</li> </ul> <p style="text-align: center;">4.0 MANUFACTURING RECORDS</p> <ul style="list-style-type: none"> <li>o Applicable code data reports.</li> </ul>								

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

**5.3 WELDING**

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

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- o Weld location diagrams.
- o Weld procedures.

**5.4 MECHANICAL**

- o Cleaning procedures and results.
- o Code data reports.
- o Installed lifting and handling equipment procedures, inspection, and test data.
- o Lubrication procedures.
- o Material properties records.
- o Pipe and fitting location reports.
- o Pipe hanger and restraint data.
- o Pressure test results (hydrostatic or pneumatic).
- o Safety valve response test procedures.

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5.5 ELECTRICAL AND INSTRUMENTATION AND CONTROL

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

5.6 GENERAL

- o As-built drawings and records. ✓
- o Final inspection reports and releases. ✓
- o Nonconformance reports. \_
- o Specifications and drawings. ✓
- o Details of equipment, methods, progress, and sequence of work.
- o Construction problems. ✓

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## QA COMPLIANCE REVIEW CHECKLIST

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	<ul style="list-style-type: none"> <li>o Anomalous conditions encountered.</li>   <li style="text-align: center;">6.0 PRE-OPERATIONAL AND START-UP TEST RECORDS</li>   <li>o Automatic emergency power source transfer procedures and results.</li> <li>o Final system adjustment data.</li> <li>o Pressure test results (hydrostatic or pneumatic).</li>   <li>o Instrument alternating current (AC) systems and inverters test procedures and reports.</li> <li>o Offsite power source energizing procedures and test reports.</li> <li>o Onsite emergency power source energizing procedure and test reports.</li> <li>o Pre-operational test procedures and results.</li>   <li style="text-align: center;">7.0 OPERATION RECORDS</li>   <li>o Records and drawing changes that identify repository design modifications made to systems and equipment described in the Final Safety Analysis Report.</li> <li>o Radioactive waste inventory, emplacement location, and transfer records.</li> </ul>	SPW 1.25.89						



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- o Changes made to Operating Procedures.
- o Sealed source leak-test results.
- o Records of annual physical inventory of all sealed source material.
- o Logs of repository operation.
- o Records and logs of maintenance activities, inspection, repair, and replacement of principal items of structures, systems, and components
- o Operational, shift supervisor, and control-room logs.
- o Licensee event reports.
- o Fire protection records.
- o Nonconformance reports.
- o Repository equipment operations instructions.
- o Security plan and procedures.
- o Emergency plan and procedures.
- o Quality Assurance and Quality Control Manuals.
- o Records of activities required by the security plan and procedures.

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- o Applicable records noted in other section of this appendix for any modification or new construction applicable to structures, systems, or components.
- o Evaluation of results of reportable safety concerns as required by regulations.
- o Annual environmental operating report.
- o Annual repository operating report.
- o Location and description of dewatering systems.

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**APPENDIX F**

**REQUIREMENTS FOR THE QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL**

**1.0 GENERAL**

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

**1.1 QUALIFICATION OF AUDITORS**

(1)The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of Quality Assurance programs. (2)Personnel selected for Quality Assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. (3)Auditors either shall have or shall be given appropriate training or orientation to develop their competence to perform required audits. The competence of personnel to perform the various auditing functions shall be developed by one or more of the methods listed below.

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<b>1.1.1 ORIENTATION</b>								
(4)Orientation to provide a working knowledge and understanding of this document and the auditing organization's procedures for implementing audits and reporting results.	4 ✓	1.1.1						
<b>1.1.2 TRAINING PROGRAMS</b>								
(5)Training programs to provide general and specialized training in audit performance. (6)General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing.	5 ✓	1.1.2						
(7)Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing audit findings.	6 ✓	1.1.2						
	7 ✓	1.1.2						
<b>1.1.3 ON-THE-JOB-TRAINING</b>								
(8)On-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. (9)Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.	8 ✓	1.1.3						
	9 ✓	1.1.3						
<b>1.2 QUALIFICATION OF LEAD AUDITORS</b>								
(10)An individual shall meet the requirements listed below before being designated a Lead Auditor:	10 ✓	1.2						
<b>1.2.1 COMMUNICATION SKILLS</b>								
(11)The prospective Lead Auditor shall have the capability to communicate effectively, both orally and in writing. (12)These skills shall be attested to in writing by the Lead Auditor's employer.	11 ✓	1.2.1						
	12 ✓	1.2.1						

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**1.2.2 TRAINING**

(13) Prospective Lead Auditors shall have training to the extent necessary to ensure their competence in auditing skills. (14) Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor:

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

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	<p><b>1.2.3 AUDIT PARTICIPATION</b></p> <p>(15)The prospective Lead Auditor shall have participated in a minimum of five Quality Assurance audits within a period of time not to exceed three years prior to the date of qualification. (16)One of the audits shall be a nuclear Quality Assurance audit that shall be made within the year prior to qualification.</p> <p><b>1.2.4 EXAMINATION</b></p> <p>(17)The prospective Lead Auditor shall pass an examination that shall evaluate his comprehension of and ability to apply the body of knowledge identified in Paragraph 1.2.2 above. (18)The test may be oral, written, practical, or any combination of the three types. (19)If any portion of the examination is oral, written documentation of the oral examination questions/content shall be maintained. (20)The development and administration of the examination shall be in accordance with Paragraph 1.4 of this section.</p> <p><b>1.3 MAINTENANCE OF QUALIFICATION</b></p> <p><b>1.3.1 MAINTENANCE OF PROFICIENCY</b></p> <p>(21)Lead Auditors shall maintain their proficiency through regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; and participation in training programs. Based on annual assessment, management may extend the qualification, require retraining, or require requalification. (22)These evaluations shall be documented.</p>							
	15 ✓	1.2.3						
	16 ✓	1.2.3						
	17 ✓	1.2.4						
	18 ✓	1.2.4						
	19 ✓	1.2.4						
	20 ✓	1.2.4						
	21 ✓	1.3.1						
	22 ✓	1.3.1						

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1.3.2 REQUALIFICATION

(23)Lead Auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. (24)Requalification shall include retraining in accordance with the requirements of Paragraph 1.2.2 of this section, reexamination in accordance with Paragraph 1.4.2, and participation as an Auditor in at least one nuclear Quality Assurance audit.

23 ✓  
24 ✓

1.3.2  
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1.4 ADMINISTRATION

1.4.1 ORGANIZATIONAL RESPONSIBILITY

(25)Training of auditors shall be the responsibility of the employer. (26)The responsible auditing organization shall select and assign personnel who are independent of any direct responsibility for the performance of the activities that they will audit. (27)The Lead Auditor shall, prior to commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

25 ✓  
26 ✓  
27 ✓

1.4.1  
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1.4.1

1.4.2 QUALIFICATION EXAMINATION

(28)The development and administration of the examination for a Lead Auditor required by Paragraph 1.2.4 is the responsibility of the employer. (29)The employer may delegate this activity to an independent certifying agency, but shall retain responsibility for conformance to this document of the examination and its administration. (30)Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. (31)Copies of the objective evidence regarding the type or types and content of the examination or examinations shall be retained by the employer.

28 ✓  
29 ✓  
30 ✓  
31 ✓

1.4.2  
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1.4.2  
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**1.5 CERTIFICATION OF QUALIFICATION**

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

- 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.

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<p>c. (6)The use of confirmatory testing which is defined as testing conducted under a 10CFR60, Subpart G QA program which investigates the properties of interest (e.g., physical, chemical, geologic mechanical) of an existing data base. (7)One example of confirmatory testing is testing conducted under the same environmental conditions and with similar or the same procedures, test material, and equipment as the original test which generated the existing data. (8)Another type of confirmatory testing is testing conducted by different test methods and equipment but which still investigates the same parameter of interest. (9)The amount of confirmatory testing required shall be dealt with on a case-by-case basis in the documented reviews for qualification.</p> <p>d. (10)Demonstrating that the existing data was collected under a QA program which is equivalent to a 10 CFR 60, Subpart G QA program.</p> <p>3.0 SELECTION AND DOCUMENTATION OF QUALIFICATION METHODOLOGY</p> <p>3.1(11)When the methods indicated in Sections 2.1b, 2.1c, and 2.1d are utilized to qualify existing data, a technical review shall be conducted to support the quality of the data.</p> <p>(12)Additional confidence/credibility can be achieved when a combination of methods is used.</p> <p>3.2 (13)Documentation of the decision process shall provide an auditable trail of all factors used in arriving at the choice of the qualification method(s), and the decision as to the qualification of the existing data. (14)The level of confidence in the existing data shall be commensurate with the intended use of the data. (15)Attributes which shall be considered in the qualification process are:</p>	6	2.1	SPJ 1-25-89					
	7 /	2.1						
	8 /	2.1						
	9 /	2.1						
	10 /	2.1						
	11 -	3.1						
	12 -	3.1						
	13 /	3.2						
	14 /	3.2						
	15 /	3.2						

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

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<p>1. The importance of the data to showing that the proposed repository design meets the performance objectives of 10 CFR 60, Subpart E.</p> <p>m. Replication of test results.</p> <p>Note: Additional guidance related to this subject can be found in NUREG-1296 "QUALIFICATION OF EXISTING DATA FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES" (February, 1988).</p>								

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<p align="center"><b>APPENDIX B</b></p> <p align="center"><b>REQUIREMENTS FOR COMPUTER SOFTWARE USED TO SUPPORT A HIGH-LEVEL NUCLEAR WASTE REPOSITORY LICENSE APPLICATION</b></p> <p>This appendix provides detailed requirements for the development, maintenance, and security of computer software. It supplements Section III of this QA plan and shall be used in conjunction with that section.</p> <p align="center"><b>1.0 OBJECTIVES</b></p> <p>(1)The purpose of this appendix is to establish requirements for the development, management, control, and documentation of software used to support the Yucca Mountain Project. (2)The attainment of software quality is dependant on the control of the entire software development process, and is not assured solely by inspection and test of the end product. (3)This appendix prescribes appropriate systematic practices that shall:</p> <ul style="list-style-type: none"> <li>o Reduce the likelihood of defects entering executable code during development.</li> <li>o Ensure that the end product answers the requirements of its intended application.</li> <li>o Reduce the likelihood that defects will be introduced into executable code during later maintenance and modification.</li> </ul>	1	1.0				See p. 53	X	
	2.	→	USGS summarizes sentences 2 and 3 with the more generic statement: "These requirements are intended to insure software quality and to satisfy existing regulations and guidelines issued by the NRC." The NNWSI/88-9 sentences 2 and 3 are applicable principally to software development and not, for example, to acquire software.					
	3	→						

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<b>2.0 APPLICABILITY</b>								
(4)The detailed requirements set forth in this appendix apply to computer software used to produce or manipulate data which is used directly in site characterization, and the design, analysis, performance assessment, and operation of repository structures, systems, and components. (5)The extent to which these requirements apply is related to the nature, complexity, and importance of the software application. (6)The application of specific requirements shall be prescribed in plan(s) for software quality assurance and in written policies and procedures.	4	2.0				See p. 53 ↓		
	5	2.0						
	6	2.0						
<b>3.0 TERMS AND DEFINITIONS</b>								
Terms and definitions for NWSI Project software are contained in Appendix A to this QA Plan.			USGS defines the terms "defect", "functional requirements", and "software lifecycle" that are not defined in Appendix A of the QAPP.					
<b>4.0 SOFTWARE LIFE CYCLE</b>								
(7)Organizations implementing software development activities shall adhere to a software life cycle model that requires that software development or acquisition proceed in a traceable, planned, and orderly manner. (8)The relative emphasis placed on each phase of the software development cycle will depend on the nature and complexity of the software being developed.	7	4.1						
	8	4.1						
	9	4.1						
(9)Each phase of the software development cycle shall provide specific attributes that shall be incorporated into verification and validation activities. (10)The documentation for each phase of the software development cycle shall be reviewed and approved as specified in each organization's software QA Plan. (11)An example of one such model is described below:	10	4.1						
	11	4.0						

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<p style="margin-left: 40px;"><u>Requirements</u></p> <p style="margin-left: 80px;"><u>Design</u></p> <p style="margin-left: 120px;"><u>Implementation</u></p> <p style="margin-left: 160px;"><u>Test</u></p> <p style="margin-left: 200px;"><u>Installation and Checkout</u></p> <p style="margin-left: 240px;"><u>Operation and Maintenance</u></p> <p style="margin-left: 100px;">4.1 SOFTWARE QA PLAN</p> <p>(12) The application of the software life cycle to the development and/or use of the software shall be as described in the Software Quality Assurance Plan.</p>	12	4.0				<p>See p. 53</p>	X	



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completed software shall be specified, documented, and reviewed. (21) These requirements shall possess the following characteristics:

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

**4.1.2.2 Design Phase**

(22) During the design phase a software design based on the requirements shall be specified, documented, and systematically reviewed. (23) The design shall specify the overall structure (control and data flow), and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). (24) The design may necessitate the modification of the requirements documentation.

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

- o The generation of design-based test cases.
- o The review and analysis of the software design.
- o The verification of the software design.

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21	4.1.2				See p. 53		X
22	4.1.3				↓		
23	4.1.3						
24	4.1.3						
25	4.1.3						

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<p><b>4.1.2.3 Implementation Phase</b></p> <p>(26) During this phase the design shall be translated into a programming language and the implemented software shall be debugged. (27) Only minor, if any, design issues shall be resolved at this phase.</p> <p>(28) Verification and validation activities during this phase shall consist of:</p> <ul style="list-style-type: none"> <li>o The possible modification of test cases necessary due to design changes made during coding.</li> <li>o The examination of source code listings to assure adherence to coding standards and conventions.</li> </ul>	26	4.1.4				<p>See p. 33</p> 		
	27	4.1.4						
	28	4.1.4						
<p><b>4.1.2.4 Testing Phase</b></p> <p>(29) During the testing phase the design as implemented in code shall be exercised by executing the test cases. (30) Failure to successfully execute the test cases may require the modification of the requirements, the design, the implementation, or the test plans and test cases.</p> <p>(31) Verification and validation activities during this phase shall consist of:</p> <ul style="list-style-type: none"> <li>o The evaluation of the completed software to assure adherence to the requirements.</li> <li>o The preparation of a report on the results of software verification and validation.</li> </ul>	29	4.1.5						
	30	4.1.5						
	31	4.1.5						

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<p>4.1.2.5 Installation and Checkout Phase</p> <p>(32) During this phase the software becomes part of a system incorporating other software components, the hardware, and production data. (33) The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating databases, and verifying that all components have been included.</p> <p>(34) Testing activities during this phase shall consist of the execution of test cases for installation and integration. (35) Test cases from earlier phases shall be enhanced and used for installation testing.</p>	32 33	4.1.6 4.1.6				See p. 53 ↓	X	
<p>4.1.2.6 Operations and Maintenance Phase</p> <p>(36) During the operations and maintenance phase the software has been approved for operational use. (37) Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the software environment (adaptive maintenance). (38) Software modifications shall be approved, documented, tested (including regression testing as appropriate), and controlled in accordance with Paragraph 5.0.</p>	34 35	4.1.6 4.1.6						
<p>5.0 SOFTWARE VERIFICATION AND VALIDATION</p> <p>(39) Verification and validation plans by the responsible project organization shall employ methods such as inspection, analysis, demonstration, and test to assure that the software adequately and correctly performs all intended functions, and that the software does not perform any function that either by itself or in combination with other functions can degrade the entire system.</p>	36 37 38 39	4.1.7 4.1.7 4.1.7 5.1						

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(40)Verification and validation activities shall be planned and performed relative to specific hardware configurations. (41)The amount of verification and validation activity shall be determined by the type and complexity of the software. (42)Prior to use for a licensing activity, verification and validation of the final version of the software product shall be accomplished by an independent individual or organization, one who did not work on the original software. (43)The results of all verification and validation activities shall be documented.	40 41 42	5.1 5.0 5.1	USGS requires independent verification of "critical" software within the USGS SW Quality Management Plan.			See p.53 ↓			
(44)Verification and/or validation of computer software should be performed in two stages:  1. By the individual generating or modifying the software  2. By an independent individual or organization, one who did not work on the original software.	43 44	5.1 5.1							
(45)The first stage should involve activities (i.e., iterations of tests and runs) to arrive at a final product. (46)It is not required to document all of the activities performed to satisfy the software developer.	45 46	5.0 5.0							
<b>5.1 VERIFICATION</b>									
(47)Verification activities shall be integrated into all applicable phases of the software life cycle and shall be performed to an extent proportional to the critical importance of the software. (48)Software verification shall be performed to assure that the software requirements are implemented in the software design, and the software design is implemented in code. (49)Appropriate methods such as inspection, analysis, test, or demonstration shall be applied to accomplish verification objectives.	47 48 49	5.0 4.1.5 5.1							

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5.2 VALIDATION									
(50) Validation activities are performed to demonstrate that the model as embodied in the computer software is a correct representation of the process or system for which it is intended. (51) This is accomplished by comparing software results against verified and traceable data obtained from laboratory experiments, field experiments or observations, or in situ testing. (52) Specific sets of data used in the validation process shall be identified and justification shall be made for their use.	50	5.2				See p. 53 ↓			
	51	5.2							
	52	5.2							
	53	5.2							
	54	5.2							
	55	5.2							
	56	6.0							
6.0 SOFTWARE CONFIGURATION MANAGEMENT									
(56) A software configuration management system shall be established to assure positive identification of software and control of all software baseline changes.	57	6.1							
	58	6.1							
	59	6.1							
	60	NA	USGS asserts that this sentence is redundant and otherwise implied						
6.1 CONFIGURATION IDENTIFICATION									
(57) A configuration baseline shall be identified at the completion of each major phase of the software development cycle. (58) Approved changes to a baseline shall be added periodically to the baseline as updates. (59) A baseline plus updates shall specify the most recent software configuration. (60) Updates shall be incorporated into subsequent baselines. (61) Both	61	NA	USGS omitted this specific sentence because its intended meaning and application were unclear						

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					See p. 53		X
					↓		

baselines and updates shall be defined by their composition of software configuration items.

(62) A labeling system for configuration items shall be implemented that:

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

**6.2 CONFIGURATION CHANGE CONTROL**

(63) Changes to baseline software configuration items shall be formally documented. (64) This documentation shall contain a description of the change, the identification of the originating organization, the rationale for the change, and the identification of affected baselines and software configuration items. (65) The change should be formally evaluated by a qualified individual or organization with the ability to approve or disapprove the proposed change. (66) Assurance shall be provided that only authorized changes are made to software baselines and software configuration items.

**6.3 CONFIGURATION STATUS ACCOUNTING**

(67) The information that is needed to manage software configuration items shall be recorded and reported. (68) This information shall include a listing of the approved configuration identification, the status of proposed changes to the configuration, the implementation status of approved changes, and all information to support the functions of configuration identification, and configuration control.

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**7.0 DOCUMENTATION**

(69) Minimum acceptable lifecycle documentation of computer software developed or modified for use on the Yucca Mountain Project shall be specified in each participant's software QA plan(s). (70) The documentation provided shall describe the following, as applicable. (71) Additional documentation may also be identified in the software quality assurance plan for each Yucca Mountain Project participant's software project.

**7.1 SOFTWARE REQUIREMENTS SPECIFICATION**

(72) A specific capability of software can be called a requirement only if its achievement can be verified by a prescribed method. (73) Software requirements documentation shall outline the requirements that the proposed software must fulfill. (74) The requirements shall address the following:

- o Functionality - the functions the software are to perform.
- o Performance - The time-related issues of software operation such as speed, recovery time, response time, etc.
- o Design constraints imposed on implementation - any elements that will restrict design options.
- o Attributes - non-time-related issues of software operation such as portability, correctness, security, maintainability, etc.
- o External Interfaces - interactions with other participants, hardware, and other software.

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69	4.1				See p. 53 ↓		
70	NA						
71	NA						
72	7.1.1						
73	7.1.1						
74	7.1.1						

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<p align="center"><b>7.2 SOFTWARE DESIGN DOCUMENTATION</b></p> <p>(75) Software design documentation is a document or series of documents that shall contain:</p> <ul style="list-style-type: none"> <li>• A description of the major components of the software design as they relate to the requirements of the software requirements specification.</li> <li>• A technical description of the software with respect to control flow, data flow, control logic, and data structure.</li> <li>• A description of the allowable and tolerable ranges for inputs and outputs.</li> <li>• The design described in a manner that is easily traceable to the software requirements.</li> <li>• Code assessment and support documentation and descriptions of mathematical models and numerical methods as required by NRC publication NUREG-0856.</li> <li>• Continuing documentation, code listings, and software summary forms as required by NUREG-0856.</li> </ul>	75	7.1.2 and 7.2				See page 53		X
<p align="center"><b>7.3 SOFTWARE IMPLEMENTATION DOCUMENTATION</b></p> <p>(76) Any design changes made to the requirement and design phase documents shall be assessed as to the impact on the design. (77) The revised requirement and design phase documents shall be reviewed to the same level of review as the original documents. (78) The results of this phase should be the basis for the software verification and validation plan(s).</p>	76 77 78	7.1.3 7.1.3 4.0						

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<p><b>7.4 SOFTWARE VERIFICATION AND VALIDATION DOCUMENTATION (TEST)</b></p> <p>(79) Software verification and validation documentation shall include a plan that describes the tasks and criteria for accomplishing the verification of the software in each phase, and the validation of the software. (80) The documentation shall also specify the hardware and system software configuration pertinent to the software. (81) The documentation shall be organized in a manner that allows traceability to both the software requirements and the software design. (82) This documentation will also include a report on the results of the execution of the software verification and validation activities. (83) This report shall include the results of all reviews, audits, and tests, and a summary of the status of the software.</p>	79	7.1.4				<p>See p. 53</p>		
	80	7.1.4						
	81	7.1.4						
	82	7.1.4						
	83	7.1.4						
<p><b>7.5 USER DOCUMENTATION</b></p> <p>(84) User documentation shall be prepared in accordance with NUREG-0856 and shall include a description of:</p> <ul style="list-style-type: none"> <li>o Program considerations, options, and initialization procedures.</li> <li>o Anticipated error situations and how the user can correct them.</li> <li>o Internal and external data files, their input sequence, structures, units, and ranges.</li> <li>o Input and output options, defaults, and formats.</li> <li>o System interface features and limitations.</li> </ul>	84	7.2						

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<ul style="list-style-type: none"> <li>o Information for obtaining user and maintenance support.</li> <li>o Sample problems.</li> </ul> <p align="center"><b>8.0 REVIEWS</b></p> <p>(85) Reviews of software development activity shall be performed as each life cycle phase is completed to assure the completeness and integrity of each phase of development. (86) The procedures used for reviews shall identify the participants and their specific responsibilities during the review and in the preparation and distribution of the review report.</p> <p>(87) The documentation for all reviews shall contain a record of review comments, a plan, and timetable for the resolution of the review comments, and the personnel responsible for this resolution.</p> <p>(88) After review comments are resolved, the approved documents shall be updated and placed under configuration management.</p> <p align="center"><b>8.1 SOFTWARE REQUIREMENTS REVIEW</b></p> <p>(89) The review of software requirements shall be performed at the completion of the software requirements documentation. (90) This review shall assure that the requirements are complete, verifiable and consistent. (91) The review shall also assure that there is sufficient detail available to complete the software design.</p>								
						See p. 53		X
	85	8.1						
	86	8.1						
	87	8.1						
	88	8.1						
	89	8.1.1						
	90	8.1.1						
	91	8.1.1						

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					See p. 53		X	
<b>8.2 SOFTWARE DESIGN REVIEW</b>								
	92	8.1.2			↓			
	93	8.1.2						
	94	8.1.2						
<b>8.3 SOFTWARE IMPLEMENTATION REVIEW</b>								
	95	8.1.3						
<b>8.4 SOFTWARE VERIFICATION AND VALIDATION REVIEW</b>								
	96	8.1.4						
	97	8.0						
<b>9.0 DISCREPANCY REPORTING AND CORRECTIVE ACTION</b>								
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	99	9.0						

(92)The software design review will be held at the completion of the software design documentation. (93)This review shall evaluate the technical adequacy of the design approach, and assure that the design answers all the requirements in the requirements documentation. (94)The complexity of the software design may require the performance of two design reviews; one at the completion of the overall software architecture, and the second at the completion of the total design.

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

(96)The software verification and validation review is an evaluation of the adequacy of verification and validation plans or procedures and completed software verification and validation activities. (97)The review results in an approval of verification and validation documentation.

(98)A formal procedure of software discrepancy reporting and corrective action shall be established. (99)This discrepancy reporting system shall be integrated with the configuration management system to assure formal processing of discrepancy resolutions.

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(100) Software discrepancy reporting and corrective action procedures shall assure that, as a minimum:

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

10.0 MEDIA CONTROL AND SECURITY

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

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11.0 ACQUIRED SOFTWARE

(102) Procedures shall be established for controlling the transfer of computer software from an outside source to a user organization and from a user organization to an outside requesting organization. (103) Software transfer requests of the organization (or purchases) from an outside source shall include appropriate criteria to enable the software received to comply, as much as possible, with the requirements of this QA Plan and the needs of

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code input data including data bases and original sources/references of and assumptions used to obtain such data, code design, user's and/or operation manuals, verification/validation test results and/or hand calculations.

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

(113) Controls shall be established for generating and documenting software used to perform technical calculations. (114) All auxiliary software used should be included in documentation of technical calculations performed and should be included in independent review as part of the calculation.

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

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USGS do not specifically distinguish "auxiliary software."

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APPENDIX I

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

1.0 GENERAL

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

2.0 QUALITY ASSURANCE CRITERIA FOR LICENSING

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

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their characterization, design, construction, and operation comply with the requirements of 10 CFR Part 60.

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

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

**2.2 CRITERIA FOR NON-Q-LIST ITEMS**

Certain items that are not important to safety and/or waste isolation shall also be addressed in the license application to demonstrate compliance with 10 CFR Part 60 requirements such as those associated with meeting the design criteria contained in 10 CFR 60.131(a) for protection of worker health and safety. While these items are not subject to the QA Level I requirements of this QA Plan, QA Level II requirements shall be applied. Additional guidance related to this subject can be found in NUREG-1318, (April, 1988), paragraph 5.1(b).

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<p><b>2.3 DATA NOT COLLECTED UNDER A 10 CFR 60 SUBPART G QA PROGRAM</b></p> <p>All data collection, interpretations, analyses, and other work to be used to support findings related to important to safety and/or waste isolation in the licensing process shall be technically and procedurally defensible. "Existing data" shall be qualified in accordance with the requirements of Appendix G of this QA Plan. In addition to existing data, some materials that may be important to safety and/or waste isolation may already have been purchased prior to implementation of a 10 CFR 60 Subpart G QA Program. Supporting documentation on these materials (e.g. the technical specifications and QA records) shall be reviewed to determine whether they meet the technical and QA requirements for their designated function. If not, they shall be "qualified" for use to assure they will perform their intended function.</p>								
<p><b>3.0 IDENTIFICATION OF ITEMS IMPORTANT TO SAFETY</b></p> <p>Items important to safety are those items essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of unrestricted area at any time until the completion of permanent closure (10 CFR 60.2). The 0.5 rem value is, therefore, the threshold for determining what structures, systems, and components shall be on the Q-List as items important to safety. The rationale for placing a system, structure, or component on the Q-list is to provide added assurance, via application of rigorous QA/QC and design requirements, that they should perform their designated function.</p>								

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

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

3.3 PRAS shall utilize the following techniques:

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

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

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

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

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

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

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

3.4 REDUNDANCY

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

3.5 USE OF PREVIOUSLY ESTABLISHED GUIDELINES AND STANDARDS

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

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<p>3.6 RETRIEVAL</p> <p>The option for retrieval of waste is addressed as a performance objective in 10 CFR 60.111(b). If retrieval is found to be necessary, analyses of retrieval operations shall be conducted at that time, to identify Q-List items.</p> <p>4.0 IDENTIFICATION OF ITEMS AND ACTIVITIES IMPORTANT TO WASTE ISOLATION</p> <p>The term "important to waste isolation" refers to engineered and natural barriers that will be relied on to meet the containment and isolation performance objectives of 10 CFR 60 Subpart E. Four of the performance objectives for waste isolation after permanent closure are stated in 10 CFR 60.112 and 60.113 and include:</p> <ul style="list-style-type: none"> <li>o ground water travel time ✓</li> <li>o waste package containment period ✓</li> <li>o maximum yearly release rate from the engineered barrier system ✓</li> <li>o the overall system performance objective in 10 CFR 60.112 for release of radioactive materials to the accessible environment (the EPA standard in 40 CFR Part 191).</li> </ul> <p>The items and activities important to waste isolation shall include:</p> <ul style="list-style-type: none"> <li>o Components of the engineered barrier system relied on to meet the performance objectives.</li> </ul>	<p>HIA ↓ SPJ 1-25-89 ↓ SPJ 1-25-89</p>							



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accordance with the QA Level I requirements of this QA Plan. However, there may be cases where it is known that data are not needed for performance assessments, or will be duplicated later in accordance with QA Level I requirements of this QA Plan and therefore would not have to be performed in accordance with the QA Level I requirements at this time. For example, scoping tests or tests to examine the feasibility and appropriateness of a data collection technique may not need to be performed in accordance with the QA Level I requirements of this QA Plan.

5.0 SUBMITTAL REQUIREMENTS

5.1 LICENSE APPLICATION

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

5.2 SITE CHARACTERIZATION PLANS

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

- o A description of the QA program to be applied to items and activities during the site characterization phase.

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

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

6.0 GRADED APPLICATION OF QA MEASURES

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

- o The impact of malfunction or failure of the item, or the impact of erroneous data associated with data collection activities, on safety or waste isolation.
- o The complexity of design or fabrication of an item, or design and implementation of a test, or the uniqueness of an item of test.
- o The special controls and surveillance needed over processes, tests, and equipment.

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- o The degree to which functional compliance can be demonstrated by inspection or test.
- o The quality history and degree of standardization of the item or test.

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

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<p>APPENDIX J</p> <p>REQUIREMENTS FOR PEER REVIEW</p> <p>1.0 General</p> <p>This appendix provides the requirements regarding the applicability of peer reviews, the structure of peer review groups, acceptability of peers, and the conduct and documentation of peer reviews.</p> <p>2.0 APPLICABILITY OF PEER REVIEW</p> <p>2.1 (1) A peer review shall be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and waste isolation cannot otherwise be established through testing, alternate calculations or reference to previously established standards and practices.</p> <p>2.2 (2) In general, the following conditions are indicative of situations in which a peer review shall be considered:</p> <p>a. Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.</p> <p>b. Decisions or interpretations having significant impact on performance assessment conclusions will be made.</p>	<p>301 1-25-89</p> <p>1</p> <p>2</p> <p>302 1-25-89</p>	<p>2.1</p> <p>2.2</p>						

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	<p>c. Novel or beyond the state-of-the-art testing, plans and procedures, or analyses are or will be utilized.</p> <p>d. Detailed technical criteria or standard industry procedures do not exist or are being developed.</p> <p>e. Results of tests are not reproducible or repeatable.</p> <p>f. Data or interpretations are ambiguous.</p> <p>g. Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program.</p> <p>2.3 (3)A peer review shall be used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means.</p> <p>3.0 STRUCTURE OF PEER REVIEW GROUP</p> <p>(4)The number of peers comprising a peer review group shall vary commensurate with the following:</p> <p>A. The complexity of the work to be reviewed.</p> <p>B. Its importance to establishing that safety or waste isolation performance goals are met.</p> <p>C. The number of technical disciplines involved.</p>	<p>3</p> <p>4</p>	<p>2.3</p> <p>3.</p>	<p>SPJ 1-25-89</p> <p>SPJ 1-25-89</p>				

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D. The degree to which uncertainties in the data or technical approach exist.								
E. The extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.								
3.2 (5)The collective technical expertise and qualifications of peer review group members shall span the technical issues and areas involved in the work to be reviewed, including any differing bodies of scientific thought. (6)The potential for technical or organizational partiality shall be minimized by selecting peers to provide a balanced peer review group. (7)Technical areas more central to the work to be reviewed shall receive proportionally more representation in the peer review group.	5 - 6 - 7 -	3.2 3.2 3.2						
<b>4.0 ACCEPTABILITY OF PEERS</b>								
4.1 (8)The technical qualification of the peer reviewers,,in their review areas, shall be at least equivalent to that needed for the original work under review and shall be the primary consideration in the selection of peer reviewers. (9)Each peer shall have recognized and verifiable technical credentials in the technical area that the peer has been selected to review.	8 - 9 -	4.1 4.1						
4.2 (10)Members of the peer review group shall be independent of the original work to be reviewed. (11)Independence in this case means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed. (12)In some cases (i.e. funding considerations) it may be difficult to meet the independence criteria without reducing the technical quality of the peer review. (13)When the independence criteria cannot be met, a documented rationale shall be included in the peer review report.	10 - 11 - 12 - 13 -	4.2 4.2 4.2 4.2						

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5.0 PEER REVIEW PROCESS

5.1 (14) Since the peer review process may vary from case to case, a peer review plan shall be prepared prior to initiating a peer review. (15) The peer review plan shall describe the work to be reviewed, the size and spectrum of the peer review group, and the suggested method and schedule necessary to produce a peer review report.

5.2 (16) The peer review group shall evaluate and report on:

- a. Validity of assumptions. ✓
- b. Alternate interpretations. ✓
- c. Uncertainty of results and consequences if incorrect. ✓
- d. Appropriateness and limitations of methodology and procedures. ✓
- e. Adequacy of application. ✓
- f. Accuracy of calculations. ✓
- h. Adequacy of requirements and criteria. ✓
- g. Validity of conclusions. ✓

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

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6.0 PEER REVIEW REPORT

6.1 (18)A report documenting the results of the peer review shall be prepared and issued under the direction of the peer review group chairperson and shall be signed by each peer review group member. (19)The peer review report shall include the following:

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- a. A clear description of the work or issue that was peer reviewed.
- b. Conclusions reached by the peer review process.
- c. Individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate.
- d. Listing of the peers and the technical qualification and evidence of independence for each peer, including potential technical and/or organizational partiality.

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

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APPENDIX K

FORMAT AND CONTENT REQUIREMENTS FOR SCP STUDY PLAN

1.0 Purpose and Objectives of Studies:

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

1.2 (2) Provide the rationale and justification for the information to be obtained by the study. (3) It can be justified by: 1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the SCP); 2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); 3) direct Federal, State, and other regulatory requirements for specific studies. (4) Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and that higher level goal.

2.0 Rational for Selected Study:

2.1 (5) Provide the rationale and justification for the selected tests and analyses (including standard tests). (6) Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. (7) Describe the advantages and limitations of the various options; and

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2.2 (8) Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). (9) This rationale should also identify reasonable alternatives; summarize reasons for not selecting these alternatives, and reference if available, reports which evaluate alternatives considered.

2.3 (10) Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. (11) Factors to be considered include:

- a) Potential impacts on the site from testing; ✓
- b) Whether the study needs to simulate repository conditions; ✓
- c) Required accuracy and precision of parameters to be measured with test instrumentation;
- d) Limits of analytical methods that will use the information from the tests;
- e) Capability of analytical methods to support the study; ✓
- f) Time required versus time available to complete the study; ✓
- g) The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field;

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- b) Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and
- i) Interrelationships involving significant interference among tests and ESF design and construction, as appropriate (refer to Section 8.4 of the SCP or its references for specific ESF design information)/

**3.0 Description of Tests and Analyses:**

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

- a) Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g., spatial location relative to the site, ESF elements, repository layout, stratigraphic units, depth, and test location);
- b) Summarize the test methods. Reference any standard procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA level 1. Reference the applicable specific QA requirements that will be applied to the test;

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- c) Specify the tolerance, accuracy, and precision required in the test, where appropriate;
- d) Indicate the range of expected results of the test and the basis for those expected results;
- e) List the equipment required for the test and describe briefly any such equipment that is special;
- f) Describe techniques to be used for data reduction and analysis of the results;
- g) Discuss the representativeness of the including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results;
- h) Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests, and
- i) Relationship of the test to the set performance goals and confidence levels.

3.2 (13) For each type of analysis:

- a) State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;

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- b) Describe the methods of analysis including any analytical expressions and numerical models that will be employed;
- c) Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA level 1. Reference the applicable QA requirements.
- d) Identify the data input requirements of the analysis;
- e) Describe the expected output and accuracy of this analysis; and
- f) Describe the representativeness of the analytical approach (e.g., with respect to spatial variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.

**4.0 Application of Results:**

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

4.2 (15) For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) that will use the information produced from the studies described above, and refer to any use of the results for model validation;

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<p>4.3 (16) For design uses, refer to, or describe, where the information from the study described above will be used in construction equipment design and development, and engineering system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals); and</p> <p>4.4 (17) For characterization uses, refer to, or describe, where the information from the study described above will be used in planning other characterization activities.</p> <p><u>Schedule and Milestones:</u></p> <p>5.1 (18) Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities;</p> <p>5.2 (19) Describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study; and</p> <p>5.3 (20) Dates for activities or milestones including durations and inter-relationships, for the study plans will be provided. These should reference the master schedules provided in Section 8.5 of the SCP.</p>	<p>SPU 1-25-89</p> <p>↓</p> <p>SPU 1-25-89</p>							