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U.S. GEOLOGICAL SURVEY

QUALITY ASSURANCE PROGRAM PLAN

REVISION 5

cc J Conway
J Hanton

Issued To:	Organization:
J. Kennedy	NRC

U.S. DEPARTMENT OF ENERGY
OCRWM
YUCCA MOUNTAIN

YUCCA MOUNTAIN PROJECT

U.S. DEPARTMENT OF THE INTERIOR
March 3, 1849

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U.S. DEPARTMENT OF ENERGY

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YUCCA MOUNTAIN

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U.S. DEPARTMENT OF THE INTERIOR March 3, 1849

United States Geological Survey

Department of the Interior

Yucca Mountain Project

QUALITY ASSURANCE PROGRAM PLAN-01

REVISION 5

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U.S. GEOLOGICAL SURVEY

QUALITY ASSURANCE PROGRAM PLAN

FOR THE

YUCCA MOUNTAIN PROJECT

Effective Date May 3, 1989

YMP-USGS QA Manager: J. R. Willmon	2-24-89 Date
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QUALITY ASSURANCE PROGRAM PLAN

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QUALITY ASSURANCE PROGRAM PLAN

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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:

- Nevada Nuclear Waste Storage Investigations (NNWSI) was changed to Yucca Mountain Project (YMP) except as used for historical reference.
- Waste Management Project Office (WMPO) was changed to Yucca Mountain Project Office (YMPO).
- References to Office of Geologic Repositories (OGR) were changed to Office of Civilian Radioactive Waste Management (OCRWM).
- The Statement of Policy has been revised to better reflect the Director's support of the YMP-USGS Quality Assurance Program.
- The Introduction has been updated to show current USGS organization for implementation of the YMP-USGS responsibilities.
- 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.
- Section 2 was revised to establish requirements for regular QA Program status reporting and readiness reviews.
- Section 2 was revised to add a requirement for non-technical implementing procedure submittal to YMPO for review and approval prior to implementation.
- 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.
- Section 2 was revised to provide commitment to meet the guidance of NUREG-1298 and NUREG-1318.

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

QUALITY ASSURANCE PROGRAM

STATEMENT OF POLICY
QUALITY ASSURANCE PROGRAM PLAN

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.

Dallas L. Peck

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

March 20, 1989
Date

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, geophysic, 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

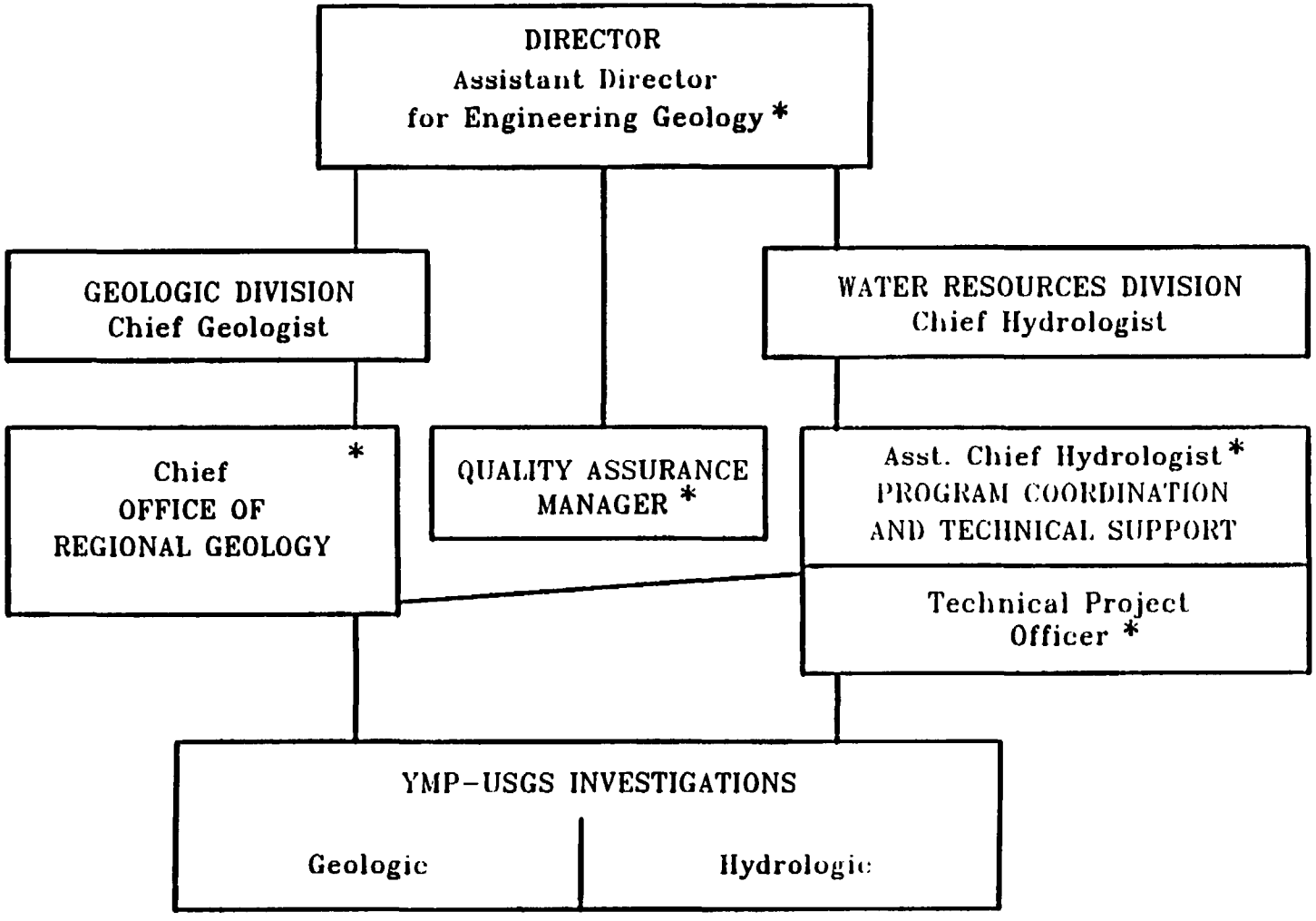

Figure 1. YMP–USGS Organizational Chart. The YMP–USGS TPO and QA Manager have access to all YMP–USGS personnel for QA, budget, and program purposes as applicable. Asterisk denotes approval authority for YMP–USGS governing documents.

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.

I.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.

I.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.

I.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:

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

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

I.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.

1.6.8 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.

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 <u>Dedicated Quality Assurance Positions</u>: 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.

SECTION 2
QUALITY ASSURANCE PROGRAM

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:

- 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.

- 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.

- Activities that could adversely impact the waste isolation capabilities of the engineered and natural barriers.

- Items that are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system.

- Items and activities that, having failed, could cause a failure of a QA Level I item, or irretrievable loss of QA Level I data.

- The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) will be assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationships. As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities shall be governed by the QA level assigned to the item.

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:

- 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.

- 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.

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

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

- 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.

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

- 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:

- Review and approval of QAPPs.
- Surveillance of participating YMP activities affecting quality to verify compliance with requirements.
- 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.

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

- 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.

- Indoctrination Records - Records of indoctrination, including the objective and content of the indoctrination, date(s) of indoctrination, and other applicable information.

- 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.

- 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.

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:

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

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:

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

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

- Prerequisites such as calibrated instrumentation, adequate and appropriate equipment and instrumentation, suitable and controlled environmental conditions, and provisions for data collection and storage. For activities of long duration, specific provisions shall be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions are to be designed to ensure validity of data throughout the scientific investigation.

- Mandatory verification points.

- Acceptance and rejection criteria, including required levels of precision and accuracy (Note: "Accept/reject criteria" means those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output that, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject" criteria" are simply the conditions and methods stated in the procedure.)

- Methods of documenting or recording data and results, including precision and accuracy.

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

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

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

<u>Initial Entries</u> - Where appropriate, and prior to initiation of an experiment, series of experiments, or research activity, the following entries, as a minimum, shall be made:

- Title of the experiments or research;
- Name of the qualified individual or individuals performing the experiment or research;
- 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-

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

- 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;
- Calibration requirements;
- Dated signature of the individual or individuals making the initial entries;
- Special training or qualification requirements;
- Documentation of suitable and controlled environmental conditions, if applicable;
- Required levels of precision and accuracy shall be identified; and
- 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.

<u>In-Process Entries</u> - 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:

- Date and name of individual making the entry;
- Provisions for assuring prerequisites have been met;
- Description of the experiment or research attempted, including detailed step-by-step process followed, either by reference to implementing procedure or by entry into a scientific notebook;
- Description of any conditions that may have adversely affected the results of the experiment or research;
- Identification of samples collected or used, and any additional equipment and materials not included as part of the initial entries;

- All data collected and a brief description of the results, including notation of any unaccepted results;
- Any deviations from the planned experiment or research; and
- 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:

- 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:

- 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.

- 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.

- Identify the required documentation to be prepared, reviewed, and maintained during software design, implementation, test, and use.

- Identify the software configuration-management methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software.

- Specify the process to be used for verification and validation of the software developed or acquired for and applied to site-characterization activities supporting geologic repository design and performance analyses.

- 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:

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

This documentation is considered to be a QA record and is subject to the requirements of Section 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.

SECTION 4
PROCUREMENT DOCUMENT CONTROL

4.1 GENERAL REQUIREMENTS

Measures shall be established to insure that applicable regulatory requirements, design or site-investigation bases, and other requirements that are necessary to assure adequate quality in scientific investigations are included or referenced in the documents for procurement of material, equipment, and services used on the Project. To the extent necessary, procurement documents of the USGS shall require subtier contractors to provide a 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:

- QA requirements are correctly stated, inspectable, and controllable.
- Adequate acceptance and rejection criteria are provided.
- 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:

- Appropriate content shall be included in procurement documents as required by Para. 4.3 of this section.
- Additional or modified design or site-investigation criteria shall be determined.
- Analysis of exceptions or changes requested or specified by the supplier, and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished, 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 documents 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.

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.

SECTION 6
DOCUMENT CONTROL

6.1 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

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

- Documents containing or specifying quality requirements; and
- 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:

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

SECTION 7
CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 GENERAL PURCHASING REQUIREMENTS

Measures shall be established to insure that purchased material, equipment, and services conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, audit, and examination of products upon delivery. Where required by code, regulation, or contract requirement, documentary evidence that material and equipment conform to the procurement requirements shall be available at the location where the material or equipment is to be used, prior to installation or use of such material and equipment. This documentary evidence shall be retained under the control of the 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:

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

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

- Acceptance of the item or service; and
- 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:

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

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

- 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:

- Technical considerations;
- QA requirements;
- Supplier's personnel;
- Supplier's production capabilities;
- Supplier's past performance;
- Alternates or replacement items; and
- 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:

- Documenting the understanding between purchaser and supplier of the provisions and specifications of the procurement documents;
- Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement-document requirements;
- Reviewing supplier documents that are generated or processed during activities fulfilling procurement-document requirements;
- Identifying and processing necessary change information. Measures to control changes in procurement documents shall be established, implemented, and documented, in accordance with the requirements of this QA Plan; and
- 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:

- The certificate shall identify the purchased material or equipment, such as by the purchase-order number.

- The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, or other specifications. This 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.

- The certificate shall identify any procurement requirements that have not been met, with an explanation and the means by which to resolve the nonconformances.

- The certificate shall be attested to by a person who is responsible for this QA function, and whose function and position are described in the purchaser's or supplier's QA program.

- The certificate system, including the procedures to be followed in filling out a certificate(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.

- 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:

- Technical verification of data produced;
- Surveillance, audit, or both, of the activity; or
- 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.

- Technical or material requirement is violated.
- Requirement in supplier documents, that has been approved by the USGS, is violated.
- Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.
- 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:

- Damage was not sustained during shipment.
- The item received was the item ordered.

- 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 require inspection and/or testing from a calibration standpoint only.

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

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

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.

SECTION 9
CONTROL OF PROCESSES

9.1 GENERAL REQUIREMENTS

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

9.2 STATEMENT OF EXCLUSION

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

SECTION 10
INSPECTION

10.1 GENERAL REQUIREMENTS

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

10.2 STATEMENT OF EXCLUSION

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

SECTION 11
TEST CONTROL

11.1 GENERAL REQUIREMENTS

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

SECTION 12
CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 INTRODUCTION

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

The USGS control program for measuring and test equipment shall include all measuring and test equipment or systems used to calibrate, measure, gage, test, or inspect; either to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known. The USGS 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.

SECTION 13
HANDLING, SHIPPING, AND STORAGE

13.1 GENERAL REQUIREMENTS

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

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

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

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

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

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

SECTION 14
INSPECTION, TEST, AND OPERATING STATUS

14.1 GENERAL REQUIREMENTS

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

14.2 STATEMENT OF EXCLUSION

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

SECTION 15
CONTROL OF NONCONFORMING ITEMS

15.1 REQUIREMENTS CONCERNING NONCONFORMING ITEMS

Measures shall be established to control items that do not conform to requirements to prevent their inadvertent installation or use. These measures shall include documented procedures for identification, documentation, evaluation, segregation (when practical), disposition, and notification to affected organizations. All USGS personnel involved in 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:

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

- Nonconformance documentation adequately identifies and describes the nonconformance.
- Appropriate justification for the disposition has been documented. In the case of use-as-is or repair dispositions, technical justification is required. The as-built records, if such records are required, shall reflect the accepted deviation.
- The disposition has referenced any approved design documents, procedures, plans, work orders, etc., that are to be used for the correction of the nonconforming condition.
- Technical details for correction of the nonconforming condition are adequate for the recommended disposition.
- If continuance has been requested, justification for the activity to continue has been documented and approved by the appropriate YMPO Branch Chief and the YMPO PQM.
- The disposition complies with existing design documents, test plans or procedures, reports, and regulatory requirements.
- If a change to reflect the as-built condition is appropriate, then the disposition addresses action to change the existing design documents, test plans or procedures, reports, etc. Any documents changed also shall be cross-referenced on the NCR.
- Disposition has identified and documented the correction as repair, rework, use-as-is, or reject/scrap.
- Disposition has identified the people or organization responsible to implement the disposition.

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:

- The nonconforming item can be removed or corrected at a later date without damage to, or contamination of, the associated permanent facility equipment or structures.
- The nonconforming item remains accessible for inspection.
- The nonconforming item is evaluated, and limitation(s) for use of the equipment or system is established.
- Traceability and identification of the nonconforming item are maintained.

15.3 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.

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:

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

16.1.2 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.

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:

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

- 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;

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

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:

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

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:

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

- Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers.

- Provisions shall be made for special processed records (e.g, radiographs, photographs, negatives, microfilm, magnetic material, etc.) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

17.4.3 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.

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 <u>Audit Preparation</u>: 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:

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

18.1.6 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:

- Identification of the entity or activities, or items audited and the individual(s) contacted during the audit(s).
- Description of any deficiencies, nonconformances, and potential quality problems identified.
- Audit plans, audit reports, written replies, the record of completion of corrective action, and the close-out of the audit.
- 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:

- Item or activity.
- Date of surveillance.
- Name of individual performing the surveillance.
- Identification of the organization(s), activities, or items surveilled, including the name or names of personnel contacted.
- Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance. Nonconformances shall be handled in accordance with the requirements of Section 15 or 16, as applicable.
- Surveillance criteria.
- Equipment used during the surveillance.
- Results.
- Acceptance statement.

APPENDIX A
TERMS AND DEFINITIONS

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

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

ACTIVITIES THAT AFFECT QUALITY: Deeds, actions, work, or performance of a specific function or task. The 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 orgainzation. 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 calculated and expressed in some quantitative way, e.g., money loss, deaths, or quantities of radionuclides released to the accessible environment.

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

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

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

CONTROLLED AREA: The surface location, which is to be marked by suitable monuments, that 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 impartially reviewed. 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 <u>adequacy</u> 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 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 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 components 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, systems, components, and related activities essential to the prevention or mitigation

of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address long-term performance of the engineered and natural barriers to inhibit the release of radionuclides from the site to the accessible environment after permanent closure. The criteria for items or activities important to safety and waste isolation are found in 10CFR60, and 40CFR191.

QUALITY ASSURANCE LEVEL II: Those activities and items related to the systems, structures, and components which require a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker 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, geomechanical, mechanical, meteorological, metallurgical, environmental, socioeconomic, and transportation studies of activities which are performed for, or in support of, the investigation, exploration, site characterization, development of design bases, licensing, construction, operation, monitoring, performance evaluation and/or closure of the geologic repository.

SCIENTIFIC NOTEBOOK: A document which may be used to provide a written record of the results of scientific investigations and experiments when the work involves a high degree of professional 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 reproducibe, 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.

APPENDIX B
DESIGN INPUTS

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

1. Basic functions of each structure, system, and component.
2. Codes, standards, and regulatory requirements including the applicable issue, agenda, or both.
3. Loads such as seismic, wind, thermal, and dynamic.
4. Environmental conditions anticipated during storage, construction, and operation such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, nuclear radiation, electromagnetic radiation, and duration of exposure.
5. Interface requirements including definition of the functional and physical interfaces involving structures, systems, and components.
6. Material requirements including such items as compatibility, protective coating, and corrosion resistance.
7. Mechanical requirements such as vibration, stress, shock, and reaction forces.
8. Hydraulic requirements such as pump net positive suction heads (NPSH), allowable pressure drops, and allowable fluid velocities.
9. Chemistry requirements such as provisions for sampling and limitations on water chemistry.
10. Layout and arrangement requirements.
11. Instrumentation and control requirements including indicating instruments, controls, and alarms required for operation, testing, and maintenance. Other requirements such as the type of instrument, installed spare, range of measurement, and location of indication are included.
12. Access and administrative control requirements for repository security.
13. Handling, storage, cleaning, and shipping requirements.
14. Materials, processes, parts, and equipment suitable for application.
15. Quality Control and Quality Assurance requirements.

16. Reliability requirements of structures, systems, and components, including their interactions, which may impair functions that are important to safety.

17. Other requirements to prevent undue risk to the health and safety of the public.

APPENDIX C
REQUIREMENTS FOR THE QUALIFICATION OF INSPECTION AND TEST PERSONNEL

Not Applicable - See Para. I.6

APPENDIX D
REQUIREMENTS FOR THE QUALIFICATION OF NONDESTRUCTIVE EXAMINATION PERSONNEL

Not Applicable - See Para. I.6

APPENDIX E
LIST OF TYPICAL USGS QA RECORDS

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

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

2.0 PROCUREMENT RECORDS

- Procurement specifications.
- Purchase orders including amendments.

3.0 GENERAL

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

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

1.0 GENERAL

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

1.1 QUALIFICATION OF AUDITORS

The USGS shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of 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:

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

APPENDIX 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 in 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).

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

1.0 OBJECTIVES

The purpose of this Appendix is to establish requirements for the development, management, control, and documentation of software used 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:

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

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

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:

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

- 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

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:

- Uniquely identifies each software configuration item or version.
- Identifies changes to software configuration items by using revision identifiers.
- 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:

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

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

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

- A description of the allowable and tolerable ranges for inputs and outputs.
- The software design described in a manner that is easily traceable to the software functional requirements.
- 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:

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

- Software Summary
- Mathematical and Numerical Models
- User's Manual
- Code Assessment and Support
- 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:

- Defects are documented and evaluated for possible corrective action.
- Defects are assessed for impact on previous applications.
- Corrections are reviewed and approved before changes to software configuration items are entered into baselines.
- 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.

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 well 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:

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

The items and activities important to waste isolation shall include:

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

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

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

It is expected that most of the data collected during the site characterization phase can potentially be used in the license application performance assessments. During the early phase of characterization in particular, when little is known about the site and the importance of data characterizing it, data collection activities shall be controlled in accordance with the QA Level I requirements of this 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:

- The impact of malfunction or failure of the item, or the impact of erroneous data associated with data collection activities, on safety or waste isolation.

- The complexity of design or fabrication of an item, or design and implementation of a test, or the uniqueness of an item of test.

- The special controls and surveillance needed over processes, tests, and equipment.

- The degree to which functional compliance can be demonstrated by inspection or test.

- The quality history and degree of standardization of the item or test.

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

APPENDIX J
REQUIREMENTS FOR PEER REVIEW

1.0 GENERAL

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

2.0 APPLICABILITY OF PEER REVIEW

2.1 A peer review shall be used when the adequacy of information (e.g., data, interpretations) 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).

APPENDIX K
FORMAT AND CONTENT REQUIREMENTS FOR SCP STUDY PLANS

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 tests 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.