

FENIX & SCISSON OF NEVADA

INTRODUCTION

QUALITY ASSURANCE PROGRAM PLAN

STATEMENT OF POLICY AND AUTHORITY

It is the policy of Fenix & Scisson of Nevada, (FSN) (formerly known as Fenix & Scisson, Inc., (F&S) Las Vegas Branch) to establish and maintain a documented Quality Assurance Program. The purpose of the FSN Quality Assurance Program is to provide confidence that FSN will continually achieve satisfactory quality of performance in all areas of its operational activities through the application of effective management systems that assure conformance to programmatic objectives.

This Quality Assurance Program Plan (QAPP-002, Revision 6 and Change Notices A and B), describes the Fenix & Scisson of Nevada, Quality Assurance Program for the DOE Yucca Mountain Project (YMP). This plan is a revision to the FSN Quality Assurance Program Plan, QAPP-002, Rev. 5. The program is based upon and satisfies the applicable requirements of the Yucca Mountain Project Quality Assurance Plan, NNWSI/88-9, Rev. 2.

The Quality Assurance Program includes controls to verify conformance of all elements of the program including personnel, organization, work assignments, procedures, calibration requirements, documentation, nonconformances, and corrective action. Where project management plans are required, this Quality Assurance Program Plan shall be incorporated.

All FSN personnel involved in the performance of quality-related functions shall comply with the policies and requirements of this Quality Assurance Program Plan and procedures that implement the Quality Assurance Program. Each member of FSN Management is responsible to assure that all quality-related work performed under their cognizance is in compliance with the requirements of this Quality Assurance Program Plan.

Quality Assurance personnel have the responsibility to recognize and reveal problems pertaining to the quality of FSN programs, projects and activities; to initiate, recommend, or provide solutions to such problems; and to verify implementation of corrective action.



CHANGE CONTROL RECORD

TITLE: YMP QUALITY ASSURANCE MANUAL

DOCUMENT NO:

See Below

REV. NO.	DATE	PAGES AFFECTED	REMARKS
	10-29-84	Original issue of QAPP-001, Rev. 0 with index of Quality Assurance Procedures	
	03-03-86	Initial release of QA Manual consisting of QAPP-002, Rev. 1 and implementing QA Procedures shown on Table of Contents dated 03-03-86.	a) QAPP-002, Rev. 1, QAP-4.1(N), Rev. 2 and QAP-4.2(N), Rev. 1 approved by WMPO 01-09-86 b) Balance of QAPs on Table of Contents approved by WMPO 02-10-86
	11-25-87	Release of QAPP-002, Rev. 2	QAPP-002, Rev. 2 approved by letter WMPO:JB-257, dated 10-29-87
	01-15-88	Issue of new and revised Procedures See Table of Contents, Revision 3.	
	03-15-88	Issue of QAP-15.2(N), Rev. 2 and Table of Contents Revision 4.	
	04-25-88	Release of QAPP-002, Rev. 3 Revision of Sections 4.0 & 7.0 Issue of new and revised procedures see Table of Contents, Revision 5.	QAPP-002, Rev. 3 approved by letter WMPO:JB-1653, dated 03-31-88
	06-01-88	Issue of QAP-3.1(N), Rev. 2, QAP-16.1(N), Rev. 3, and Table of Contents, Revision 6.	
	07-27-88	Issue of QAP-2.1(N), Rev. 4, - QAP-3.3(N), Rev. 0, and Table of Contents, Revision 7.	
	08-02-88	Issue of QAP-3.2(N), Rev. 3, and Table of Contents, Revision 8.	
	09-15-88	Issue of revised procedures QAP-1.1(N), Rev. 4, QAP-2.2(N), Rev. 3, QAP-2.3(N), Rev. 3, Table of Contents, Rev. 9, and Delete Procedure QAP-10.2(N), Rev. 2.	



CHANGE CONTROL RECORD

TITLE:

YMP QUALITY ASSURANCE MANUAL

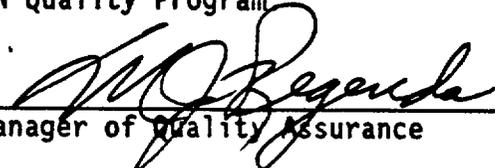
DOCUMENT NO:

See Below

REV. NO.	DATE	PAGES AFFECTED	REMARKS
11-15-88		Issue of revised procedures QAP-3.1(N), Rev. 3, QAP-6.1(N) Rev. 2, QAP-15.2(N), Rev. 3 QAP-16.1(N), Rev. 4, Table of Contents, Rev. 10.	
11-18-88		Release of QAPP-002, Rev. 5	QAPP-002, Rev. 4 and 5 approved by letter YMP:NAV-424, dated 10-31-88 QAPP-002, Rev. 4 not issued
01-06-89		Issue of revised procedures QAP-4.1(N), Rev. 4, QAP-5.1(N), Rev. 3, QAP-12.1(N), Rev. 1, QAP-16.2(N), Rev. 1, QAP-16.3(N), Rev. 1, QAP-18.1(N), Rev. 4, QAP-18.3(N), Rev. 1, Table of Contents, Rev. 11.	
02-09-89		Release of QAPP-002, Rev. 6	QAPP-002, Rev. 6 approved by Letter YMP:JB-1763 dated 01-31-89
06-08-89		Issue of revised procedures QAP-1.1(N), Rev. 5 and QAP-5.1(N), Rev. 4. Issue of new procedure QAP-2.4(N), Rev. 0 and Table of Contents, Rev. 12.	
07-10-89		Release of QAPP-002, Rev. 6 Change Notice A (Affected Pages: Introduction, Pages 1 & 2; Section I, Table of Contents; Section I, 2.0, Pages 2-1 - 2-12; and Section II, Appendix A, Page 7).	QAPP-002, Rev. 6, Change Notice A approved by Letter YMP:JB-4432, dated June 16, 1989
07-24-89		Release of QAPP-002, Rev. 6 Change Notice B (Affected Pages: Introduction, Pages 1 & 2, Section I, Table of Contents; 2.0, Page 1-5).	QAPP-002, Rev. 6 Change Notice B approved by Letter YMP:NAV-4995

INTRODUCTION

The Manager of Quality Assurance is responsible for the establishment, implementation and verification of the Quality Assurance Program to assure compliance with the policies and requirements set forth herein. The Manager of Quality Assurance is responsible for keeping management informed as to the status of the FSN Quality Program

Approved by:  Date: 7/7/89
Manager of Quality Assurance

Approved by:  Date: 7/12/89
General Manager

FENIX & SCISSON, INC.
LAS VEGAS BRANCH
QUALITY ASSURANCE PROGRAM PLAN

SECTION I

A DESCRIPTION OF THE
FENIX & SCISSON QUALITY ASSURANCE PROGRAM PLAN
FOR THE YUCCA MOUNTAIN PROJECT

FENIX & SCISSON OF NEVADA
QUALITY ASSURANCE PROGRAM PLAN

SECTION I

TABLE OF CONTENTS

	<u>TOTAL PAGES</u>
TABLE OF CONTENTS.....	1
1.0 ORGANIZATION.....	5
2.0 QUALITY ASSURANCE PROGRAM.....	12
3.0 SCIENTIFIC INVESTIGATION AND DESIGN CONTROL.....	10
4.0 PROCUREMENT DOCUMENT CONTROL.....	3
5.0 INSTRUCTIONS, PROCEDURES, PLANS AND DRAWINGS.....	1
6.0 DOCUMENT CONTROL.....	2
7.0 CONTROL OF PURCHASED ITEMS AND SERVICES.....	8
8.0 IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES AND DATA.....	2
9.0 CONTROL OF PROCESSES.....	2
10.0 INSPECTION.....	4
11.0 TEST CONTROL.....	2
12.0 CONTROL OF MEASURING AND TEST EQUIPMENT.....	2
13.0 HANDLING, SHIPPING, AND STORAGE.....	1
14.0 INSPECTION, TEST, AND OPERATING STATUS.....	1
15.0 CONTROL OF NONCONFORMING ITEMS.....	4
16.0 CORRECTIVE ACTION.....	1
17.0 QUALITY ASSURANCE RECORDS.....	6
18.0 AUDITS.....	5

1.0 ORGANIZATION

- 1.1 Fenix & Scisson, Inc. (F&S) is the AE for the Exploratory Shaft Facility (ESF) for the Yucca Mountain Project. Responsibilities include field surveillance and inspection of drilling, mining, and sub-surface facilities construction. F&S is responsible for the establishment and execution of a Quality Assurance Program Plan (QAPP). F&S 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 will retain the responsibility therefore. The delegation of the execution of the QAPP requirements will be documented. The organizational structure, lines of communication, authority and duties of persons and organizations affecting quality is clearly established in this document. These activities affecting quality include both the performing functions of attaining quality objectives and the QA functions. While the line organization is responsible for performing these activities properly, the QA organization will verify the proper performance of work through implementation of appropriate controls. The organizational structure is defined in Figure 1, shown in Section II. The responsibilities of all organizational elements depicted on organization charts relative to the Quality Program shall be described. The responsibilities and authority of key personnel follow.
- 1.1.1 The Vice President and General Manager, Las Vegas Branch has the overall responsibility for the assigned portion of the Yucca Mountain Project. In his absence, the responsibility is delegated to the Nevada Test Site Operations Manager and Assistant Manager.
- 1.1.2 The Yucca Mountain Project Manager/Technical Project Officer (TPO) is responsible to the YMPO Director to ensure that the Project activities for which F&S is responsible, Title I, II and III, are performed to this QAPP and implementing procedures that are consistent with NNWSI/88-9. This includes the drilling and subsurface design, cost estimation and inspection of the ESF. Responsibilities also include field surveillance and inspection of drilling, mining, and subsurface facilities construction.
- 1.1.3 The Yucca Mountain Project Design Manager has the responsibility for the development of the subsurface design of the ESF. This includes technical studies, Title I and Title II design, excluding cost estimation. This activity will result in a design package complete enough for an NTS Support Contractor and subcontractor to perform procurement and construct the underground facility.
- 1.1.4 The Nevada Test Site Operations Manager and Assistant Manager has the overall responsibility for Nevada Test Site activities including Technical Support, Geology/Hydrology, Drilling and Mining Support to the Yucca Mountain Project.
- 1.1.5 The Drilling Manager has the responsibility for providing field personnel necessary to support the Yucca Mountain Project drilling activities.

- 1.1.6 The Mining Manager has the responsibility for providing engineering and field personnel necessary to support Yucca Mountain Project mining and testing activities.
- 1.1.7 The Manager of Geology/Hydrology has the responsibility to provide Geology/Hydrology personnel as requested by the Yucca Mountain Project Manager and approved by DOE/YMPO to support investigations conducted by the U. S. Geological Survey (USGS). F&S Geology/Hydrology personnel perform support activities as directed by the USGS in accordance with their approved Quality Assurance and Implementing Procedures. Details of the F&S interface with USGS are described in the YMP Geology/Hydrology Organization Interface Procedure.
- 1.1.8 The Manager of Technical Support is responsible for providing all support to Yucca Mountain Project activities for records management and surveillance of geophysical logging and may provide a portion of the support for estimating, subcontract administration, reports, word processing, and other related technical services.
- 1.1.9 The Manager of Administration is responsible for providing support to Yucca Mountain Project activities for accounting and budgets, payroll, personnel relations, recruiting, training, procurement, and data processing systems.
- 1.1.10 The Safety Specialist is responsible for assuring all health and safety requirements as well as environmental considerations are incorporated in ESF underground design and facilities.
- 1.1.11 The Manager of Quality Assurance reports to the Vice President and General Manager and has been delegated the authority and execution responsibility for establishing, maintaining, directing and managing the F&S Quality Assurance Program and for assuring that the Quality Assurance Program is effectively executed within F&S, between F&S and DOE/YMPO, Participating Organizations, NTS Support Contractors, and F&S suppliers. Full-time Quality Assurance Representatives, under the direction of the Manager of QA, have responsibility for performing QA functions.
- 1.2 The QA functions are those of assuring that an appropriate QA Program is established and executed effectively and of verifying, such as by checking, auditing, surveillance and inspection, that activities that affect the quality functions have been performed correctly. Additionally, the Manager of QA may utilize Technical Specialists and Management Representatives to assist in auditing. Personnel performing QA functions have sufficient authority, access to work areas, and organizational freedom to identify quality problems; to initiate, recommend or provide solutions through designated channels; to verify implementation of solutions; and to assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. This includes the ability to stop (or cause to be stopped) unsatisfactory work through established channels. Such persons have direct access

to responsible management at a level where appropriate action can be effected and report to a management level at which this required authority and organizational freedom are provided, including sufficient independence from cost and schedule.

- 1.2.1 The Manager of Quality Assurance is responsible for directing and managing the overall F&S QA Program and has an appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. The Manager of Quality Assurance has appropriate management and QA knowledge and experience, and is at the same or higher organizational level as the highest line manager responsible for performing activities affecting quality and sufficiently independent from cost and schedule. The Manager of QA has responsibility for approval of QAPPs, changes thereto, and interpretations thereof, and implementing procedures and all changes thereto. The Manager of QA has effective communication channels with other senior management positions. The Manager of QA has the responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA program implementation by F&S and its subordinate organizations. The Manager of QA, who retains overall authority and responsibility for the QA Programs, and personnel considered to be "full-time dedicated", is not assigned duties that would prevent full attention to Yucca Mountain Project QA responsibilities or that would conflict with the reporting and resolution of QA issues and problems related to the Yucca Mountain Project.
- 1.2.2 Should a dispute involving quality arising from a difference of opinion between QA personnel and others occur, this will be brought to the attention of the Manager of QA and the manager of the other organization. Should this not achieve a resolution, the matter shall be referred to F&S Vice President and General Manager for resolution. If the dispute can not be resolved within F&S, the dispute will be elevated to the YMPO Project Quality Manager (PQM).
- 1.3 This Quality Assurance Program Plan applies to all items and activities of all organizations affecting quality. The organization structures and responsibilities are clearly established in this plan and implementing procedures so that the results described below are obtained.
 - 1.3.1 Quality is achieved and maintained by those who have been assigned responsibility for performing work.
 - 1.3.2 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 the QA organization unless specifically exempted in this Quality Assurance Program Plan.
- 1.4 If more than one organization is involved in the execution of activities affecting quality, then the responsibility and authority of each organization will be established clearly and documented.

- 1.4.1 The external interfaces between organizations and the internal interfaces between organizational units and changes thereto are documented. All interface responsibilities will be defined and documented. The interfaces between F&S, and the other NTS Support Contractors, YMPO, and the Participating Organizations are briefly described below. Specific interfaces are described in Administrative Procedures and Implementing Procedures.
- 1.4.1.1 Holmes & Narver (H&N) - F&S has a design interface with H&N on the ESF. F&S may use H&N for material testing and nondestructive testing services.
- 1.4.1.2 Reynolds Electrical and Engineering Company (REECO) - F&S is responsible for inspection and surveillance of drilling, mining, and construction performed by REECO and its subcontractors. F&S may purchase equipment through REECO and utilizes their calibration facility for the calibration of measuring and test equipment.
- 1.4.1.3 Lawrence Livermore National Laboratory (LLNL) - F&S receives direction through YMPO to support LLNL in site investigations.
- 1.4.1.4 Los Alamos National Laboratory (LANL) - F&S receives direction through YMPO to support LANL in site investigations.
- 1.4.1.5 Sandia National Laboratories (SNL) - F&S receives direction through YMPO to support SNL in site investigations.
- 1.4.1.6 Science Applications International Corporation (SAIC)/T&MSS is the integrating contractor for YMPO and provides broad technical, operational, and managerial support for Yucca Mountain Project activities. F&S interfaces with SAIC are through YMPO as described in Section 1.4.1.8.
- 1.4.1.7 United States Geologic Survey (USGS) - F&S receives direction through YMPO to support USGS in site investigations. Additionally, F&S provides USGS with Geology/Hydrology personnel as described in Section 1.1.7.
- 1.4.1.8 Yucca Mountain Project Office (YMPO) - YMPO manages and provides technical direction of the activities of F&S through the issuance of technical and programmatic guidance and QA programmatic guidance. F&S is responsible to YMPO for technical activities assigned in the Yucca Mountain Project Work Breakdown Structure Dictionary (WBS), and project-specific technical plans.
- 1.4.2 From an overall Yucca Mountain Project standpoint, the above interfaces are exchanges of technical requirements of work to be performed and liaison until completion of work. The Yucca Mountain Project Administrative Procedures (APs) provide the implementing interface controls utilized by F&S while its implementing procedures describe the methods of conducting inter-organizational interfaces.

- 1.5 Allegations of inadequate quality shall be resolved in accordance with the requirements of YMP Administrative Procedure AP-5.8Q, Resolution and Reporting of Quality Concerns.

CHANGE NOTICE A

2.0 QUALITY ASSURANCE PROGRAM**2.1 Extent of the Quality Assurance Program**

FSN has developed a Quality Assurance Program Plan which provides the description of the FSN QA program and commits to the applicable Yucca Mountain Project QA requirements given in NNWSI/88-9. This Quality Assurance Program Plan (QAPP) includes consideration of the activities affecting quality and generated by the Quality Assurance Division with assistance from the technical staff. The QAPP provides instruction to implement and apply the QA requirements to the technical activities of the YMP. It is planned, implemented, and maintained in accordance with NNWSI/88-9 and is consistent with and addresses all of the applicable requirements of this Yucca Mountain Project QA Plan.

Management above or outside of the QA organization regularly receives information as to the scope, status, adequacy, compliance, etc. of the QA Program by means of audits, surveillances, weekly reports and quarterly reports. Management shall perform readiness reviews, as deemed appropriate. Readiness reviews shall apply to major scheduled/planned activities which could affect quality. Readiness reviews shall be used in verifying that specified prerequisites and programmatic requirements have been identified prior to starting a major activity.

The hierarchy of criteria applicable to FSN are in Figure 2, see Section II. Where deviations between the requirements of these documents exist, the requirements of NNWSI/88-9 shall prevail.

- 2.1.1 The QA criteria and specific requirements associated with these criteria have been adapted to the Yucca Mountain Project activities through NNWSI/88-9 and are addressed in QAPP-002. When a specific criteria is not applicable to FSN activities, it will be noted in the QAPP and recorded on the checklist required in Paragraph 2.1.2 below with justification.
- 2.1.2 The FSN Quality Assurance Program consists of QAPP-002 plus appropriate implementing procedures required to provide and implement control over activities affecting quality. - FSN has three types of implementing procedures as follows:
- a. Project Procedures controlled by the Project Manager which apply to Project personnel, and in specific instances to QA personnel (for example, Quality Assurance Records, Personnel Qualification Evaluations, Training, etc.)
 - b. Design Control Procedures controlled by the Project Manager which apply to FSN design personnel and other personnel involved in the design process including QA personnel.

CHANGE NOTICE A

- c. Quality Assurance Procedures controlled by the QA Manager which apply primarily to QA Personnel but also apply to other personnel performing work on the project.

The control is consistent with the importance of the activity. These procedures are developed by qualified personnel and reviewed and approved by Quality Assurance prior to implementation to assure they meet all the requirements of QAPP-002.

The QAPP is submitted to YMPO for review prior to implementation and includes a checklist based on NNWSI/88-9 which identifies how and where each of its requirements are addressed. YMPO comments will be resolved and YMPO approval will be obtained. Editorial changes to the QAPP and those which have no effect on the Quality Program will be issued without YMPO approval. These will be in the form of Change Notices in lieu of Revisions. Change Notices will be incorporated in the subsequent Revisions.

- 2.1.3 FSN Management will monitor QAPP-002 through internal audits to assess the adequacy of the program and assure its effective implementation.
- 2.1.4 As an NTS Support Contractor, FSN is not responsible for the acceptance of data or data interpretations for the use in licensing activities that were not generated under the controls of the Yucca Mountain Project QA Plan (QAP). When requested, FSN will provide Participating Organizations primary data or primary data interpretations and reports that were generated by FSN.
- 2.1.5 FSN does not have responsibility for the development of "Q" Lists.
- 2.1.6 FSN uses the Yucca Mountain Project approach to QA that recognizes the differences between items and activities that affect radiological health and safety and waste isolation, and those that do not. The approach is designed to ensure that each item and activity is assigned a QA Level that is consistent with its potential impact or importance, or both, in terms of radiological health and safety, waste isolation, non-radiological health and safety, the U. S. Nuclear Regulatory Commission (NRC) licensing requirements, the operability and maintainability of the repository, cost, and schedules. The Participating Organizations or YMPO will identify the appropriate upper-tier QA Level, or a lower-tier QA Level will be assigned by FSN in accordance with YMP Administrative Procedures for all items and activities that affect quality associated with site characterization, facility and equipment construction, and facility operations. Once assigned, the QA Level for a particular item or activity will be applied by FSN.

CHANGE NOTICE A

2.1.7 QAPP-002 which complies with the requirements of NNWSI/88-9 has been established by FSN consistent with the schedule for accomplishing the activities. QAPP-002 assures that procedures required to implement the requirement of NNWSI/88-9 are properly documented, controlled, and are mandated by the General Manager in the policy statement. QAPP-002 will be applied throughout the life of the Yucca Mountain Project in accordance with established policies, procedures and instructions. QAPP-002 applies to all items and activities identified as QA Level I and II affecting quality. It also identifies the major organizations participating in the project and designated functions of these organizations. QAPP-002 provides control over activities that affect the quality of the identified structures, systems, and components to an extent consistent with their importance. The activities that affect quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that all prerequisites for the given activity have been satisfied. The program takes into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection, test, peer review, or a combination of these. The program provides for indoctrination and, as necessary, training of personnel performing activities that affect quality to assure that suitable proficiency is achieved and maintained.

The YMPO will regularly assess the status and adequacy of the FSN QA Program by overview, surveillance and audit activities.

2.2 Application of Graded Quality Assurance

2.2.1 SCOPE

2.2.1.1 EXTENT OF APPLICATION

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

CHANGE NOTICE A

be necessary to exempt certain YMP items and activities from QA Level assignment. Requests for exemptions shall be documented and shall contain sufficient justification to support the exemption request. Such exemptions shall be approved by the YMPO PQM.

2.2.1.2 PURPOSE OF A GRADED QA PROGRAM

The purpose of a graded QA program is to select the QA requirements and measures to be applied to items and activities in the Repository Program consistent with their importance to safety, waste isolation, and the achievement of U.S. Department of Energy (DOE) mission objectives. This will be accomplished by deliberate quality planning and selective application of QA requirements on the item or activity to be performed, with varying degrees of QA applied, depending on item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations. The FSN QA organization is involved in portions of the high-level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the FSN QA Staff in combination with the line staff in accordance with YMP Administrative Procedures.

2.2.1.3 DETERMINATION OF THE DEGREE TO WHICH APPLICATION IS NECESSARY

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

2.2.1.4 FLEXIBILITY OF QA REQUIREMENT SELECTION

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

CHANGE NOTICE A

2.2.2 Requirements

The requirements specified in this section are to be used to apply the graded quality philosophy to all YMP QA Level I and II items and activities.

2.2.2.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QA REQUIREMENTS

FSN is not responsible for the selection of upper-tier Quality Assurance Levels. If FSN subdivides upper-tier QA Levels to lower-tier QA Levels, this will be accomplished in accordance with YMP Administrative Procedures. The appropriate Quality Assurance Level for any item or activity shall be determined by the application of decision criteria as provided by the YMP Administrative Procedures. The basis for the selection of the Quality Assurance Level and assigned QA requirements shall be documented. The assigned Quality Assurance Levels and QA requirements must be submitted to the YMPO for review, resolution of comments, and approval prior to implementation or use. This review and approval shall be performed by the YMPO PQM and appropriate YMPO Branch Chiefs.

2.2.2.2 SELECTION OF SPECIFIC QA LEVELS

This approach incorporates three Quality Assurance Levels (QA Level) of which one will be assigned to each technical task that affects the quality of the Yucca Mountain Project. The definition, application, and assignment to each of the three QA Levels are described in the following discussion.

- 2.2.2.2.1 QA Level I** - are those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological health and safety of the public. Items and activities important to safety are those engineered structures, systems, components, and related activities essential to the prevention or mitigation of an accident that could result in a radiation dose either to the whole body or to any organ of 0.5 rem or greater either at or beyond the nearest boundary of the unrestricted area at any time until the completion of the permanent closure of the repository. Items and activities important to waste isolation are those barriers and related activities which must meet the criteria that address post-closure performance of the engineered and natural barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10 CFR 60, and 40 CFR 191.

CHANGE NOTICE A

- 2.2.2.2.2 QA Level II - are those activities and items related to the systems, structures, and components which require a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE and YMPO concerns, and the environment.
- 2.2.2.2.3 QA Level III - are those activities and items not classified as QA Levels I and II.

2.2.2.3 Application of Levels

FSN will apply upper-tier QA Levels as assigned by the Participating Organization. If it is necessary to subdivide a QA Level, lower-tier QA Levels will be assigned in accordance with YMP Administrative Procedures consistent with the requirements that follow.

2.2.2.3.1 QA Level I

QA Level I is the most stringent level of quality assurance. It is to be applied to those items and activities that may affect the ability of the repository to meet the preclosure and postclosure performance objectives specified by the NRC and the U.S. Environmental Protection Agency (EPA) for protecting public health and safety from radiological hazards. QA Level I activities which are on the Q-List will provide the primary data input to the basis for the NRC to authorize construction and to issue a license for the DOE to receive and possess source, special nuclear, and byproduct material (waste) at the geologic repository. QA Level I control and documentation must be applied to activities, including site characterization, scientific investigation, facility and equipment design, procurement, and construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities when they are specifically concerned with the protection of the public's health and safety with respect to a radiological hazard.

To keep radionuclides out of man's environment, a high level radioactive waste repository will utilize engineered systems, structures, and components to contain the waste and ensure the short-term safety. The repository also will utilize the natural barriers to afford long-term isolation. Within this context, QA Level I must be applied for near-term safety as well as long term isolation as per the following:

CHANGE NOTICE A

- o Where items and activities could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, or result in, an accident that could result in a radiation dose, either to the whole body or to any organ, of 0.5 rem or greater, either at or beyond the nearest boundary of the unrestricted area, at any time until the permanent closure of the repository.
- o Where items and activities will provide primary data which will be relied on for performance assessment of the repository system. These data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research which have a significant impact to site-characterization or are an essential part of the data base that directly support the final design of the repository and waste package performance.
- o Where activities could adversely impact the waste isolation capabilities of the engineered and natural barriers.
- o Where items are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system.
- o Where items and activities that, having failed, could cause a failure of a QA Level I item, or irretrievable loss of QA Level I data.
- o The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) will be assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationships. As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities shall be governed by the QA level assigned to the item.

2.2.2.3.2 QA LEVEL II

QA Level II is the second highest level of quality assurance. QA Level II controls and documentation shall be applied to the Yucca Mountain Project activities, and items that are specifically concerned with nonradiological operation of the

CHANGE NOTICE A

exploratory shaft facilities and repository, and the radiological safety of the repository worker. The high-level waste (HLW) repository will utilize engineered systems, structures, and components which must be designed, constructed, fabricated, tested, and operated to meet the performance objectives during the operational phase and to minimize the nonradiological hazard to the public and repository worker and the radiological hazard to the repository worker. Additionally, activities that have a major impact on project costs or schedules that could delay the achievement of DOE/Office of Civilian Radioactive Waste Management (OCRWM) milestones must be appropriately controlled.

Therefore, Quality Assurance Level II must be applied to activities and items as follows:

- o Where items and activities that are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and could have a major impact on the non-radiological health and safety of the public and repository worker.
- o Where items and activities which having failed or which are performed inadequately would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10CFR20.
- o Where items and activities could affect the retrievability of waste up to the time of repository closure.
- o Where items and activities that involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components.
- o The Design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/methods/equipment is preferred, shall be assigned a QA Level of II prior to execution. Where a particular item can be identified and defined during this phase, a separate QA Level assignment may be made for that item. Once the QA Level for such an item is identified and approved, design procurement and construction activities shall be governed by the QA Level assigned to the item.
- o Where items and activities that, having failed, could result in a major cost overrun.
- o Where items and activities that, if failed, could result in a major schedule slippage.

CHANGE NOTICE A

Quality Assurance Level II activities may have as much importance as Quality Assurance Level I activities; however, except when used to support a Quality Assurance Level I activity as indicated in the following, they do not provide primary information in the licensing efforts. In most cases, activities controlled in accordance with a Quality Assurance Level II program cannot be used subsequently to directly support Quality Assurance Level I activities unless it can be substantiated that quality assurance requirements equivalent to those which would have been applied to a Quality Assurance Level I activity were implemented or that a technical justification process is applied in accordance with YMP AP 5.9Q "Acceptance of Data and Data Interpretations Not Developed Under the YMP Project QA Program."

2.2.2.3.3 QA LEVEL III

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

In some cases, data interpretations generated as a result of activities controlled in accordance with QA Level II or III programs, or activities performed prior to the complete implementation of the Yucca Mountain Project Quality Assurance Plan may be used in the licensing process as background or corroborative information.

- 2.2.2.4 The requirements contained in this document apply to Quality Assurance Levels I and II items and activities unless otherwise noted herein. The requirements imposed for QA Level III items and activities are those managerial, administrative, scientific, engineering, commercial, and laboratory practices that are commonly used by FSN.

2.3 QA Activities2.3.1 Overview

FSN shall perform overview of the QA activities of all organizations (including subcontractors doing supportive work) under their purview. This excludes other project participants (see Para. 7.5.2.1). Overview is to include the following as appropriate:

CHANGE NOTICE A

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

2.3.2 Review and Approval of QA Programs

Procedures are to be established by FSN for the review of QA program documentation of those organizations under their purview for adequacy, completeness and relevance. The procedures shall identify the types of documents to be submitted for review and approval, assign responsibility for review, and identify the methods for documenting review and approval action. Reviews of QA program documentation shall be recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance.

2.4 Management Assessment

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

2.4.2 Performance of Management Assessment Management assessments are performed by FSN in accordance with procedures for planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results and tracking of recommendations. Copies of 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

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

CHANGE NOTICE A

- 2.5.1.1 Position Description Minimum education and experience requirements are established and documented in position descriptions for each position involved in the performance of activities that affect quality.
- 2.5.1.2 Personnel Qualification Evaluation Personnel selected will have education and experience commensurate with the minimum requirements specified in the position description. Relevant education and experience will be verified. This verification will be documented. The initial capabilities of an individual will be based upon an evaluation of their education, experience, and training and compared to those established for the position. Evaluations will be documented by managers or supervisors responsible for the activities to be performed.
- 2.5.1.3 Indoctrination Prior to assigning personnel to perform activities affecting quality, they will be indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the work to be accomplished.
- Indoctrination may be accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or other instructional methods.
- o FSN QAPP
 - o Implementing Procedures and Work Instructions (applicable to the individual's responsibilities)
 - o Regulations
 - o Project Level Documents
- 2.5.1.4 Training Prior to assigning personnel to perform quality affecting activities training if needed, will be conducted to gain the required proficiency. The training (in-depth instruction) will include the principles, techniques, and requirements of the activity. Such in-depth instructions may be internal or external class room sessions, classroom sessions supplemented by hands-on workshops, on-the-job training, other instructional methods, or combinations thereof.
- 2.5.1.5 Proficiency Evaluation After the initial personnel qualification evaluation, the job proficiency of personnel who perform activities affecting quality will be evaluated and documented at least annually. Proficiency evaluations may be performed in conjunction with periodic or day-to-day employee performance evaluations. Proficiency evaluations will be performed by managers or supervisors who have responsibility for the activities being performed or verified.

CHANGE NOTICE A

- 2.5.1.6 Records Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations will be retained as lifetime QA records. These records will include, as a minimum, the items listed below:
- o Personnel Qualification Evaluation Records Records of the verification and evaluation of a candidates education, experience, and training, compared to those for the position.
 - o Indoctrination Records Records of indoctrination which include the objective and content of the indoctrination, date or dates of indoctrination, and other applicable information.
 - o Training Records Records of training which include the objective and content of the training, name of the instructor, attendees, dates of attendance and results of proficiency evaluations (where applicable), and other applicable information.
 - o Proficiency Evaluation Records Records of proficiency evaluation will include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.

3.0 SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL

3.1 Scientific Investigation Control

F&S participation in Scientific Investigation is limited. F&S performs a support function for the Principal Investigators (PI). F&S prepares plans for specific investigations from criteria supplied by the PI with the approval of YMPO/NTSO. These plans are known as drilling programs or mining programs. These programs contain a description of the work to be performed, and the equipment required to perform the work. F&S also supplies personnel to work under the direction of PI personnel. F&S may also provide the services of support subcontractors when directed by the PI.

3.2 Design Control

3.2.1 General

3.2.1.1 Definition The design process is defined, controlled and verified in accordance with established, approved procedures contained in the Project Control Manual utilized by the Design Organization. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed implementing procedures for data collection and analyses and related information such as test results and analysis. The data collection activities result from scientific investigations and produce design input. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters.

It is the policy of the Yucca Mountain Project that a completed or final design of a facility or item evolves from a sequential order of design activities (or phases) wherein each phase becomes more detailed in nature than the preceding phase. It is recognized that the number and length of design phases required to produce a completed or final design of any particular item or facility may vary, among organizations responsible for design, according to the timeliness and availability of pertinent information and the complexity of the item or facility. It is also recognized that all Project design activities, although undertaken by different organizations, which may progress at different rates, are dependent on and require an interface with each other to produce a unified facility design.

- 3.2.1.2 Quality Assurance Level Assignment All design phases will be assigned a Quality Assurance Level prior to execution in accordance with the methods specified in the YMP Administrative Procedure Manual.
- 3.2.1.3 Qualification of Personnel Personnel performing design work will be indoctrinated, trained, and qualified in accordance with the requirements of Section 2 of this document. Instructions, procedures and drawings for design work will be in accordance with the requirements of Section 5 of this document.
- 3.2.1.4 Peer Review For design activities including design output documents which involve use of untried or state-of-the-art testing and analysis procedures and methods, or where detailed technical criteria and requirements do not exist or are being developed, a peer review will be conducted. The peer review will meet the requirements of Paragraph 3.4 of this section of the Quality Assurance Program Plan.
- 3.2.2 Design Input
- 3.2.2.1 Identification, Review and Approval of Input Applicable design input, such as site characterization data, criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards, will be identified, documented, and their selection reviewed and approved by F&S Design and the F&S QA organization. The purpose of the QA review is to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.
- 3.2.2.2 Changes to Design Input Changes to approved design input, including the reason for the changes, will be identified, documented, approved, and controlled by the responsible design organization.
- 3.2.2.3 Considerations for Design Input Considerations for design inputs as they apply to specific items or systems are contained in Appendix B of this document.
- 3.2.3 Design Analysis
- 3.2.3.1 Design Analysis Documents Design analyses will be performed in a planned, controlled, and documented manner. Design analysis will be performed and documented in sufficient detail as to purpose, method, assumptions, design input, design calculations, references and units such that a technically qualified

person may review, understand, and verify the analysis without recourse to the originator. These documents will be legible and in a form suitable for reproduction, filing, and retrieval.

Calculations will be identifiable by subject (including structure, system, or component) originator, reviewer, and date.

3.2.3.2 Documentation of Design Analysis

Documentation of design analysis will include as a minimum the following:

- o Definition of the objective of the analysis.
- o Definition of design input and their sources.
- o A listing of applicable references.
- o Results of literature searches or other background data.
- o Identification of assumptions and indication of those which require verification as the design proceeds.
- o A logical sequenced list showing the design calculations.
- o Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem.
- o Signatures and dates of review and approval by appropriate personnel including QA Personnel. The purpose of the QA review is to assure that the documentation is prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

3.2.3.3 Use of Computer Programs Computer programs that are used to support a licence application will be documented and controlled as specified in Paragraph 3.3 of this Section and Appendix H of this QAPP.

3.2.4 Design Verification

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

3.2.4.2 Timing of Verification Verification of the adequacy of design will be performed prior to release for procurement, construction, or release to another organization for use in other design activities. In those cases where this timing can not be

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

- 3.2.4.3 Extent of Verification The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with Paragraph 3.2.4 of this Section, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, will be verified for each application. Known problems affecting the standardized or previously proven designs and their effects on other features will be considered. The original design and associated verification measures will be adequately documented and referenced in the files of subsequent application of the design.
- 3.2.4.4 Changes to Verified Designs Changes to previously verified designs will require verification including evaluation of the effects of those changes on the overall design.
- 3.2.4.5 Personnel Performing Verification Design verification will be performed in accordance with the requirements of Paragraph 3.2.4.6 of this Section by any competent, certified individual or individuals or certified group or groups other than those who performed the original design. This includes the following:
- 3.2.4.5.1 Individuals or groups from the originator's same organization.
- 3.2.4.5.2 Individuals or groups from other organizations contracted for this purpose.
- 3.2.4.5.3 The originator's supervisor providing all of the following requirements are met:
- o The supervisor is the only individual in the organization competent to perform verification.
 - o The supervisor did not establish the design input used, specify a singular design approach, or rule out certain design considerations.
 - o The rationale for satisfying the two requirements above is documented and approved by management superior to the supervisor. The Manager of QA or his designee will also concur with this rationale.

- 3.2.4.6 Methods of Design Verification Design verification will be accomplished by any one or a combination of the following: design reviews, alternate calculations, qualification testing, or peer review.
- 3.2.4.6.1 Design Reviews Design reviews are detailed critical reviews to provide assurance that the design is correct and satisfactory. At a minimum, the items below will be considered during the review and the results of such deliberations will be documented.
- o Were the design inputs correctly selected?
 - o Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
 - o Was an appropriate design method used?
 - o Were the design inputs correctly incorporated into the design?
 - o Is the design output reasonable compared to design inputs?
 - o Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?
 - o Are computer programs used for analysis identified and verified in accordance with the methods specified in Paragraph 3.3 of this section.
- 3.2.4.6.2 Alternate Calculations Alternate calculations are a form of analysis which may be used to determine the adequacy of the original analyses. The use of alternate calculations will include a review of the appropriateness of assumptions, inputs and computer programs or other calculation method used.
- 3.2.4.6.3 Qualification Tests Qualification tests that involve actual physical testing of systems, structures, or components may be used to verify the adequacy of design. Where design adequacy is to be verified by qualification tests, the tests will be identified. The test configuration will be clearly defined and documented. Testing will demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily will be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design will be verified by other means. Test results will be documented and evaluated by the responsible design organization to assure that test requirements have been

met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification will be documented and the item modified and re-tested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mockups, scaling laws will be established and verified. The results of model test work will be subject to error analysis, where applicable, prior to use in the final design work.

3.2.4.6.4 Peer Review

Peer review is an acceptable method of design verification when the design is beyond state-of-the-art and other methods of design verification are not feasible.

3.2.5 Design Change Control

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

3.2.6 Design Interface Control

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

3.2.6.2 Information Transmitted Across Interfaces Design information transmitted across interfaces will be documented and controlled. Transmittals shall identify the status of the design information or document provided and, where necessary, identify

incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal will be confirmed promptly by a controlled document.

3.2.7 Design Output Requirements

3.2.7.1 Design Output Documents Design output documents will:

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

3.2.7.1.2 Identify assemblies or components or both that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection or testing or both, to requirements that are more restrictive than the Supplier's published product description, the component part will be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

3.2.7.1.3 Show evidence that the required review and approval cycle has been achieved prior to release for procurement, construction, or release to another organization for use in other design activities. As a minimum, the review and approval cycle will include the participation of the technical and QA elements of both the responsible design organization and the WMPO or their designee. The purpose of the QA review is to assure that the documents are prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

3.2.8 Design Documents as QA Records Design documentation, including design inputs, analyses, drawings, specifications, approved changes thereto, evidence of design verification and records confirming interface control will be collected, controlled, stored, and maintained as QA records in accordance with procedures which met the requirements of Section 17 of this document.

3.3 Software Quality Assurance Requirements

3.3.1 Computer Software Documentation and Control

For a geologic repository, computer software used to perform analysis in support of the license application shall be controlled to the same level of requirements as software used to perform direct design analysis. Auxiliary software used to support primary analysis software shall be controlled at a level commensurate with the complexity of that software.

Where commercial auxiliary software is used, all available documentation from the software supplier shall be obtained. It is recognized that source code is generally not available and controls are limited to unique version identification and user-related

manuals. Supplemental, detailed requirements for the development, maintenance, and security of computer software based on the life cycle model are contained in Appendix H of this QAPP.

- 3.3.1.1 Fenix & Scisson, Inc., shall prepare a description of their software design, test and configuration management system, and submit it to DOE/YMPO for review and approval. The description shall:
- o Provide criteria for application of the requirements of this section based on the complexity and importance of the software used to perform analysis in support of the design of a geologic repository.
 - o Indicate the methods to be used to develop computer program requirements, to translate those requirements into a detailed design, and to implement that design in executable code.
 - o Relate the types of documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use.
 - o Identify the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software.
 - o Specify the process to be used for verification and validation of the software developed or applied to geologic repository design analysis.
 - o Identify the procedure for reporting and documenting software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action.
- 3.3.1.2 Software shall be placed under configuration management as each baseline element is approved. Software baseline elements shall be uniquely identified to assure positive control of all revisions; the identification of each code version shall be directly related to the associated documentation.
- 3.3.1.3 Changes to software shall be systematically evaluated, coordinated, and approved to assure that the impact of a change is carefully assessed prior to updating the baseline, required action is documented, and the information concerning approved changes is transmitted to all affected organizations. Changes to computer software shall be subject to the same level of approval, verification, and validation as the original software.
- 3.3.1.4 Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. This requirement may be met in part by

existing documentation if properly referenced and related to the NUREG-0856 requirements.

- 3.3.1.5 Testing of software, including new or modified software, shall be performed for those inputs and conditions necessary to exercise the software, identify boundary conditions and to provide a suitable benchmark or sample problem for installation. The goal of testing is to develop a set of test cases that have highest probability of detecting the most errors in order to identify under what conditions the software does not perform properly.
- 3.3.1.6 Verification and validation of computer software shall be performed prior to the use of such software to perform technical calculations in support of site-characterization, performance assessment analyses, and the design, analysis, and operation of repository structures, systems, and components. In those cases where this requirement cannot be met, the portion or portions of software which have not been verified and validated shall be identified and controlled. In all cases, the verification and validation of software shall be completed prior to relying on the software to support the license application.
- 3.3.1.7 Verification and validation procedures shall assure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.
- 3.3.1.8 Existing software shall be qualified for use. This qualification shall be based on the ability of the software to provide acceptable results for specific applications and compliance with the requirements of this section. Software that has not been developed in accordance with this QAPP may be qualified for use provided the software is verified and validated, a software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this section.
- 3.3.1.9 Methods for determining the applicability of requirements and managing interfaces involving the documentation, configuration management, change, qualification, verification, and validation are contained in the F&S Software QA Plan and Implementing Procedures.

3.3.2 Documentation of Computer Software

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

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

This documentation is considered to be a QA Record and is subject to the requirements of Section 17.0 of this QAPP. Appendix H to the QAPP provides detailed requirements on the content of the documentation for this software and other computer software used on the Yucca Mountain Project.

3.3.3 Software Configuration Management

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

3.4 Peer Reviews

F&S shall institute a peer review process, when applicable, to provide adequate confidence in the work being reviewed. Peer reviews shall meet the requirements of NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories" (Feb. 1988). These requirements are contained in Appendix J 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.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1.1 Measures to Assure Adequate Quality

Measures will be established to assure that applicable regulatory requirements, design or site investigations bases, and other requirements that are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment and services utilized on the Yucca Mountain Project. To the extent necessary, procurement documents will require subcontractors to provide a Quality Assurance (QA) Program that is consistent with the pertinent provisions of NNWSI/88-9 as required for the specified Quality Assurance Level. In lieu of requiring subcontractors to have a Quality Assurance Program, they may be required to work in accordance with the F&S QAPP and Procedures. The extent of F&S responsibility for procurements which involve REECo will be defined in Yucca Mountain Project Administrative Procedures.

4.2 Additional Requirements for QA Level I Activities

Procurement documents issued at all tiers of procurement will include provisions for the items listed below as deemed necessary by F&S:

4.2.1 Content of Procurement Documents

4.2.1.1 Scope of Work

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

4.2.1.2 Technical Requirements

Technical requirements will be specified in the procurement documents. Where necessary, these requirements will be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items of services to be furnished. The procurement documents will provide for identification of test, inspection, and acceptance requirements of the purchaser for monitoring and evaluating the supplier's performance.

4.2.1.3 QA Requirements

4.2.1.3.1 Procurement documents will require that the supplier have a documented QA Program that implements either portions or all of the requirements of NNWSI/88-9. Quality Assurance Program Plans and Documents of subcontractors for QA Level I purchases will be reviewed and approved by F&S. Those which do not adequately define QA requirements, as judged by the QA representative of F&S, will be corrected prior to initiation of activities specified by the purchase order or contract.

The extent of the program required will depend on the type and use of the item or service being procured. The procurement documents will require the supplier to incorporate appropriate QA Program requirements in subtier procurement documents. In lieu of requiring subcontractors to have a Quality Assurance Program, they may be required to work in accordance with the F&S QAPP and Procedures.

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

4.2.1.4 Rights of Access

At each tier of procurement, the procurement documents will provide for access to the suppliers' facilities and records for inspection or audit by the purchaser, appropriate YMPO personnel, or other YMPO authorized representatives. YMPO access to subtier contractor facilities will be arranged by F&S.

4.2.1.5 Documentation Requirements

The procurement documents at all tiers will identify the documentation required to be submitted to the purchaser. The time of submittal will also be established. If F&S requires the supplier to maintain specific QA records, then the retention times and disposition requirements will be specified in accordance with Section 17 of this document.

4.2.1.6 Nonconformance

The procurement documents will prescribe the F&S requirements for reporting and approving disposition of nonconformances.

4.2.1.7 Spare and Replacement Parts

The procurement documents will 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 will be equal to or better than the original. If QA or technical requirements of the original item cannot be determined, then an engineering evaluation will be conducted by qualified individuals to establish the requirements. The evaluation will consider the interchangeability, function and safety of the item. The evaluation will be documented.

4.2.2 Procurement Document Review

A review of the procurement documents and changes thereto will 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 will be performed prior to contract award. Procurement document reviews will be performed by personnel who have access to pertinent information and who have adequate understanding of the requirements and intent of the procurement documents. The review will include, as a minimum, the cognizant technical organization and QA organization. The review by the QA organization will assure that the following requirements are met:

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

4.2.3 Procurement Document Changes

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

- o Appropriate content will be included in procurement documents as required by Paragraph 4.2.1 of this section.
- o Additional or modified design or site investigation criteria will be determined.
- o Analysis of exceptions or changes requested or specified by the supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished.

4.2.4 Distribution of Procurement Documents

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

5.0 INSTRUCTIONS, PROCEDURES, PLANS AND DRAWINGS

5.1 General

Activities affecting quality will be prescribed by and performed in accordance with documented instructions, procedures, plans or drawings of a type appropriate to the circumstances. These documents will include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Instructions and procedures will 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, will be controlled as required in Section 6.0 of this document.

5.2 Reviews

An independent review of all instructions, procedures, plans and drawings shall be performed by F&S to assure technical adequacy and inclusion of appropriate quality requirements. These reviews shall be performed by individual(s) other than those who developed these documents. If applicable, the 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 Distribution

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

6.0 DOCUMENT CONTROL

6.1 Document Preparation, Review, Approval, and Issuance

6.1.1 Methods

The preparation, review, approval, and issuance of documents such as instructions, procedures, plans and drawings, including changes thereto, will be controlled through the implementation of methods that assure that only correct documents are used.

Document Control will be applied to the following:

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

6.1.2 The document control system will be documented and F&S QA will provide the appropriate review, resolution of comments, and concurrence with respect to quality-related aspects of the documents.

6.1.3 Implementation

Implementation of document control will provide for the following:

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

6.2 Document Changes

6.2.1 Minor Changes

Minor changes to documents, such as inconsequential editorial corrections, will not require that the revised documents receive the

same review and approval as the original documents. To avoid 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 will be clearly delineated.

6.2.2 Major Changes

Changes to documents, other than those defined above as minor changes are considered as major changes and will be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated by the organization responsible for the document. The reviewing organization will 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.

6.3 Distribution of Documents

Document Control System

The document control system will assure that documents requiring verification are not released prior to verification or, if they must be released before verification, they are uniquely identified as such and controlled in accordance with Para. 6.1.3 of this QAPP. A master list or equivalent used to identify the correct, current and updated versions of documents will be submitted to the YMPO PQM and the SAIC/T&MSS Project Quality Assurance Department Manager. In the case of implementing procedures, this will be accomplished by incorporating in the manuals a table of contents showing the latest revisions.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 General Requirements

Measures will be established to ensure that purchased material, equipment, and services conform to the procurement documents. These measures will 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 will 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 will be retained under the control of YMPO QA Records Management System (QARMS) and will be sufficient to identify the specific requirements, such as codes, standards, or specifications, that are to be met by the purchased material and equipment.

The extent of F&S responsibility for procurements which involve REECo will be defined in Yucca Mountain Project Administrative Procedures.

Specific requirements for the control of purchased items and services are listed below.

7.2 Procurement Planning

7.2.1 Procurement activities will be planned and documented to ensure a systematic approach to the procurement process. Procurement planning will result in the documented identification of procurement methods and organizational responsibilities. Appropriate Quality Assurance (QA) organization participation will be provided for evaluation and selection of suppliers, verification of suppliers activities and receiving inspections.

Planning will determine the following:

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

7.2.2 Procurement Timing

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

7.2.3 Procurement Methods

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

Planning will provide for the integration of the following:

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

7.3 Source Evaluation and Selection

7.3.1 Selection of Suppliers

The selection of suppliers will 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.

7.3.2 Source Evaluation and Selection Measures

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

7.3.3 Measures for Evaluation and Selection of Procurement Sources

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

- o Evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history shall reflect current capability.
- o Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.
- o Supplier's technical and quality capability as determined by a direct evaluation of their facilities and personnel and the implementation of his QA program.

7.4 Bid Evaluation

7.4.1 Extent of Conformance

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

- o Technical considerations.
- o QA requirements.
- o Supplier's personnel.
- o Supplier's production capabilities.
- o Supplier's past performance.
- o Alternates.
- o Exceptions.

7.4.2 Resolution of Unacceptable Quality Assurance Conditions

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

7.5 Supplier Performance Evaluation

7.5.1 Interface Measures

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

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

- o Requiring the supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements.
- o Reviewing supplier documents that are generated or processed during activities fulfilling procurement document requirements.
- o Identifying and processing necessary change information. Measures to control changes in procurement documents will be established, implemented and documented in accordance with the requirements of this QA Plan.
- o Establishing methods of document information exchange between purchaser and supplier.

7.5.2 Verification Measures

7.5.2.1 Extent of Verification

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

When F&S utilizes a Participating Organization or NTS Support Contractor for Yucca Mountain Project activities for which they are responsible, F&S will initiate a request to YMPO to conduct a YMPO surveillance of the organization performing the work. The surveillance will be conducted to determine that the item or activity is being produced or performed in accordance with F&S requirements. These surveillances may utilize F&S personnel as technical advisors.

The extent of verification activities, including planning, will be a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance. Verification activities will be accomplished by qualified personnel assigned to check, inspect, audit, or witness the supplier's activities. These verification activities will be conducted as early as practicable. However, the purchaser's verification activities will not relieve the supplier of his responsibilities for verification of quality achievement.

7.5.2.2 Record of Verification Activities

Activities performed to verify conformance to requirements of procurement documents will be recorded. Source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions will be documented. These completed documents will be considered QA records and will be controlled in accordance with Section 17.0 of the Quality Assurance Program Plan (QAPP).

The purchaser will ensure that this documentation is evaluated to determine the supplier's QA program effectiveness.

7.6 Control of Documents Generated by Suppliers

Documents that are generated by suppliers will be controlled, handled, and approved in accordance with documented procedures. Means will be implemented to ensure that the submittal of these documents is accomplished in accordance with the procurement document requirements. These measures will provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.

7.7 Acceptance of Item or Service

7.7.1 Methods for Acceptance

Methods will 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 will 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 will be either a supplier Certificate of Conformance, a source verification, a receiving inspection or post-installation test at the facility site, or a combination thereof. Requirements applicable to these methods of acceptance are listed below:

7.7.2 Certificate of Conformance

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

- o The certificate will identify the purchased material or equipment, such as by the purchase order number.
- o The certificate will identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, or other specifications. This may be accomplished by including a list of the specific requirements or by providing, at the point of receipt, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include approved changes, waivers, or deviations applicable to the subject material or equipment.
- o The certificate will identify any procurement requirements that have not been met, together with an explanation and the means by which to resolve the nonconformance.
- o The certificate will be attested to by a person who is responsible for this QA function and whose function and position are described in the purchaser's or supplier's QA program.

- o The certificate system, including the procedures to be followed in filling out a certificate and the administrative procedures for the review and approval of the certificates, will be described in the purchaser's or supplier's QA program.
- o Means will be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification will be conducted by the purchaser at intervals commensurate with the supplier's past quality performance.

7.7.3 Source Verification

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

7.7.4 Receiving Inspection

When receiving inspection is used, purchased items will be inspected as necessary to verify their conformance to specified requirements, by taking into account source verification and audit documentation and the demonstrated quality performance of the supplier. Receiving inspection will be performed in accordance with established procedures and inspection instructions to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. Receiving inspection will be coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection. Receiving inspections associated with engineered items shall be planned, performed and documented in accordance with the requirements specified in Section 10.0, Para. 10.2.1, 10.4, 10.4.1, 10.6.1, 10.9 and 10.9.1 of this document. Personnel selected to receipt inspection activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities. When required, personnel shall also be indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are applicable.

7.7.5 Post-Installation Testing

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

7.8 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 purchaser will accept the service by any or any combination of the following methods:

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

7.9 Control of Supplier Nonconformances

The purchaser and supplier will establish and document methods for disposition of items and services that do not meet procurement document requirements. These methods will include the following provisions:

- 7.9.1 Provisions for evaluation of nonconforming items.
- 7.9.2 Provisions for submittal of nonconformance notice to purchaser by supplier as directed by the purchaser. These submittals will include disposition (e.g., use-as-is or repair) and technical justification that are recommended by the supplier. Nonconformances to the procurement requirements or purchaser approved documents that consist of one or more of the items listed below will be submitted to the purchaser. Approval of the recommended disposition will be in accordance with documented procedures.
 - o Technical or material requirement is violated.
 - o Requirement in supplier documents, which has been approved by the purchaser, is violated.
 - o Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.
 - o The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.
- 7.9.3 Provisions for purchaser disposition of supplier recommendation.
- 7.9.4 Provisions for verification of the implementation of the disposition.
- 7.9.5 Provisions for maintenance of records of nonconformances that are submitted by the Supplier.

7.10 Commercial-Grade Items

7.10.1 Alternatives

If a design requires commercial-grade items, then the following requirements are an acceptable alternative to other requirements of this section except as noted in paragraph 7.10.1.2 below and the requirements of Section 4.0 of this QAPP. If a scientific investigation requires commercial-grade items, they may be controlled by the use of the following requirements (except Para. 7.10.1.1) and Section 4.0 of this QAPP.

7.10.1.1 Identification of Commercial-Grade Items

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

7.10.1.2 Source Evaluation and Selection

Source evaluation and selection will be in accordance with Paragraph 7.3, if it is determined necessary by the purchaser based on the complexity of the item and importance to safety.

7.10.1.3 Purchase Order

Commercial-grade items will be identified in the purchase order by the manufacturer's published product description (e.g., the catalog number).

7.10.1.4 Receipt of Commercial-Grade Item

After receipt of a commercial-grade item, the purchaser will determine that the following conditions have been met:

- o Damage was not sustained during shipment.
- o The item received was the item ordered.
- o Inspection, testing, or both, is accomplished by the purchaser, in accordance with written procedures, to ensure conformance with the manufacturer's published requirements. If applicable, acceptance of the item may be accomplished via the calibration program in accordance with the requirements of Section 12.0 of this QA Program Plan.
- o Documentation, as applicable to the item, was received and is acceptable.

8.0 IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES AND DATA

This section provides the requirements for the identification and control of items, samples and data and consists of three separate parts. The requirements for items are stated in part A of NNWSI/88-9, Section VIII; in part B for samples; and part C for data resulting from scientific investigations. Part A applies to activities related to the engineered items and does not apply to scientific investigations. Parts B and C apply to scientific investigation activities and do not apply to engineered items. At this time, identification and control of samples does not apply to F&S.

IDENTIFICATION AND CONTROL OF ITEMS

- 8.1 Identification Identification requirements will be imposed, as appropriate, on suppliers and subcontractors, by inclusion in technical specifications and/or drawings.

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.

- 8.1.1 Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impracticable or insufficient, physical separation, procedural control, or other appropriate means shall be employed.
- 8.1.2 Identification markings, when used, shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.
- 8.1.3 When specified by codes, standards or specification that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part or serial number; or specified inspection, test or other records) the program shall be designed to provide such identification and traceability control.

- 8.1.4 Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.
- 8.2 Control Provisions shall be made for the control of item identification consistent with the planned duration and condition of storage, such as: (1) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; (2) protection of identification on items subject to excessive deterioration due to environmental exposure; (3) provisions for updating existing facility records.

Identification and Control of Data

8.3 Identification

Data generated from a Yucca Mountain Project (YMP) scientific investigation shall be identified to assist in the determination of its correct use. Identification of such data shall be provided in all documents, information systems, or both, in which such data appear.

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

- 8.4 Control measures shall be established and implemented to assure that Yucca Mountain Project data are properly identified. These measures shall include verification of the identification of such data prior to release for use.

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 portion of the data.

9.0 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 will be established to ensure that processes that affect quality of items or services are controlled either by instruction, procedures, or other appropriate means. Special processes that control or verify quality, such as those used in welding, heat treating and nondestructive examination will be accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria and other special requirements. These requirements will be imposed, as appropriate, on suppliers and subcontractors by inclusion in technical specifications and/or drawings.

9.2 Process Control All processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall ensure that process parameters are controlled and that specified environmental conditions are maintained.

9.2.1 Identification of Special Processes It is the responsibility of Fenix & Scisson to identify which portions of its activities involve the use of special processes. A special process is a process in which the results are highly dependent on either the control of the process or the operator's skill, or both, and in which the specified quality cannot be readily determined by inspection or testing of the item.

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

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

9.2.2.2 Applicable Codes and Standards The requirements of applicable codes and standards, including acceptance criteria for the special process, shall be specified or referenced in the procedures or instructions.

9.2.2 Qualification of Special Process Procedures

Program for Qualification Procedures shall be qualified in accordance with applicable codes, standards or other specifications. The program for qualification of procedures shall be specified in documents prepared by F&S. F&S QA will provide appropriate reviews to assure compliance with these requirements.

9.2.3 Qualification of Personnel Performing Special Processes

9.2.3.1 Training, Qualification, and Certification Personnel shall be trained, qualified, and certified in accordance with written procedures. The training and qualification, and certification shall be the responsibility of the organization that is performing the work. These procedures shall be reviewed by F&S Quality Assurance (QA) for compliance with requirements.

9.2.3.2 Procedures Qualification shall utilize the actual working procedure, to the extent possible.

9.2.3.3 Personnel Qualification Requirements Qualification of personnel shall incorporate the personnel qualification requirements of the applicable codes, standards, or specifications.

9.2.4 Special Process Equipment

Special process equipment shall be checked out, qualified, and certified in accordance with specified requirements. These requirements shall implement the requirements of applicable codes, standards, and specifications. Equipment checkout, qualification, and certification shall be the responsibility of the organization performing the work. F&S QA shall review the procedures for qualification of equipment for compliance with requirements.

9.2.5 Special Process Records

Records shall be maintained for the currently qualified personnel, procedures, and equipment of each special process and the requirements for maintenance of these records shall be specified. Special process verification methods and criteria shall also be documented and retained.

10.0 INSPECTION

10.1 General Requirements

Measures will be established by Fenix & Scisson to provide Drilling and Mining Inspection required to verify conformance of an item or activity to specified requirements. These measures will provide for: (1) inspections to be performed in accordance with written procedures by qualified personnel who did not perform the work being evaluated; (2) criteria for determining when inspections are required or how and when inspections are to be performed; (3) sampling methodology, if used; (4) the identification of mandatory hold points; and (5) identification of inspections requiring special expertise. The results of all inspection activities will 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 Personnel

10.2.1 Reporting Independence of Personnel

Inspection will be performed by personnel who are part of the Yucca Mountain Project and do not report directly to the immediate supervisor(s) who is/are responsible for performing the activity being inspected. The work will not be performed by F&S; it will be performed by REECO or their subcontractor(s). Qualified individuals from outside of the QA organization will be utilized because special Mining and Drilling expertise is necessary. Inspection personnel 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. F&S Quality Assurance shall overview and monitor the inspection activity.

10.2.2 Qualification

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

10.3 Inspection Hold Points

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

10.4 Inspection Planning

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

- o Identification of characteristics and activities to be inspected.
- o A description of the method of inspection.
- o Identification of the individuals or groups responsible for performing the inspection operation.
- o Acceptance and rejection criteria.
- o Identification of required procedures, drawings, and specifications and revisions.
- o Recording inspector or data recorder and the results of the inspection operation.
- o Specifying necessary measuring and test equipment including accuracy requirements.

10.4.1 Sampling

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

10.5 In-process Inspection

Inspection of items in-process or under construction will be performed for work activities where necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel will be provided.

10.5.1 Combined Inspection and Monitoring

Where a combination of inspection and process monitoring methods is used, it will be performed in a systematic manner to ensure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process. Both inspection and process monitoring will be provided when other techniques cannot provide adequate control.

10.5.2 Controls

Where required, controls will be established and documented for the coordination and sequencing of activities at established inspection points during successive stages of the conducted process or construction.

10.6 Final Inspection

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

10.6.1 Inspection Requirements

Completed items will be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the item's quality and conformance to specified requirements. If not previously examined, then quality records will be examined for adequacy and completeness.

10.6.2 Acceptance

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

10.6.3 Modifications, Repairs, or Replacements

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

10.7 In-service Inspection

F&S is not responsible for in-service inspection.

10.8 Qualification Requirements

Appendix C of this document defines the requirements for the qualification for the inspection personnel who perform inspection to verify conformance to specified requirements for the purpose of acceptance.

10.9 Records

The following are requirements for inspection records which will be retained in accordance with Section 17 of this QAPP.

10.10 Inspection Records

As a minimum, inspection records will identify the following:

- o Item or activity.
- o The date of the inspection.
- o Name of individual performing the inspection.
- o Name or names of personnel contacted during the inspection.
- o A description of the type of observation (method of inspection).
- o Inspection criteria including identification of drawing, specification, etc. (and applicable revision).
- o Equipment used during the inspection.
- o Evidence as to the acceptability of the results.
- o Acceptance Statement.
- o References to information on action taken in connection with conditions adverse to quality, nonconformances and/or actions taken to resolve any discrepancies.

10.10.1 Personnel Qualification Records

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

11.0 TEST CONTROL

11.1 General Discussion

Tests required to verify conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in service will be planned and executed. Characteristics to be tested and test methods to be employed will be specified. The test procedures will be implemented by trained and appropriately qualified personnel. The requirements of this section apply to engineered items and do not apply to scientific investigation activities. Test control requirements will be imposed, as appropriate on suppliers and subcontractors by inclusion in Technical Specifications and/or drawings.

11.2 Test Requirements

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

11.3 Test Procedures

11.3.1 Test Instructions, Procedures and Drawings Instructions, procedures, and drawings for tests shall be prepared in accordance with the requirements of Section 5 of this document. Test procedures or instructions shall contain criteria for determining when a test is required and how the test is performed.

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

- 11.3.3 Review of Procedures Test plans and procedures shall be reviewed in accordance with the verification requirements defined in Paragraph 3.2.4 of Section 3 of this document. They shall prescribe mandatory inspection hold points (as required), methods of documenting test data and results, and methods of data analysis.
- 11.3.4 Potential Sources of Error The potential sources of uncertainty and error in test procedures which must be controlled and measured to assure that tests are well controlled shall be identified.
- 11.3.5 Alternatives In lieu of specifically prepared written test procedures, appropriate sections of related documents, such as American Society for Testing and Materials (ASTM) methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to assure the required quality of work.

11.4. Test Results

Test results shall be documented and their conformance with acceptance criteria evaluated by a responsible authority to assure that test requirements have been satisfied.

11.5. Test Records

Test records shall, as a minimum, identify the following:

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

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 General

12.1.1 Maintaining Accuracy of Equipment

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

12.1.2 Scope of Control Program

The scope of control of F&S Measuring and Test Equipment includes those items necessary to conduct Mining and Drilling Inspections. The methodology for accomplishing this follows: Standard F&S Measuring and Test Equipment will be calibrated by REECO. Quality Assurance will ensure that equipment is provided to REECO for calibration. If F&S utilizes an outside calibration lab, the applicable requirements of this document will be imposed. This will include all measuring and test equipment or systems used to calibrate, measure, gage, test or inspect either to control or acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known.

12.1.3 Description of Responsibilities

The responsibilities of F&S and REECO will be described in an NNWSI Project Administrative Procedure for the establishment, implementation and assurance that the calibration program is effective.

12.2 Purpose of Equipment

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 listed below:

12.2.1 Selection

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

12.2.2 Calibration

Measuring and test equipment will be calibrated against certified equipment having known valid relationships to the National Bureau of Standards or other nationally recognized standards and will be calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the basis for calibration will be documented. Calibrating standards shall have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function shall be identified.

12.2.3 Control

The method and interval of calibration for each item will 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 which indicates the due date of the next calibration and to provide traceability to calibration data. If measuring and test equipment is found to be out of calibration, an evaluation will be made and documented of the validity of previous results obtained and of the acceptability of items previously inspected, tested or data gathered since last calibration. Devices that are out of calibration will be tagged or segregated and will not be used until they have been recalibrated. If any measuring or test equipment is found to be out of calibration consistently, then it shall be repaired or replaced. A calibration will be performed when the accuracy of equipment is suspect.

12.2.4 Commercial Devices

Calibration and control measures are not required for rulers, tape measure, levels, and other devices, if normal commercial equipment provides adequate accuracy.

12.2.5 Handling and Storage

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

12.2.6 Records

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

13.0 HANDLING, STORAGE AND SHIPPING**13.1 General Requirements**

Measures will 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 will be conducted in accordance with established work and inspection or instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity. Specific requirements are listed below. Handling, storage and shipping requirements will be imposed, as appropriate, on suppliers and subcontractors by inclusion in Technical Specifications and/or drawings.

13.1.1 General Equipment and Protective Environments

When required for particular items, special equipment (e.g., containers, shock absorbers, and accelerometers) and special protective environments (e.g., and 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 Procedures

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

13.1.3 Inspection and Testing of Special Tools and Equipment

Special handling tools and equipment shall be utilized and controlled as necessary to ensure 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.

14.0 INSPECTION, TEST AND OPERATING STATUS**14.1 Indication of Status**

The requirements of this section apply to engineered items and do not apply to scientific investigations. The status of inspection and test activities will be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. F&S is not responsible for indicating the operating status of systems and components at the facility.

14.2 Methods of Indicating Status

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

14.3 Application and Removal of Status Indicators

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

15.0 CONTROL OF NONCONFORMING ITEMS**15.1 General Requirements**

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

- 15.1.1 Identification of nonconforming items will be made by marking, tagging or other methods that will not adversely affect the end use of the item. The identification will be legible, easily recognizable, and will contain a nonconformance report number. The nonconformance report number will be a sequential number preceded by an organizational acronym (e.g., F&S-N-0001). If tags are used, they will be securely attached to avoid loss during handling.
- 15.1.2 If identification of each nonconforming item is not practical, the container, package or segregated storage area, as appropriate, will be identified.

15.1.3 Conditional Release

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

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

15.1.4 Logging

F&S will maintain a nonconformance control log to track nonconforming items. This log will contain the following information:

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

15.1.5 Segregation

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

15.1.6 Disposition

- 15.1.6.1 Nonconforming characteristics will be reviewed and recommended dispositions of nonconforming items will be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item will be controlled pending an evaluation and an approved disposition by authorized personnel. Distribution of nonconformance documentation will be to all affected organizations.
- 15.1.6.2 The responsibility and authority for the evaluation, disposition, and close-out of nonconforming items will be defined and documented. Those personnel assigned signature approval of the disposition will be identified. Quality Assurance (QA) responsibilities relating to nonconformances will be described.
- 15.1.6.3 Personnel performing evaluations to determine a disposition will have demonstrated competence in the specific area that they are evaluating, have an adequate understanding of the requirements and have access to pertinent background information.
- 15.1.6.4 The person or organization assigned the responsibility of dispositioning the NCR will ensure the following:
 - o Nonconformance documentation adequately identifies and describes the nonconformance.

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

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

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

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

15.2 Repetitive Nonconformances

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

15.3 Trending

Nonconformance reports will be periodically analyzed by F&S to show quality trends and to help identify root causes of nonconformances. Results will be reported to upper management for review and assessment.

15.4 Distribution of Documents

Copies of nonconformance reports for items will be sent to the YMPO PQM and the SAIC/T&MSS Project QA Department (QA Engineering Division Manager) by the originating organization upon issuance and upon closure. The original nonconformance reports will be sent to the YMPO for approval when required by Paragraph 15.1.6.5 of this section.

16.0 CORRECTIVE ACTION

16.1 The corrective action system will ensure that significant conditions 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 management and upper levels of management for review and assessment. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability. Significant conditions include, but are not limited to breakdowns in the Quality Assurance program and repetitive nonconformances. Upon discovering or receiving notification that a significant condition adverse to quality or unusual occurrence exists, F&S shall ensure that:

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

16.1.2 Follow-Up Action

F&S QA 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 F&S QA 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 reports will be periodically analyzed by F&S QA to show quality trends. Results will be reported to upper management for review and assessment.

16.2 Copies of corrective action reports will be sent to the SAIC/T&MSS Project QA Department (QA Engineering Division Manager) by F&S upon issuance and closure.

17.0 QUALITY ASSURANCE RECORDS

- 17.1** Records that furnish documentary evidence of quality will be specified, prepared, and maintained in accordance with NNWSI Project Administrative Procedures. This will include the requirements that all documents be legible, identifiable, and retrievable.
- 17.1.1** A document or other item is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined below.

The term records, used throughout this section is to be interpreted as Quality Assurance Records. Quality Assurance Records include 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; documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports); procurement documents; other documents, such as plans, correspondence, documentation of telecons, specifications, technical data, books, maps, papers, photographs, and data sheets; magnetic media; and other materials that provide data and document quality regardless of the physical form or characteristic. A completed record is a document that will either receive no more entries or whose revision would normally consist of the reissue of the document; and is signed and dated by the originator and, as applicable, by personnel authorized to approve the document. Records will be distributed, handled and controlled in accordance with written procedures. All records (including superseded records) shall be retained for the Yucca Mountain Project.

- 17.1.2** A Record System will be established by F&S, at the earliest practicable time consistent with the schedule for accomplishing work activities.
- 17.1.2.1** The Record System will be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation prepared in accordance with Section 5.0 of this document. The records management activities to be performed by F&S when processing QA records are detailed in the Yucca Mountain Project Administrative Procedures Manual.
- 17.1.2.2** Sufficient records will be specified, prepared and maintained to furnish documented evidence of activities that affect quality. The records will include at least the following: operating logs, the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. Also, the records will include closely related data such as qualifications of personnel, procedures and equipment. A list of typical QA records is contained in Appendix E.

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

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

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

17.2 Generation of Records

17.2.1 The applicable design specifications, procurement documents, implementing procedures, operational procedures, or other documents will specify the records to be generated, supplied, or maintained by or for F&S.

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

17.2.1.2 Documents that are designated to become records will be completed in accordance with the methods specified in the Yucca Mountain Project Administrative Procedures Manual.

17.3 Validation of Records

17.3.1 Documents will 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.

17.3.2 F&S will maintain a list which contains the signature and initials of the personnel authorized to authenticate records.

17.4 Receipt of Records

17.4.1 F&S will designate a person or organization to be responsible for receiving the records. The designee will be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage in accordance with approved procedures. The receipt control system will 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 will include the following:

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

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

17.5 Records Identification

17.5.1 Records or indexing systems or both will provide sufficient information to permit identification between the record and the items or activities to which it applies. Records will be clearly identified by a unique number or other designation which is directly traceable to controlling programmatic information (e.g., project, contract number, test number, preparing organization, author, date, title, subject, etc.). This unique identification number or other designation will not be repeated anywhere in the Yucca Mountain Project. The Yucca Mountain Project Office (YMPO) or its designee will review and approve the records identification system of all its contractors and sub-contractors to ensure consistency.

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

17.6 Permanent Storage Facility

Records will be controlled from the time they are completed until the time they are stored in a permanent storage facility. Temporary storage, preservation, safekeeping, and retrievability of completed records will 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.

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

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

- o A description of the storage facility.
- o The filing system to be used.
- o The method for verifying that the records received are legible and are in agreement with the transmittal document.
- o The method of verifying that the records are those designated (see Paragraph 17.4.1 of this section).
- o The rules governing access to and control of the file.
- o The method for maintaining control of and accountability for records removed from the storage facility.
- o A method for filing supplemental information (see Paragraph 17.9 of this section).

17.7 Preservation

Records will be stored in a manner approved by F&S or other organizations responsible for storage. In order to preclude deterioration of the records, the following requirements will apply.

- o Provisions will be made in the storage arrangement to prevent damage from moisture, temperature, and pressure.
- o Records will be firmly attached in binders or placed in folder or envelopes for storage in steel file cabinets or on shelving in containers.
- o Provisions will 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.

17.8 Safekeeping

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

17.9 Corrected Information in Records

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

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

17.10 Storage Facility

F&S does not have the responsibility for the permanent records storage.

The following requirements apply to temporary record storage facilities:

- 17.10.1 Records will be stored in facilities constructed and maintained in a manner that minimizes the risk of damage or destruction from natural disasters, such as winds, floods, or fires; environmental conditions such as high and low temperatures and humidity; and infestation of insects, mold, or rodents.
- 17.10.2 F&S will utilize the alternate single facility. The following is an acceptable alternative to the criteria for a single facility:
- o Two-hour fire rated Class B file containers that meet the requirements of NFPA 232-1975.

17.11 Retrieval

- 17.11.1 Storage systems will provide for retrieval of information in accordance with planned retrieval times based upon the record type. Final reports will 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 will 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' handbooks, etc., will be retrievable from the Records Management System (RMS).
- 17.11.2 A list will be maintained that designates those personnel who will have access to the files.
- 17.11.3 Records maintained by F&S at their facility or other location (on an interim or other basis) will be accessible to the YMPO or its designated alternate.

17.12 Disposition

- 17.12.1 Records that are accumulated at various locations, prior to transfer, will be made accessible to the YMPO either directly or through the procuring organization.

- 17.12.2 The Custodian will inventory the submittals, acknowledge receipt, and process these records in accordance with this document or the procedures implementing this document.
- 17.13 Various regulatory agencies have requirements concerning records that are within the scope of this document. The most stringent requirements will be used to determine final dispositions.

18.0 **AUDITS**

- 18.1 Fenix & Scisson, Inc., activities will be subject to internal and external audits to assure that procedures and activities comply with the overall Quality Assurance program and to determine their effectiveness. The F&S Quality Assurance Program Plan (QAPP) includes a system of planned, periodic audits to provide an objective evaluation of the quality-related practices, procedures, instructions, activities, and items including the review of documents and records to ensure that the QA program is effective and properly implemented. The audits will 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 will be documented, reported to, and reviewed by responsible management. Tracking systems will be instituted for audit findings to assure that all findings are appropriately addressed and to identify quality trends. All deficiencies, nonconformances, and potential quality problems identified during the audit are to be documented and monitored until verification of effective corrective action is made. The audited organization shall describe in a formal report the corrective action to be taken to address findings, and shall submit the report to the auditing organization and their own responsible management. F&S will not conduct audits of other Participating Organizations or NTS Contractors; however, if invited, F&S will provide representatives to participate in YMPO audits. F&S will conduct internal (covering the entire QAPP on an annual basis) and external audits, if applicable, of activities under its direct control. These audits will be scheduled, planned, conducted, and reported as described in this document and NNWSI/88-9. External and internal audit schedules, and changes thereto, will be sent to the SAIC/T&MSS Project QA Department (QA Verification Division Manager). Audit schedules will identify the date of the audit, the activities to be audited, and the requirements to which the activities are to be audited.
- 18.2 Internal and External QA Audits will be scheduled in a manner that provides coverage and coordination with ongoing QA program activities. Audits will be scheduled at a frequency commensurate with the status and importance of the activity and shall be initiated early enough to assure effective QA. F&S shall perform or arrange for annual evaluations of suppliers. These evaluations shall be documented and shall take into account, where applicable, (1) review of supplier furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions; (2) results of previous source verifications, audits, and receiving inspections; (3) operating experience of identical or similar products furnished by the same supplier; and (4) results of audits from other sources, e.g., DOE/YMPO or NRC audits.

Applicable elements of F&S's QAPP will be audited at least annually or at least once during the life of the activity, whichever is shorter. The scope of the audit will be established by: considering the results of any previous audits, the nature and frequency of identified deficiencies, and any significant changes in personnel, organization, or in the QA Program. 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.

Elements of an external organization's QA program will 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 suppliers whose activities are less than four months in duration shall be documented and approved by the Manager of QA prior to implementation of the activity. A copy of the documented justification shall be provided to the YMPO PQM.

- 18.3 F&S will develop and document an audit plan for each audit. This plan will identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be audited, organizations to be notified, applicable documents, schedule, and checklists. F&S will select and assign auditors who are independent of any direct responsibility for the performance of the activities they are to audit. If the audit is to be an internal one, then the personnel who have direct responsibility for performing the activities to be audited will not be involved in the selection of the audit team. The Vice President and General Manager will select the Audit Team Leader for audits of the Quality Assurance Division. Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective. Appendix F defines the requirements for the qualification of audit personnel.

An audit team will be identified before the beginning of each audit. The team will consist of one or more auditors and will have an individual qualified as a lead auditor who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates the responses. The audit team leader shall identify the technical specialists, if any, who will participate in the audit and include this information in the audit plan. Audit team members selected to participate in audits for technical consideration purposes shall have appropriate technical expertise or experience in the work being audited. Multidisciplinary audit

teams shall be employed when activities to be audited involve more than a single technical area. The audit team leader will ensure that the audit team is prepared before the audit begins.

- 18.4 Audits will be performed in accordance with written procedures using checklists as early in the life of the activity as practical and will be continued at intervals consistent with the schedule for accomplishing the activity. Elements that have been selected for audit will 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 will 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 will be documented by audit personnel and will be reviewed by management having responsibility for the area being audited. Conditions that require prompt corrective action will be reported immediately to the management of the audited organization. Audit findings will be reviewed with the audited organization at a closing meeting.
- 18.5 The audit report, signed by the audit team leader, should be issued within 30 calendar days and will include the following information, as appropriate:
- o Description of the audit scope.
 - o Identification of the auditors.
 - o Identification of persons contacted during audit activities.
 - o Summary of audit results, including a statement of the effectiveness of the QA program elements that were audited.
 - o Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.
- 18.6 Management of the audited organization or activity will investigate adverse audit findings; determine root cause; schedule corrective action, including measures to prevent recurrence; and within thirty (30) calendar days of receipt of the audit report, notify the appropriate organizations in writing of action taken or planned. The adequacy of audit responses shall be evaluated by the auditing organization.
- 18.7 Follow-up action will be taken to determine whether or not corrective action has been accomplished as scheduled and will be verified by the auditing organization. An analysis of audit results will be performed by F&S QA to identify quality trends. The results will be reported to responsible management for review, assessment, and appropriate action.

- 18.8 As a minimum, audit records will include the following:
- o Identification of the organization or organizations, activities, or items audited and the individual or individuals contacted during the audit or audits.
 - o Description of any deficiencies, nonconformances, and potential quality problems identified during the audit or audits.
 - o Audit plans, audit reports, written replies, and the record of completion of corrective action, and close out of the audit.
- 18.9 Records of personnel qualifications for Auditors and Lead Auditors performing audits will be established and maintained by F&S. Records for each lead auditor will be maintained and updated annually.

18.10 Surveillances

The F&S Yucca Mountain Project Audit Program is 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 will be conducted by F&S Quality Assurance, and will be either scheduled or implemented on a random basis.

Measures for the Surveillance of site investigations will be established and executed in accordance with procedures prepared by F&S. Surveillances are scheduled and conducted based on the activity's relative impact or importance, or both, to the Yucca Mountain Project. All deficiencies, nonconformances, and potential quality problems identified during surveillances will be documented and monitored until verification of effective corrective action is made.

- 18.10.1 Surveillances will be performed to written checklists or surveillance plans whenever practical. The documentation shall identify characteristics, methods, and acceptance criteria, shall provide for recording objective evidence of results, and accuracy of the equipment necessary to perform surveillance. 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."
- 18.10.2 Surveillance Personnel do not report directly to the immediate supervisors who are responsible for the work being surveyed.
- 18.10.3 As a minimum, surveillance records will identify the following:
- o Item or activity.
 - o Date of the surveillance.
 - o Name of the individual performing the surveillance.

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