PROJECT OFFICE QUALITY ASSURANCE AUDIT PLAN FOR

THE YUCCA MOUNTAIN PROJECT OFFICE AUDIT OF

FENIX & SCISSON OF NEVADA

AUDIT NO. 90-07

SEPTEMBER 25 THROUGH 28, 1990

Prepared by: _____ Date: 8/28/90
Thomas J. Higgins
Lead Technical Specialist

Prepared by: _____ Date: 8/28/90
Frank J. Kratzinger
Audit Team Leader

Approved by: _____ Date: 8/29/90
Donald G. Horton, Director
Quality Assurance
Yucca Mountain Project Office

ENCLOSURE

1.0 SCOPE

The scope of this audit is to evaluate the Fenix & Scisson of Nevada (FSN) Quality Assurance (QA) Program to determine whether it meets requirements and commitments imposed by the Yucca Mountain Project Office (Project Office). This will be accomplished by verifying implementation and effectiveness of the program in place, as well as verifying compliance with requirements.

Discrepancies identified during previous Project Office audits and surveillances of FSN that have not been closed will be added to the scope of this audit to determine whether FSN has taken effective corrective actions in those program areas.

The programmatic and technical elements to be audited, as well as the programmatic elements that have not been included, are identified in Section 5.0 of this audit plan.

2.0 ORGANIZATION TO BE AUDITED

Fenix & Scisson of Nevada, Las Vegas, Nevada

3.0 AUDIT SCHEDULE

Final Pre-Audit Team Meeting	9:00 a.m. September 20, 1990 Las Vegas, Nevada
Pre-Audit Team/Observer Meeting	9:00 a.m. September 25, 1990 Las Vegas, Nevada
Pre-Audit Conference	10:00 a.m. September 25, 1990 Las Vegas, Nevada
Audit Activities	12:30 - 4:00 p.m. September 25, 1990 Las Vegas, Nevada 8:30 a.m. - 4:00 p.m. September 26-27 Las Vegas, Nevada 8:30 - 11:30 a.m. September 28, 1990 Las Vegas, Nevada
Post-Audit Conference	2:00 p.m. September 28, 1990 Las Vegas, Nevada

4.0 REQUIREMENTS TO BE AUDITED AND APPLICABLE REFERENCES

The requirements to be evaluated through the audit process are contained in the programmatic and technical checklists. These checklists were developed from the following documents:

- Yucca Mountain Project Administrative Procedures (Quality) (AP-Qs).
- FSN Quality Assurance Program Plan (QAPP), Revision 6, and applicable implementing procedures.

The conduct of the audit will be guided by the documents listed below:

- QMP-18-01, "Audit System for the Waste Management Project Office," Revision 3.
- QMP-16-03, "Standard Deficiency Reporting System," Revision 1.
- QA Audit Task Organization.
- Audit Observer Inquiry.
- Policy for Participation of State, Tribal, and U.S. Nuclear Regulatory Commission Representative Observers on U.S. Department of Energy (DOE) Audits.
- High Level Waste Division Procedures for Conducting Observation Audits of U.S. Department of Energy High Level Waste Repository Program Quality Assurance Audits.
- Headquarters Observation of Project Office QA Audits.

5.0 ACTIVITIES TO BE AUDITED

The audit will be limited to a review of activities in the following areas:

QA Program Elements

1.0 Organization
2.0 Quality Assurance Program
3.0 Scientific Investigation Control and Design Control
5.0 Instructions, Procedures, Plans, and Drawings
6.0 Document Control
16.0 Corrective Action
17.0 Quality Assurance Records
18.0 Audits

The following QA Program Elements, with no activity since the last audit or no applicability to the FSN scope of work, will not be reviewed during this audit:

4.0 Procurement Document Control
7.0 Control of Purchased Items and Services
8.0 Identification and Control of Items, Samples, and Data

9.0 Control of Processes
10.0 Inspection
11.0 Test Control
12.0 Control of Measuring and Test Equipment
13.0 Handling, Shipping, and Storage
14.0 Inspection, Test, and Operating Status
15.0 Control of Nonconforming Items

Technical Elements

Technical specialists will review the following areas to evaluate performance of ongoing, new, and near-term technical activities:

1. Technical Qualifications of Scientific Investigators and Design Personnel.

2. Understanding of procedural requirements as they pertain to scientific investigation and design control activities.

3. Adequacy of technical procedures.

4. Alternative studies for the exploratory shaft facility.

If the audit team identifies a need to verify additional programmatic or technical areas during the audit, they will be added to the audit checklists and verified accordingly.

6.0 AUDIT TEAM MEMBERS

Frank J. Kratzinger, Audit Team Leader, Science Applications International Corporation (SAIC), Las Vegas, Nevada
Edward A. Cocoros, Auditor, MAC Technical Services Company (MACTEC), Las Vegas, Nevada
Neil D. Cox, Auditor, SAIC, Las Vegas, Nevada
Robert H. Klemens, Auditor, SAIC, Las Vegas, Nevada
Kenneth T. McFall, Auditor, SAIC, Las Vegas, Nevada
Craig Walenga, Auditor-In-Training, CER Corporation, Arlington, Virginia
Richard L. Weeks, Auditor, SAIC, Las Vegas, Nevada
Thomas J. Higgins, Lead Technical Specialist, SAIC, Las Vegas, Nevada
Edward M. Cikanek, Technical Specialist, Harza, Las Vegas, Nevada

7.0 AUDIT CHECKLISTS

90-07-1, Programmatic Audit Checklist
90-07-2, Technical Audit Checklist

ACTIVITIES TO BE AUDITED

QA Program Elements

1.0 Organization
2.0 Quality Assurance Program
3.0 Scientific Investigation Control and Design Control
5.0 Instructions, Procedures, Plans, and Drawings
6.0 Document Control
16.0 Corrective Action
17.0 Quality Assurance Records
18.0 Audits

Technical Elements

ESF Alternative Studies

Study Plans for Soil and Rock Properties of Locations of Surface ESF (8.3.1.14.2.x)

YUCCA MOUNTAIN PROJECT OFFICE

FSN AUDIT 90-7

SEPTEMBER 25 - 28, 1990

PROGRAMMATIC AUDITORS:

ED COCOROS	CRITERIA 16, 17
NEIL COX	CRITERION 3 (PLUS SQA)
BOB KLEMENS	CRITERION 3
KEN McFALL	CRITERIA 5, 6
CRAIG WALENGA (AIT)	CRITERIA 1, 2, 18
RICK WEEKS	CRITERIA 1, 2, 18

TECHNICAL AUDITORS:

TOM HIGGINS	ESF ALTERNATIVE STUDIES AND STUDY PLANS 8.3.1.14.2.X
ED CIKANEK	ESF ALTERNATIVE STUDIES AND STUDY PLANS 8.3.1.14.2.X

OBSERVERS:

JOHN BUCKLEY	NRC
JIM CONWAY	NRC
JOHN PESHEL	NRC
SUSAN ZIMMERMAN	STATE OF NEVADA

FSN
AUDIT 90-7

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
		8:30 am TPO Meeting	8:30 am TPO Meeting	8:30 am TPO Meeting
		8:30-11:30 am Audit Criteria 1, 3, 5, 16	8:30-11:30 am Audit Criteria 2, 3, 6, 17	8:30-11:30 am Audit Criteria 3, 6, 17, 18
	10:00 am Pre-Audit Conference	ESF Alternate Studies Study Plans 8.3.1.14.2.X	ESF Alternate Studies SQA	ESF Alternate Studies SQA
		QA Grading		

LUNCH

	12:30-4:00 pm Audit Criteria 1, 3, 5, 16	12:30-4:00 pm Audit Criteria 2, 3, 6, 16	12:30-4:00 Audit Criteria 3, 6, 17, 18	12:30-2:00 pm Audit Wrap-Up
	Study Plans 8.3.1.14.2.X	ESF Alternate Studies	ESF Alternate Studies	2:00 pm Post-Audit Conference
	QA Grading	QA Grading	SQA	
	4:00 pm Team Mtg.	4:00 pm Team Mtg.	4:00 pm Team Mtg.	

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

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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.

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.

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.

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 or- ganizations. 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

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.

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.

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:

- Where items and activities could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, or result in, an accident that could result in a radiation dose, either to the whole body or to any organ, of 0.5 rem or greater, either at or beyond the nearest boundary of the unrestricted area, at any time until the permanent closure of the repository.

- Where items and activities will provide primary data which will be relied on for performance assessment of the repository system. 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.

- Where activities could adversely impact the waste isolation capabilities of the engineered and natural barriers.

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

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

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

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

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

- Where items and activities that are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and could have a major impact on the non-radiological health and safety of the public and repository worker.

- Where items and activities which having failed or which are performed inadequately would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10CFR20.

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

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

- The Design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/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.

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

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

Quality Assurance Level II activities may have as much importance as Quality Assurance Level I activities; however, except when used to support a Quality Assurance Level I activity as indicated in the following, they do not provide primary information in the licensing efforts. In most cases, activities controlled in accordance with a Quality Assurance Level II program cannot be used subsequently to directly support Quality Assurance Level I activities unless it can be substantiated that quality assurance requirements equivalent to those which would have been applied to a Quality Assurance Level I activity were implemented or that a technical justification process is applied in accordance with 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 Activities

2.3.1 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:

- 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.

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.

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:

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

This documentation is considered to be a QA Record and is subject to the requirements of Section 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 precontract 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 pre-paring, 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;

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

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

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

- 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 or 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:

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

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

- Identification of characteristics and activities to be inspected.
- A description of the method of inspection.
- Identification of the individuals or groups responsible for performing the inspection operation.
- Acceptance and rejection criteria.
- Identification of required procedures, drawings, and specifications and revisions.
- Recording inspector or data recorder and the results of the inspection operation.
- 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:

- Item or activity.
- The date of the inspection.
- Name of individual performing the inspection.
- Name or names of personnel contacted during the inspection.
- A description of the type of observation (method of inspection).
- Inspection criteria including identification of drawing, specification, etc. (and applicable revision).
- Equipment used during the inspection.
- Evidence as to the acceptability of the results.
- Acceptance Statement.
- 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:

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

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

- 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.

- Identification of the organization(s), activities or items surveilled, including the name or names of personnel contacted.

- Description of any deficiencies, nonconformances and potential quality problems identified during the surveillance. Nonconformances shall be handled in accordance with the requirements of Section 15 or 16, as applicable.

- Surveillance Criteria

- Equipment used during the surveillance.

- Results.

- Acceptance statement.

FENIX & SCISSON, INC.

LAS VEGAS BRANCH

QUALITY ASSURANCE PROGRAM PLAN

SECTION II

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construction
management

FENIX & SCISSON, INC.

ORGANIZATION

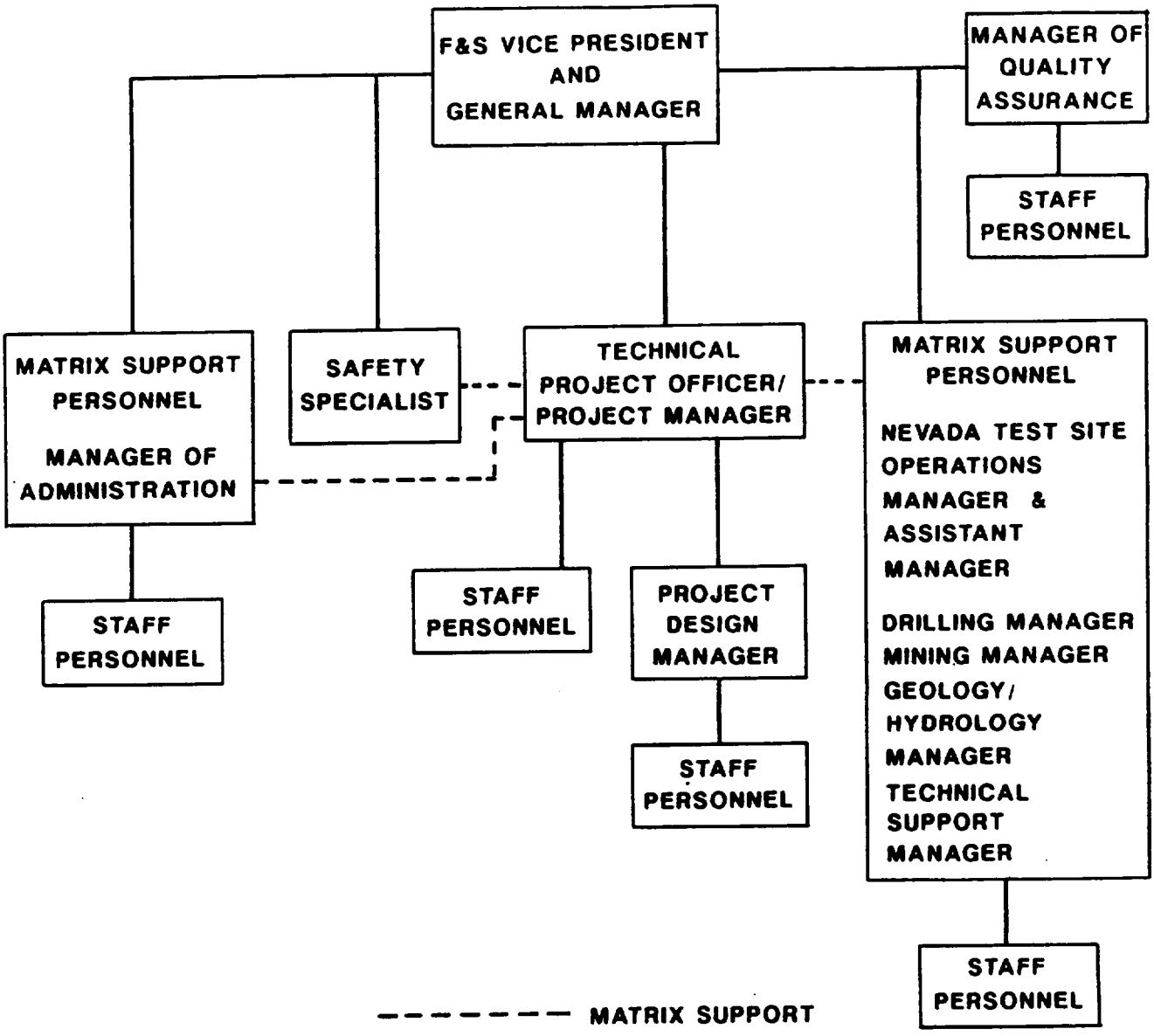

FIGURE 1

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CRITERIA FOR QUALITY ASSURANCE

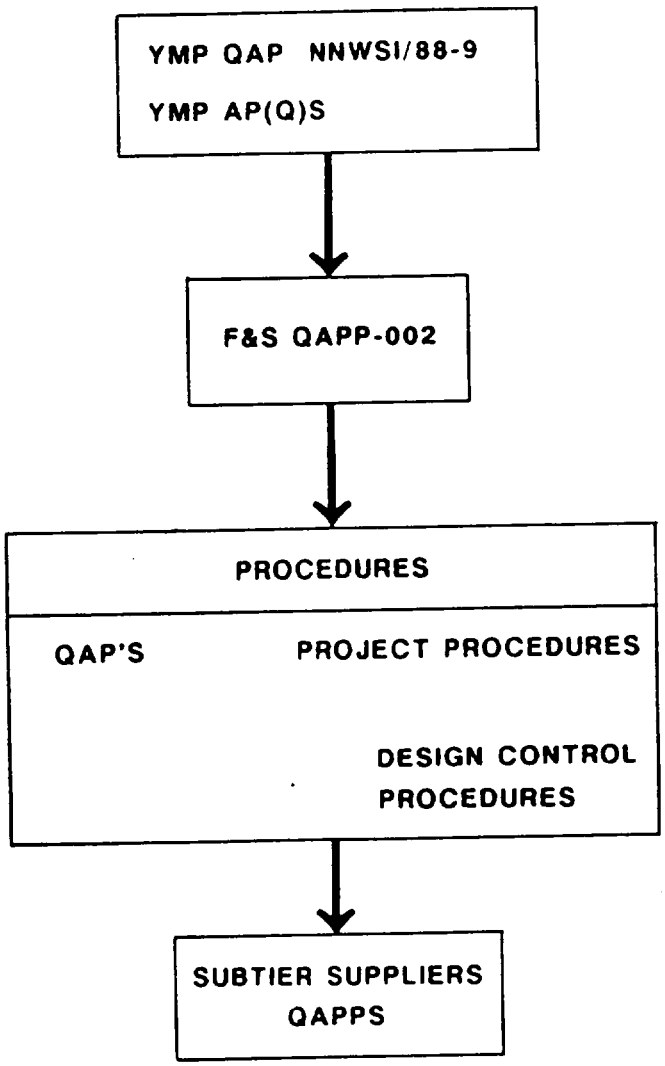

FIGURE 2

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TERMS AND DEFINITIONS

ACCEPTANCE CRITERIA: Specified limits defined in codes, standards, or other required documents placed on characteristics of an item, process or service. Acceptance criteria related to surveillances may be as simple as verifying proper implementation of procedures or verifying conformance to requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX A

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

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

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

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

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

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

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

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

DEVIATION: A departure from specified requirements.

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

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

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

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

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

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

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

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

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

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

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

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

IMPORTANT TO WASTE ISOLATION: The barriers that must meet the criteria that address long-term performance of the engineered and natural barriers to prevent the release of radionuclides from the site to the accessible environment (i.e. for achieving the postclosure performance objectives in 10 CFR 60, Subpart E).

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

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

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

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

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

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

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

LOGGING ENGINEER: Individual responsible for overseeing/supervising the F&S NTS Logging subcontractor in Log Data Acquisition for Drilled Holes.

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

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

MINING: All subsurface excavation, including the surface shaft collars, headframe, and hoist.

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

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

NTS: Nevada Test Site.

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

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

OBSERVATION: The recognition of a weakness in a Quality Assurance program that if left uncorrected could result in a condition adverse to quality.

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

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

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

PARTICIPATING ORGANIZATION: This term applies to the following: (1) The government agencies external to the DOE, (2) national laboratories, and (3) organizations participating directly in Yucca Mountain Project activities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

QUALIFICATION TESTING: Demonstration that an item meets design requirements.

QUALIFIED DATA: Data initially collected under a 10 CFR 60, Subpart G, quality assurance program or existing data qualified in accordance with Appendix G of NNWSI/88-9.

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

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

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

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

QUALITY ASSURANCE LEVEL I: Those radiological health and safety related items and activities that are important to either safety or waste isolation and that are associated with the ability of a geologic nuclear waste repository to function in a manner that prevents or mitigates the consequences of a process or event that could cause undue risk to the radiological

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

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

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

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

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

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

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

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

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

REPOSITORY: See Geologic Repository Operations Area.

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

APPENDIX A

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

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

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

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

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

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

SITE: Location of the controlled area.

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

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

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

APPENDIX A

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

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

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

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

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

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

UNRESTRICTED AREA: Any area, to which access is not controlled to protect individuals from exposure to radiation and radioactive materials, and any area used for residential quarters.

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

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

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

WAIVER: Documented authorization to depart from specified requirements.

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

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YMP: Yucca Mountain Project

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

YMP PROJECT PERSONNEL: All U.S. Department of Energy participating Organizations, and NTS Support Contractors personnel involved in Yucca Mountain Project activities.

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

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

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

APPENDIX B

DESIGN INPUTS

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

1. Basic functions of each structure, and component.

2. Performance requirements such as capacity rating and system output.

3. Codes, standards, and regulatory requirements including the applicable issue, addenda, or both.

4. Design conditions such as pressure, temperature, fluid chemistry, and voltage.

5. Loads such as seismic, wind, thermal, and dynamic.

6. Environmental conditions anticipated during storage, construction, and operation such as pressure, temperature, humidity, and corrosiveness, site elevation, wind direction, nuclear radiation, electromagnetic radiation, and duration of exposure.

7. Interface requirements including definition of the functional and physical interfaces involving structures, systems, and components.

8. Material requirements including such items as compatibility, electrical insulation properties, protective coating, and corrosion resistance.

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

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

11. Hydraulic requirements such as pump net positive suction heads (NPSH), allowable pressure drops, and allowable fluid velocities.

12. Chemistry requirements such as provisions for sampling and limitations on water chemistry.

13. Electrical requirements such as source of power, voltage, raceway requirements, electrical insulation, and motor requirements.

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14. Layout and arrangement requirements.

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

16. Instrumentation and control requirements including indicating instruments, controls, and alarms required for operation, testing, and maintenance. Other requirements such as the type of instrument, installed spares, range of measurement, and location of indication are included.

17. Access and administrative control requirements for the exploratory shaft facility or future repository security.

18. Redundancy, diversity, and separation requirements of structures, systems, and components.

19. Failure effects requirements of structures, systems, and components including a definition of those events and accidents that they must be designed to withstand.

20. Test requirements including pre-operational and subsequent periodic in-service tests and the conditions under which they will be performed.

21. Accessibility, maintenance, and repair, and in-service inspection requirements for the exploratory shaft facility or future repository including the conditions under which these will be performed.

22. Personnel requirements and limitations including the qualification and number of personnel available for the exploratory shaft facility or future repository operation, maintenance, testing, inspection, and radiation exposures to the public and repository personnel.

23. Transportability requirements such as size and shipping weight, limitation, and Interstate Commerce Commission regulations.

24. Fire protection or resistance requirements.

25. Handling, storage, cleaning and shipping requirements.

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

27. Materials, processes, parts, and equipment suitable for application.

APPENDIX B

28. Safety requirements for preventing injury to personnel including such items as radiation safety that restrict the use of dangerous materials, escape provisions from enclosures, and grounding of electrical systems.

29. Quality control and Quality Assurance requirements.

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

31. Interface requirements between the exploratory shaft facility or future repository equipment and operation and maintenance personnel.

32. Requirements for criticality control and accountability of nuclear materials.

APPENDIX C

REQUIREMENTS FOR THE QUALIFICATION OF INSPECTION AND TEST PERSONNEL

1.0 GENERAL

The following are the requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. The requirements for the qualification of personnel performing nondestructive examination are specified in Appendix D.

2.0 FUNCTIONAL QUALIFICATIONS

Three levels of qualification will be utilized depending on the complexity of the functions involved. The requirements for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional activities.

2.1 LEVEL I PERSONNEL CAPABILITIES

A Level I person will be capable of performing and documenting the results of inspections or tests that are required to be performed in accordance with document procedures, acceptance standards, and/or industry practices as defined in user's written procedures.

2.2 LEVEL II PERSONNEL CAPABILITIES

A Level II person will have all of the capabilities of a Level I person for the inspection or test category or class in question. Additionally, a Level II person will have demonstrated capabilities in planning inspections and tests; in setting up tests, including preparation and setup of related equipment, as appropriate; in supervising and certifying lower level personnel; and in evaluating the validity and acceptability of inspection and test results.

2.3 LEVEL III PERSONNEL CAPABILITIES

A Level III person will have all of the capabilities of a Level II person for the inspection, test category or class in question. In addition, the individual will also be capable of evaluating the adequacy of specific programs used to train and certify inspection and test personnel whose qualifications are covered by this section.

3.0 EDUCATION AND EXPERIENCE QUALIFICATIONS

These education and experience requirements will be considered with recognition that other factors commensurate with the scope,

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complexity, or special nature of the activity may provide reasonable assurance that a person can competently perform a particular task.

Other factors which may demonstrate capability in a given job are previous performance or satisfactory completion of capability testing. These factors and the basis for their equivalency will be documented.

3.1 LEVEL I EDUCATION AND EXPERIENCE REQUIREMENTS

- Two years of related experience in equivalent inspection or testing activities; or
- High school graduation and six months of related experience in equivalent inspection or testing activities; or
- Completion of college level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspection or testing activities.

3.2 LEVEL II EDUCATION AND EXPERIENCE REQUIREMENTS

- One year satisfactory performance as a Level I in the corresponding inspection or test category or class; or
- High school graduation plus three years of related experience in equivalent inspection or testing activities; or
- Completion of college work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspection or testing activities; or
- Graduation from a four-year college plus six months of related experience in equivalent inspection activities or testing activities.

3.3 LEVEL III EDUCATION AND EXPERIENCE REQUIREMENTS

- Six years satisfactory performance as a Level II in the corresponding inspection or test category or class; or high school graduation plus ten years of related experience in equivalent inspection or testing activities; or high school graduation plus eight years of experience in equivalent inspection of testing activities with at least two years associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or

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- Completion of college level work leading to an associate degree and seven years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or

- Graduation from a four-year college plus five years related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities or, if not, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility.

4.0 CERTIFICATION

4.1 QUALIFICATION REQUIREMENTS

The responsible organization will designate those inspection and test activities that require qualified inspection and test personnel and the minimum qualification requirements for such personnel. Further, the responsible organization will establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the established requirements are permitted to perform inspection and test activities. If single inspection or test requires implementation by a team or a group, then personnel who do not meet the requirements of this section may be used in data-taking assignments or in repository or equipment operation, provided they are supervised or overseen by a qualified individual.

4.2 PERSONNEL SELECTION

Personnel selected to perform inspection and test activities will have the experience or training commensurate with the scope, complexity, or special nature of the activities.

4.3 INDOCTRINATION

Provisions will be made for the indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards and the elements of the Quality Assurance Program Plan and procedures that are to be employed.

4.4 TRAINING

The need for a formal training program will be determined, and such training activities will be conducted as required to qualify personnel who perform inspection and tests. On-the-job training will

be included also in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests. Training will also be provided with regard to those changes to the QAPP and implementing procedures that affect previous training.

4.5 DETERMINATION OF INITIAL CAPABILITY

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

4.6 EVALUATION OF PERFORMANCE

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

4.7 CERTIFICATION OF QUALIFICATION

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

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

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- Results of physical examinations (when required).
- Signature of employer's designated representative who is responsible for such certifications.
- Dates of certification and certification expiration.

4.8 PHYSICAL

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

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REQUIREMENTS FOR THE QUALIFICATIONS OF NON-DESTRUCTIVE EXAMINATION PERSONNEL

The requirements of this Appendix will be included in F&S specifications, drawings and work programs. This Appendix provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), and leak-testing (LT), which is hereinafter referred to as nondestructive examination (NDE), to verify conformance to specified requirements.

1.0 CERTIFICATION

1.1 APPLICABLE DOCUMENTS

The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 edition, and its applicable supplements will apply as requirements to NDE personnel covered by this section.

1.2 PROGRAM

The responsible organization will establish written procedures for the control and administration of NDE personnel training, examination and certification.

1.3 CERTIFICATE OF QUALIFICATION

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

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

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- Signature of employer's designated representative who is responsible for such certification.

- Dates of certification and certification expiration.

1.4 PHYSICAL

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

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LIST OF TYPICAL QA RECORDS

The following is a list of typical QA records. The Yucca Mountain Project retention period is defined as lifetime. QA records will be submitted to the Project Records Center by the originating organization of the record.

1.0 SITE CHARACTERIZATION

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

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2.0 DESIGN RECORDS

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

3.0 PROCUREMENT RECORDS

- Procurement specifications.
- Purchase order including amendments.

4.0 MANUFACTURING RECORDS

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

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

5.0 INSTALLATION AND CONSTRUCTION RECORDS

5.1 RECEIVING AND STORAGE - NONCONFORMANCE REPORTS

5.2 CIVIL

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

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

5.3 WELDING

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

5.4 MECHANICAL

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

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

5.5 ELECTRICAL AND INSTRUMENTATION AND CONTROL

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

5.6 GENERAL

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

6.0 PRE-OPERATIONAL AND START-UP TEST RECORDS

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

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

7.0 OPERATION RECORDS

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

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

APPENDIX F

REQUIREMENTS FOR THE QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL

1.0 GENERAL

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

1.1 QUALIFICATION OF AUDITORS

F&S will establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of Quality Assurance programs. Personnel selected for Quality Assurance auditing assignments will have experience or training commensurate with the scope, complexity or special nature of the activities to be audited. Auditors either will have or will be given appropriate training or orientation to develop their competence to perform required audits. The competence of personnel to perform the various auditing functions will be developed by one or more of the methods listed below.

1.1.1 ORIENTATION

Orientation to provide a working knowledge and understanding of this document and the auditing organization's procedures for implementing audits and reporting results.

1.1.2 TRAINING PROGRAMS

Training programs to provide general and specialized training in audit performance. General training will include fundamentals, objectives, characteristics, organization, performance and results of quality auditing. Specialized training will include methods of examining, questioning, evaluating and documenting specific audit items and methods of closing audit findings.

1.1.3 ON-THE-JOB-TRAINING

On-the-job-training, guidance and counseling under the direct supervision of a Lead Auditor. Such training will include planning, performing, reporting and follow-up action involved in conducting audits.

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1.2 QUALIFICATION OF LEAD AUDITORS

An individual will meet the requirements listed below before being designated a Lead Auditor:

1.2.1 COMMUNICATION SKILLS

The prospective Lead Auditor will have the capability to communicate effectively, both orally and in writing. These skills will be attested to in writing by the Lead Auditor's employer.

1.2.2 TRAINING

Prospective Lead Auditors will have training to the extent necessary to ensure their competence in auditing skills. Training in the following areas will be given based upon management evaluation of the particular needs of each prospective Lead Auditor:

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

1.2.3 AUDIT PARTICIPATION

The prospective Lead Auditor will have participated in a minimum of five Quality Assurance audits within a period of time not to exceed

three years prior to the date of qualification. One of the audits will be a nuclear Quality Assurance audit that will be made within the year prior to qualification.

1.2.4 EXAMINATION

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

1.3 MAINTENANCE OF QUALIFICATION

1.3.1 MAINTENANCE OF PROFICIENCY

Lead Auditors will maintain their proficiency through regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; and participation in training programs. Based on annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations will be documented.

1.3.2 REQUALIFICATION

Lead Auditors who fail to maintain their proficiency for a period of two years or more will require requalification. Requalification will include retraining in accordance with the requirements of Paragraph 1.2.2 of this section, reexamination in accordance with Paragraph 1.4.2, and participation as an Auditor in at least one nuclear Quality Assurance audit.

1.4 ADMINISTRATION

1.4.1 ORGANIZATIONAL RESPONSIBILITY

Training of auditors will be the responsibility of the employer. The responsible auditing organization will select and assign personnel who are independent of any direct responsibility for the performance of the activities that they will audit. The Lead Auditor will, prior to commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

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1.4.2 QUALIFICATION EXAMINATION

The development and administration of the examination for a Lead Auditor required by Paragraph 1.2.4 is the responsibility of the employer. The employer may delegate this activity to an independent certifying agency, but will retain responsibility for conformance to this document of the examination and its administration. Integrity of the examination will be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of objective evidence regarding the type or types and content of the examination or examinations will be retained by the employer.

1.5 CERTIFICATION OF QUALIFICATIONS

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

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

APPENDIX H

REQUIREMENTS FOR COMPUTER SOFTWARE USED TO SUPPORT A HIGH-LEVEL NUCLEAR WASTE REPOSITORY LICENSE APPLICATION

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

1.0 OBJECTIVES

The purpose of this appendix is to establish requirements for the development, management, control, and documentation of software used to support the Yucca Mountain Project. The attainment of software quality is dependent on the control of the entire software development process, and is not assured solely by inspection and test of the end product. This appendix prescribes appropriate systematic practices that shall:

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

2.0 APPLICABILITY

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

3.0 TERMS AND DEFINITIONS

Terms and definitions for Yucca Mountain Project software are contained in Appendix A to this QAPP.

4.0 SOFTWARE LIFE CYCLE

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

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

Requirements

Design

Implementation

Test

Installation and Checkout

Operation and Maintenance

4.1 Software QA Plan

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

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

- o The software products to which it applies.
- o The organizations responsible for software quality and their tasks and responsibilities.
- o Required documentation.
- o The required software reviews.

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

4.1.2 Within the software QA Plan, software life cycle management shall be described. F&S shall present the specific software life cycle controls for their organization in their software QA Plan. The following life cycle elements shall apply, as appropriate, for the specific life cycle model defined, interpreted, and described in the F&S software QA Plan.

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4.1.2.1 Requirements Phase

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

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

4.1.2.2 Design Phase

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

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

- o The generation of design-based test cases.
- o The review and analysis of the software design.
- o The verification of the software design.

4.1.2.3 Implementation Phase

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

Verification and validation activities during this phase shall consist of:

- o The possible modification of test cases necessary due to design changes made during coding.

- The examination of source code listings to assure adherence to coding standards and conventions.

4.1.2.4 Testing Phase

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

Verification and validation activities during this phase shall consist of:

- The evaluation of the completed software to assure adherence to the requirements.

- The preparation of a report on the results of software verification and validation.

4.1.2.5 Installation and Checkout Phase

During this phase the software becomes part of a system incorporating other software components, the hardware, and production data. The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating databases, and verifying that all components have been included. Testing activities during this phase shall consist of the execution of test cases for installation and integration. Test cases from earlier phases shall be enhanced and used for installation testing.

4.1.2.6 Operations and Maintenance Phase

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

5.0 SOFTWARE VERIFICATION AND VALIDATION

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

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

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

1. By the individual generating or modifying the software.

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

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

5.1 Verification

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

5.2 Validation

Validation activities are performed to demonstrate that the model as embodied in the computer software is a correct representation of the process or system for which it is intended. This is accomplished by comparing software results against verified and traceable data obtained from laboratory experiments, field experiments or observations, or in situ testing. Specific sets of data used in the validation process shall be identified and justification shall be made for their use.

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

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6.0 SOFTWARE CONFIGURATION MANAGEMENT

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

6.1 Configuration Identification

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

A labeling system for configuration items shall be implemented that:

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

6.2 Configuration Change Control

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

6.3 Configuration Status Accounting

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

7.0 DOCUMENTATION

Minimum acceptable life cycle documentation of computer software developed or modified for use on the Yucca Mountain Project shall be specified in the software QA Plan. The documentation provided shall

describe the following as applicable. Additional documentation may also be identified in the software quality assurance plan for F&S.

7.1 Software Requirements Specification

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

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

7.2 Software Design Documentation

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

- o A description of the major components of the software design as they relate to the requirements of the software requirements specification.
- o A technical description of the software with respect to control flow, data flow, control logic, and data structure.
- o A description of the allowable and tolerable ranges for inputs and outputs.
- o The design described in a manner that is easily traceable to the software requirements.
- o Code assessments and support documentation and descriptions of mathematical models and numerical methods as required by NRC publication NUREG-0856.
- o Continuing documentation, code listings, and software summary forms as required by NUREG-0856.

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7.3 Software Implementation Documentation

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

7.4 Software Verification and Validation Documentation (Test)

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

7.5 User Documentation

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

- Program considerations, options, and initialization procedures.
- Anticipated error situations and how the user can correct them.
- Internal and external data files, their input sequence, structures, units, and ranges.
- Input and output options, defaults, and formats.
- System interface features and limitations.
- Information for obtaining user and maintenance support.
- Sample problems.

8.0 REVIEWS

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

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

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

8.1 Software Requirements Review

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

8.2 Software Design Review

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

8.3 Software Implementation Review

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

8.4 Software Verification and Validation Review

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

9.0 DISCREPANCY REPORTING AND CORRECTIVE ACTION

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

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

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

10.0 MEDIA CONTROL AND SECURITY

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

11.0 ACQUIRED SOFTWARE

Procedures shall be established for controlling the transfer of computer software from an outside source to a user organization and from a user organization to an outside requesting organization.

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

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

12.0 COMPUTER SOFTWARE APPLICATIONS

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

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

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

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

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

APPENDIX J

REQUIREMENTS FOR PEER REVIEW

1.0 GENERAL

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

2.0 APPLICABILITY OF PEER REVIEW

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

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

a. Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.

b. Decisions or interpretations having significant impact on performance assessment conclusions will be made.

c. Novel or beyond the state-of-the-art testing, plans and procedures, or analyses are or will be utilized.

d. Detailed technical criteria or standard industry procedures do not exist or are being developed.

e. Results of tests are not reproducible or repeatable.

f. Data or interpretations are ambiguous.

g. Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program.

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

3.0 STRUCTURE OF PEER REVIEW GROUP

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

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a. The complexity of the work to be reviewed.

b. Its importance to establishing that safety or waste isolation performance goals are met.

c. The number of technical disciplines involved.

d. The degree to which uncertainties in the data or technical approach exist.

e. The extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.

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

4.0 ACCEPTABILITY OF PEERS

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

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

5.0 PEER REVIEW PROCESS

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

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5.2 The peer review group shall evaluate and report on:

a. Validity of assumptions.

b. Alternate interpretations.

c. Uncertainty of results and consequences if incorrect.

d. Appropriateness and limitations of methodology and procedures.

e. Adequacy of application.

f. Accuracy of calculations.

g. Validity of conclusions.

h. Adequacy of requirements and criteria.

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

6.0 **PEER REVIEW REPORT**

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

a. A clear description of the work or issue that was peer reviewed.

b. Conclusions reached by the peer review process.

c. Individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate.

d. Listing of the peers and the technical qualification and evidence of independence for each peer, including potential technical and/or organizational partiality.

Note: Additional guidance related to this subject can be found in NUREG-1297, "PEER REVIEW FOR HIGH LEVEL NUCLEAR WASTE REPOSITORIES" (FEBRUARY, 1988).

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1-1	QAPP-002, Rev. 6 Para. 1.1 General	The responsibilities of all organizational elements depicted on organization charts relative to the Quality Program shall be described. 1. Verify that all organizational elements depicted on the organization chart relative to the Quality Program are described.			

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1-2	QAFP-002, Rev. 6 Para. 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.			
	QAP-1.1(N), Rev. 5 Para. 6.1	1. Verify that full-time dedicated Quality Assurance Representatives, including the Director of QA Engineering YMP and QA Engineers and QA Specialists at various levels, under direction of the Manager of QA, have the responsibility for performing QA functions.			

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1-3	QAPP-002, Rev. 6 Para. 1.2.1	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.			
	QAP-1.1(N), Rev. 5 Para. 6.1	1. Verify that the Manager of Quality Assurance is the same or higher organizational level as the highest Line Manager responsible for performing activities affecting quality.			

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1-4	QAPP-002, Rev. 6 Para. 1.2	States in part...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.			
	QAP-1.1(N), Rev. 5 Para. 6.1	States in part...The Manager of Quality Assurance has the authority to stop unsatisfactory work.			
	QAP-2.4(N), Rev. 1 Para. 6.1.2	1. Verify that when a Stop Work Order (SWO) is issued, the Manager of Quality Assurance or his designee prepares a SWO utilizing Form LV-393 Stop Work Order which delineates the following as a minimum: a. Scope of activity to be stopped b. Effective date of stoppage c. Reason for Stoppage d. Actions to be taken to correct the situation and enables the SWO to be lifted e. CAR number			

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1-4 Cont.		f. Limited work authorization, delineating work which may be continued under controlled conditions while the SWO is in effect, including an explanation of the imposed conditions which will be utilized to control the limited work authorization i.e., hold points, notification, inspections, etc. g. Manager of Quality or his designee, Assurance signature and date.			
	QAP-2.4(N), Rev. 1 Para. 6.1.4	2. Verify that the Manager of QA or his designee ensures that each SWO is numbered and logged in accordance with the following and distributed to the highest responsible authority necessary to obtain timely and effective corrective action. a. Each SWO shall be numbered sequentially and prefixed with the current year (SWO-90-XX). b. The SWO log shall list as a minimum the SWO number, date issued, brief description of condition, associated CAR Number and date lifted.			

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1-4 Cont.	QAP-2.4(N), Rev. 1 Para. 6.2.1	3. Verify that the Manager of QA or his designee, distributes the SWO to the highest authority necessary to obtain timely and effective corrective action via a memorandum or letter.			
	QAP-2.4(N), Rev. 1 Para. 6.2.2	4. Verify that copies of the memorandum or letter along with the SWO have been distributed to the following as a minimum: a. FSN Manager b. Cognizant Division Managers c. SAIC/T&MSS Project QA Department (QA Engineering Division Manager) d. YMP Project Office QA Manager			

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1-4 Cont.	QAP-2.4(N), Rev. 1 Para. 6.3.2	5. Verify that when the review and/or verification for an SWO is acceptable, the QA Manager or his designee issues a memorandum or letter lifting the SWO and delineates the following as a minimum, and signs/dates the SWO, when the SWO is lifted. - Scope of work which can resume under the normal program - Effective date work can resume - Justification for lifting the SWO, (May be based upon the resolution of the associated CAR) - Additional corrective actions to be taken (if applicable).			

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1-4 Cont.	QAP-2.4(N), Rev. 1	6. Verify that if the review and/or verification is unacceptable, the Manager of QA or his designee will send copies of the original SWO and CAR by memorandum or letter of explanation to the next higher level of management continuing the SWO and delineating the following: a. Scope of activity which remains under the SWO b. Additional scope of activity to be stopped, if applicable c. Reason for rejection of original corrective action d. Effective date of stoppage e. Actions necessary to correct the situation and enable the SWO to be lifted f. Limited work authorization delineating work which may be continued under controlled conditions while the SWO is in effect, including an explanation of the imposed conditions to control the authorized limited work i.e., hold points, notification, inspection, etc.			

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1-5	QAPP-002, Rev. 6 Para. 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).			
	QAP-1.1(N), Rev. 5 Para. 6.3	1. Verify that unresolved disputes are elevated to higher levels of management within FSN and should this not achieve resolution, the Manager of QA contacts YMPO Project Quality Manager for resolution.			

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1-6	QAPP-002, Rev. 6 Para. 1.4.1 PP-10-00, Rev. 1 Para. 6.4	States in part...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. 1. Verify that interface responsibilities are defined and documented in the FSN implementing procedures.			

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2-1	QAPP-002, Rev. 6 Change Notice A Para. 2.1 PP-10-09, Rev. 1 Para. 6.2.2	Management shall perform readiness reviews, as deemed appropriate. Readiness reviews shall apply to major scheduled/planned acctivities 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. 1. Verify that the Readiness Review Notice has been issued by the PM to the Board Chairperson and the Team Chairperson and provides the following: a. Readiness review scope and purpose identifying areas and items to be reviewed including an indication of the required depth. b. Planned readiness review date, time, location, and other logistical information for the review meeting. c. Board Chairperson d. Team Chairperson e. Other information as shown on form in Atachment 1.			

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2-1 Cont.	FP-10-09, Rev. 1 Para. 6.3.1	2. Verify that Board Chairperson completes the following activities: a. Determines the technical disciplines to be used to accomplish the scope and purpose of the review. b. Established minimum qualifications (e.g., education, experience and independence) needed by the Review Board and Team Review members (hereinafter referred to as Board members and Team members, respectively) to provide the technical disciplines to accomplish the scope and purpose of the review. c. Obtains suitable documentation of review board members' qualifications for the various technical disciplines, as described in Section 6.3.2 below. d. Ensures that the documentation of the review board members' qualifications meets the needs of the review, and signs and dates the Readiness Review Member Selection Record (see Attachment 2). At a minimum, the information needed on the form shown as Attachment 2 shall be satisfied. this may be accomplished by the use of the form itself or a suitable alternate. e. Determines the number of reviewers for the Readiness Review Board. f. Ensures that assigned board members are trained to this procedure and other applicable documents in accordance with PP-10-02.			

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2-1 Cont.	PP-10-09, Rev. 1 Para. 6.4	3. Verify that the Readiness Review Checklist was prepared and included the following information as a minimum: a. Checklist questions b. Space for the response to the checklist questions c. Space for indication of the team members' evaluation of the response (satisfactory, unsatisfactory, or open item). d. Space for comments, which will include the document, person interviewed, or other source of the response to the question. e. Signature of the team member(s) who perform(s) evaluation f. Approval signature of the Team Chairperson			

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2-1 Cont.	PP-10-09, Rev. 1 Para. 6.7.1	4. Verify that the Review Record Memorandum includes the following, as applicable: a. Summary of scope and applicability b. Listing of readiness review team members c. Completed checklist with the signature of the responsible team member indicating the specific information for which each is responsible, and the signature of the Team Chairperson, indicating acceptance of all data in the completed checklist. d. Completed readiness review comment record forms containing the readiness review board ccomments and the review team's resolutions, including any open items as applicable. e. Reference to information reviewed by the readiness review team, including names of individuals and dates interviewed, as applicable. f. Evaluation of readiness. g. Agenda of readiness review team activities. h. Revisions that occurred in accomplishing readiness review team activities.			

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2-2	QAPP-002, Rev. 6 Change Notice A Para. 2.4.1 PP-10-04, Rev. 4 Para. 6.3.1	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. 1. Verify that the PM has completed an annual, independent assessment of the QA Program.			

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2-3	QAPP-002, Rev. 6 Change Notice A Para. 2.4.2 PP-10-04, Rev. 4 Para. 6.3.4	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. 1. Verify that the Assessment Report includes the following information: a. A summary. b. A description of the scope of the assessment activity. c. The identification of the personnel contacted during the assessment activity. d. Positive findings to substantiate a favorable summary of results. e. A summary of the results of the assessment which addresses the scope, status, adequacy, compliance and effectiveness of implementation of the YMP QA Program requirements. f. A description of any adverse conditions in sufficient detail to enable determination of root cause, action to correct the observed condition and to prevent recurrence, to be established by the affected organization. These are documented as action items for tracking and close-out. g. The identification of the team members originating the assessment report.			

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2-3 Cont.	PP-10-04, Rev. 4 Para, 6.4.1	2. Verify that PM assures that affected managers analyze assessment reports, investigate adverse conditions and determine their cause, implement or schedule necessary corrective action including methods to prevent recurrence, and notify the PM, in writing.			
	PP-10-04, Rev. 4 Para. 6.4.2	3. Verify that PM assures that responses from affected FSN Managers are evaluated for adequacy, and that implementation and verification status of corrective actions are tracked until resolution is completed and approved by PM.			

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2-4	QAPP-002, Rev. 6 Change Notice A Para. 2.5.1 PP-60-01, Rev. 3 Para. 6.1	FSN has established requirements for 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. 1. Verify that position descriptions for all personnel who perform quality affecting activities have been developed. 2. Verify that each Manager or Supervisor signs, dates and maintains on file copies of position descriptions for their subordinates. 3. Verify that Human Resources maintains the original position descriptions.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
2-4 Cont.	QAPP-002, Rev. 6 Change Notice A Para. 2.5.1.2 PP-60-01, Rev. 3 Para. 6.2	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. 1. Verify that the Director of Human Resources has verified the education and experience of employees of the FSN YMP Office, prior to their performing quality related activities. 2. Verify that the above verification is certified on Attachment 1.			

(9) Auditor Signature (10) Date

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2-5	QAPP-002, Rev. 6 Change Notice A Para. 2.5.1.2 PP-60-01, Rev. 3 Para. 6.2	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. 1. Verify that Managers and Supervisors have certified that requirements have been met in the format specified in Attachment 1.			

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2-6	QAPP-002, Rev. 6 Change Notice A Para. 2.5.1.2	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. o FSN QAPP o Implementing Procedures and Work Instructions (applicable to the individual's responsibilities) o Regulations o Project Level Documents			
	PP-10-02, Rev. 3 Para. 6.1.3	1. Verify that prior to performing quality related activities, personnel received at a minimum indoctrination into the purpose, scope, methods of implementation, and applicability of the following documents: o FSN QAPP o Implementing Procedures and Work Instructions applicable to the individual's responsibility. o Federal Regulation applicable to the individual's responsibilities, such as 10CFR60, 10CFR50 APP. B, 10CFR960, and 40CFR191. o Project Level Documents applicable to the individual's responsibility, as assigned by his immediate Manager/Supervisor.			

(9) Auditor Signature (10) Date

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2-6 Cont.	EP-10-02, Rev. 3 Para. 6.1.4	2. Verify that the above training is documented on the Attachment 1, 2, and/or 3 as applicable. 3. Verify that the completed indoctrination training form(s) have been forwarded to the Training Coordinator and is included in the employee's training file.			

(9) Auditor Signature (10) Date

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2-6 Cont.	QAP-2.2(N), Rev. 4 Para. 6.1.1.1	4. Verify that prior to performing quality-related work, Director of QA Engineering, QA engineers and specialists are required to read current versions of the following documents: a. 10CRF60 Subpart G b. 10CRF50 Appendix B c. NNWSI/88-9 d. YMP Project Administrative Procedures e. QAPP-002 f. FSN YMP Quality Assurance Procedures g. FSN YMP Project Procedures h. FSN YMP Design Control Procedures i. Additional documents as determined by the MQA or D			
	QAP-2.2(N), Rev. 4 Para. 6.1.1.1	5. Verify that the aforementioned reading list is documented in the format specified in PP-10-02, Attachment 2.			

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2-7	QAPP-002, Rev. 6 Change Notice A Para. 2.5.1.5	After the initial personnel qualification evaluation, the proficiency of personnel who perform activities affecting quality will be evaluated and documented at least annually....Proficiency evaluations will be performed by managers or supervisors who have responsibility for the activities being performed or verified.			
	PP-60-01, Rev. 3 Para. 6.4	1. Verify that the Manager or Supervisor performs a proficiency evaluation on an annual basis and certifies that employee(s) have the required proficiency for the position (See Attachment 2, Form LV-389).			
		2. Verify that the records of the proficiency evaluation include as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
		NDE Personnel Qualification and Certification			
2-8	QAPP-002, Rev. 6 APPENDIX D Para. 1.3	The qualification of personnel will be certified in writing in an appropriate form, including the following information: o Employer's name. o Identification of person being certified. o Activities certified to perform. o Basis used for certification that includes such factors as; - Education, experience and training (when necessary) - Test results (where applicable). - Results of capability demonstration. o Results of periodic evaluation. o Results of physical examinations (when required). o Signature of employer's designated representative who is responsible for such certification. o Dates of certification and certification expiration.			
	QAP-2.5(N), Rev. 0 Para. 6.6.3	1. Verify that Personnel certifications and copies of FSN written procedure is maintained on file by FSN.			

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2-8 Cont.	QAP-2.5(N), Rev. 0 Para. 6.6.4	2. Verify that FSN qualification and certification records the following: a. Employer's name. b. Name of certified individual. c. Level of certification and test method. d. Educational background, experience and training in accordance with this written procedure. e. Statement(s) indicating satisfactory completion of training in accordance with this written procedure. f. Results of present physical examinations. (Annual) g. Current examination copy(ies) or evidence of successful completion of examinations. h. Other suitable evidence of satisfactory qualifications when such qualifications are used by FSN in lieu of examinations (Level III). i. Composite grade(s) or suitable evidence of grades for general, specific, and practical for Level I and II individuals, and basic, method and specific for Level III individuals. j. Dates of certification and certification expiration, and/or recertifications including results of periodic evaluations. k. Signature of FSN certifying individual.			

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2-8 Cont.	QAP-2.5(N), Rev. 0 Para. 6.6.5.1	3. Verify that all FSN NDE personnel are recertified every three years in accordance with criteria established procedure.			

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3-1	QAPP-002, Rev. 6 Sec. III, Para. 3.2.3.1	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.			
	QC-03, Rev. 8, PIC 5 Para. 5.1	1. Verify that the PM, or his designee, assigns design responsibility for a particular structure, system, or component to the appropriate discipline engineer, and is responsible for approving the analysis.			

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3-1 Cont.	DC-03 Para. 5.2	2. Verify that the discipline engineer is responsible for performing design analyses in accordance with this procedure.			
	DC-03 Para. 6.1	3. Verify the following examples of design analyses being performed by FSN: a. General studies which are reports generated to investigate approaches, parameters, concepts or feasibility in support of engineering efforts. b. Calculations which support the designed structure, system, or component. c. Trade-off studies which are documented reports stating two or more alternatives to a design of structures, systems, components, or operational procedures.			

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3-1 Cont.	DC-03 Para. 6.2	4. Verify that design analyses are performed by FSN when designing any structure, system, or component with an approved QA Level I, II, or III assignment.			
	DC-03 Para. 6.3	5. Verify that the following mandatory listing of items is contained in design analyses: a. Objectives of the analysis. b. Method used. c. Criteria source, date, subject, and originating organization. d. Codes and standards. e. Reference Material f. Assumptions g. Computer Programs h. Units i. Calculations or analyses			

(9) Auditor Signature (10) Date

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3-1 Cont.	DC-03 Para. 6.3.9	6. Verify that calculations made during design analysis by FSN personnel are documented on the Design Sheet, or reasonable facsimile. 7. Verify that Design Sheets contain: o Calculation Number o Checked By and Date o Design For o Sheet Numbers o WBS No. o Date			
	DC-03 Para. 6.4	8. Verify that all design analyses are checked by a person whom the Project Design Manager evaluates as qualified in the purpose or subject of the analyses. 9. Verify that a Document Review Notice Form LV-316 is used to identify the history of the checking. Errors or discrepancies found by the checker shall be clearly documented either on the same page or an attached page.			

(9) Auditor Signature (10) Date

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3-1 Cont.	DC-03 Para. 6.4 Cont.	10. Verify that corrections are reviewed and resolved with the originator and this resolution clearly documented on the original page or attached page. Where resolution cannot be reached, between the originator and the checker, the resolution shall be resolved by the next level of supervision. 11. Verify that upon resolution of all errors or discrepancies in an analysis, the originator and checker shall initial and date each page of the Design Sheet plus any attached pages, and the checker shall sign the "Reviewer" block on Form LV-308. 12. Verify that for QA Level III items, the completed analysis is transmitted to project records per PP-50-01. For QA Level I and II items, the completed analysis is verified in accordance with DC-04.			

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3-1 Cont.	DC-03 Para. 6.4 Cont.	13. Verify that prior to the design analysis being submitted for review external to the discipline, the L Engineer shall verify that inputs used in the development of the analysis have been properly documen on a Design Baseline Memo per DC-26 . The LDE shall transmit the DBM to the Configuration control manager.			
	DC-03 Para. 6.6	a. Verify that changes made to an approved design analysis are processed in accordance with this procedure and DC-28.			
	DC-03 Para. 6.7	b. Verify that a copy of each analysis is provided to the Configuration Control Manager for incorporation in the Configuration Status Report per DC-27.			
	DC-03 Para. 6.8	c. Verify that Design Analyses performed by F&S subcontractors are in accordance with the QAPP and implementing procedures of F&S. Design Analyses prepared by subcontractors must be reviewed and approved by the F&S Lead Design Engineer, QA, and the F&S Project Manager or his designee.			
	DC-03 Para. 6.10	d. Verify that general studies are checked by an individual other than the originator using the DRN and are not required to be reviewed and verified per DC-09 & DC-04. Approval by the PM and QAR is required.			

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3-2	QAPP-002, Rev. 6 Para. 3.2.3.2	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 QA requirements.			

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3-2 Cont.	DC-03 Para. 6.5	1. Verify that the completed design analyses are subjected to a review in accordance with DC-09 and DC-04 for QA levels I and II items. (Reference Para. 6.10, PIC-3).			
	DC-03 Para. 7.0	2. Verify that the QA Records include the following: Design Sheets Design analysis sheets (LV-308 & LV-309) Design Studies Calculations Design Analyses Performed by Subcontractors Attachments to the above			
	QAP-3.3 (N) Para. 6.1	3. Verify that Design Analyses performed in accordance with DC-03 are submitted to QA for review and approval. Comments are resolved between the originator and the QA Rep. Disputes are elevated to upper FSN QA Management and Project Management.			
	QAP-3.3 (N) Para. 6.2	4. Verify transmittal of Design Analysis via a transmittal document or hand carried to QA for review and approval. Verify that a Record of all design analyses reviewed and their status is maintained in a Log by QA.			

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3-2 Cont.	QAP-3.3(N) Para. 6.3.1	5. Verify that the responsible QA Representative (QAR), utilizing the Design Analysis Checklist, Form LV-328, performs the review of the design analysis to assure that it is prepared, reviewed, and approved in accordance with the requirements of DC-03. Any item on the checklist which is marked "no" requires an explanation under "comments" and disapproves the design analysis. If the item is not applicable, the "N/A" column will be marked.			
	QAP-3.3(N) Para. 6.3.2	6. Satisfactory QA Design Checklists will be signed and dated and copies will be retained in the QA Working Files for reference until the design analysis is transmitted to the Record Center.			
	QAP-3.3(N) Para. 6.3.3	7. Verify that when Design Analyses are disapproved, the reasons are provided under "Comments", and the QA Design Analysis Checklist is marked as not approved, signed and returned with the analysis to the originator for resolution. The disapproval is logged and a copy of the signed checklist will be retained in the QA working file for use when the design analysis is returned.			

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3-2 Cont.	QAP-3.3(N) Para. 6.3.4	8. Verify that when a previously disapproved Design Analysis is corrected and returned to QA, the QAR will enter it into the Log and perform the review, including verifying that previous QA comments have been resolved and/or incorporated into the analysis.			
	QAP-3.3(N) Para. 6.3.5	9. Verify that after completing a satisfactory QA Design Analysis review, the QAR will sign and date the Design Analysis Cover Sheet, Form LV-308, for approval, attach a copy of the signed QA Design Analysis Checklist to the analysis package, return the package to the originator and enter the approval in the log.			
	QAP-3.3(N) Para. 7.0	10. Verify that completed Design Analysis Checklists are QA Records and are handled in accordance with PP-50-01 requirements.			

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3-3	FSN QAPP-002, Rev. 6 Para. 2.2.2.1	...If FSN subdivides upper-tier QA levels to lower tier QA levels, this will be accomplished in accordance with 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.			
	FSN PP-70-04 Para. 6.1	For the purpose of this procedure, Section 4.0 of AP-5.28Q will be adopted as the FSN procedure.			
	Para. 6.2	A log will be maintained for the purpose of tracking the QAG Reports. 1. Verify activity on QA Grading via the above log.			
	AP-5.28Q, Rev. 0 Para. 4.1 (3)	2. Verify that the QAG preparer determined the importance of assigned items or activities appearing the on Non-Selection Record using the instructions contained in Exhibit 3.			

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3-3 Cont.	AP-5.28Q, Rev. 0 Para. 4.2 (6)	3. Verify that the QAG preparer evaluated the characteristics of assigned items or activities appearing on the Q-List, Quality Activities List, and Non-Selection Record and completes the work sheet for evaluation of characteristics (Exhibit 1) using the instructions in Exhibit 4.			
	Para. 4.3 (9)	4. Verify that the preparer prepared QAG Reports for those items or activities that fall within the participants area(s) of responsibility, using the instructions attached to Exhibit 2, the information developed in Sections 4.1 and 4.2, and the guidance in Exhibit 5.			
	Para. 4.4 (12)	5. Verify that the QA Manager and the TPO signed and dated the QAG Report.			

(9) Auditor Sign: (10) Date

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3-4	DOE Content Requirements For Descriptions Of Studies In Study Plans. Chapter 8 AP-1-10Q, Rev. 1 Para. 5.1.1	Details for studies, tests, and analyses will be presented in Study Plans. A study may involve a single test or a set of tests and analyses, as appropriate. Tests include those measurements of physical parameters, or observations of physical phenomena that are performed in the field or in the laboratory. Test activities include preparation of procedures, test set-up, conduct of the test, data acquisition, and data reduction. The analyses include those calculations or other evaluations needed to assess site characteristics and support design activities. 1. Verify that study plans are prepared in accordance with the following requirements: a. Plans should be editorially consistent with the OCRWM Production Guidance Manual (1985) to the extent practicable. b. Plans should conform to level of detail, format, and content specified in the May 7 & 8, 1986 DOE/NRC Agreement as follows: a. Purpose and Objectives of studies b. Rationale for Selected Study c. Description of Tests and Analyses d. Application of results e. Schedules and Milestones			

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3-4 Cont.	AP-1.10Q Para. 5.1.1 Cont.	2. Verify that Plans include an abstract provided in front of the Table of Contents.			
	AP-1.10Q Para. 5.1.2	3. Verify that participating organizations perform technical and Quality Assurance reviews of Study Plans prepared by them, by staff other than the authors, in accordance with their procedures prior to submittal to the YMP.			
	AP-1.10Q Para. 5.1.3	4. Verify that the TPO or a designee ensures that the Study Plans meet the requirements given in Para. 5.1.1 and that the plans are prepared and reviewed by qualified staff.			
	AP-1.10Q Para. 5.1.4	5. Verify that if the study plan differs significantly from the "Technical Planning Basis: SCP" in objectives, scope, or testing methods, the TPO, or designee, prepares an ICN to request changes to the SCP.			

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3-4 Cont.	AP-1.10Q Para. 5.1.5	6. Verify that the TPO, or designee, submits the participant approved Study Plan, any ICNs and documentation of the qualifications of the principal investigators to the Director, R & SED.			
	AP-1.10Q Para. 5.2	7. Verify that upon receipt of a draft study plan, the Branch Chief or a designee, initiates a screening review of the Study Plan, comments are generated on Comment Resolution Forms, and the plan is either approved or returned to the TPO with the comment resolution forms.			
	AP-1.10Q Para. 5.2.4	8. Verify that after the study plan is judged to be acceptable for Project Review, the Branch Chief, or designee, initiates Quality Assurance and Technical Reviews of the Study Plan per this procedure.			
	AP-1.10Q Para. 5.2.6	9. Verify that reviews of study plans are performed only by qualified staff and documentation of the qualifications of reviewers are completed internally by participant organizations prior to initiation of the Project Review.			

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3-4 Cont.	AP-1.10Q Para. 5.4	10. Verify that upon completion of the QA and Technical reviews, a copy of the revised Study Plan and the CRFs are submitted to the Director, R & SED, and the Director, QAD, for Study Plan approval , or for transmittal to OCRWM for review.			
	AP-1.10Q Para. 5.5.1	11. Verify that the Study Plan is submitted to OCRWM for review and approval in parallel with or following the Project review.			
	AP-1.10Q Para. 5.6.1	12. Verify that after OCRWM approval, the Study Plan is sent to the NRC for review and to the State of Nevada for their information.			
	AP-1.10Q Para. 5.6.4	13. Verify that the Branch Chief, RIB, or a designee, reviews the revised Study Plan to verify that the NRC comments have been adequately addressed. If comment resolution is incomplete, the Study Plan is returned to the responsible TPO for revision. If comment resolution is adequate, the Director, R & SED, and the Project Quality Manager sign the approval sheet. The Project Manager forwards the Study Plan to the OCRWM for their approval.			

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5-1	QAPP-002, Rev. 6, Para. 5.1	These documents will include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished...If plans are used in lieu of procedures, then these plans shall also include or reference acceptance criteria and identify the QA records which are generated.			
	PP-10-01, Rev. 6, Para. 6.1.7.6	This section shall contain the specific requirements, methods, and activities necessary for the implementation of the procedure (i.e., the what, how, where, when, and by whom) and the inclusion of, or reference to, appropriate quantitative or qualitative acceptance criteria, as necessary, for determining that procedural activities have been satisfactorily accomplished.			
		1. Verify that the procedures or plans include or reference appropriate acceptance criteria for determining that required activities have been satisfactorily accomplished.			

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5-2	QAPP-002, Rev. 6 Para. 5.1 PP-10-01, Rev. 6 Para, 6.1.7.7	Instructions and procedures will include a section which identifies the QA records which are generated during implementation of the document. This section identifies the Quality Assurance Records required for and generated by the implementation of the procedure. 1. Verify that the Quality Assurance Records required for and generated by the implementation, of the procedure are identified.			

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5-3	QAPP-002, Rev. 6, Para. 5.2	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.			
	QAP-5.1(N), Rev. 5 Para. 6.2.2 a	As a minimum, one other QAR, other than the preparer shall be assigned to conduct an independent review of the procedure on the Form LV-495. 1. Verify that an independent review of procedures by at least one other QAR is conducted, and that the reviewer was not among those that developed the document.			
	QAP-5.1(N), Rev. 5 Para. 6.2.3	Comments by reviewers shall be documented on form 495, Review of Documents Sheets. 2. Verify that comments by reviewers are documented.			

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5-3 Cont.	QAP-5.1(N), Rev. 5 Para. 6.2.4	After the comments are resolved, the QAR shall obtain a new or revised original and shall circulate it it for approval and dating to the MQA and the GM. 3. Verify that after the comments are resolved the document (either a revised original or new) receives the dated approvals of the MQA and the GM.			
	QAP-5.1(N), Rev. 5 Para. 6.2.6	When the QAP has been approved, an effective date shall be assigned and typed on the Front Page. It shall not exceed ten (10) working days in order to permit publication and distribution before the date. 4. Verify that the assigned effective date for procedures is not more the ten working days from the approval date.			

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5-3 Cont.	QAP-5.1(N), Rev. 5 Para. 6.3	A maximum of five (5) PICs may be issued against a specific procedure revision. A procedure shall be revised in accordance with Section 6.2 following issuance of the fifth PIC against it and in lieu of issuing a sixth PIC. 5. Verify that a new procedure revision is issued after a procedure receives five PICs rather than issuing a sixth PIC.			

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6-1	QAPP-002, Rev. 6 Para. 6.2.1	The document control system will be documented and F&S will provide the appropriate review, resolution of comments, and concurrence with respect to quality-related aspects of the documents.			
	QAP-6.1(N), Rev. 3 Para. 6.1.2	The Manager of QA, The DQAE, QA Engineers and QA Specialists are required to conduct an independent review of instructions, procedures, plans, drawings and other documents as specified in FSN procedures. 1. Verify that the document control system is documented and implemented as it applies to instructions, procedures, plans, drawings and technical work products.			

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6-2	QAPP-002, Rev. 6 Para. 6.1.3	Implementation of document control will provide for the following: o Identification of documents to be controlled. o Identification of assignments of responsibility for preparing, reviewing, approving, and issuing documents. o Review of documents for technical adequacy, completenes 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.			
	QAP-6.1(N), Rev. 3 Para. 6.1.1.1	The QA Procedures shall define who is responsible for preparing, reviewing, approving, and issuing documents controlled by the QA Division. 1. Verify by examination of the QA procedures that the appropriate personnel are identified for the above listed responsibilities.			

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6-2 Cont.	QAP-6.1(N), Rev. 3 Para. 6.1.1.2	The QA Procedures shall define who is responsible for reviewing documents controlled by the QA Division for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements prior to approval and issuance. 2. Verify that the personnel responsible for the above requirements are identified in the the QA Procedures.			
	QAP-6.1(N), Rev. 3 Para. 6.1.1.3	QA shall maintain a master list or equivalent to identify the correct and updated revisions of documents. Each time a Quality Assurance Procedure is revised, the table of contents is revised and issued to controlled QA Manual holders. The table of contents identifies the correct and updated revisions of QA Procedures... 3. Verify that a master list of controlled documents or equivalent which contains all the correct and updated revisions of documents is issued each time there is a revision or PIC added to a controlled document and that it is distributed to QA Manual holders. (Tables of contents and Change Control Records are equivalent to a master list)			

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6-2 Cont.	QAP-6.1(N), Rev. 3 Para. 6.1.1.4	QA shall maintain distribution lists for the controlled documents which are controlled by the QA Division... The DQAE shall review these lists annually, and if necessary, require the lists to be updated... Controlled QA Documents include an assignment sheet which indicates "CONTROLLED COPY NO" and a unique number assigned to each manual holder. The assignment Sheet also identifies the holder of the document. 4. Verify that QA maintains distribution lists for controlled documents. 5. Verify that these lists are reviewed for updating annually. 6. Verify that controlled QA documents include a unique controlled copy number and an assignment sheet which identifies the holder of the document.			

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6-2 Cont.	QAP-6.1(N), Rev. 3 Para. 6.1.1.5	QA Documents shall be distributed to each controlled document holder by a Document Transmittal form which requires a sign-off and return to acknowledge receipt and handling of obsolete documents within fifteen (15) days. If the signed copy is not returned within Thirty (30) days from the date the document was originally sent, then a SECOND NOTICE will be sent requesting receipt acknowledgment within fifteen (15) days. If receipt acknowledgment is not received within fifteen (15) days, then a FINAL NOTICE will be sent requesting a response within fifteen (15) days and advising the recipient that failure to respond will result in removal of the document holders name from the Controlled Distribution List and that copies will no longer be sent to the document holder. Quality Assurance will maintain a log to track return of transmittals. 7. Verify that the above series of events is followed in the case of non-acknowledgment of controlled distribution transmittals. 8. Verify that QA maintains a log to track return of transmittals.			

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6-2 Cont.	QAP-6.1(N), Rev. 3 Para. 6.1.1.6	QA Procedures and the QA Program Plan are reviewed in accordance with Section 6.1.2 if this procedure and are distributed to the Technical Project Officer and other interfacing organizations for review and comments. 9. Verify that the TPO and interfacing organization are identified and are sent copies of the above for review and comments.			

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6-3	QAPP-002, Rev. 6 Para. 6.2.2	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 organization that performed the original review and approval.			
	QAP-6.1(N), Rev. 3	Changes to QA Documents, other than those defined below as minor changes, are considered as major changes and shall b reviewed and approved by the same organizations that performed the original review and approval.			
		1. Verify that all major changes are reviewed and approved by the same organization that performed the original review and approval.			

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6-4	QAPP-002, Rev. 6 Para. 6.3	The document control system will assure that documents requiring verification are not released prior to verification. 1. Where is the QAP or lower tier reference to this requirement and how is the requirement satisfied.			

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16-1	QAPP-002, Rev. 6 Para. 16.1.1 QAP-16.1(N), Rev. 6 Para. 6.0	1. Verify that CARs are initiated by QA when other usual means for obtaining corrective action have proven ineffective and/or when one or more of the conditions outlined in Para. 6.0 exist. 2. Select six (6) CARs and identify which of the criteria of Para. 6.0 caused the initiation of the CAR.			

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	QAP-16.1(N), Rev. 6 Para. 6.2	3. Verify that a CAR log is maintained to track CARs and and contains the information referred by para. 6.2 of QAP-16.1(N), Rev. 6. NOTE: The CAR distribution referred to in para. 6.7.3 is an error in the Para. 6.4 - instead of para. 6.3 is specified.			

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16-2	QAPP-002, Rev. 6 Para. 16.1.1 QAP-16.1(N)m Rev. 6 Paras. 6.0 thru 6.7	1. Select a representative sample of CARs and verify that they have been filled out properly and contain the proper reviews and approvals required by procedure QAP-16.1.			
16-3	QAPP-002, Rev. 6 Para. 16.1.2 QAP-16.1(N), Rev. 6 Paras.6.6 & 6.7	1. Verify that QA takes follow-up action to verify that the proper implementation of corrective and preventive actions specified by the CAR were taken and the CAR is closed in a timely manner required by paras. 6.6 & 6.7 2. Conduct study on the time that is taken to close a representative sample of CARs from the time of initiation.			

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16-4	QAPP-002, Rev. 6 Para. 16.1.1 QAP-16.1(N), Rev. 6 Para. 6.3.1	1. Verify that managers at all levels affected by the CAR have been notified of the adverse conditions and of lessons to be learned to improve conditions or avoid similar occurrences.			

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16-5	QAPP-002, Rev. 6 Para. 16.1.1 QAP-16.2(N), Rev. 2 Para. 6.0	1. keview a representative sample of deficiency reports and related deficiency report responses and verify that they have been prepared, processed and closed as required by para. 6.0.			

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16-6	QAPP-002, Rev. 6 Para. 16.1.7 QAP-16.2(N), Rev. 2 Para. 6.2.3 QAP-16.2(N), Rev. 2 Para. 6.5	1. Verify that a log is maintained by QA of DRs and Observations in order to track action of these documents from initiation to closing. 2. How is the responsible manager notified of the closing of DRs and Observations?			

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16-7	QAPP-002, Rev. 6 Para. 16.1.1 QAP-16.2(N), Rev. 2 Para. 6.3.1	1. Verify that responses to DRs and Observations are provided within the requirements of para. 6.3.1. 2. Identify the number of follow-up letters and memos sent to responsible managers who are delinquent in the responses in the last year.			

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16-8	QAPP-002, Rev. 6 Para. 16.1.3 QAP-16.3(N), Rev. 2 Para. 6.0 QAP-16.3(N), Rev. 2 Para. 6.5	1. Verify that a semi-annual trend analysis is performed and reported on documented quality problems and trends adverse to quality are identified as required by paras. 6.1 thru 6.4. 2. Verify that trend analysis reports are reviewed and followed up as required by para. 6.5.			

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17-1	QAPP-002, Rev. 6 Para. 17.1.2.2 PP 50-01, Rev. 4 Para. 6.12	1. Verify that a record type list is maintained by FSN RC which includes a listing of YMP QA record types (including record types) and the identification of the procedure that creates the records. 2. Verify that this list is updated as appropriate or at least annually.			

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17-2	QAPP-002, Rev. 6 Para. 17.1.2 PP 50-01, Rev. 4 Para. 6.17	1. Verify that records center personnel were trained with the requirements for managing, handling and processing QA records.			

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17-3	QAPP-002, Rev. 6 Para. 17.4 PP 50-01, Rev. 4 Para. 6.1	1. Verify FSN RC personnel perform selected receipt/ control tasks specified by para. 6.1 of PP 50-01, Rev. 4.			

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17-4	QAPP-002, Rev. 6 Para. 17.5.2 PP 50-01, Rev. 4 Paras. 6.2 & 6.6	1. Verify that document indexing is performed per para. 0.2 of PP 50-01, Rev. 4, to provide unique identification, location, retrieval, and traceability information. 2. Verify that the CRF has processed the data supplied by FSN into the RIS and verified entry of the data by providing verification transmittal.			

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17-5	QAPP-002, Rev. 6 Para. 17.3.2 PP 50-01, Rev. 4 Para. 5.6	1. Verify that a list is maintained which contains the signature and initials of person or persons having the authority to sign and authenticate QA records and record packages.			

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17-6	QAPP-002, Rev. 6 Para. 17.3.1 PP 50-01, Rev. 4 Para. 6.1.d	1. Verify that documents considered valid records are stamped, initialed or signed and dated by authorized personnel or otherwise authenticated in accordance with approved procedure.			

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17-7	QAPP-002, Rev. 6 Para. 17.8.1 PP 50-02, Rev. 2 Paras. 6.6.1 & 6.6.2	1. Verify that an approved list is posted at the entrance to the FSN RC designating the FSN personnel authorized access to the FSN RC. 2. Verify that an approved list is posted on files by FSN Record Center supervisor designating the FSN personnel authorized access to the QA records.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
17-8	QAPP-002, Rev. 6 Para. 17.5 PP 50-01, Rev. 4 Para. 4.29	1. Verify that records and record packages are identifiable by accession numbers, WBS number, QA designation and record package identifiers.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
17-9	QAPP-002, Rev. 6 Para. 17.2.1.1 PP 50-01, Rev. 4 Para. 6.1	1. Verify that records are legible, reproducible, microfilmable, identifiable, accurate, and complete.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
17-10	QAPP-002, Rev. 6 Para. 17.9 PP 50-01, Rev. 4 Para. 6.11	1. Verify that corrections or changes are performed per para. 6.11.b.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
17-11	QAPP-002, Rev. 6 para. 17.6 PP 50-01, Rev. 4 Para. 6.4	1. Verify that adequate interim storage is provided by FSN RC for records prior to shipment to the CRF/PMC. NOTE: This does not apply to one-of-a-kind records.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
17-12	QAPP-002, Rev. 6 Para. 17.7 PP 50-01, Rev. 4 Para. 6.8	1. Verify that the microfilm cartridges and aperture cards are filed in accordance with the requirements of Para. 6.8.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
17-13	QAPP-002, Rev. 6 Para. 17.11 PP 50-01, Rev. 4 Para. 6.10	1. Verify that documents can be retrieved by using the printed index and the computer database.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
17-14	QAPP-002, Rev. 6 Para. 17.4.1 PP 50-01, Rev. 4 Para. 6.5	1. Verify that the transfer of records to the CRF/PMC by the FSN RC personnel is performed per para. 6.5 (verify select items of items A through G.)			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
17-14 Cont.	QAPP-002, Rev. 6 Para. 17.11 PP 50-02, Rev. 2 Para. 6.8 & 6.9	1. Verify that the request for withdrawal YMP Archived Records form is processed per para. 6.8 for one-of-a-kind record, including the filling out of Record Withdrawal Request Log, and the requirements of para. 6.9 are complied with when the records are returned following recall.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
	QAPP-002, Rev. 6 Para. 17.1.2 PP 50-01, Rev. 4 Appendix A	1. Verify that the checklist (Appendix A) is used for the identifying and submitting records used.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-1	QAPP-002, Rev. 6 Sect. 18.1 & 18.2 QAP-18.1(N) Paras. 6.2, 6.2.1 & 6.2.2	1. Identify work activities performed by FSN or its subcontractors since the last YMP audit that require implementation of a QA program. 2. Based on the audit schedules for the last 18 months, Verify if internal and external audits have been scheduled and conducted to meet the QAPP-002 and QAP-18.1(N) requirements.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-2	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N), Para. 6.2	1. Verify that the FSN audit schedule complies with the QAPP-002 requirements.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-3	QAPP-002, Rev. 6 Sect. 18.1, QAP-18.1(N) Paras. 6.3 & 6.14	1. Verify that an audit log is maintained as required. Determine that the log has been maintained current by reviewing the logged information against the audit schedule and by reviewing completed audit reports and interviewing the Manager of QA or other persons responsible for the log. To determine if the audit log accurately reflects closed audits, review the documentation that shows the status of audit nonconformances, deficiencies, and observations. 2. For each audit (up to a sample of 10) that have been closed, verify that the lead auditor has notified the audited organization in writing of the audit closure.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-4	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N), Para. 6.4.1	1. Check the audit plan and the corresponding audit reports to establish who were members of the audit team their position as an auditor or technical specialist. Verify that the members of the audit team had: - sufficient authority and organizational freedom - had the technical competence necessary - were qualified IAW QAP-2.3(N) - had verified technical qualifications IAW PP-60-01.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-5	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N) Para. 6.4.1	1. For each audit plan, verify that the required information is provided and the proper approval was obtained.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-6	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N), Paras. 6.4.3	2. Verify that the plans were forwarded as required. With external audits, ensure that the plans were forwarded through the cognizant purchasing organization.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-7	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N) Para. 6.4.4.	1. Evaluate the checklists to establish if the checklists contained items that attempted to address the verification objectives.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-8	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N) Para. 6.6	1. Evaluate each completed checklist for documented objective evidence, adequacy of the information documented to substantiate the findings, and pertinence of the objective evidence to the item being verified. Determine the completeness of the auditor in assessing the item based on the documented objective evidence found in the checklist.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-9	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N) Para. 6.11	1. Verify that each audit report contains the appropriate information as required by the QAP-18.1(N). 2. Evaluate if the report reflects the audit findings as documented on the audit checklists. 3. Verify that the proper audit report approval was obtained. 4. Verify that an established distribution lists exists for the distribution of both internal and external audit reports.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-10	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N) Paras. 6.7, 6.8, 6.9, 6.12, & 6.13	1. Obtain copies of nonconformance, deficiency and observation reports that resulted from the audits being reviewed, verify that the ATL or a Lead Auditor had (1) accepted the corrective action, (2) verified its effective implementation, and (3) documented the basis of the corrective action in accordance with the applicable procedure. 2. Review the accepted corrective actions and determine if the basis for acceptance is adequate for the significance of the problem. 3. Verify that the requirements of QAPP-002, Rev. 6, Sects. 18.6 and 18.7 have been complied with.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-11	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N) Para. 6.15	1. For each audit under review, verify that an audit file exists and contains the pertinent documents for the current status of the audit process.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-12	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N) Para. 7.0	1. Sample three closed audits to verify that the audit files were submitted as Record Packages to the records facility in accordance with PP-50-01. 2. Visit the records facility and examine the audit record packages to determine if the packages contain the required documentation. 3. Select several supplier annual evaluations and verify that the annual evaluations are in the records center.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-13	QAPP-002, Rev. 6 Sect. 18.1 QAP-18.1(N) Para. 6.2	1. Identify suppliers to FSN and verify that annual evaluations are being performed and documented as required.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-14	QAPP-002, Rev. 6 Sect. 18 QAP-18.2(N) General	1. Technically review the procedure for adequacy of requirements, ease of use, and pertinence of information.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-15	QAPP-002, Rev. 6 Sect. 18.10 QAP-18.3(N) Para. 6.2	1. Identify work activities performed by FSN or its subcontractors since the last YMP audit that require implementation of a QA program. 2. Based on the surveillance schedules over the last 18 months, determine if internal and external surveillances have been scheduled and conducted to meet the QAPP-002 and QAP-18.3(N) requirements.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-16	QAPP-002, Rev. 6 Sect. 18.10 QAP-18.3(N) Para. 6.8	1. Verify that a surveillance log is maintained as required. Determine that the log has been maintained current by reviewing the logged information against the surveillance schedule and by reviewing draft or completed surveillance reports and interviewing the Manager of QA or other person responsible for the log. To determine if the surveillance log accurately reflects closed surveillances, review the documentation that shows the status of surveillance nonconformances, deficiencies, and observations. 2. Selectively sample at least 10 audits that were conducted and have audit reports complete or in draft form. Of the 10 audits selected, ensure hat at least 3 are external audits. Obtain the audit files for the selected audits. For each audit being reviewed, evaluate the following:			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-17	QAPP-002, Rev. 6 Sect. 18.10 QAP-18.3(N) Para. 6.3	1. Evaluate the surveillance checklists for surveillances under review and determine if the checklists meet the requirements of the QAP paragraph. 2. Determine if the criteria identified on the checklists are reasonable and adequate for the area being surveilled. 3. For the area of personnel qualification, evaluate the qualifications of the persons who performed the surveillances related to the scope of the surveillance conducted. Determine if the persons were qualified.			

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18-18	QAPP-002, Rev. 6 Sect. 18.10 QAP-18.3(N) Para. 6.4	1. Review the completed surveillance checklists to assess if the requirements of this QAP subsection have been complied with. 2. Evaluate if sufficient objective information has been documented on the checklists to support the findings. 3. Based on the surveillance checklists, determine if the person performing the surveillance conducted a reasonable and adequate surveillance of the area being surveilled.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-19	QAPP-002, Rev. 6 Sect. 18.10 QAP-18.3(N) Para. 6.5	1. Verify that for each surveillance, a report was issued in accordance with the QAP requirements; that the report reflects the objective evidence documented in the checklists; and the report was issued in a timely			

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18-20	QAPP-002, Rev. 6 Sect. 18.10 QAP-18.3(N) Para. 6.9	1. Fro each surveillance under review, verify that an surveillance file exists and contains the pertinent documents for the current status of the surveillance process.			

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18-21	QAPP-002, Rev. 6 Sect. 18.10 QAP-18.3(N) Para. 7.0	1. Sample three closed surveillances to verify that the surveillance files were submitted as Record Packages to the records facility in accordance with PP-50-01. 2. Visit the records facility and examine the surveillance record packages to determine if the packages contain the required documentation.			

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18-22	QAPP-002, Rev. 6 Sect. 18.10 QAP-18.3(N) General	1. Technically review the procedure for adequacy of requirements, ease of use, and pertinence of information.			

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SQA-1	FSN SQAP, Rev. 0 Para. 3.1	The original Software Environment Configuration (SEC) description shall be entered in the Software Environment Configuration Management Log (SECML). Entry into the SECML establishes the baseline of the environment....			
	PP-80-02, Rev. 0 Para. 6.1	CCRS and CCTO make initial log entries or update existing log entries in the Software Environment Configuration Management Log (SECML). The information required in this log is provided in Attachment 1 (that is pages 4 and 5 of the procedure). 1. Examine several SECMLs, selected randomly, to determine if the required information is complete.			
	PP-80-02, Rev. 0 Para. 6.6	A status report of baselined hardware and software shall be prepared by the configuration management on monthly basis and provided to the users. 2. Examine all available status reports to determine the history of software items and the number of software items currently in the inventory. (Be prepared to select one or more items for subsequent review of the documentation).			
	PP-80-09, Rev. 0 Para. 5.2	Computer Certification Technical Officer (CCTO) is responsible for installation of the Controlled Computer System and Preparing the Hardware Certification Report (HCR) in accordance with this procedure. (The CCTO is responsible for insuring that any and all problems with activating the hardware are resolved, including Nonconformance Reports and hold status if necessary.) 3. Determine that descriptions of the controlled computer system (HCRs) are baselined in the SECML.			

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SQA-2	FSN SQAP, Rev. 0 Para. 3.2.1	The FSN software configuration management system uniquely identifies all baselines and systematically controls, and records changes and modifications to software products to assure positive identification of software and control of all software baseline changes, a brief chronology of the software versions, including descriptions of changes made between versions. The software configuration management system requirements are specified in the section and the methodology for application of these requirements is specified in PP-80-01, Software Configuration Management.			
	PP-80-01, Rev. 0 Para. 6.1	Computer Certification Records Specialist (CCRS) receives software document and makes initial log entries or updates existing entries in the Software Configuration Management Log (SCML) in accordance with Attachment 1 (pages 5 and 6 of the procedure) as required by applicable controlling procedures.			
	Para. 6.2.3 and 6.2.4	CCRS updates the file index ... for the new documentation and files the folder...for retention in the designated controlled area. 1. Verify that the SCML exists and contains all pertinent software documentation.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
SQA-2 cont'd	PP-80-01, Rev. 0 Para. 6.3	CCRS or CCTO places software products on "HOLD" status as required by controlling procedures or as directed by management.... using a "HOLD" tag or label... and records this action or removal in the SCML. 2. Verify that any software product deficiency has been handled as stated above.			
	Para. 6.5	SCML numbers are issued in accordance with Attachment 1 (pages 5 and 6 of the procedure). The CCRS shall assign a unique number and revision to each document as required by the controlling procedure.... The CCRS shall maintain logs or computerized tracking systems for assigning document identification numbers. 3. Examine the identification number log and obtain an explanation of the numbering system.			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
		TECHNICAL CHECKLIST ESF Alternatives Study			
T-01		What is FSN's involvement in the ESF Alternatives Study? For what work is FSN responsible and for what work does FSN lend support?			
T-02		What were the criteria used to select key FSN personnel to participate in these studies? What evidence does FSN have that demonstrates the personnel selected have the experience and qualifications necessary for the ESF Alternatives Study?			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
		ALTERNATIVES STUDY TASK: Identification of Options*			
T-03		Please explain the interfaces and interaction between ITM 010 Task 4, Options, amd Tasks 2 - Methodology, 3 - Requirements, and 5 - Selection.			
T-04		What were the criteria or method by which the Task team would know that it had a complete, or at least acceptable, set of options for the satisfactory completion of Task 4? Were these technically defensible?			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-05		In Section 5.0, the ESF Alternatives Study Implementation Plan (ESFASIP) requires the identification of all configuration options and construction methods that have been considered in the past. Describe the method FSN used to achieve this. How can FSN be certain that all options and methods were found? (ITM 010 Task 4)			
T-06		The FSN Task Plan for Task 4 states : "Guidelines will be developed to determine the quality of the concepts identified in the literature survey" Please discuss these guidelines and their application.			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-07		What formal records did FSN keep of ESF options evaluations?			
T-08		During the survey of historical options, were any existing designs excluded from the list of options that would be subjected to the "initial screening process to identify viable options for further evaluation"? (ESFASIP, Executive Summary)			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-09		If some historical designs were excluded, what methodology or criteria were used to reach a decision for exclusion?			
T-10		Was any software (other than basic CADD) used? If so, what documentation is there to demonstrate that the software is suitable for the use?			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-11		Was this proceduralized? What procedure(s)? Are these prodedures technically adequate?			
T-12		What training was given to individuals who performed this work?			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-13		Do the records of the decision process for exclusion of options seem technically complete and defensible? Look at software documentation if software has been used.			
T-14		Did FSN identify any historical options that required refinements? If so, what was the process FSN used to to identify those requiring refinements? What was the process FSN used to identify the refinements needed?			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-15		Was this proceduralized? What procedure? Are these technically adeqaute?			
T-16		What training was given to individuals who performed this work?			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-17		Was any software (other than basic CADD) used? If so, what documentation is there to demonstrate that the software is suitable for the use?			
T-18		Do the records of the process to refine existing options seem technically complete and defensible? Look at software documentation if software has been used.			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-19		What additional options were generated during the course of Task 4? If so, what was the process or methodology for the generation of new options?			
T-20		Was this proceduralized? What procedure(s)? Are these technically adequate ?			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-21		Was any software (other than basic CADD) used? If so, what documentation is there to demonstrate that the software is suitable for the use?			
T-22		What training was given to individuals who performed this work?			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-23		Do the records of the process generate/evaluate new options seem technically complete and defensible? Look at software documentation if software has been used.			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-24		What was the interface between the ESF Alternative Study and the Calico Hills Risk-Benefit Study?			
T-25		What was the impact of the Calico Hills Study (CHS) on the Alteernative Study? Were the results accepted without question or was some validation process employed? If validation was employed, repeat questions on method, criteria, proedure(s), training, and records.			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-26		If CHS resulted in additional options, what methodology/criteria were employed to generate/identify such options?			
T-27		Was this proceduralized? What procedure(s)? Are these technically adequate?			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-28		Was any software (other than basic CADD) used? If so, what documentation is there to demonstrate that the software is suitable for the use?			
T-29		What training was given to individuals who performed this work?			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-30		Was a milestone report or document, or portion thereof, generated as a result Task 4 activity? Is it technically defensible?			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
		ESF Soil and Rock Properties Study Plan, 8.3.1.14.2 Submitted to the Project Office on August 27, 1990.			
T-31		What process did FSN use to determine the extent of the information to be determined?			
T-32		Who will perform the site drilling? USGS, REECo, or a private contractor that specializes in this kind of work? If a private contractor, how will he be procured and how controlled?			

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-33		Section 2.2.3, paragraph 3, as well as several other locations, refers to a "sand cone penetration resistance". If this is not a typographical error, please describe the equipment used and the general test procedure.			
T-34		What involvement will FSN have in the soils portion of the study? What are the qualifications of those involved?			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-35		What involvement will FSN have in the rock portion of the study? What are the qualifications of those involved?			
T-36		The second sentence of 3.1.3 states, "The laboratory soil tests can be conducted on disturbed samples except for the density and porosity tests. These two soil tests will require undisturbed samples." Please clarify the intent of this because porosity is not listed under item 1 of 3.1.2 as one of the parameters to be obtained.			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-37		The first sentence of 3.2.2 and 4.2.2 states, "The data and parameters listed in this section will be collected, evaluated, or both, to fulfill the objectives of this activity". Describe the process planned to implement this statement, especially how data may be only collected or evaluated.			
T-38		The last sentence of the first paragraph of 4.2.3 states, "However, the in situ loading tests can be extrapolated only if properties of the soil or rock are uniform both laterally and with depth, otherwise potential deep-seated settlement resulting from the entire foundation loading will not be recognized from the results of the in situ loading test". Please expand on this concept. What will be done if conditions are not uniform? Modify the field testing? What kind of non-uniform conditions can cause this unrecognized result? Is this statement intended to apply only to pile loading tests, or to plate loading tests also?			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-39		Table VII does not give a reference procedure for plate loading tests. What procedure will be used?			
T--40		In the listing of Study Plan References, a number of the ASTM test methods listed are outdated versions. For example: The first one is listed as ASTM D-1586-67, but the current version is ASTM D-1586-84. The fourth one is listed as ASTM D-421-58, but the current version is ASTM D-421-85. There are other such examples. Does FSN intend that the older versions be followed? If so, please explain why.			

(9) Auditor Signature (10) Date

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(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
T-41		Some of the ASTM titles in the listing of Study Plan References do not agree with those in current ASTM publications. For instance, ASTM 2166-66 is given the title "...Uniaxial Compressive Strength of Rock Materials...", but the current version is ASTM D-2166-85 and is titled "...Unconfined Compressive Strength of Cohesive Soils". This and a number of previous questions related to this study plan seem to indicate that it was sent to the Project Office without being properly checked. Please describe FSN's policy and procedures regarding checking of documents prior to submittal.			

(9) Auditor Signature (10) Date

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
4/89

Completed by Originating QA Organization

1 Date	2 Severity Level ☐ 1 ☐ 2 ☐ 3	Page of
3 Discovered During	3a Identified By	4 SDR No. _____ Rev. _____
5 Organization	6 Person(s) Contacted	7 Response Due Date is 20 Working Days from Date of Transmittal
8 Requirement (Audit Checklist Reference, if Applicable)		
9 Deficiency		
10 Recommended Action(s): ☐ Remedial ☐ Investigative ☐ Corrective		

Aprvl.

11 QAE/Lead Auditor/Date	12 Division Manager/Date	13 Project Quality Mgr./Date

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

18 Signature/Date

Comp. by Orig. QA Org.

19 Response Accepted	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
20 Corrective Action Verif. Satisfactory	QAE/Lead Auditor/Date	Division Manager/Date	Project Quality Mgr./Date
21 Remarks			
22 QA CLOSURE	QAE/Lead Auditor/Date	Division Manager/Date	PQM/Date

YMPO STANDARD DEFICIENCY REPORT
CONTINUATION SHEET

N-QA-038
2/89

SDR No.

Page of

YUCCA MOUNTAIN PROJECT OFFICE

N-QA-012
4/89

[1] YMPO OBSERVATION NO._____

Completed by Originating Organization

[2] Noted During:	[3] Identified By:	[4] Date:
[5] Organization:	[6] Person(s) Contacted:	[7] Response Due Date is 20 Days from Date of Transmittal

[8] Discussion:

[9] QAE/Lead Auditor	Date	[10] Branch Manager	Date

Completed by Respondee

[11] Response:

[12] Signature: Date:

Completed by QA Or...

[13] Response Receipt Acceptable ☐

Initiator	Date	QA/Lead Auditor	Date

[14] Remarks:

YMPO OBSERVATION NO._____
CONTINUATION PAGE

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1/89

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YUCCA MOUNTAIN PROJECT
AUDIT OBSERVER INQUIRY

N-QA-084
4/89

Audit No. _____

Log No. _____

Name _____ Organization _____

YMP Requirement Reference _____

Question/Concern _____

Response _____

_____
Observer's Acknowledgement

Cleared for Submittal to YMP Participant

_____
Lead Auditor / Lead Technical Specialist

☐ *Incorporated in YMP Audit Checklist...Ref* _____

_____
Audit Team Leader

89-3603

Department of Energy
Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

WBS #1.2.9.3
"QA"

MAY 05 1989

Richard L. Bullock
Technical Project Officer for Yucca Mountain Project
Fenix and Scisson of Nevada
101 Convention Center Drive
Phase II, Suite P-250
M/S 403
Las Vegas, NV 89109

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT 89-1 OF FENIX & SCISSON OF NEVADA (FSN) (NN1-1989- 2160)

Reference: Letter, Blaylock to Bullock, dtd. 4/24/89

Enclosed is the report of QA Audit 89-1, which was conducted by the Project Office at the FSN facilities in Las Vegas, Nevada, on April 10, 1989, through April 14, 1989.

During the course of the audit, the audit team generated two Standard Deficiency Reports (SDRs), 313 and 314; 19 Observations; and 7 Recommendations. The SDRs were previously transmitted to you for response (see referenced letter). Copies of the SDRs are enclosed with the audit report for your information.

Written responses to the 19 observations contained in this report are required. These responses are due within 20 working days of the transmittal date of this report. Please address your responses to me and concurrently send a copy of each observation response to Nita J. Brogan of Science Applications International Corporation, Las Vegas, Nevada.

N Voellmer for

James Blaylock
Project Quality Manager
Yucca Mountain Project Office

YMP:JB-3603

Enclosure:
QA Audit 89-1 Report

cc w/o encl:
Ralph Stein, HQ (RW-30) FORS
Dwight Shelor, HQ (RW-3) FORS
M. J. Regenda, FSN, Las Vegas, NV
Stephen Metta, SAIC, Las Vegas, NV
H. H. Caldwell, SAIC, Las Vegas, NV
E. P. Ripley, SAIC, Las Vegas, NV
J. C. Friend, SAIC, Las Vegas, NV
L. G. Scherr, SAIC, Las Vegas, NV
J. J. Brogan, SAIC, Las Vegas, NV
S. W. Zimmerman, NWPO, Carson City, NV
J. W. Gilray, NRC, Las Vegas, NV
J. E. Kennedy, NRC, Washington, DC

PROJECT OFFICE QUALITY ASSURANCE AUDIT REPORT FOR

THE YUCCA MOUNTAIN PROJECT OFFICE AUDIT OF

FENIX & SCISSON, INC.

AUDIT NO. 89-1

Conducted: April 10 - 14, 1989

Prepared By: _____ Date: 4/27/89
John C. Friend,
Lead Auditor

Approved By: _____ Date: 28 Apr 89
Henry H. Caldwell,
Division Manager, Audits

Approved By: _____ Date: 4/28/89
James Blaylock
Project Quality Manager

ENCLOSURE

EXECUTIVE SUMMARY

PROJECT OFFICE AUDIT REPORT NO. 89-1

FENIX & SCISSON, INC. (F&S)

LAS VEGAS, NEVADA

APRIL 10 - 14, 1989

In the opinion of the Project Office Audit Team, the effectiveness of the Quality Assurance (QA) Program at F&S cannot be determined at this time. However, based on the results of the audit, the F&S QA Program appears adequate to support the initiation of Title II design. This is based upon the fact that staffing appears adequate, training is satisfactory, most required procedures are in place, and there are no major outstanding deficiencies.

It should be noted that the F&S QA Program, at this point, is not in total compliance with NNWSI QA Plan 88-9, Revision 2. The areas not in compliance are Procurement and the Software QA Program. In addition, the 19 Observations identified should be an indication that the full program is not yet totally complete. If quality related work governed by the program had been in progress, some of the Observations would have been documented as deficiencies. These Observations should be closely scrutinized and actions taken where necessary.

The effectiveness of the QA program cannot be determined until such time as the program is completed and objective evidence to demonstrate technical adequacy and program implementation can be reviewed.

1.0 Introduction

This report contains the results of a QA Audit of F&S Yucca Mountain Project activities. The audit was conducted at the F&S facilities in Las Vegas, NV, April 10 through 14, 1989. The audit was conducted in accordance with the requirements of QMP-18-01, Revision 3, "Audit System for the Waste Management Project Office." The QA Program requirements to be verified were taken from NNWSI QA Plan 88-9, Revision 2.

2.0 Audit Scope

The purpose of this audit was to evaluate the F&S Quality Assurance Program through verification of implementation of the F&S QAPP, Revision 6 (2/13/89) and its implementing procedures. Additionally, a technical review was performed to determine readiness to start Title II design activities.

3.0 Audit Team Personnel

John Friend	Audit Team Leader/Lead Auditor	SAIC, Las Vegas, NV
Stephen Hans	Auditor	" " "
Stephen Dana	Auditor	" " "
James Clark	Auditor	" " "
Sydney Crawford	Auditor	" " "
Neil Cox	Auditor-In-Training	" " "
Thomas Watson	Technical Specialist	HARZA " "
Thomas Ricketts	Technical Specialist	SAIC, " "
Arthur Watkins	Technical Specialist	" " "
John Gilray	Observer	NRC, Las Vegas, NV
John Peshel	Observer	NRC, Washington, D.C.
Michael Gonzalez	Observer	NRC, " "
Susan Zimmerman	Observer	State of Nevada
Gary Faust	Surveillant	DOE/HQ Weston
Vic Montenyohl	Surveillant	DOE/HQ Weston
Wendell Mansel	Observer	YMP, Las Vegas, NV
Ram Murthy	Observer	YMP, Las Vegas, NV
Edward Cikanek	Observer	HARZA, Las Vegas, NV

4.0 Summary of Audit Results

4.1 Statement of Program Effectiveness

In the opinion of the Project Office Audit Team, the effectiveness of the Quality Assurance Program at F&S cannot be determined at this time. Until such time as the program is completed and objective evidence to demonstrate technical adequacy and program implementation can be reviewed, the effectiveness will remain indeterminate.

However, based on the results of the audit, the F&S QA Program appears to be adequate to support the initiation of Title II design. This is based upon the fact that staffing appears adequate, training is satisfactory, most required procedures are in place, and there are no major outstanding deficiencies.

4.2 Summary of Technical Evaluation

Based upon the responses to the technical questions that the technical specialists asked of Fenix & Scisson, Inc. during the audit, it was concluded that the F&S Quality Assurance program is technically adequate. The F&S design control procedures were reviewed and found to be technically adequate for the performance of Title II design. The F&S design personnel appeared to be well qualified in the specific areas for which they have been assigned design responsibility and had an adequate understanding of their design control procedures. In summation, the technical specialists found no reason to impede F&S from starting Title II design.

4.3 Summary

A total of two Standard Deficiency Reports (SDRs)/(Enclosure 3), and 19 Observations (Enclosure 4) were identified as a result of this audit. In addition, the audit team generated seven Recommendations for consideration by F&S. A synopsis of each SDR and Observation, and the complete Recommendations, are contained in Section 6.0 of this report.

Deficiencies identified by the Project Office are qualified by Severity Level, which is related to the significance of the deficiency. A discussion of Severity Levels is provided in Enclosure 1.

At the time of the audit, one SDR (No. 267) remained open from previous Project Office surveillances and audits. The corrective actions to this SDR could not be verified during the audit. The SDR involves the use of commercial computer software; however, Fenix & Scisson's software QA Program has not yet been approved or implemented.

The following program elements were deemed to meet the requirements of NNWSI/88-9, Revision 2; and F&S QAPP, Revision 6:

1.0 - Organization
2.0 - QA Program
5.0 - Instructions, Procedures, Plans and Drawings
6.0 - Document Control
15.0 - Control of Nonconforming Items
16.0 - Corrective Action
17.0 - Quality Assurance Records
18.0 - Audits

Program elements that are not in total compliance with program requirements are:

3.0 - Scientific Investigation and Design Control

Program elements or portions of elements that are not in compliance with program requirements are:

4.0 - Procurement Document Control
7.0 - Control of Purchased Software QA Program

The following program elements were reviewed during the audit; however, no activities had taken place that would have required these elements to be controlled:

10.0 - Inspection
12.0 - Control of Measuring and Test Equipment

The following program elements were not audited during this audit because they are not currently an F&S responsibility and have been explained in the F&S QAPP:

8.0 - Identification and Control of Items, Samples and Data
9.0 - Control of Processes
11.0 - Test Control
13.0 - Handling, Shipping, and Storage
14.0 - Inspection, Test, and Operating Status

Technical review was limited during this audit to the following:

o Technical Qualifications of Design Personnel
o Understanding of the Design Control Process and Procedural Requirements
o Procedural Adequacy from a Technical Standpoint

5.0 Audit Meetings

5.1 Preaudit Conference

A preaudit conference was held with the F&S Technical Project Officer (TPO) and his staff at 10:00 a.m. on April 10, 1989. The purpose, scope, and proposed agenda for the audit were presented and the audit team was introduced. A list of attendees for this meeting is provided in Enclosure 2.

5.2 Audit Status Meetings

Audit Status Meetings were held with the F&S TPO and his key staff at 8:30 a.m. on April 11, 12, and 14, 1989. A status of how the audit was progressing and identification of discrepancies were discussed daily.

5.3 Postaudit Conference

The postaudit conference was held at 10:00 a.m. on April 14, 1989. A synopsis of the preliminary SDRs and Observations identified during the course of the audit was presented to the TPO and his staff. A list of attendees of this meeting is provided in Enclosure 2.

6.0 Synopsis of SDRs, Observations, and Complete Recommendations

6.1 Standard Deficiency Reports (SDRs)

1. F&S is logging the receipt of transmittals rather than document type as required. Severity Level 2, SDR No. 313.

2. F&S Procedure DC-14, Rev. 7, was issued before all documented reviews were obtained. Severity Level 3, SDR No. 314.

6.2 Observations

1. Channels have not been established at F&S to elevate disputes progressively to the Project Quality Manager. Observation No. 89-1-01.

2. A carefully designed and detailed plan needs to be implemented during shaft and drift blasting that integrates blast design and blast damage assessment activities. The efforts of J. McKenzie (Senior Mining Engineer) and M. Mrugala (Senior Mining Engineer/ Specialist) must be closely integrated in a definite plan. These individuals must work together in the planning and during the blasting operations.

   After operations begin, there must be some flexibility to modify blast design when needed during day-to-day operations without going through a lengthy design process that would not change the overall design basis. Observation No. 89-1-02.

3. A documented policy is needed to establish a hierarchy among the implementing procedures, along with a delineation of the purpose and applicability of each type of procedure. Observation No. 89-1-03.

4. There is no centralized system at F&S to control the preparation and issuance of documents affecting quality. Observation No. 89-1-04.

5. The Subsystem Design Requirements Document (SDRD) draft review versions have been used by F&S as a primary input source for the Basis for Design (BFD). Observation No. 89-1-05.

6. The work authorization and planning process resulting in "Design Scope and Planning Documents" is not procedurally described, and does not require F&S QA review. Observation No. 89-1-06.

7. The BFD, Issue 2, cover sheet does not include provisions for the QA representative's approval signature. Observation No. 89-1-07.

8. Many codes and standards listed in the BFD are not identified by specific year/edition. Observation No. 89-1-08.

9. Reviews of the BFD, Issue 2, which were performed to F&S procedure DC-09, Interdiscipline Review, were not totally conducted as DC-09 requires. The BFD has not received final approval. Observation No. 89-1-09.

10. F&S procedure DC-15, "Basis for Design" program, does not describe the specific format and content for the BFD. Observation No. 89-1-10.

11. F&S procedures DC-14, "Technical Studies," and DC-09 discuss design verification as occurring before interdiscipline review; interdiscipline review occurs prior to design verification. Observation No. 89-1-11.

12. F&S procedure DC-07 does not clearly describe comment documentation and resolution at the check and initial review points for F&S Technical Specifications. Observation No. 89-1-12.

13. F&S performed reviews of the SDRD to DC-09. However, DC-09 does not specifically address the review of the SDRD, and some portions of the procedure are not applicable. Observation No. 89-1-13.

14. F&S Procedure DC-11 does not adequately define responsibilities and control of the Project Control Log. Observation No. 89-1-14.

15. F&S Discrepancy Report DR-10 (6/2/88) does not show independence in that the DR was written against, dispositioned, and verified by virtually the same QA organization. Observation 89-1-15.

16. Trend analysis should be performed on a more timely basis and future Trend Analysis Reports should provide for additional justification as to whether a trend is or is not adverse to quality. Observation No. 89-1-16.

17. F&S has not developed a method to identify what training is required for each person. Current practice is to train personnel in all procedures. Observation No. 89-1-17.

18. Subcontract SC-TS-88-269 did not contain technical requirements as required. This work was done for Title I; however, the contract does require Title II work and must be revised. Observation No. 89-1-18.

19. F&S does not currently have in place sufficient implementing procedures to meet the requirements of Criteria 7, "Control of Purchased Items and Services." Observation 89-1-19.

6.3 Recommendations

Recommendation No. 1

There is a requirement in QAPP-002, Rev. 6, Section 6.0, para. 6.2.2 that a reviewing organization have access to pertinent background data or information upon which to base approval of documents. The required access is difficult to prove by objective evidence; however, it was noted that no information was sent with revised procedures to explain

why changes were necessary or the rationale for the approach taken in the revision. It is recommended that in the future, document review coordinators provide such basic information to assist the reviewers in their evaluation of changed documents.

Recommendation No. 2

In F&S Procedure PP 50-01, Rev. 3, para. 6.8, the F&S Records Coordinator (RC) takes the responsibility for ensuring records have been correctly filmed, despite the verification activities performed by the Microfilm and Archival Storage Services Facility (MASSF). If the F&S RC wishes to confirm microfilming accuracy and/or completeness, the procedure should reflect this activity as a voluntary action rather than a procedural requirement.

Recommendation No. 3

The statements of cause on Corrective Action Reports associated with the deficiency reports examined during the audit were often not clear with respect to the underlying root cause. The statements were often not to the point. For example, a statement implying the "Press of Business" is not as clear as stating "insufficient time Between Release of the YMP Procedure and the Surveillance Date for the available people to update the internal procedure."

The cause statement should be to the point and should serve as the basis for preventing recurrences.

Recommendation No. 4

Design Control procedure DC-03 defines the methods to be used by Fenix and Scisson personnel in performing and documenting Design Analyses. Design Analysis Form LV-308, first sheet, has nine instructions for the originator/discipline engineer (DE) to accomplish. This completed, the discipline engineer is at liberty to proceed with the design based on all of the input required by Form LV-308.

It is suggested changing the procedure such that the Lead Discipline Engineer (LDE) should be required to review and accept the criteria written by the DE. This would ensure that any omissions of codes/ regulations, or any unreasonable assumptions that may have been included, can be assessed for impact to the design by the LDE, rather than the DE completing his calculations and waiting till the interdiscipline review.

Recommendation No. 5

The education requirements for the LDE are less stringent than those of subordinate leads and senior engineer/specialists. It is the opinion of the Technical Specialists that two years of engineering education and

four years of engineering field experience do not provide an adequate educational background for the job responsibilities. To lend additional credibility to the technical decisions, judgments, and approvals of the LDE, it is recommended that the educational requirement for the position be changed to a B.S. in Civil, Mechanical, Structural, or Mining Engineering.

Recommendation No. 6

Based on responses to questions in the Technical Checklist, certain areas are considered to be lacking in personnel knowledge, which would justify the recommendation that refresher training be provided prior to the commencement of Title II design work. These areas are interface control and configuration management. Due to the importance of the subject matter that these procedures control, it is recommended that such training be provided to all design personnel for the following procedures: DC-05, DC-25, DC-26, DC-27, and DC-28.

Recommendation No. 7

In DC-04, Design Verification, the following two sentences should be deleted: "In those cases, where this timing cannot be met, the portion or portions of design which have not been verified shall be identified and controlled. In all cases, the verification shall be completed prior to relying on the component, system, or structure to perform its function." The reasons for this deletion are (1) to remove the contradiction with the Section 2.0, Applicability, and (2) to avoid the possibility of compromising the site's ability to meet its site characterization or repository performance requirements and objectives. This compromise could occur by prematurely or improperly performing construction activities at the site in accordance with the unverified designs. This change would not violate the QAP, since the deletion of these two sentences makes the verification requirements more stringent, not less.

7.0 Required Action

A written response is required for each SDR delineated in Section 6.0. Responses to each SDR are due 20 working days from the date of the SDR transmittal letter. Upon response, acceptance, and satisfactory verification of all remedial and corrective actions, the SDRs will be closed and F&S will be notified by letter of closure.

A written response is required for the 19 Observations contained in Enclosure 4 of this report. Responses are due 20 working days after the transmittal letter of this report.

Written responses are not required for the recommendations contained in this report. The recommendations were generated by the audit team for the F&S staff to consider during implementation of its QA Program.

ENCLOSURE 1

Severity Levels

Severity Level 1

Significant deficiencies considered of major importance. These deficiencies require remedial, investigative, and corrective actions to prevent recurrence.

Severity Level 2

A deficiency which is not of major importance, but may also require remedial, investigative, and/or corrective action to prevent recurrence.

Severity Level 3

A minor deficiency in that only remedial action is required. These deficiencies are generally isolated in nature or have a very limited scope. In addition, the integrity of the end result of the activity is not affected nor does the deficiency affect the ability to achieve those results.

ENCLOSURE 2

ATTENDEES

AUDIT REPORT S89-1

ENCLOSURE 2

NAME	TITLE	ORGANIZATION	PREAUDIT	DURING AUDIT	POSTAUDIT
Arshad, Ali	Sr. QA Engineer	F&S	X	X	X
Blaylock, Jim	Project QA Manager	DOE/YMP	X		X
Bolling, Pat	Div./H. Resources	F&S	X	X	X
Booth, Henry W.	Sr. QA Proc. Spec.	F&S	X	X	X
Bullock, R. L.	Sr. Project Manager	F&S	X	X	X
Burns, Allan	Observer	SAIC			X
Caldwell, Henry H.	Manager, Audit Div.	SAIC	X		
Chytrowski, B. R.	Project Design Manager	F&S	X	X	X
Cikanek, Edward	Observer	HARZA	X		X
Clark, James E.	QA Auditor	SAIC	X		X
Cocoros, A. E.	Sr. QA Engineer	F&S	X		
Cox, Neil D.	AIT	SAIC	X		X
Crawford, Sidney	QA Auditor	SAIC	X		X
Cross, Jack A.	General Manager	F&S	X		X
Dana, Stephen	QA Auditor	SAIC	X		X
Edwards, Roxanne	Engineer	DOE			X
Faust, Gary L.	HQ Surv. Lead	Weston	X		X
Furguson, J. E.	Sr. Rec. Spec.	F&S	X	X	X
Garms, Bill	Sr. Project Engineer	F&S	X	X	
Gelinger, T. H.	Chief Comp. Serv.	F&S		X	X
Gilray, John	On-Site Rep., Observer	NRC	X		X
Gonzales, M. R.	Observer	NRC	X		X
Graves, B. J.	Manager Administration	F&S	X	X	X
Grenis, James D.	Lead Design	F&S/PB	X	X	X
Hale, Paul B.	QA Specialist	F&S	X	X	X
Hampton, Catherine	QA Specialist	DOE			X
Hans, Stephen	QA Auditor	SAIC	X		X
Jacocks, Harry L.	Dir. Procurement	F&S	X	X	
Johnson, Janet	Sr. QA Engineer	F&S		X	X
Kratzinger, Frank	Observer	SAIC			X
Mansel, Wendell B.	Observer	DOE/YMP	X		X
McConville, James	Tech. Spec. Trainee	HARZA	X		
Metta, Stephen	QA	SAIC	X		X
Mika, Deborah L.	Personnel Admin.	F&S	X	X	X

AUDIT REPORT S89-1

ENCLOSURE 2

(Continued)

NAME	TITLE	ORGANIZATION	PREAUDIT	DURING AUDIT	POSTAUDIT
Mirza, Mahmood B.	Config. Cont. Manager	F&S		X	X
Montenyohl, Vic	Surveillant	Weston	X		X
Morrison, Gary L.	Cont./Proc. Specialist	F&S		X	X
Murthy, Ram B.	Observer	DOE	X		X
Pershel, John	Observer	NRC	X		X
Prestholt, Paul	On-Site Representative	NRC			X
Regenda, Michael	Manager QA	F&S	X	X	X
Ricketts, Tom	Technical Specialist	SAIC	X		X
Rue, Joseph L.	QA Coordinator	F&S		X	X
Ruth, Frederick J.	QA Engineer	SAIC			X
Sanchez, Nickie	Personnel Specialist	F&S	X	X	X
Tunney, D. J.	Director QA Engineer	F&S	X	X	X
Walkins, Arthur	Technical Specialist	SAIC	X		X
Watson, Tom	Technical Specialist	HARZA	X		X
Wilson, Matt	YMP Admin. Manager	F&S	X	X	X
Zimmerman, Susan	QA Manager	State of Nevada	X		X

ENCLOSURE 3

SDRs

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
12/88

Completed by Originating QA Organization

1 Date 4/11/89	2 Severity Level ☐ 1 ☐ 2 ☒ 3	Page 1 of 1

3 Discovered During Audit 89-1	3a Identified By J. E. Clark	3b Branch Chief Concurrence Date	4 SDR No. 314 Rev. 0

5 Organization Fenix & Scisson	6 Persons(s) Contacted J. May, J. Rue	7 Response Due Date is 20 Working Days from Date of Transmittal

8 Requirement (Audit Checklist Reference, If Applicable)
Checklist Item 6-4, NNWSI 88-9, Rev. 2, Sec. 6, Par. 2.1, states, "Changes to documents shall be reviewed and approved by the same organization that performed the original review and approval..."

9 Deficiency
Evidence was discovered that indicated issuance of DC-14, Rev. 7 was made before a documented review by all reviewers of the previous revision. The above requirement was therefore violated.

10 Recommended Action(s): ☒ Remedial ☐ Investigative ☒ Corrective

1. Assure that personnel are trained to prevent this condition from recurring.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
4/18/89	18 Apr 89	4/18/89

Completed by Organization In Block 9

14 Remedial/Investigative Actions(s)

15 Effective Date _____

16 Cause of the Condition & Corrective Action to Prevent Reacurrence

17 Effective Date _____

18 Signature/Date

Comp. by Orig. QA Org.

19 Response	☐ Accept ☐ Reject ☐ Amended Response	QAE/Lead Auditor/Date	Branch Manager/Date
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☐ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date	Branch Manager/Date

22 Remarks

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date

YMPO STANDARD DEFICIENCY REPORT

N-QA-038
12/88

Completed by Originating QA Organization

1 Date 4/13/89	2 Severity Level ☐ 1 ☒ 2 ☐ 3	Page 1 of 2	
3 Discovered During Audit 89-1	3a Identified By J. E. Clark	3b Branch Chief Concurrence Date	4 SDR No. 313 Rev. 0
5 Organization Fenix & Scisson	6 Persons(s) Contacted J. E. Ferguson, Y. Hendricks	7 Response Due Date is 20 Working Days from Date of Transmittal	

8 Requirement (Audit Checklist Reference, If Applicable)
Checklist Item 17-1, F&S Procedures PP-50-01, Rev. 3, states in part "Upon receipt, the F&S Records Center Coordinator performs the following receipt/control tasks: a. Identifies the document as a required record per the

9 Deficiency
Contrary to the above requirement, F&S is logging the receipt of transmittals rather than document type as required by procedure.

10 Recommended Action(s): ☒ Remedial ☒ Investigative ☒ Corrective

1. Initiate logging activities per procedure requirements.
2. Investigate to determine impact on retrievability.

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
4/18/89	4/18/89	4/18/89

Completed by Organization in Block 5

14 Remedial/Investigative Actions(s)

15 Effective Date _____

16 Cause of the Condition & Corrective Action to Prevent Reacurrence

17 Effective Date _____

18 Signature/Date

Comp. by Orig. QA Org.

19 Response	☐ Accept ☐ Reject ☐ Amended Response	QAE/Lead Auditor/Date	Branch Manager/Date
20 Amended Response	☐ Accept ☐ Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☐ Satisfactory ☐ Unsatisfactory	QAE/Lead Auditor/Date	Branch Manager/Date

22 Remarks

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date

6 Persons contacted (continued)

8 Requirement (continued)

document type list and logs in receipt..."

10 Recommended Actions (continued)

3. Train personnel in more stringent receipt control measures.

ENCLOSURE 4
OBSERVATIONS

WMPO OBSERVATION NO. 89-1-01

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
QA Audit 89-1	Stephen P. Hans	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 20 Days from Date of Transmittal**
Fenix & Scisson	Dan Tunney	

Discussion:

No channels have been established at F & S to elevate disputes progressively to the YMP, PQM.

Reference: NNWSI 88-9, Rev. 2, Sec. 1, Par. 2.2

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature]	25 Apr 89

Completed By Responsible Org.

Response:

Signature: **Date:**

Completed By QA Org.

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

WMPO OBSERVATION NO. 89-1-02

N-QA-012
8/88

Noted During:	Identified By:	Date:
QA Audit 89-1	Tom Ricketts	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 20 Days from Date of Transmittal**
Fenix & Scisson	J. McKenzie and M. Mrugala	

Discussion:

A major concern of NRC is the damage around the shaft and underground openings produced by blasting during excavation. This can create man-made preferential pathways for fluid flow and the possible transport and release of radionuclides in the environment. Once the excavation is completed, the blast damage effects remain, and thus they need to be controlled in order to not compromise the site. Blasting can also affect the results of site characterization testing if it is not done carefully and if its effects are not well understood.

QAE/Lead Auditor	Date	Branch Manager	Date
John C. Linn	4/25/89	[illegible]	25 Apr 89

Completed by Originating QA Organization

Response:

Signature: **Date:**

Completed By Resp. #

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

Completed By QA Org.

Thus, it is necessary that a carefully designed and detailed plan be implemented during shaft and drift blasting that integrates blast design and blast damage assessment activities. This plan basically consists of conducting a blast(s), performing blast damage assessment measurements and then using these damage zone results to modify the blast design before the next round(s) are conducted. This process should be done on a frequent basis to insure damage is not being produced as rock properties or other site conditions change. In addition, a strict quality control program should be implemented on the drill/blast process, as well as, the explosives and detonators.

This concern translates to the fact that the efforts of J. McKenzie and M. Mrugala must be closely integrated, not only by words, but in a definite plan and by areas of responsibility defined by management. These individuals must work together both in the planning and during the blasting operations for the plan to be successful. F&S may choose to set up a working group of experts to help formulate and review the planning phase and even evaluate the results of blast damage measurements during operations. The identification of a damage assessment method or a correlation of damage zone to peak particle velocity will be difficult and suggests the use of a highly qualified and somewhat diverse working group.

Once operations commence, there is the additional concern that the blasting engineer will not have the flexibility to modify the blasting design without going through what could be a timely change control process. This needs to be thought out so that shaft sinking operations are not brought to a standstill. This concern is, at least partly, tied to the blasting specifications which need to be very carefully formulated to allow some latitude of minor design changes during day-to-day operations without going through the change control process, and would not change the overall design basis. The specifications also need to reflect the blast damage assessment issue so a blast design change will be required when a certain blast damage parameter value is exceeded.

WMPO OBSERVATION NO. 89-1-03

N-QA-012
8/88

Noted During:	Identified By:	Date:
QA Audit 89-1	J. E. Clark	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 30 Days from Date of Transmittal**
Fenix & Scisson	J. Rue, J. May, D. Tunney	

Completed by Originating QA Organization

Discussion:

There are discrepant conclusions drawn among F&S QA personnel regarding the relative purposes and applications of QAPs, PPs, and DCs. These procedures constitute the F&S QA Program implementing documents, yet there was no consistent explanation as to how and to whom each type of procedure applies. A documented policy is needed to establish a hierarchy among the implementing procedures, along with a delineation of the purpose and applicability of each type of procedure.

QAE/Lead Auditor	Date	Branch Manager	Date
John C Trimm	4/25/89	A A Caldwell	25 Apr 89

Completed By Responsible Organization

Response:

Signature: **Date:**

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Completed By QA Org.

Remarks:

WMPO OBSERVATION NO. 89-1-04

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
QA Audit 89-1	J. E. Clark	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 20 Days from Date of Transmittal**
Fenix & Scisson	J. Rue, J. May, B. Chytrowski	

Discussion:

There is no centralized system at F&S to control the preparation and issuance of documents affecting quality. It is recognized that document control activities are handled by several essentially identical procedures in separate work functions, but a single procedure prescribing a standard method for controlling all quality affecting documents would provide greater consistency, and simplify procedure revision and training.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature]	25 Apr 89

Completed By Resp. Org.

Response:

Signature: **Date:**

Completed By QA Org.

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

WMPO OBSERVATION NO. 89-1-05

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
Audit 89-1	S. Crawford	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 20 Days from Date of Transmittal**
Fenix & Scisson	J. Grenia/B. Chytrowski	

Discussion:

The Subsystem Design Requirements Document (SDRD) has been prepared in draft review versions, but has not been formally received by F&S as Design Basis Information (logged, controlled QA record, etc.) because the SDRD had not been approved by the Project Office. Nonetheless, F&S has used the SDRD, Benchmark 3 (1/23/89) as a primary input source for the Basis for Design (BFD), Issue 2 document. Furthermore, SDRD, Benchmark 4 (1/31/89) has been used by F&S to update the BFD.

QAE/Lead Auditor	Date	Branch Manager	Date
J Grenia	4/25/89	R J Caldwell	25 Apr 89

Completed by Responsible Organization

Response:

Signature: **Date:**

Completed By QA Org.

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

WMPO OBSERVATION NO. 89-1-06

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
Audit 89-1	S. Crawford	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 20 Days from Date of Transmittal**
Fenix & Scisson	J. Grenia/A. Ali/B. Chytrowski	

Discussion:

The work authorization and planning process, resulting in "Design Scope and Planning Documents", is not procedurally described, and does not require F&S QA review of the Design Scope and Planning Documents. Although work scope and Qa Levels may be determined by other documents including WBS Dictionary, QA Level Assignment Sheets, Basis for Design Document, etc., the scoping and planning documents should be subject to QA review.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature]	25 Apr 89

Completed By Respo...se

Response:

Signature: **Date:**

Completed By QA Org.

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

WMPO OBSERVATION NO. 89-1-07

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
Audit 89-1	S. Crawford	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 20 Days from Date of Transmittal**
Fenix & Scisson	J. Grenia/A. Ali/B. Chytrowski	

Discussion:

The Basis for Design Document, Issue 2, Cover Sheet (draft) does not include provision for QAR approval signature, a procedurally required action.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature]	25 Apr 89

Completed By Resp.

Response:

Signature: **Date:**

Completed By QA Org.

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

WMPO OBSERVATION NO. 89-1-08

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
Audit 89-1	S. Crawford	4/14/89
Organization: Fenix & Scisson	**Person(s) Contacted:** J. Grenia/B. Chytrowski	**Response Due Date is 20 Days from Date of Transmittal**

Discussion:

Many codes and standards listed in the BFD are not identified by specific year/edition, although a few (notably ACI standards) have been listed with specific year. The BFD should reflect actual editions of codes and standards to be used for design basis.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature]	25 Apr 89

Completed By Responder

Response:

Signature: **Date:**

Completed By QA Org.

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

WMPO OBSERVATION NO. 89-1-09

N-QA-012
8/88

Noted During:	Identified By:	Date:
QA Audit 89-1	S. Crawford	4/14/89
Organization: Fenix & Scisson	**Person(s) Contacted:** J. Grenia/B. Chytrowski	**Response Due Date is 30 Days from Date of Transmittal**

Completed by Originating QA Organization

Discussion: BFD (Issue 2) was reviewed by F&S for updates resulting from SDRD Benchmark 4; the review was performed to the provisions of DC-09, Interdiscipline Review. The review was documented using a Review Comment Record (RCR), Form LV-317 instead of the Document Review Notice (DRN), form LV-316, identified in DC-09. The reviews were not logged in the Project Control Logs, either the Review Comment Record Log or on the Document Review Notice Log. Although the BFD is not finally approved, the review comments and resolution are a part of the quality record base for the BFD and should be logged in the Project Control Logs.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature]	25 Apr 89

Completed by Responsible Organization

Response:

Signature: **Date:**

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Completed by QA Org.

Remarks:

WMPO OBSERVATION NO. 89-1-10

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
QA Audit 89-1	S. Crawford	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 30 Days from Date of Transmittal**
Fenix & Scisson	J. Grenia/B. Chytrowski	

Discussion:

Design procedure DC-15 describes the "Basis for Design" program and provides administration provisions for the control of the BFD document. However, DC-15 does not describe specific format and content provisions for the BFD, e.g., boundaries and interfaces; applicable codes, standards, and regulations; functional requirements; performance criteria; constraints; and assumptions. The preliminary BFD, Issue 2, did contain the above information.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature] Caldwell	25 Apr 89

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Response:

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QAE/Lead Auditor	Date	Branch Manager	Date

Completed By QA Org.

Remarks:

WMPO OBSERVATION NO. 89-1-11

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
QA Audit 89-1	S. Crawford	4/14/89
Organization: Fenix & Scisson	**Person(s) Contacted:** J. Grenia/B. Chytrowski	**Response Due Date is 20 Days from Date of Transmittal**

Discussion:

DC-14, Technical Studies (Par. 6.5.2 and 6.5.4) and DC-09, Interdiscipline Review (Par. 6.1.2) discuss design verification as occurring before interdiscipline review; interdiscipline review occurs prior to design verification.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature]	25 Apr 89

Completed By Resp. Org.

Response:

Signature: **Date:**

Completed By QA Org.

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

WMPO OBSERVATION NO. 89-1-12

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
QA Audit 89-1	S. Crawford	4/14/89
Organization: Fenix & Scisson	**Person(s) Contacted:** J. Grenia/B. Chytrowski	**Response Due Date is 30 Days from Date of Transmittal**

Discussion:

Design Procedure DC-07 describes measures for preparation, review, and approval for F&S Technical Specifications (Construction and Performance). DC-07 does not clearly describe comment documentation and comment resolution at the check and initial review points; requirements to retain review comments and resolutions as QA records is not noted; Specification Engineer signoff shown on Attachment 1 of the procedure is not described in the body of the procedure.

QAE/Lead Auditor	Date	Branch Manager	Date
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Signature: **Date:**

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QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

WMPO OBSERVATION NO. 89-1-13

N-QA-012
8/88

Noted During:	Identified By:	Date:
QA Audit 89-1	S. Crawford	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 30 Days from Date of Transmittal**
Fenix & Scisson	D. Bullock	

Completed by Originating QA Organization

Discussion:

As part of its internal review of the Subsystems Design Requirements Document (SDRD), F&S performed a review of the SDRD to F&S procedure DC-09, "Interdiscipline Review." However, DC-09 does not specifically address review of the SDRD. For example, Par. 1.0, "Scope", states, "The Purpose of this procedure is to describe the interdiscipline review system that is employed on this project for technical design products," and Par. 4.1, states "Technical Work Products - These products consist of design drawings, technical specifications, technical reports, and design analysis."

QAE/Lead Auditor	Date	Branch Manager	Date
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QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

The definition for a technical work product does not include or reference the SDRD. In addition, sections of this procedure would not be applicable for review of the SDRD. For example: (1) Par. 6.1.2 states that, "All technical work products shall be complete and checked in accordance with the requirements of DC-03 before beginning the inter-discipline review process; (2) Par. 6.2.2, 2nd paragraph, states, "If interdiscipline review is not necessary...". If F&S intends to continue use of DC-09 for review of the SDRD, the procedure definition for a technical work product should be revised to include the SDRD; and, the procedure should be revised (e.g., Section 6.1, "General") to exclude those portions of the procedure that are not applicable to review of the SDRD.

WMPO OBSERVATION NO. 89-1-14

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
QA Audit 89-1	S. Dana	4/14/89
Organization: Fenix & Scisson	**Person(s) Contacted:** A. Ali/J. Grenia	**Response Due Date is 30 Days from Date of Transmittal**

Discussion:

F&S Procedure DC-11, Rev. 6, Par. 6.1.2, states, "The external source Review and Comment transmittals are recorded in the Project Control Log Book and forwarded to the PM or his designee for action." The Review and Comment transmittals are being recorded in the Incoming Correspondence Log, not the Project control Log. The Project Control Log contains a number of other logs (e.g., Document Review Notice Log, Comment Control Program Log,

QAE/Lead Auditor	Date	Branch Manager	Date
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QAE/Lead Auditor	Date	Branch Manager	Date

Closed By QA Org.

Remarks:

Review Comment Log, Design Sheet Log, Review Comment Record Log, Design Interface Control Log, Specification Log), which some of the logs (identified above) are designated as QA records. If F&S intends for the Project Control Log to incorporate the logs mentioned above within a single binder, the procedure should be revised to reflect the intended usage of the Log. In addition, no procedure was found that identified responsibilities for control of the Project Control Log.

WMPO OBSERVATION NO. 89-1-15

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
QA Audit 89-1	S. Dana	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 30 Days from Date of Transmittal**
Fenix & Scisson	D. Tunney/J. Johnson	

Discussion:

F&S DR-010, written 6/2/88 by J. Johnson, documents, (1) No PP-60-01 presentation of the F&S QAPP, REV. 3, and (2) the Manager, Technical Support did not attend the indoctrination and training class. The initial DR response was provided by M. Regenda, an amended response was provided by D. Tunney (for M. Regenda), and the DR was closed by D. Tunney (3/6/89). All individuals involved in the initiation, response to, and closure of DR-010 are QA personnel, even though part 1 of the DR, QAPP training, was and still is the responsibility of F&S QA.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature]	25 Apr 89

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QAE/Lead Auditor	Date	Branch Manager	Date

Completed By QA Org.

Remarks:

To assure independence of areas for which QA has direct responsibility, F&S should detail how it plans to handle audits/surveillances relative to QAPP training in the future and resolution of DRs in areas for which they have responsibility.

WMPO OBSERVATION NO. 89-1-16

N-QA-012
8/88

Noted During:	Identified By:	Date:
QA Audit 89-1	S. Dana	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 30 Days from Date of Transmittal**
Fenix & Scisson	D. Tunney	

Completed by Originating QA Organization

Discussion:

1. F&S Procedure QAP-16.3(N), "Trend Analysis," states that trend analysis shall be performed on a yearly basis. It is recommended that the procedure be revised so that trend analysis can be performed more frequently (e.g., quarterly). This will ensure if an adverse trend is identified, immediate actions can be taken to correct the condition. Considering the many tasks involved in Title II design, it would be advantageous to identify an adverse trend before it is allowed to continue from one task to another.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature]	25 Apr 89

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Response:

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Reviewed By QA Org.

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QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

2. The F&S Trend Analysis Report, dtd. 3/28/89, does not go into sufficient detail explaining why the trends identified are not adverse to quality. The report stated that, "A Corrective Action Request is not required for these since this is the first analysis..." . The analysis covered the period from 5/86 - 2/89 with a sample-size (population) of 143 (deficiency reports). Two areas were identified as comprising 29% (procedure violation) and 31% (Inadequate/ incomplete procedures) of the total population. The above would indicate that 2 1/2 years with a sample-size of 143 is sufficient data to conclude whether the trends are adverse to quality or not.

   It is recommended that future Trend Analysis Reports provide additional justification whether a trend is or is not adverse to quality.

WMPO OBSERVATION NO. 89-1-17

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
QA Audit 89-1	Stephen P. Hans	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 30 Days from Date of Transmittal**
Fenix & Scisson	Joe Rue	

Discussion:

F&S has not developed a method to identify the training needs of personnel to gain the required proficiency prior to performing quality affecting work. The current practice is to train all engineers to all DC. This practice, however, does not address interaction between QA & Engineering, and DC training for QA personnel, nor has interaction with Project Procedures been established.

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QAE/Lead Auditor	Date	Branch Manager	Date

Completed By QA Org.

Remarks:

WMPO OBSERVATION NO. 89-1-18

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
QA Audit 89-1	Stephen P. Hans	4/14/89
Organization:	**Person(s) Contacted:**	**Response Due Date is 30 Days from Date of Transmittal**
Fenix & Scisson	H. Jacocks	

Discussion:

A review of subcontract SC-TS-88-269, Arthur D. Little, Inc., revealed that no technical requirements, Right of Access or Documentation Requirements had been established or referenced in the subcontract. This work was accomplished during Title I; therefore, an SDR is not appropriate. However, the subcontract does include a specific Title II scope of work. Should the specific scope of work be accomplished in Title II without a modification of the subcontract, a violation of the requirements would result.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature]	25 Apr 89

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QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

WMPO OBSERVATION NO. 89-1-19

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
QA Audit 89-1	Stephen P. Hans	4/14/89
Organization: Fenix & Scisson	**Person(s) Contacted:** Dan Tunney	**Response Due Date is 30 Days from Date of Transmittal**

Discussion:

F&S does not currently have in place sufficient implementing procedures to meet the requirements of Criteria F; "Control of Purchased Items and Services." This fact is established in F&S letter: YMP 1238, dtd. 3/24/89, J. A. Cross to K. Gertz. Since no QA Level I or II procurement activity has taken place to date, a SDR is not appropriate. However, if QA Level I or II procurements are processed without a modification to current implementing procedures, a violation of the requirement would result. This problem has been previously identifed on F&S DR-044.

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	4/25/89	[signature] Caldwell	25 Apr 89

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Response:

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QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

Department of Energy
Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

APR 24 1989

WBS #1.2.9.3
"QA"

QA RECEIVED

Richard L. Bullock
Technical Project Officer for Yucca Mountain Project
Fenix & Scisson, Inc.
101 Convention Center Drive
Phase II, Suite P-250
M/S 403
Las Vegas, NV 89109

ISSUANCE OF STANDARD DEFICIENCY REPORTS (SDRs) 313 AND 314, RESULTING FROM YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE) QUALITY ASSURANCE (QA) AUDIT 89-1 OF FENIX & SCISSON, INC. (F&S) (NN1-1989-2018)

Enclosed are SDRs 313 and 314, generated as a result of Project Office QA Audit 89-1 of F&S.

Please identify the corrective actions to be taken and implemented to correct the deficiencies by completing blocks 14 through 18, as appropriate, on each SDR.

Responses to the SDRs are due within 20 working days of the date of this letter. Any extension to these due dates must be requested in writing with appropriate justification prior to the due date. Please send the original of your responses to Nita Brogan, Science Applications International Corporation, 101 Convention Center Drive, Las Vegas, Nevada, 89109, and a copy to Ralph Gray, U.S. Department of Energy, P. O. Box 98518, Las Vegas, Nevada, 89193.

Your cooperation and timely response is appreciated. If you have any questions, please contact Wendell B. Mansel of my staff at 794-7945, or John C. Friend of Science Applications International Corporation at 794-7164.

James Blaylock
Project Quality Manager
Yucca Mountain Project Office

YMP:WBM-3442

Enclosure:
SDRs 313 and 314

BACKUP INFORMATION

cc w/encl:
J. J. Brogan, SAIC, Las Vegas, NV
L. G. Scherr, SAIC, Las Vegas, NV
J. C. Friend, SAIC, Las Vegas, NV

cc w/o encl:
Ralph Stein, HQ (RW-30) FORS
Dwight Shelor, HQ (RW-3) FORS
M. J. Regenda, F&S, Las Vegas, NV
H. H. Caldwell, SAIC, Las Vegas, NV
E. P. Ripley, SAIC, Las Vegas, NV
J. W. Gilray, NRC, Las Vegas, NV