

YUCCA MOUNTAIN PROJECT DOCUMENT TRANSMITTAL/ACKNOWLEDGMENT RECORD

Y-AD-075
09/88

TO: BELKE W L
NRC
1717 H STREET N.W.
4H-3
WASHINGTON, DC 20555-0000

FROM: Science Applications International Corp.
Document Control Center
101 Convention Center Drive
Suite 407, Mail Stop 517/T-34
Las Vegas, Nevada 89109
FTS 544-7810 or (702) 794-7810

TRANSMITTAL DATE: March 28, 1990

COPY NUMBER: 223

DOCUMENT TITLE: YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM PLAN

DOCUMENT REVISION: 3

DOCUMENT IDENTIFICATION NUMBER: YMPO/88-1

DIRECTIONS

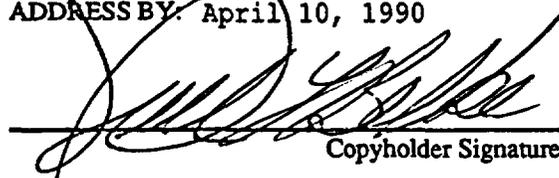
NOTE - THE FOLLOWING CHANGES WILL TAKE PLACE ONLY IN THE QUALITY ASSURANCE PROGRAM PLAN AND NOT IN THE QUALITY MANAGEMENT PROCEDURES.

REPLACE - The following pages with newly revised pages effective 03/20/90. The overall revision level of this plan is now Revision 3.

- Title Page.
- Signature Page.
- Preface.
- Policy Statement.
- Table of Contents.
- Section I.
- Section II.
- Section III.
- Section IV.
- Section V.
- Section XII.
- Section XV.
- Section XVI.
- Section XVIII.

cc: Study Oversight etc

SIGN AND DATE BELOW TO CONFIRM THAT THE ABOVE DIRECTIONS HAVE BEEN FOLLOWED. RETURN THIS TRANSMITTAL RECORD, WITH THE OBSOLETE MATERIAL, AS APPROPRIATE, TO THE ABOVE ADDRESS BY: April 10, 1990



Copyholder Signature

4/2/90

Date

<<< FOR DOCUMENT CONTROL CENTER USE ONLY >>>

OBSOLETE MATERIAL RECEIVED:

DCC Personnel Initials

Date

102.7
WM-11

9004030280 900319
PDR WASTE
WM-11 PDC

FULL TEXT ASCII SCAN

ADD: WBelke, 4H-3

NH03

*ENCLOSURE
IN JACKET
YMPO/88-1 A&U3*

YUCCA MOUNTAIN PROJECT
DOCUMENT TRANSMITTAL/ACKNOWLEDGMENT RECORD

Y-AD-075
09/88

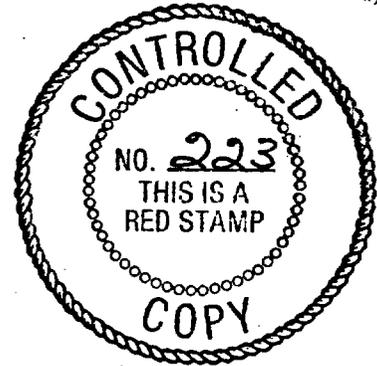
DIRECTIONS
(CONTINUED)

Appendix A.
Appendix E.

- (*) Destroy or mark obsolete material "Superseded"
- () Return obsolete material with this transmittal record
- () New issue - no obsolete material

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89



**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

YMPO/88-1

REVISION 3

UNITED STATES DEPARTMENT OF ENERGY

NEVADA OPERATIONS OFFICE

LAS VEGAS, NV

ISSUED FOR INTERIM USE PENDING OCRWM APPROVAL

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
3	3/20/90	TITLE PAGE	i-1

Rec'd. w/tr. dtd. 3/19/90
Accession No. 9004030380

YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN

N-QA-045
5/89

YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN

YMPO/88-1

REVISION 3

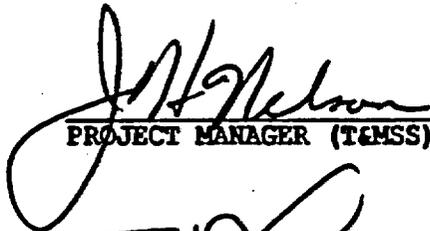
APPROVAL/SIGNATURE PAGE


PROJECT MANAGER, YUCCA MOUNTAIN PROJECT OFFICE

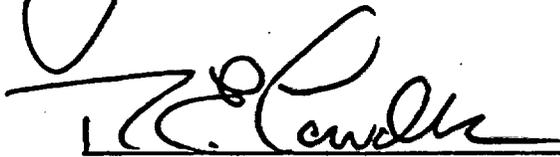
3/19/90
DATE


YUCCA MOUNTAIN PROJECT OFFICE
DIRECTOR, QUALITY ASSURANCE

3/19/90
DATE


PROJECT MANAGER (T&MS)

3/19/90
DATE


TECHNICAL PROJECT OFFICER (MACTEC)

3/19/90
DATE

OCRAM DIRECTOR, OFFICE OF
QUALITY ASSURANCE

DATE

Effective Date: 3/20/90

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
3	3/20/90	SIGNATURE PAGE	ii-1

PREFACE

This document is the seventh edition of the U. S. Department of Energy Yucca Mountain Project Office (Project Office) Quality Assurance Program Plan (QAPP). This document has been revised to reflect the latest organizational structure, to delete the application of quality levels I, II, and III previously delineated throughout this document, and to change the title of Project Quality Manager (PQM) to Director, Quality Assurance. It has also been revised to delete reference to a revised Project Office procedural system which was described in the Preface of the previous revision of the QAPP. In addition, the term Waste Management Project Office (WMPO) is superseded by Yucca Mountain Project Office (Project Office).

The Project Office QAPP was developed from the Quality Assurance (QA) requirements which are described in the Yucca Mountain Project (YMP) Quality Assurance Plan (QAP). These requirements are imposed on the YMP by the Office of Civilian Radioactive Waste Management (OCRWM); and the U. S. Nuclear Regulatory Commission (NRC). Accordingly, this document establishes the QA requirements that are applicable to the Project Office in performing its functions and responsibilities for the YMP.

3

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
3	3/20/90	PREFACE	iii-1

YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN

N-QA-045
5/89

POLICY STATEMENT

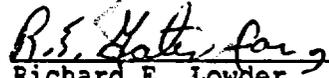
It is the policy of the U. S. Department of Energy, through OCRWM, that the achievement of quality in fulfilling the responsibilities of the Yucca Mountain Project (YMP) is essential to success and is of the highest priority in the conduct of our activities. To meet this objective, we must establish effective networks of management plans and procedural controls and take the necessary actions to demonstrate to the public, our ability to safely and efficiently handle and dispose of spent nuclear fuel and high-level radioactive waste. Concurrently, we must demonstrate compliance with legislative, regulatory, and DOE requirements for control and documentaion of quality. The establishment and implementation of the Yucca Mountain Project Office (Project Office) Quality Assurance Program Plan (QAPP) will provide the Project Office, Science Applications International Corporation/Technical and Management Support services (SAIC/T&MSS) management, and Mac Technical Services (MACTEC) with the controls necessary to verify compliance with the licensing and regulatory commitments that govern the Project Office.

In order to meet our management responsibilities for achieving and ensuring quality, OCRWM has established the Project Office and delegated appropriate authority to the Project Manager, YMP, for the management and direction of the YMP. The Project Manager, YMP, has direct primary responsibility and accountability for the execution and implementation of the QAPP in accordance with the Project Charter, Project Management Plan, and the Project Office QAP.

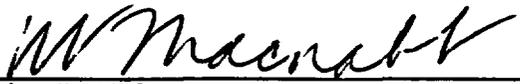
The Project Office has developed the Project Office QAPP, YMPO/88-1, in accordance with the requirements of the YMP QAP. To meet YMP QA requirements, this document establishes a framework for consistency in the development of quality-related implementing procedures at all levels within the Project Office. The requirements of this document, which are mandatory, apply to personnel from the Project Office, SAIC/T&MSS, Mac Technical Services, and DOE Nevada Operations Office (DOE/NV) matrix support personnel, who perform quality-related activities which support the YMP.



Carl P. Gertz
Project Manager, DOE/Yucca Mountain
Project Office



Richard E. Lowder
Technical Project Officer,
Mac Technical Services



John H. Nelson
Project Manager,
Technical and Management
Support Services

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	POLICY STATEMENT	iv-1

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

YMPO/88-1

REVISION 3

TABLE OF CONTENTS

<u>Section</u>	<u>Title</u> Title Page	<u>Revision</u>	<u>Effective</u> <u>Date</u>	<u>Page</u>
		3	3/20/90	i
	Signature Page	3	3/20/90	ii
	Preface	3	3/20/90	iii
	Policy Statement	2	3/20/90	iv
	Table of Contents	3	3/20/90	v
I	Organization	2	3/20/90	I-1
II	Yucca Mountain Project Office Quality Assurance Program	2	3/20/90	II-1
III	Scientific Investigation Control and Design Control	2	3/20/90	III-1
IV	Procurement Document Control	2	3/20/90	IV-1
V	Instructions, Procedures, Plans, and Drawings	2	3/20/90	V-1
VI	Document Control	1	4/20/89	VI-1
VII	Control of Project Office Purchased Items and Services	1	4/20/89	VII-1
VIII	Identification and Control of Items, Samples, and Data	1	4/20/89	VIII-1
IX	Control of Processes	1	4/20/89	IX-1
X	Inspection	1	4/20/89	X-1
XI	Test Control	1	4/20/89	XI-1
XII	Control of Measuring and Test Equipment	2	3/20/90	XII-1
XIII	Handling, Shipping, and Storage	1	4/20/89	XIII-1

REV. NO. 3	ISSUED 3/20/90	SECTION TITLE TABLE OF CONTENTS	PAGE NO. v-1
---------------	-------------------	------------------------------------	-----------------

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

<u>Section</u>	<u>Title</u>	<u>Revision</u>	<u>Effective Date</u>	<u>Page</u>
XIV	Inspection Test, and Operating Status	1	4/20/89	XIV-1
XV	Control of Nonconforming Items	2	3/20/90	XV-1
XVI	Corrective Action	2	3/20/90	XVI-1
XVII	Quality Assurance Records	1	4/20/89	XVII-1
XVIII	Audits	2	3/20/90	XVIII-1
Appendix A	Terms and Definitions	2	3/20/90	A-1
Appendix B	List of Typical QA Records	1	4/20/89	B-1
Appendix C	Requirements for Qualification of Existing Data	1	4/20/89	C-1
Appendix D	Requirements for Computer Systems	1	4/20/89	D-1
Appendix E	Requirements for the Identification of Items and Activities Subject to Quality Assurance Requirements	2	3/20/90	E-1
Appendix F	Requirements for Peer Review	1	4/20/89	F-1
Appendix G	SCP Study Plans	1	4/20/89	G-1

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

SECTION I

ORGANIZATION

1.0 GENERAL

The Nuclear Waste Policy Act of 1982 (NWPA) established within the Department of Energy (DOE) an Office of Civilian Radioactive Waste Management (OCRWM) and specified that the office should be headed by a Director, to be appointed by the President, by and with the advice and consent of the Senate. The Act further specified that the Director should be responsible for carrying out the functions of the Secretary of Energy under the Act, and should report directly to the Secretary. Subsequently, the Nuclear Waste Amendments Act of 1987 named the Yucca Mountain site in the State of Nevada as the sole site for study.

The responsibility for implementing the requirements for the Yucca Mountain geologic repository and site investigation which are described in the Yucca Mountain Project (YMP) Quality Assurance Plan (88-9), rests with the DOE Project Office at Las Vegas, Nevada. The Director, OCRWM, established the YMP and has assigned a Project Manager to carry out those responsibilities.

2.0 INTRODUCTION

This section describes the lines of reporting of the DOE Yucca Mountain Project Office (Project Office) to OCRWM; the organizational responsibilities and interfaces of each of the organizations making up the Project Office. It also describes the responsibilities and interfaces of each of the YMP participants as they interface with the Project Office in the execution of the duties associated with the geologic repository and site investigation activities.

3.0 YUCCA MOUNTAIN PROJECT ORGANIZATION

3.1 PRIMARY PARTICIPANTS

The Yucca Mountain Project Organization is comprised of the DOE Project Office including its matrixed personnel from the DOE Nevada Operations Office (DOE/NV), its integrating contractor, Science Applications International Corporation - Technical & Management Support Services (SAIC/T&MSS), and support contractor MAC Technical Services Company (MACTEC). In addition to these organizations, there are primary participants who perform specialized services for the Project Office. Their responsibilities are described in their own QA program documents. These primary participants are:

- (a) Los Alamos National Laboratory (LANL)

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-1

2

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- (b) Lawrence Livermore National Laboratory (LLNL)
- (c) United States Geological Survey (USGS)
- (d) Sandia National Laboratories (SNL)
- (e) Fenix & Scisson of Nevada, Incorporated (FSN)
- (f) Holmes and Narver, Incorporated (H&N)
- (g) Reynolds Electrical and Engineering Company (REECO)
- (h) SAIC/T&MSS units performing direct geologic repository & site investigation activities

3.1.1 DOE/NV matrix support personnel and MACTEC fall under the auspices of this Quality Assurance Program Plan (QAPP) in their implementation of quality requirements. SAIC/T&MSS utilizes this QAPP to implement quality requirements with the exception of those quality affecting activities which are identified as SAIC/T&MSS's sole responsibility as a primary participant.

3.1.2 Each of these primary participants noted in para. 3.1 is required to develop and implement a QA program that (1) meets all applicable requirements identified in the YMP Quality Assurance Plan (88-9), and reflects applicable Project-wide QA systems or methods specified by the Project Office.

Each of the above organizations, except the DOE YMP Project Office, is represented in its interfaces with the Project Manager by a Technical Project Officer (TPO). For the purposes of this project, each TPO is the accountable officer of the organization that is represented.

3.1.3 An organizational chart depicting the Yucca Mountain Project is provided in Figure 1 of this Section.

3.2 PROJECT OFFICE ORGANIZATION

The Project Office organization reporting to the YMP Project Manager comprises the following organizational entities:

- (a) Engineering and Development Division
- (b) Regulatory and Site Evaluation Division
- (c) Project and Operations Control Division

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-2

2

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- (d) Project Office Quality Assurance
- (e) DOE/NV Matrixed Support Personnel
- (F) SAIC/T&MSS
- (g) MAC Technical Services Company (MACTEC)

An organizational chart depicting the Project Office is provided in Figure 2 of this Section.

The Project Office establishes Project policy within the constraints of requirements set forth in NWPAs, licensing regulations and DOE policy and provides Project management direction, guidance, and overview. The Project Office has sole responsibility and authority for authorization of work, management and technical direction of the activities of the primary participating organizations through the issuance of technical and programmatic guidance, technical integration of the Project, Project planning and documentation, and QA programmatic guidance. In addition, the Project Office is responsible for conducting the technical activities described under the responsibilities of the appropriate Project Office Division Director. The Project Manager holds each DOE Project Office Division Director responsible for assuring effective implementation of the Project quality assurance program within the Director's scope of delegated responsibility and authority.

3.2.1 YMP PROJECT MANAGER

The Project Manager reports to the OCRWM Associate Director, Office of Facility Siting and Development (OFSD). The Project Manager has overall authority, responsibility, and accountability for Project cost, schedule, technical and quality performance. The following responsibilities directly affecting the Project quality assurance program are specifically included:

- a. Interprets program policies and guidance and provides Project policies and guidance for the management of the Yucca Mountain Project.
- b. Directs the primary participants and other supporting contractors in the technical Project management.
- c. Approves the YMP Quality Assurance Plan as well as this QAPP.
- d. Approves other Project Plans as necessary to establish the basis for orderly achievement of Project technical and quality objectives,

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-3

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- e. Assures adequate staffing and funding for essential technical and quality assurance activities,
- f. Assures effective line implementation of the Project quality assurance program,
- g. Monitors quality assurance program implementation on an ongoing basis and taking remedial action as necessary, and
- h. Initiates formal assessments at least annually, by management above or outside the Project Office Quality Assurance organization, for overall effectiveness of the Project quality assurance program, and takes corrective action as necessary.

3.2.1.1 The Director, Engineering and Development Division, has Project management responsibility for direction, guidance, and overview of:

- a. Systems engineering, including the Systems Engineering Management Plan and systems integration,
- b. Establishment and maintenance of system requirements,
- c. Integration of geologic repository and site investigation activities,
- d. Design and development for the waste package,
- e. Design and development for the repository,
- f. Engineering testing and equipment development, and
- g. Exploratory Shaft Facility planning, design, and construction.

3.2.1.2 The Director, Regulatory and Site Evaluation Division, has been assigned Project management responsibility for direction, guidance, and overview of:

- a. Geologic repository and site investigation requirements development, planning, data collection and analysis,
- b. Field testing,
- c. Performance assessment,
- d. Development, operation, and modification of computer codes for site characterization,

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-4

2

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- e. Development and operation of technical data and reference information data bases,
- f. Sample management,
- g. Nuclear Regulatory Commission (NRC) interactions, including site visits, workshops, Appendix 7 meetings, review of regulations, and preparation or coordination of Project reports required by the NRC, licensing regulation, and agreements with the NRC, and
- h. Geotechnical interactions with the public and with professional and technical organizations.
- i. The preliminary analysis and evaluations of Project technical reports and performance assessment calculations.
- j. The development and application of site models.

3.2.1.3 The Director, Project and Operations Control Division, has Project responsibility for direction, guidance and overview of:

- a. Management controls including planning, management systems and procedures, and Project status,
- b. Work definition (Work Breakdown Structure) and work authorization,
- c. Project integration,
- d. Project capital procurement, land access, and acquisition,
- e. Project environmental program, including geologic repository and site investigation plan and environmental and socioeconomic monitoring and mitigation plans.
- f. Analysis of social and economic impacts of Project activities,
- g. Project transportation program, and
- h. Project records and information management system.

3.2.1.4 The Director, Project Office Quality Assurance

The Project Office QA Organization, under the leadership of the Director, QA, has Project Office responsibility for:

2

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-5

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- a. Ensuring that the Project Office QA program as well as the primary participants QA programs are established and executed effectively and of verifying such as by overview, monitoring, auditing and surveillance, that activities affecting quality functions have been correctly performed.
- b. Providing for the development, documentation, administration, interpretation and implementation of the QA programmatic requirements documents, and changes thereto specifically the YMP Quality Assurance Plan and this QAPP.
- c. Reviewing and approving the primary participants QA program plans or manuals.
- d. Reviewing and approving YMP documents which describe activities affecting quality.
- e. Operation of the Project quality concerns and allegations resolution programs.
- f. Quality assurance systems improvement.
- g. Supporting the Project Office Division Directors in their implementation of the quality assurance program.

The Director, Quality Assurance, reports to the OCRWM Director, Quality Assurance. The Director, QA, has direct access to other Division Directors and the Project Manager relative to quality issues. This position has no other duties or responsibilities unrelated to QA that would preclude full attention to QA matters.

3.2.1.5 QUALITY ASSURANCE ORGANIZATION

The Project Office Quality Assurance organization is staffed by quality assurance personnel from DOE, SAIC/T&MSS, and MACTEC. The Director, Quality Assurance, has apportioned quality assurance management overview responsibilities functionally between Verification and Quality Assurance Systems. DOE quality assurance staff, responsible to the Director, has been assigned the lead in each function, and is directly supported by dedicated personnel from SAIC/T&MSS and MACTEC, who have been integrated into the two functions. The Project Office Quality Assurance Organization is depicted in Figure 3 of this Section.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-6

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

A. Verification

The Verification function is responsible to the Director for the following:

- a. Internal Project Office audits and Project Office audits of Project participants and suppliers,
- b. Quality Assurance participation in supplier surveys, selection, and evaluations,
- c. Overview of Project participant audit, surveillance, and corrective action effectiveness.
- d. Corrective action (CARs, SDRs, NCRs) status, follow-up, and close-out,
- e. Software quality assurance audit and surveillance,
- f. Trending program input,
- g. Quality assurance training program input,
- h. Quality assurance responses to NRC observations and audit reports, and
- i. Interface with other governmental agencies (i.e., NRC, OCRWM, State of Nevada, etc.) with respect to audit and surveillance-related matters.

B. Quality Assurance Systems

The Quality Assurance Systems function is responsible to the Director for:

- a. Preparation and review of quality assurance program planning, direction, and implementation documents (QAP, QAPP, QMPs),
- b. Review of Project Office quality-affecting documents (BTPs and APQs) and recommendation for Director approval or disapproval,
- c. Review of Project participant quality assurance programs and recommendation for Director approval or disapproval,
- d. Review of software quality assurance programs and recommendation for Director approval or disapproval,

2

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-7

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- e. Review of the quality assurance programs of Project Office suppliers and recommendation for Director approval or disapproval,
- f. Review and approval of quality-related procurement document packages
- g. Follow-up and close-out of quality-related NRC open items,
- h. Corrective action tracking system,
- i. Project Office readiness review support, as needed,
- j. Review and approval of dispositions of Project Office-initiated Standard Deficiency Reports (SDRs),
- k. Coordination, development, and maintenance of quality assurance training programs,
- l. Establishment of quality-related Project hold points,
- m. Establishment and overview of Project quality assurance trending programs and evaluation of trends,
- n. Auditor qualification files, and
- o. Interface with other governmental agencies (e.g., NRC, DOD, OCRWM, state of Nevada, etc.) on quality assurance systems matters.

3.2.1.6 DOE/NV MATRIXED SUPPORT PERSONNEL

A. Nevada Test Site Office (NTSO)

The NTSO provides matrix support personnel functionally responsible to the Project Office for field direction and coordination of the Nuclear Test Site (NTS) support contractor operations, including architect-engineering, drilling, mining, construction, and logistical support for work performed at the NTS. The NTSO acts on requests for NTS support contractor services submitted by participating organizations through Project Office and provides assistance to other Project participants in areas of specialized expertise.

B. Health Physics and Environmental Division (HP&ED)

Upon the request of the Project Office, the HP&ED may provide matrix support personnel to the Project Office and are responsible

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-8

2

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

for review of procedures, facility designs, and operations plans applicable to radiological monitoring of the environment, radiological health of the public and radiological workers, compliance with environmental laws, and radiological operations of the DOE/NV, its contractors, or the national laboratories at NTS. The HP&ED acts on requests for support submitted by participating organizations through Project Office and provides document reviews, advice, and assistance to the Project Office.

C. Safety and Health Division (S&HD)

Upon the request of the Project Office, the S&HD may provide matrix support personnel to the Project Office and is responsible for review of procedures, facility designs, and operations plans applicable to the occupational health and industrial and fire safety of site workers and facilities. The S&HD acts on requests for support submitted by participating organizations through Project Office and provides document reviews, advice, and assistance to the Project Office.

D. Contracts and Property Division (CPD)

Upon the request of the Project Office, the CPD may provide matrix support personnel to the Project Office and is responsible for preparing and negotiating contracts and other agreements with the national laboratories and other federal agencies (except the NRC for which DOE Headquarters (HQ) is responsible) on behalf of the DOE/NV in support of the YMP. The CPD acts on requests for support submitted by the Project Office and provides procurement package reviews, advice, and assistance to the Project Office.

E. Personnel and Industrial Relations Division

The Project Office relies on the DOE/NV Personnel and Industrial Relations Division to provide personnel for Project Office DOE positions and to verify that such personnel meet applicable position qualification requirements defined by the Project Office.

3.2.2 SAIC/T&MSS ORGANIZATION

3.2.2.1 PROJECT MANAGER, T&MSS

The Project Manager, T&MSS, reports directly to the Project Manager, Project Office. The Project Manager, T&MSS, has administrative authority over T&MSS personnel assigned to the Yucca Mountain Project. This position is responsible for the performance of the following SAIC/T&MSS activities in support of the Project Office.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-9

2

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- a. Planning and directing activities.
- b. Complying with the requirements of work assignments performed by T&MSS for the Project Office.
- c. Meeting staffing, cost and schedule, and deliverable requirements.
- d. Approving and implementing the Project Office QAPP and its implementing procedures for assigned quality related activities and items.
- e. Implementing quality related YMP Administrative Procedures.
- f. Serving as the primary contact with the Project Office and the primary spokesman for T&MSS.
- g. Implementing corrective actions for deficiencies relating to assigned quality related activities and items.

3.2.2.2 The SAIC/T&MSS organization (hereinafter referred as T&MSS) is comprised of a Deputy Project Manager; five Offices of Assistant Project Managers (APMs); an Office of Institutional and External Affairs and a Quality Assurance Manager reporting to the T&MSS Project Manager. The Quality Assurance Manager administers the T&MSS quality assurance program specific to T&MSS scope of work as described in the T&MSS QAPP. During the transition to full participant status, Project Office QA performs quality assurance functions for T&MSS QA as necessary. Upon completion of the transition, this arrangement will expire (i.e., upon approval of the T&MSS Quality Assurance Program Description).

The Offices of Assistant Project Managers (APMs) consist of:

- (a) APM, Project Management
- (b) APM, Technical Support
- (c) APM, Regulatory and Licensing Support
- (d) APM, Programs and Operations
- (e) APM, Resource Management

T&MSS is the integrating contractor for Project Office and provides broad technical, operational, and managerial support for YMP activities. T&MSS efforts involve both the direct provision of technical, scientific and institutional expertise, and the management and integration of support provided by all Project participants in connection with planning, design, field investigations, laboratory work, construction, regulatory, licensing and institutional activities related to the YMP.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-10

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

SAIC/T&MSS assists the Project Office in such areas as (a) the identification and analysis of, and compliance with applicable statutory, regulatory, and program requirements, (b) the Project Procedure development and execution of Project management plans and strategies, (c) the monitoring and coordination of work performed by Project participants, including the review of their work for completeness, technical sufficiency, and compliance with Project requirements, (d) the preparation of assigned management, technical, and scientific reports and studies, (e) presentations to the public, the program office, and affected federal, state, and other agencies, on Project positions, plans, and other Project related information, (f) the execution, on an assigned basis, of any of the activities specified by the OCRWM approved work breakdown structure (WBS), and (g) primary data-gathering activities in such areas as socioeconomics, meteorology, radiological monitoring and air quality, and other assistance as requested by the Project Office, (h) records management and (i) training.

The Deputy Project Manager assists the Project Manager as required and acts in the capacity of the Project Manager during his absence or at the explicit direction of the Project Manager.

3.2.3 MAC TECHNICAL SERVICES COMPANY (MACTEC)

MACTEC, who is headed by a Technical Project Officer, (TPO) provides support functions to the Project Office which include:

- a. Assistance in development and implementation of the Project quality assurance program,
- b. Assistance in development and implementation of the YMP quality verification process,
- c. Assistance in the assessment and implementation of Project Management Systems, Engineering Systems, Licensing Systems, and processes for Project Management and Information Resources Management, and
- d. Providing similar support requested by the Project Office for other Project participants in areas of MACTEC special expertise.

3.3 PRIMARY PARTICIPANTS SUPPORTING THE PROJECT OFFICE

The primary participants supporting the Project Office for geologic repository and site investigation activities are:

- (a) Los Alamos National Laboratory (LANL)

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-11

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- (b) Lawrence Livermore National Laboratory (LLNL)
- (c) United States Geological Survey (USGS)
- (d) Sandia National Laboratories (SNL)
- (e) Fenix and Scisson of Nevada, Inc. (FSN)
- (f) Holmes and Narver, Inc. (H&N)
- (g) Reynolds Electrical and Engineering Company (REECO)
- (h) SAIC/T&MSS units involved in direct performance of technical work specified by the Project Office

3.3.1 Los Alamos National Laboratory (LANL)

LANL has prime responsibility, subject to Project Office management direction and guidance, for:

- a. The function of lead technical organization for coordination and scheduling of the exploratory shaft testing program,
- b. Nuclide migration studies,
- c. Geochemistry studies,
- d. Mineralogy and petrology studies,
- e. Design of the integrated data acquisition system for the exploratory shaft facility, and
- f. Assistance to other Project participants in areas of LANL special expertise.

3.3.2 Lawrence Livermore National Laboratory (LLNL)

LLNL has prime responsibility, subject to Project Office management direction and guidance, for:

- a. Definition of the waste package environment,
- b. Waste package material development and testing,
- c. Waste package design, performance analysis, and testing, and
- d. Assistance to other Project participants in areas of LLNL special expertise.

2

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-12

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

3.3.3 United States Geological Survey (USGS)

The USGS has prime responsibility, under Project Office management direction and guidance, for:

- a. Acting as lead technical participant for site characterization drilling activities,
- b. Site characterization of geology, hydrology, tectonism, volcanism, and seismicity, and
- c. Assistance to other Project participants in areas of USGS special expertise.

3.3.4 Sandia National Laboratories (SNL)

SNL has prime responsibility, subject to Project Office management direction and guidance, for the following:

- a. Repository systems development,
- b. Repository conceptual design,
- c. Data management and analysis,
- d. Systems performance assessment of the repository,
- e. Determination of thermal properties of the host rock,
- f. Repository sealing performance requirements, materials evaluation, design, and testing, and
- g. Assistance to other YMP participants in SNL areas of special expertise.

3.3.5 Fenix & Scisson of Nevada (FSN)

FSN is the Exploratory Shaft Facility architect/engineer for drilling and mining for the Project. FSN has prime responsibility, subject to Project Office management direction and guidance, for:

- a. Exploratory shaft subsurface design,
- b. Subsurface facilities construction and testing, and
- c. Field surveillance and inspection of drilling and mining.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-13

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

3.3.6 Holmes & Narver, Inc. (H&N)

H&N is the Exploratory Shaft Facility architect/engineer for subsurface support systems and surface facilities. H&N has prime responsibility, subject to Project Office management direction and guidance, for:

- a. ESF subsurface support systems design,
- b. ESF surface facilities,
- c. Field surveillance and inspection of construction activities,
- d. Material test laboratory support,
- e. Nondestructive examination services,
- f. Field surveying,
- g. Microfilming and archival storage of YMP Project records.

3.3.7 Reynolds Electrical and Engineering Company (REECO)

REECO is the support contractor for the site. REECO has prime responsibility, subject to Project Office management direction and guidance, for:

- a. ESF surface and subsurface construction, drilling, and mining,
- b. Operation and maintenance of site facilities, except the YMP Sample Management Facility, and
- c. Procurement and logistical services for the Project as requested.

3.3.8 SAIC/T&MSS Primary Participant Role

SAIC/T&MSS has prime responsibility in their primary participant role, subject to Project Office management direction and guidance, for:

- a. Geotechnical services,
- b. Transportation, land access, and socioeconomic studies,
- c. Environmental, meteorological, and radiological monitoring, and field programs,

2

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-14

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- d. Performance of peer reviews,
- e. Procurement of items/services purchased by SAIC/T&MSS,
- f. Records management,
- g. Such other field and study programs as directed by the Project Office.

3.4 QUALITY ASSURANCE ORGANIZATIONAL STATUS

3.4.1 Independence

The Project Office Director, Quality Assurance, and the Project Office Quality Assurance staff, occupy dedicated positions. Their assigned responsibilities include none that preclude full attention to Project quality assurance issues.

Quality Assurance personnel 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 approved 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.

The reporting levels that have been established give the QA organizations direct access to responsible management at a level where appropriate action can be effected and have appropriate authority and organizational freedom, including independence from cost and schedule when opposed to safety and waste isolation-related concerns.

3.4.2 STOP WORK AUTHORITY

Stop work authority is implicitly vested in line management throughout the Project for situations in which eminent danger to personnel is identified, or where it is determined that continued work will produce results that cannot be used in support of Project objectives.

In addition, authority to cause work to be stopped, through management channels specified by procedures, is explicitly vested in members of Project QA organizations if the work is being performed contrary to or in the absence of prescribed controls or approved methods, and if further work would make it difficult or impossible to establish acceptability of the results.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-15

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

The Project Manager and the Director, Quality Assurance, shall be notified immediately of any Stop Work on the Project. Notification is expected to include parameters of work stopped and the intended criteria for resumption of work. The Project Manager reserves the authority to require that work be resumed only upon his approval. Stop Work Orders and the resulting corrective action documents are Project QA records.

3.4.3 RESOLUTION OF DISPUTES INVOLVING QUALITY

Disputes or disagreements involving differences of opinion between Project Office QA personnel and other Division personnel of the Project, and involve quality assurance matters, are elevated through the respective management channels of the disputants to a level where agreement can be reached, up to and including OCRWM. Project-wide procedures establish the mechanism(s) for dispute resolution.

3.5 INTERFACES

3.5.1 BETWEEN THE PROJECT OFFICE AND OCRWM

The primary interface between OCRWM and the Project Office in the establishment and execution of the Project QA program involves the Office of Facility Siting and Development (OFSD).

- a. The Project Office Project Manager interfaces directly with and reports to the Director, OFSD. Technical and administrative information is shared through this interface.
- b. The Project Office Director, Quality Assurance, reports to the OCRWM Director, Quality Assurance. Information relative to quality affecting activities and items are shared in this medium.
- c. Those OFSD functions that are executed both by OCRWM and the Project Office have their interfaces and parameters of responsibility procedurally documented and controlled.

3.5.2 BETWEEN PROJECT OFFICE AND THE PROJECT PARTICIPANTS

The Project Office relies on its primary participants to carry out specific and designated assignments. The interfaces that exist by which technical information is shared is through the Project Office Project Manager and each participant's Technical Project Officer (TPO). The sharing of quality assurance information is executed through the interface of the Project Office Division Director, Quality Assurance and the top level of quality management of each participant.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-16

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

When responsibilities for assignment cross organizational boundaries, (i.e., Project Office with a participant(s)) the interfaces and execution of work are appropriately described and procedurally controlled.

3.5.3 BETWEEN AND AMONG PROJECT PARTICIPANTS

The interfaces for sharing information between and among participants is with each respective TPO. Each participant communicates with each other to ensure effective transition and minimum overlap of responsibilities and work assignments. Each TPO shall apprise the Project Office Project Manager of activities that cross participant boundaries.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	ORGANIZATION	I-17

2

YUCCA MOUNTAIN PROJECT ORGANIZATION

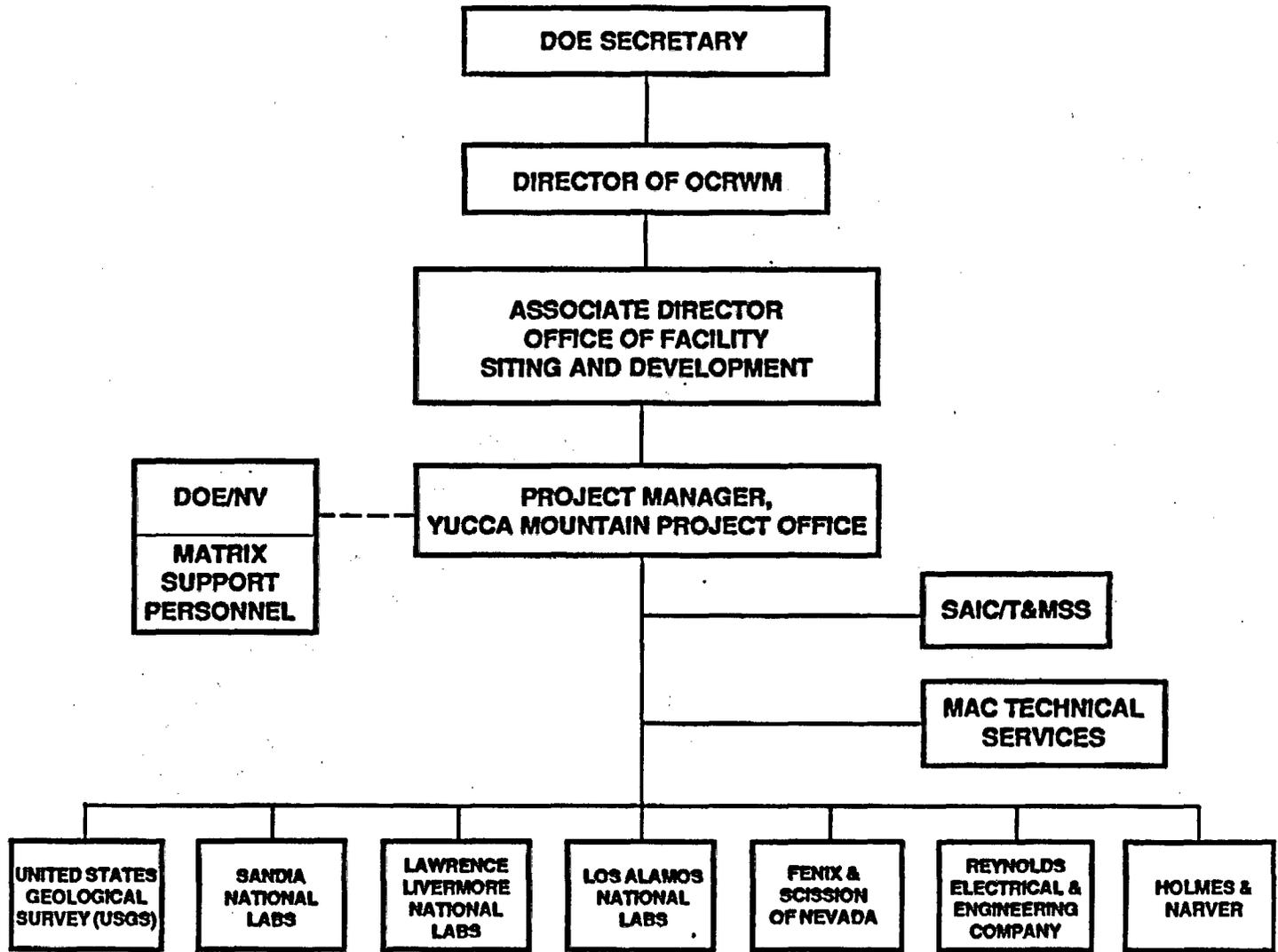


Figure 1

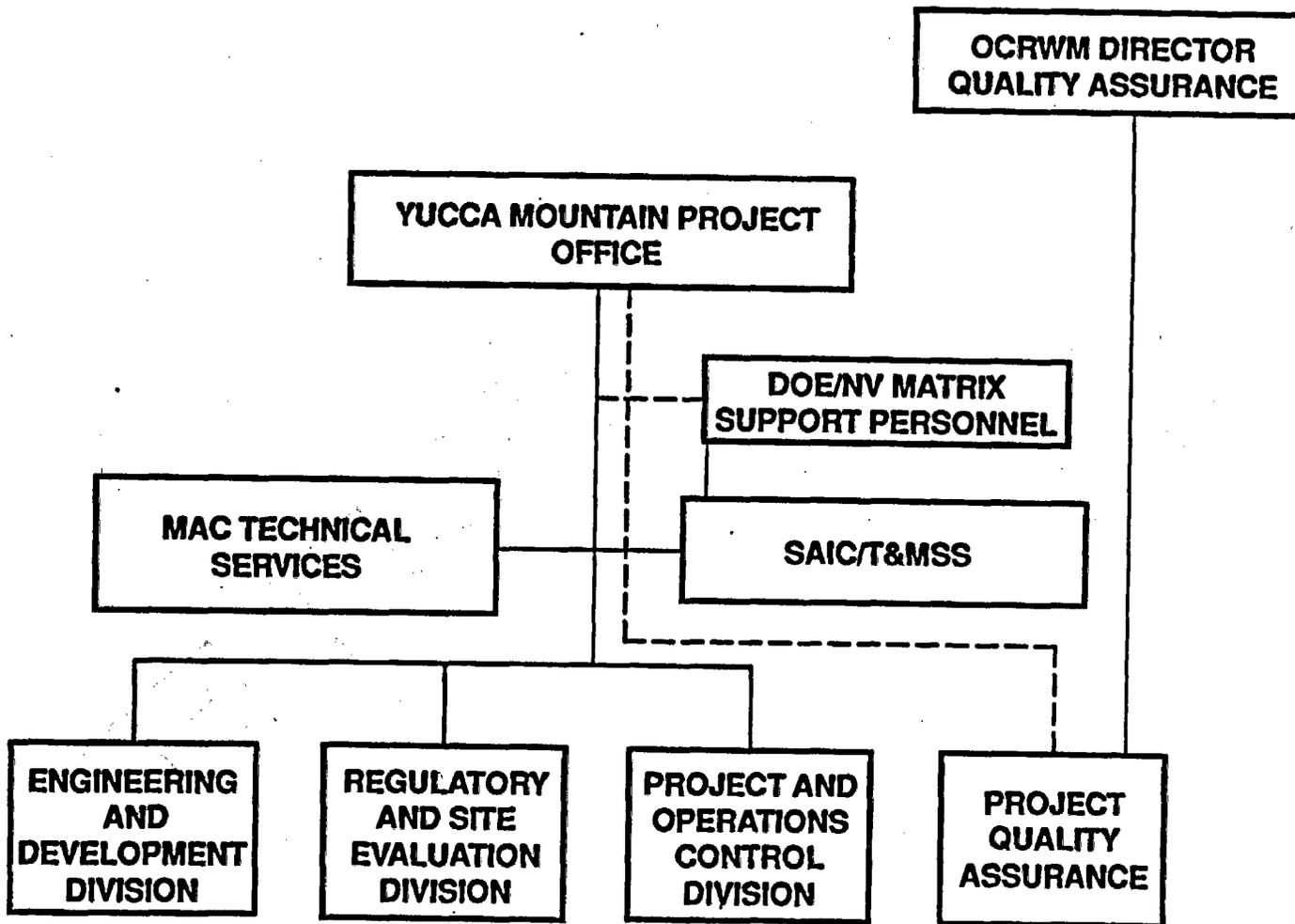
YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN

N-QA-045
5/89

YMPORGSP.A35/3-10-90

REV. NO. 2
ISSUED 3/20/90
SECTION TITLE ORGANIZATION
PAGE NO. I-18

PROJECT OFFICE ORGANIZATION



YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN

Figure 2

N-QA-045
5/89

REV. NO.
2

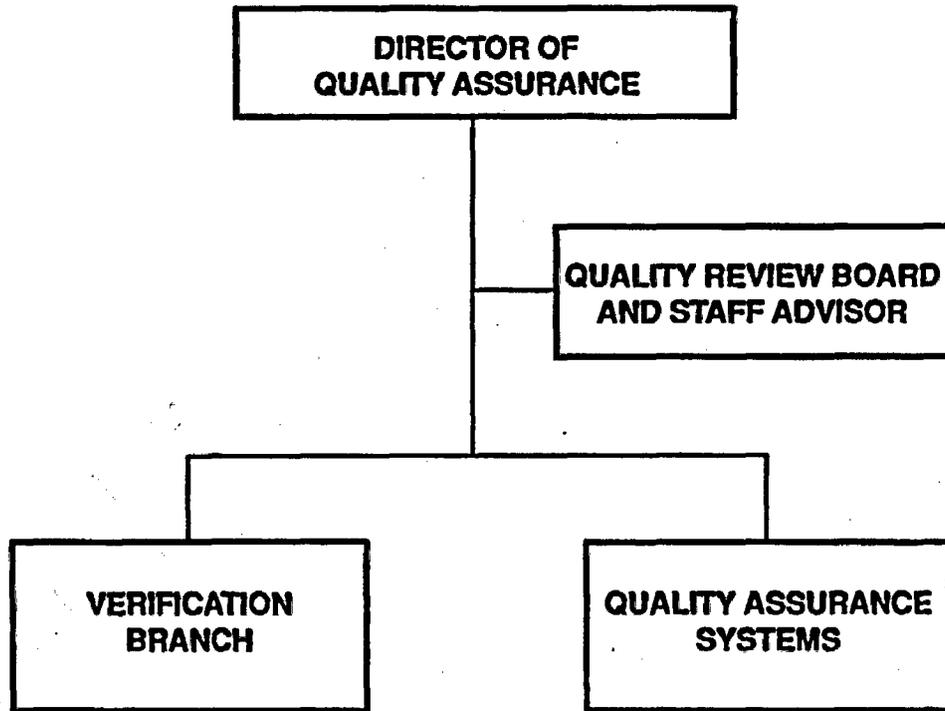
ISSUED
3/20/90

SECTION TITLE
ORGANIZATION

PAGE NO.
I-19

Figure 3

PROJECT OFFICE QUALITY ASSURANCE ORGANIZATION



YMPORG9P.A35/3-6-90

REV. NO.
2

ISSUED
3/20/90

SECTION TITLE
ORGANIZATION

PAGE NO.
I-20

YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM PLAN

N-QA-045
5/89

SECTION II

PROJECT OFFICE QUALITY ASSURANCE PROGRAM

1.0 PROJECT OFFICE QUALITY ASSURANCE PROGRAM DOCUMENTATION

The Yucca Mountain Project Office (Project Office) Quality Assurance (QA) Program for the YMP is documented in the Project Office Quality Assurance Program Plan (QAPP), Project Office Quality Management Procedures (QMP), Branch Technical Procedures (BTP), and quality related YMP Administrative Procedures (APQs). These documents are further described below.

1.1 THE PROJECT OFFICE QA PROGRAM PLAN (QAPP)

The Project Office has developed this Quality Assurance Program Plan, WMPO/88-1 (formerly NVO-196-18), which provides the description of the QA program and indicates commitment to the applicable YMP QA requirements defined in the YMP QAP. The QA criteria and specific requirements associated with regulatory documents and the YMP QAP are addressed in the Project Office QAPP. QA criteria not applicable to a Project Office activity is noted in the QAPP with justification of its exception. A checklist based on the YMP QAP has been completed which identifies how and where each requirement is addressed within this document. The Project Office QAPP includes consideration of the technical aspects of those activities affecting quality that are the responsibility of the Project Office and has been developed by the Project Office QA Organization with assistance from the Project Office technical staff. The Project Office QAPP provides instruction for implementing and applying the QA requirements to the technical activities of the YMP that are within the Project Office scope of work. The Project Office QAPP is implemented and maintained in accordance with the YMP QAP requirements. Project Office management regularly receives information as to the scope, status, adequacy, compliance, etc. of the QA program.

Project Office management performs readiness reviews, as deemed appropriate. Readiness reviews shall be used in verifying that specified prerequisites and programmatic requirements of major scheduled/planned activities have been identified prior to starting a major activity.

The controls described in the Project Office QAPP are to be applied consistent with the importance of the activity.

The Project Office QAPP is reviewed and approved by the Project Manager, Project Office; the Project Office Director, Quality Assurance; the Project Manager, T&MSS, and the TPO, MACTEC, prior to implementation. The Project Office QAPP is also submitted to DOE/OCRWM for review and approval.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM	II-1

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

1.2 PROJECT OFFICE QUALITY MANAGEMENT PROCEDURES (QMP)

The Project Office Quality Management Procedures are consistent with the QAPP and delineate the specific administrative and management controls for project office quality related activities. These procedures which are prepared at the project office level describe the responsibilities of two or more Project Office organizations involved in a specific activity. These procedures are prepared and controlled by Project Office. The affected organizations review the procedures to assure that appropriate requirements and interfaces are defined. The Project Office QMPs are approved by the Project Office Project Manager; Project Manager, T&MSS; and the Project Office Director, Quality Assurance.

1.3 BRANCH TECHNICAL PROCEDURES (BTPs)

BTPs are procedures which are prepared at the division level and describe the responsibilities of a single organization involved in a specific activity. These procedures govern the conduct of administrative, technical or quality affecting activities (i.e., operation, task, function, service, or process). BTPs are approved by the responsible Project Office Division Director, Assistant Project Manager (T&MSS), and the Project Office Director, Quality Assurance.

1.4 YMP ADMINISTRATIVE PROCEDURES (AP)

These procedures describe the methodology and responsibility for implementing specific requirements that have been established in the QAP. APs are provided when two or more organizations are involved in an activity with at least one organization being external to the Project Office. APs are not prepared for activities that are solely conducted by the Project Office. APs are approved by the Project Office.

1.5 QAPP VERIFICATION

Assurance that the QA requirements have been adequately addressed and effectively implemented is provided by the Project Office QA Organization. This is accomplished during the review and approval of this QAPP, through monitoring, overview, and surveillance operations, and by conducting internal audits to assess the adequacy of the Project Office program and ensure its effective implementation. These activities are conducted and documented in accordance with Project Office Quality Management Procedures.

1.6 USE OF DATA NOT GENERATED UNDER QA CONTROLS

The Project Office QA Program provides for the acceptance of data or data interpretations for use in licensing activities that were not generated under the controls of the YMP QAP. Once accepted, this data is classified as "primary data" for licensing purposes.

REV. NO. 2	ISSUED 3/20/90	SECTION TITLE YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM	PAGE NO. II-2
---------------	-------------------	---	------------------

YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM PLAN

N-QA-045
5/89

Specific methods for acceptance of this information are contained in the AP 5.9Q, "Qualification of Data or Data Analysis not Developed Under the NNWSI Project QA Program," and Appendix C of this QAPP.

1.7 METHODOLOGY FOR FORMULATING THE "Q" LIST AND QUALITY ACTIVITIES LIST

The Project Office shall implement the appropriate YMP APs for determining the items and activities to be placed on the Project Q-List and Quality Activities List. These procedure(s) shall meet the requirements of NUREG - 1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements" (April, 1988). These requirements are contained in Appendix E to this QAPP.

1.8 APPROACH TO QA

The YMP uses an approach to QA that recognizes the differences between items and activities that affect radiological health and safety and waste isolation and those that do not. The approach is designed to ensure that each item or activity is consistent with its potential impact or importance, or both, in terms of radiological health and safety, waste isolation, nonradiological health and safety, the U.S. Nuclear Regulatory Commission (NRC) licensing requirements, the operability and maintainability of the repository, costs, and schedules. The Project Office is responsible for applying graded QA measures for items and activities that affect quality associated with site characterization, facility and equipment design and construction, facility operations, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities, that are within the Project Office scope of responsibility, as defined in appropriate project APs.

1.9 APPLICATION OF QA

The Project Office QAPP will be applied throughout the life of the YMP to activities conducted by the Project Office and support organizations described in Section I, in accordance with the established policies, procedures, and instructions. The Project Office QAPP applies to all items and activities affecting quality which are the responsibility of the Project Office; these activities are described in Section I. The Project Office QAPP provides control over Project Office activities that affect the quality of the identified structures, systems and components to an extent consistent with their importance. Project Office activities that affect quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that all prerequisites for the given activity have been satisfied. The Project Office QA Program takes into

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM	II-3

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

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 thereof. The Project Office QA Program provides for indoctrination and training of personnel performing activities that affect quality to ensure that suitable proficiency is achieved and maintained. The controls that apply to each of these areas are described in the corresponding Sections of this QAPP.

The Project Office regularly assesses the status and adequacy of the QA Programs of the YMP participating organizations and NTS support contractors by means of overview, surveillance, and audit activities.

2.0 APPLICATION OF GRADED QUALITY ASSURANCE

2.1 SCOPE

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 do not require grading, except for project level documents which are specifically required by the Nuclear Waste Policy Act of 1982, or are required for licensing. In addition, procurement of administrative items (i.e., office supplies) do not require grading. The Project Office has developed YMP Administrative Procedures for the application of graded QA measures. These procedures are in consonance with the QA requirements specified herein.

It may be necessary to exempt certain YMP items and activities from and grading. Requests for exemptions are documented and contain sufficient justification to support the exemption request. Such exemptions are approved by the Project Office Director, Quality Assurance.

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, depending on item function, complexity, consequence of failure, reliability, replicability of results, and economic considerations.

REV. NO. 2	ISSUED 3/20/90	SECTION TITLE YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM	PAGE NO. II-4
---------------	-------------------	---	------------------

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 Project Office 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.

2.1.4 FLEXIBILITY OF QA REQUIREMENTS

The graded approach set forth in this document provides for selective application of the quality assurance requirements to be applied to an item or activity that is commensurate with the relative importance of the role or function assigned to the item or activity.

2.2 REQUIREMENTS

The requirements for the identification of items and activities subject to quality assurance requirements are described in Appendix E of this document.

3.0 QA ACTIVITIES

3.1 OVERVIEW

The Project Office performs overview of the technical and QA activities of all YMP Participants under its purview and overview of the Project Office internal activities affecting quality. Overview is to include the following as appropriate:

- o The review and approval of YMP Participant QAPPs in accordance with QMP-06-03, "Document Review/Acceptance/Approval."
- o Surveillance of external YMP Project Participant and internal Project Office activities affecting quality to verify compliance with QA requirements in accordance with QMP-18-02, "Surveillance."
- o Performance of both internal and external QA audits to verify the adequacy and compliance of YMP participant and the Project Office QA programs in accordance with QMP-18-01, "Audit System for the Waste Management Project Office."

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM	II-5

YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM PLAN

N-QA-045
5/89

3.2 REVIEW AND APPROVAL OF PARTICIPANT QA PROGRAMS

QMP-06-03, "Document Review/Acceptance/Approval," has been established for the review of YMP participant QA program documents. In addition, this QMP identifies the types of documents submitted by the YMP participants for review and approval, assigns responsibility for review, and identifies the methods for documenting the review and approval action. Reviews of participant QAPPs are recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance.

4.0 MANAGEMENT ASSESSMENT

Management assessments of the Project Office QA Program are conducted by the Project Office at least annually in order to determine: (1) The effectiveness of the Project Office system and management controls that are established to achieve and assure quality; and, (2) The adequacy of resources and personnel provided to support and implement the Project Office QA Program.

Project Office management verifies that the QA program is being effectively implemented and that personnel are trained to the QA requirements of the program. Management assessments are accomplished in accordance with Project Office implementing procedures. These procedures establish the methods for planning, organizing, performing, and documenting the management assessment. These procedures also include provisions for establishing and discussing the analysis, the reporting of results and the tracking of recommendations. Project Office management (personnel above or outside the QA organization) shall be responsible for the management assessment activity. Copies of the Project Office management assessment are provided to the Project Manager, Project Office; the YMP Project Office; and DOE/OCRWM.

5.0 PERSONNEL SELECTION, INDOCTRINATION, AND TRAINING PROCEDURES

5.1 GENERAL

Requirements for the selection, indoctrination, and training of Project Office personnel performing or verifying activities that affect quality are contained in this section of the QAPP. The implementation and documentation of these requirements are performed and maintained in accordance with QMP-02-01, "Qualification, Proficiency, Indoctrination, and Training of Waste Management Project Personnel." Detailed requirements for the certification, indoctrination, and training of personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, etc.) are specified in the appropriate sections of this QAPP.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM	II-6

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

5.1.1 POSITION DESCRIPTION

Minimum education and experience requirements are established and documented in position descriptions or equivalent for each Project Office position involved in the performance of activities that affect quality.

5.1.2 PERSONNEL QUALIFICATION EVALUATION

Personnel selected to perform an activity affecting quality must have education and experience commensurate with the minimum requirements specified in position descriptions or equivalent. Relevant education and experience are verified. The initial capabilities of an individual is based upon an evaluation of their education, experience, and training as compared to those established for the position. Evaluations of personnel performance are conducted by those managers or supervisors responsible for the activities at least annually to determine need for retraining or reassignment.

5.1.3 INDOCTRINATION

Prior to assigning personnel to perform activities affecting quality, they are indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents and changes thereto, as a minimum, as they relate to the work to be accomplished. Indoctrination may be accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or by any other instructional methods.

- o YMP QA Plan
- o YMP Administrative Procedures (Quality Related)
- o Project Office QA Program Plan, WMPO/88-1 (formerly NVO-196-18)
- o Project Office Quality Management Procedures
- o Project Office Branch Technical Procedures
- o Federal Regulations (including 10CFR60; 10CFR960; 40CFR191; and 10CFR50, Appendix B)
- o Other Appropriate Project Documents (applicable to an individual's responsibilities/work functions)

5.1.4 TRAINING

Prior to assigning personnel to perform quality affecting activities, training, if needed, is conducted to gain the required proficiency. Personnel responsible for making this determination and the extent of required training are identified in QMP-02-01, "Qualification, Proficiency, Indoctrination, and Training of Waste Mangement Project Personnel.

REV. NO. 2	ISSUED 3/20/90	SECTION TITLE YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM	PAGE NO. II-7
---------------	-------------------	---	------------------

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

5.1.5 PROFICIENCY EVALUATION

After the initial personnel qualification evaluation, the job proficiency of Project Office personnel who perform activities affecting quality is evaluated and documented at least annually. Proficiency evaluations may be performed in conjunction with periodic or day-to-day employee performance evaluations.

Proficiency evaluations are performed by managers or supervisors who have responsibility for the activities being performed or verified.

5.1.6 RECORDS

Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations are retained as lifetime QA records in accordance with QMP-17-01, "Record Source and Record User Responsibilities." As a minimum, these records include the items listed below:

5.1.6.1 Personnel Qualification Evaluation Records

Records of the verification and evaluation of a candidate's education, experience and training, as compared to the qualifications required for the position.

5.1.6.2 Indoctrination Records

Records of indoctrination which include the objective and content of the indoctrination, date(s) of indoctrination, and other applicable information.

5.1.6.3 Training Records

Records of training which include the objective(s) and content of the training, name of the instructor, attendees, dates of attendance, and result of proficiency evaluations (where applicable), and other applicable information.

5.1.6.4 Proficiency Evaluation Records

As a minimum, records of proficiency evaluation include the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM	II-8

SECTION III

SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL

1.0 SCIENTIFIC INVESTIGATION CONTROL

1.1 PREPARATION OF PLANS

1.1.1 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

Prior to the start of any Project Office scientific investigation, the responsible Project Office Principal Investigator (PI) develops a Scientific Investigation Planning Document. Scientific investigations categorized as site characterization activities as defined in the Nuclear Waste Policy Act as amended shall utilize study plans as the scientific investigation planning document. Scientific investigations conducted in the environmental area utilize Environment Field Activity Plans (EFAPs). The Project Office shall conduct a technical, QA, and management review of the study plan and approve the document prior to implementation. Such plans are developed in accordance with YMP AP-1.10Q, "Preparation, Review, and Approval of SCP Study Plans," and QMP-03-02, "Scientific Investigation Control," as appropriate, and contain or reference the following:

1.1.1.1 Description of Work to be Performed

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

1.1.1.2 Description of Previous Work

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

1.1.2 PLANNING DOCUMENTS

The scientific investigation planning document contains a level of detail which would enable an independent reviewer to determine the appropriate QA controls to be applied to the investigation. For Site Characterization activities, the purpose and key milestones of study plans is controlled in the SCP. The format and content of study plans shall meet the requirements of Appendix G of this QA Plan.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	III-1

2

1.2 ASSIGNMENT OF QUALITY ASSURANCE LEVELS

1.2.1 ASSIGNMENT

Once a Scientific Investigation Planning Document has been developed, the QA controls for all of the items and activities which are associated with that work, may be assigned. It may be necessary in some cases to assign QA controls to items and activities that were identified prior to implementation of the graded QA approach.

1.3 REVIEW AND APPROVAL PROCESS

1.3.1 RESPONSIBILITY

The Project Office conducts a technical review of Project Office generated Scientific Investigation Planning Documents. This review is performed by qualified individual(s) other than those who developed the original plan. In exceptional cases, the originator's immediate supervisor can perform the review if the supervisor is the only technically qualified individual, and if the need is individually documented and approved in advance with the concurrence of the Project Office Project Director, Quality Assurance. cursory supervisory reviews do not satisfy the intent of this requirement. The results of this technical review and the resolution of any comments by the reviewer(s), are documented and become a part of the QA records.

1.3.2 REVIEW OF PROJECT OFFICE GENERATED SCIENTIFIC INVESTIGATION PLANNING DOCUMENTS

The Project Office Director, Quality Assurance, the appropriate Project Office Division Director, and OCRWM review and approve Project Office generated Scientific Investigation Planning Documents prior to implementation in accordance with QMP-03-02, "Scientific Investigation Control," and YMP AP-1.10Q, "Preparation, Review, and Approval of SCP Study Plans," as appropriate.

1.3.3 PEER REVIEW

Peer reviews of Project Office scientific investigation planning documents will be conducted, when deemed necessary by the Project Office Division Director in accordance with QMP-03-01, "Peer Reviews." The general requirements for the peer review process are contained in Appendix F.

1.4 SCIENTIFIC INVESTIGATION DATA INTERPRETATION AND ANALYSIS

1.4.1 INTERPRETATION

Interpretation/analysis shall be performed in a planned, controlled, and documented manner. Interpretation/analysis shall be performed and documented

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	III-2

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

1.4.2 DOCUMENTATION OF INTERPRETATION/ANALYSIS

Documentation of interpretation/analysis shall include the following:

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

1.5 USE OF COMPUTER PROGRAMS

Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subsection 4.0 and Appendix D of this QAPP. The documentation and control measures shall be consistent with the guidance contained in NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."

1.6 THE USE OF SCIENTIFIC NOTEBOOKS VERSUS THE USE OF TECHNICAL IMPLEMENTING PROCEDURES

1.6.1 DOCUMENTATION

There are two basic kinds of documentation which can be used for the quality assurance documentation and control of scientific work; these are the scientific notebook system and the technical implementing procedure system. The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgment or trial and error methods, or developing the methodology by which an activity will be accomplished. When the scientific notebook system is used, the study plan or scientific investigation planning document shall be the document that controls the activity since it describes the proposed approach or general procedure for accomplishing the work. Alternatively, the technical implementing procedure system will generally be used when qualified personnel are performing

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	III-3

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

repetitive work which does not include the use of professional judgment or trial and error methods in the performance of the work. Detailed technical implementing procedures are required when it is not possible to deviate from a strict sequence of actions, without affecting the validity of the results that will be obtained from the work. Modifications may be made to these procedures as detailed in Para. 1.6.4.1. Logbooks or appropriate forms or both are used, particularly in repetitive work, to document the performance of the work according to the technical implementing procedure, and to maintain absolute control over all other aspects of the work. The specific method chosen for the documentation of Project Office scientific work is stipulated in the Project Office scientific planning document per QMP-05-02, "Preparation and Control of Branch Technical Procedures."

1.6.2 TECHNICAL IMPLEMENTING PROCEDURES

Detailed Project Office Branch Technical Procedures together with appropriate logbooks and other supporting documents, shall be used whenever the work is repetitive. Project Office Branch Technical Procedures shall be developed in accordance with the requirements specified in QMP-05-02, "Preparation and Control of Branch Technical Procedures". Modifications may be made to the technical aspects of branch technical procedures by the individual utilizing the procedure. Changes to field and laboratory procedures associated with scientific investigations shall be controlled to assure such changes are documented and verified in a timely manner by authorized personnel. If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer.

Requirements and acceptance or rejection criteria, including required levels of precision and accuracy, shall be provided or approved by the organization responsible for the scientific investigation, unless otherwise designated.

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

- o Requirements, objectives, methods and characteristics to be tested or observed.
- o Acceptance limits, if applicable, contained in applicable documents, including precision and accuracy.
- o Prerequisites such as calibrated instrumentation, adequate and appropriate equipment and instrumentation, suitable and controlled environmental conditions, and provision for data collection and storage. For activities of long duration, specific provisions shall be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. such provisions are to be designed to ensure validity of data throughout the scientific investigation.

REV. NO. 2	ISSUED 3/20/90	SECTION TITLE SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	PAGE NO. III-4
---------------	-------------------	---	-------------------

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- o Mandatory verification points.
- o Acceptance and rejection criteria, including required levels of precision and accuracy (NOTE: "Accept/reject criteria" means those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output that, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject criteria" are simply the conditions and methods stated in the procedure.)
- o Methods of documenting or recording data and results, including precision and accuracy.
- o Methods of data reduction.
- o Provision for ensuring that prerequisites have been met.
- o Special training or qualification requirements for personnel performing the scientific investigation.
- o Personnel responsibilities.

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

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

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

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

1.6.3 SCIENTIFIC NOTEBOOKS

Scientific notebooks along with other appropriate documents are used to document Project Office scientific investigations and experiments. In such cases, this documentation is sufficient such that another qualified scientist can use the notebook to retrace the investigation and confirm the results, or repeat the experiment and achieve the same results without recourse to the PI. Scientific notebooks become permanent project records upon completion.

REV. NO. 2	ISSUED 3/20/90	SECTION TITLE SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	PAGE NO. III-5
---------------	-------------------	---	-------------------

1.6.4 DOCUMENTATION REQUIREMENTS

Documentation of scientific work, i.e. experiments and research, is to be accomplished using bound logbooks or notebooks to provide a written record of the experiment or research. As a minimum, logbooks or notebooks will document the following:

1.6.4.1 INITIAL ENTRIES

Prior to initiation of the experiment or research, the following entries are required, as a minimum:

- o Title of the experiment or research.
- o Name of the qualified individual or individuals performing the experiment or research.
- o Description of the experiment's objective or objectives and the proposed approach or procedure for achieving these objectives. This may be accomplished by reference to the appropriate study plan or other scientific investigation planning document which controls the work.
- o Equipment and materials to be employed during the experiment or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material.
- o Calibration requirements.
- o Special training or qualification requirements.
- o Dated signature of the individual or individuals making the initial entries.
- o Documentation of suitable and controlled environmental conditions, if applicable.
- o Where appropriate, required levels of precision and accuracy shall be identified.
- o Where appropriate, the potential sources of uncertainty and error in scientific investigations which must be controlled and measured to assure the investigations are well controlled shall be identified.

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	III-6

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

1.6.4.2 IN-PROCESS ENTRIES

Entries are made during the experiment or research, on either a daily or as appropriate basis, and are sufficiently detailed so that another competent experimenter/researcher could repeat the experiment or research. This information includes:

- o Date and name of individual making the entry.
- o Provisions for assuring prerequisites have been met.
- o Description of the experiment or research attempted, including detailed step-by-step process followed; either by reference to implementing procedure or by actual entry into the notebook.
- o Description of any conditions which may adversely affect the results of the experiment or research.
- o Identification of samples used and any additional equipment and materials not included as part of the initial entries prescribed by Paragraph 1.6.4.1 of this section.
- o All data taken and a brief description of the results, to include notation of any unexpected result.
- o Any deviations from the planned experiment or research.
- o Any interim conclusions reached, as appropriate.

1.6.4.3 Final Entries

As a minimum, the final entries in the record will have the signature of the experimentalist and the signature of a competent technical reviewer.

1.6.4.4 Final Results

Final results and a summary of the outcome of the experiment or research shall be documented (e.g. in a technical report). This shall include a discussion of whether the experiment's objectives as outlined in the initial entries (Paragraph 1.6.4.1) were achieved. This document shall become part of the QA records of the activity.

1.7 CHANGES TO SCIENTIFIC INVESTIGATION PLANNING DOCUMENTS

All changes to Project Office generated Scientific Investigation Planning Documents shall go through the same review and approval process as specified in Paragraph 1.3 of this Section. The Project Office is responsible for evaluating the impacts of such changes on the applied QA controls.

REV. NO. 2	ISSUED 3/20/90	SECTION TITLE SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	PAGE NO. III-7
---------------	-------------------	---	-------------------

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

1.8 SCIENTIFIC INVESTIGATION INTERFACE CONTROL

1.8.1 COORDINATION

Internal and external scientific investigation interfaces are identified and scientific investigation efforts are coordinated among and within the responsible Project Office personnel and any affected participating organization(s). The chain of authority and responsibility among participants is based on the purpose and objectives of the activity involved in the interface. Interface controls include the assignment of responsibility and establishment of procedures among and within the Project Office and any affected participating organization(s) for the review, approval, release, distribution, and revision of documents involving scientific investigation interfaces. Interfaces within a participating organization shall be coordinated according to procedures developed by that participating organization. Interfaces between scientific investigations, or between a scientific investigation and any other Project activity including design activities, are coordinated among Project participants in accordance with YMP APs established by the Project Office. In addition, interfaces between the Project Office and its suppliers are also controlled in accordance with YMP APs. Ongoing field or laboratory scientific investigations shall be identified to preclude inadvertent interruption and to ensure operational compatibility. Such identification shall be clearly evident at the location at which the scientific investigation is being performed. Field investigations shall identify the location of the investigation.

1.8.2 TRANSMITTAL

The method of transmittal of information or items, including samples of natural or man-made materials, across interfaces is documented and controlled in accordance with Project Office Branch Technical Procedures.

1.9 SCIENTIFIC INVESTIGATION REPORTS, CONCLUSIONS, AND RECOMMENDATIONS

The Project Office conducts the technical review and approval of the results of Project Office scientific investigations/experiments in accordance with QMP-06-03, "Document Review/Acceptance/Approval." This procedure includes the Project Manager, Project Office; the respective Project Office Division Director(s); and the Project Office PQM in the review and approval cycle of the final report.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	III-8

1.10 CLOSE OUT VERIFICATION OF SCIENTIFIC INVESTIGATION QA RECORDS

The Project Office performs a close out verification upon the completion of any scientific investigation/experiment to ensure that the QA records for that investigation/experiment are adequate and complete because it may be a considerable period of time after the work is completed and before the investigation or experiment results are used in the licensing process. Close out verifications are performed by a team consisting of qualified technical personnel and QA personnel; this activity is performed and documented in accordance with Project Office Quality Management Procedures.

1.11 VERIFICATION OF SCIENTIFIC INVESTIGATIONS

1.11.1 VERIFICATION

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

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

1.11.2 VERIFICATION HOLD POINTS

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

1.11.3 REPORTING INDEPENDENCE OF PERSONNEL

Verification shall be performed by personnel who do not report directly to the immediate supervisor(s) who is/are responsible for performing the activity being verified. If these personnel are not part of the Project Office QA organization, they shall have sufficient authority, access to work areas, and

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	III-9

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. When these persons or organizations who perform the verification activities are not part of the Project Office QA organization (i.e., part of line management), then the Project Office QA organization shall overview and monitor the verification activity.

1.12 SURVEILLANCE OF SCIENTIFIC INVESTIGATIONS AND EXPERIMENTS

1.12.1 LOGISTICS OF SURVEILLANCE

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

1.12.2 SURVEILLANCE TEAM

The Technical member or members of the QA surveillance team shall be familiar with the plan for the scientific investigation.

2.0 DESIGN CONTROL

2.1 DEFINITION OF PROJECT OFFICE RESPONSIBILITIES

The Project Office holds no responsibilities for the performance of design activities, however, the Project Office is responsible for the management, coordination, review, and acceptance of design efforts for the repository, waste package, and the ESF. With respect to the ESF, the Project Office is responsible for assigning responsibilities to determine the QA controls and the grading of ESF items and activities as delineated in YMP APs.

2.2 DESIGN INPUT

The Project Office shall provide for preparation and maintenance of the ESF Subsystems Design Requirements Document (SDRD), which provides the functional requirements and the performance criteria for systems and subsystems within the scope of the ESF. The SDRD, including revisions, shall be distributed as a controlled document in accordance with AP-1.5Q, "Issuance and Maintenance of Controlled Documents", to affected organizations, including the responsible design organizations, for their consideration as design input.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	III-10

2

2.3 DESIGN INTERFACE CONTROL

Internal and external design interfaces are identified and controlled and design efforts are coordinated among responsible design organizations. Interface controls include the assignment of responsibility and the establishment of administrative procedures among responsible design organizations for the review, approval, acceptance, release, distribution, and revision of documents involving design interfaces. The Project Office is responsible for ensuring these procedures exist at a Project level and are adequate to control interfaces occurring between the repository, ESF, waste package, and scientific investigation activities (through technical data management).

2.4 DESIGN OUTPUT DOCUMENT REVIEWS

The Project Office review of design output documents ensures that the required review/ acceptance/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/acceptance/approval cycle includes the participation of the technical and QA elements of both the responsible design organization and the Project Office. The purpose of the QA review is to ensure that the documents are prepared, reviewed, accepted, and approved in accordance with documented procedures and quality assurance requirements. The Project Office acceptance of design output documents is done on an acceptance of Architect/Engineer (A/E) services in accordance with QMP-07-03, "Control of Purchased Items and Services." The acceptance does not include the actual approval, analysis, and verification of the output documents. The responsibility for approval, analysis and verification remains that of the Architect/Engineer.

3.0 PEER REVIEWS

The Project Office retains the authority and responsibility to initiate peer reviews. All peer reviews are documented and controlled in accordance with QMP-03-01, "Peer Reviews," which, as a minimum, addresses the requirements provided in Appendix F.

4.0 SOFTWARE QUALITY ASSURANCE REQUIREMENTS

4.1 COMPUTER SOFTWARE DOCUMENTATION AND CONTROL

Computer software used to support a high-level nuclear waste repository license application is documented and controlled according to the requirements stipulated in the YMP Project Office "Software QA Plan." Software requests, development, verification, validation and configuration management are controlled by implementing QMP's. Computer programs shall be completed in accordance with QMP-03-04, "Software Development and Maintenance." The documentation and control measures contained in these procedures are con-

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	III-11

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

sistent with the guidance contained in NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."

Auxiliary software used to support Primary Data analysis software is controlled at a level commensurate with the complexity of the software by QMP-03-03, "Use of 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. Requests to develop computer software are approved in accordance with QMP-03-07, "Software Approval." Supplemental, detailed requirements for the development, maintenance, and security of computer software based on the Project Office life cycle model are contained in Appendix D to this QAPP, the Project Office "Software QA Plan," and QMP-03-08, "Technical Systems Operations and Maintenance".

4.1.1 The Project Office T&MSS contractor shall prepare a "Project Office Software QA Plan" containing a description of the software design, development, test, documentation and configuration management program and submit it to the Project Office for review and approval. The "Software QA Plan" 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 consistent with the Project Configuration Management Plan and the associated implementing procedures.
- o Specify the process to be used for verification and validation of the software developed or applied to geologic repository scientific investigation.
- o Identify the procedure for reporting and documenting software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action.

4.1.2 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 as specified in QMP-03-06, "Software Configuration Management."

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	III-12

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

- 4.1.3 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 qualify affecting computer software shall be subject to the same level of approval, verification, and validation as the original software.
- 4.1.4 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, as specified in QMP-03-04, if properly referenced and related to the NUREG-0856 requirements.
- 4.1.5 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.
- 4.1.6 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.
- 4.1.7 Verification and validation is controlled by QMP-03-05, "Verification and Validation of Software" which assures 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.
- 4.1.8 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 QA Plan may be qualified for use provided the software is verified and validated, a software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this section.

REV. NO. 2	ISSUED 3/20/90	SECTION TITLE SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	PAGE NO. III-13
---------------	-------------------	---	--------------------

YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM PLAN

N-QA-045
5/89

4.1.9 Methods and procedures for determining the applicability of requirements and managing interfaces involving the documentation, configuration management, verification, and validation of software are contained in Project Office Quality Management Procedures and the "Project Office Software QA Plan".

4.2 DOCUMENTATION OF SCIENTIFIC AND ENGINEERING COMPUTER SOFTWARE

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

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

Appendix D of this QAPP provides detailed requirements on the content of this software documentation and documentation of other computer software used on the YMP. This documentation is considered to be a QA Record and is subject to the requirements of Section XVII of this QAPP.

4.3 SOFTWARE CONFIGURATION MANAGEMENT

The Project Office has instituted a software configuration management program appropriate to the software activities it conducts and documented this program for the records management system. The minimum requirements for this software configuration management program are: (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. Implementation of the Project Office software configuration management program is documented and controlled in accordance with QMP-03-06, "Software Configuration Management."

5.0 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.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL	III-14

SECTION IV

PROCUREMENT DOCUMENT CONTROL

1.0 REQUIREMENTS

1.1 MEASURES TO ENSURE ADEQUATE QUALITY FOR PROJECT OFFICE PROCURED ITEMS AND ACTIVITIES

Measures have been established per QMP-04-01 and QMP-04-02, "Procurement Document Control," to ensure that applicable regulatory requirements, design or site investigation bases, and other requirements that are necessary to ensure adequate quality are suitably included or referenced in the documents for procurement of quality affecting items and activities utilized by the Project Office on the YMP. To the extent necessary, Project Office procurement documents require subtier suppliers to provide a QA program that is consistent with the pertinent provisions of the Project Office QAPP, as required by the specified QA Level of the item or activity being procured.

The procurement documents for Project Office initiated procurements of commercial grade items shall include the applicable requirements of Section VII, Paragraph 2.0.

Project Office initiated procurements for items and activities are controlled through the use of the Federal Acquisition Regulations (FAR), Department of Energy Acquisition Regulations (DEAR), and the requirements of Sections IV and VII of this QAPP. When the Project Office procures services from suppliers or requests services from national laboratories and supporting federal agencies, the Project Office prepares work agreements, memos of understanding, interagency agreements, management agreements, or other suitable documents. These documents are considered to serve the same function as "procurement documents," as referenced throughout this QAPP, and meet the requirements established in the following paragraphs. As used in this QAPP, the term "services" is synonymous with "activities."

2.0 CONTENT OF PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement include provisions for the following, as deemed necessary by the Project Office:

2.1 SCOPE OF WORK

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	PROCUREMENT DOCUMENT CONTROL	IV-1

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

2.2 TECHNICAL REQUIREMENTS

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

2.3 QA PROGRAM REQUIREMENTS

Project Office procurement documents require that the supplier have a documented QA program which implements either specific portions or all of the requirements of the YMP QA Plan. The extent of the QA program required of the supplier depends upon the type and use of the item or service being procured. The Project Office procurement documents require the supplier to incorporate appropriate QA program requirements in subtier procurement documents. In addition Project Office procurement documents require the supplier of a quality affecting item or activity to submit its QAPP, related implementing procedures, and other specifically identified documentation to the Project Office for review and approval in accordance with QMP-06-03, "Document Review/Acceptance/Approval." When the Project Office determines that the documents provided by the supplier do not adequately define the QA requirements established by the Project Office, the supplier is directed by the Project Office to correct the inadequate documents. The supplier obtains Project Office approval of the corrected documents prior to initiation of activities specified in the procurement documents.

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).

2.4 RIGHTS OF ACCESS

At each tier of procurement, the procurement documents provide for access to the supplier's facilities and records for inspection or audit by Project Office personnel, or other Project Office authorized representatives. Project Office access to subtier contractor facilities of Project participant organizations is arranged by the contracting organization.

2.5 DOCUMENTATION REQUIREMENTS

Project Office procurement documents and those of its suppliers/subcontractors, identify the documentation required to be submitted to the Project Office. The time of submittal is also established. If the Project Office requires the supplier to maintain specific QA records, then the retention times and disposition requirements will be specified in accordance with Section XVII of this QAPP.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	PROCUREMENT DOCUMENT CONTROL	IV-2

YUCCA MOUNTAIN PROJECT OFFICE QUALITY ASSURANCE PROGRAM PLAN

N-QA-045
5/89

2.6 NONCONFORMANCES

Project Office procurement documents prescribe the requirements for reporting and approving dispositions of supplier nonconformances per Section XV of this QAPP.

2.7 SPARE AND REPLACEMENT PARTS

Project Office procurement documents 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 are 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 considers the interchangeability, function and safety of the item, and is documented in accordance with QMP-04-01 or QMP-04-02, as appropriate.

3.0 PROCUREMENT DOCUMENT REVIEWS

3.1 PROJECT OFFICE REVIEWS

Reviews of Project Office procurement documents and changes thereto are performed to ensure that documents transmitted to the prospective supplier or suppliers include appropriate provisions to ensure that items or services will meet the specified requirements. These reviews are performed and documented in accordance with QMP-04-01 or QMP-04-02, as appropriate, prior to contract award or prior to issuing a contractual change, as applicable. Procurement document reviews are performed by Project Office personnel who have access to pertinent information and who have adequate understanding of the requirements and intent of the procurement documents. As a minimum, these reviews include the Project Office QA Organization and the cognizant Project Office Technical Branch. The review by the Project Office QA Organization ensures that the following requirements are met:

- o QA requirements are correctly stated, inspectable and controllable.
- o There are adequate acceptance and rejection criteria established.
- o Procurement documents have been prepared, reviewed, and approved in accordance with the QA requirements of this QAPP.

The review by the cognizant Project Office Technical Branch ensures that the following requirements are met:

- o Technical requirements are correctly stated.
- o Appropriate standards, codes, regulations, procedures or instructions, including revisions thereto, which describe the items or services to be furnished are referenced.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	PROCUREMENT DOCUMENT CONTROL	IV-3

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- o Procurement documents contain or reference sufficient technical information (i.e., design drawings, specifications, etc.).
- o Identification of Project Office test, inspection and acceptance requirements which will be utilized for monitoring and evaluating the supplier's performance.

3.2 PROCUREMENT DOCUMENT CHANGES PRIOR TO CONTRACT AWARD

Changes that are made as a result of the bid evaluation or precontract negotiations are incorporated into the procurement documents. Prior to contract award, the review of such changes and their effects will be completed and documented in accordance with QMP-04-01 or QMP-04-02, as appropriate. This review includes the following considerations:

- o Appropriate requirements are included in procurement documents as specified by Paragraph 2.0 of this Section.
- o Additional or modified design or site investigation criteria is determined.
- o Analysis of exceptions or changes requested or specified by the supplier and a 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.

3.3 PROCUREMENT DOCUMENT CHANGE CONTROL

Procurement document changes are subject to the same degree of control as utilized in the preparation of the original documents.

4.0 DISTRIBUTION OF PROCUREMENT DOCUMENTS

The originating Project Office Division is required to forward an "as-issued" copy of procurement documents, including changes, for quality affecting items or activities to the Project Office QA Organization for consideration in scheduling Project Office QA Organization verification activities. Only those procurement documents which identify the supplier, describe the scope of work, and detail when work is to start are required to be submitted to the Project Office QA Organization. Copies of Project Office procurement documents are maintained in accordance with QMP-17-01, "Record Source and Record User Responsibilities."

| 2

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	PROCUREMENT DOCUMENT CONTROL	IV-4

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

SECTION V

INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

1.0 GENERAL

Project Office activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, plans, or drawings, of a type appropriate to the circumstances except as noted in paragraph 3.0 of this Section. These documents include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Instructions, procedures, and plans 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 include or reference appropriate acceptance criteria and identify the QA records which are generated. These documents, including drawings, are controlled in accordance with the requirements contained in Section VI of this document. Project Office generated documents which are covered by this Section include:

- o YMP QA Plan
- o YMP Administrative Procedures affecting quality related activities
- o Project Office QA Program Plan, WMPO/88-1 (formerly NVO-196-18)
- o Project Office Quality Management Procedures
- o Project Office Branch Technical Procedures
- o YMP and Project Office Generated Plans affecting quality related activities. (e.g., SEMP, ESF Project Management Plan, etc.)

2.0 REVIEWS

An independent review of all instructions, procedures, plans, and drawings is performed in accordance with approved procedures to assure technical adequacy and inclusion of appropriate quality requirements. This review shall consider whether the activities have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities.

3.0 INSTRUCTIONS FOR SCIENTIFIC NOTEBOOKS

The Project Office prepares procedures for the control of scientific notebooks, plans and any other documentation that will be used during the conduct of Project Office controlled scientific investigations in accordance with QMP-05-02, "Preparation and Control of Branch Technical Procedures."

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS	V-1

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

When scientific notebooks are used in lieu of technical implementing procedures to perform scientific investigations, the requirements of Section III, paragraph 1.4.3.1 shall prevail over the requirements of this Section.

4.0 DISTRIBUTION

The Project Office maintains controlled distribution of all implementing procedures, plans, instructions and drawings used for quality affecting Project Office activities in accordance with QMP-06-02, "Document Control." Controlled copies of these documents are provided to the Project Office Director, Quality Assurance and the YMP QA Support Contractor Manager, and other appropriate staff members.

| 2
| 2

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS	V-2

SECTION XII

CONTROL OF MEASURING AND TEST EQUIPMENT

1.0 GENERAL

1.1 MAINTAINING ACCURACY OF EQUIPMENT

This section of the Project Office QAPP establishes the requirements necessary to ensure that tools, gages, instruments, and other measuring and test equipment (M&TE) used in Project Office activities that affect quality (QA Level I or II) are properly controlled, adjusted and calibrated at specified periods to maintain accuracy within necessary limits. The appropriate Project Office Division Director(s) are responsible for the implementation of an effective calibration program which meets the requirements of this section.

1.2 PURPOSE AND SCOPE OF CONTROL PROGRAM

The controls established in this Section apply to all tools, gages, instruments and other M&TE used in Project Office quality affecting activities. The methodology for the control of this equipment is described in Project Office Branch Technical Procedures (BTPs) and applies to all M&TE or systems used to calibrate, measure, gage, test, or inspect for the purpose of either: (1) controlling or acquiring data to verify conformance to a specified requirement; or (2) establishing characteristics or values not previously known.

2.0 REQUIREMENTS

Specific requirements for control of M&TE are listed in Paragraphs 2.1 through 2.6 below and are specified in the appropriate Project Office BTP.

2.1 SELECTION

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

2.2 CALIBRATION

Measuring and test equipment shall be calibrated against certified equipment having known valid relationships to the National Bureau of Standards or other nationally recognized standards and shall be calibrated, adjusted, and maintained at prescribed intervals.

REV. NO. 2	ISSUED 3/20/90	SECTION TITLE CONTROL OF MEASURING AND TEST EQUIPMENT	PAGE NO. XII-1
---------------	-------------------	---	-------------------

If no nationally recognized standards exist, the basis for calibration shall be documented. Calibrating standards shall have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function shall be identified.

2.3 CONTROL

The method and interval of calibration for each item is defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. M&TE must be labeled, tagged, or otherwise documented in a manner which indicates the due date of the next calibration and to provide traceability to calibration data. If M&TE is found to be out of calibration, an evaluation is made and documented on the validity of previous results obtained, on the acceptability of items previously inspected or tested or on data gathered since the last calibration. Devices that are out of calibration are documented on a Project Office NCR in accordance with QMP-15-01, "Control of Nonconformances," tagged or segregated, and are not used until they have been dispositioned and the related NCR's corrective action has been satisfactorily verified. If any M&TE is found to be consistently out of calibration, then it is repaired or replaced. A calibration is performed when the accuracy of equipment is suspect.

2.4 COMMERCIAL DEVICES

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

2.5 HANDLING AND STORAGE

M&TE is handled properly and stored to maintain accuracy in accordance with requirements specified by either the manufacturer or the respective Project Office Division.

2.6 RECORDS

Records are maintained and equipment is suitably marked to indicate calibration status. Project Office BTPs and QMP-17-01, "Record Source and Record User Responsibilities," provide for the generation, review and maintenance of M&TE related records in accordance with the requirements of Section XVII of this QAPP. Calibration records identify the calibration procedure (including revision) utilized to perform the calibration.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	CONTROL OF MEASURING AND TEST EQUIPMENT	XII-2

SECTION XV

CONTROL OF NONCONFORMING ITEMS

1.0 GENERAL REQUIREMENTS

The Project Office has established measures for the control of items which are the responsibility of the Project Office and which do not conform to specified requirements in order to prevent their inadvertent installation or use. These measures are implemented in accordance with QMP-15-01, "Control of Nonconformances," which provides for the identification, documentation, evaluation, segregation (when practical), disposition, and notification of nonconformances to affected organizations. All Project Office and DOE/NV matrix support personnel are responsible for reporting nonconformances in accordance with QMP-15-01, "Control of Nonconformance," which implements the minimum requirements described in this section of the QAPP.

1.1 IDENTIFICATION

1.1.1 METHOD OF IDENTIFICATION

Identification of nonconforming items is made by marking, tagging, or other methods that do not adversely affect the end use of the item. The identification is legible, easily recognizable, and contains the Project Office NCR number. The NCR number is a sequential number preceded by the Project Office acronym (e.g, PO-01, etc). When tags are used, they are to be securely attached to avoid loss during handling.

1.1.2 EXCEPTIONS

If identification of each nonconforming item is not practical, the container, package, or segregated storage area is identified, as appropriate.

1.1.3 CONDITIONAL RELEASE

Work on the nonconforming item will be stopped until completion of the action specified in the Project Office NCR disposition. If only a specific portion of the item is in nonconformance, then that specific area is identified and work may proceed on the remaining areas as long as the previously noted nonconformances does not render the item unusable. If work on a nonconforming item must be continued (conditional release) prior to implementation of the disposition, the responsible Project Office Division Director and the Project Office PQM approves the conditional release. Requests for conditional releases on nonconforming items include documented justification that the following conditions are met:

- o The nonconforming item can be removed or corrected at a later date without damage to, or contamination of the associated permanent facility equipment or structures.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	CONTROL OF NONCONFORMING ITEMS	XV-1

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

1.2 LOGGING

1.2.1 NONCONFORMANCE CONTROL LOG

The Project Office maintains a nonconformance control log to track nonconforming items. This log contains the following information:

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

1.3 SEGREGATION

1.3.1 HOLD AREA

When practical, nonconforming items are segregated by placing them in a clearly identified and designated hold area until properly dispositioned.

1.3.2 ALTERNATIVE

When segregation is impractical or impossible because of physical conditions, such as size, weight, or access limitations, other precautions are employed to preclude inadvertent use of a nonconforming item.

1.4 DISPOSITION

1.4.1 NONCONFORMANCE CHARACTERISTICS

Nonconforming characteristics will be reviewed and recommended dispositions are to be proposed and approved. Further processing, delivery, installation, or use of a nonconforming item must be controlled pending an evaluation and an approved disposition by authorized personnel. Distribution of nonconformance documentation is to all affected organizations.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	CONTROL OF NONCONFORMING ITEMS	XV-2

1.4.2 RESPONSIBILITY AND AUTHORITY

The responsibility and authority for the evaluation and disposition of all nonconforming items includes the respective Project Office Division Director and the Project Office Director, Quality Assurance, or their respective designees, as a minimum. Project Office QA Organization responsibilities relating to nonconformances are defined in QMP-15-01, "Control of Nonconformances." In those cases where the proposed disposition is "repair," the disposition must be approved prior to implementation. In those cases where the proposed disposition is "use-as-is," the disposition must be approved only after all actions necessary to support technical justification of the disposition have been completed. The appropriate Project Office Division Director and the Project Office Director, Quality Assurance, approve NCR dispositions involving "repair" or "use-as-is" determinations and conditional release recommendations.

1.4.3 PERSONNEL

Project Office personnel performing evaluations to determine a disposition have demonstrated competence in the specific area that they are evaluating, have an adequate understanding of the requirements, and have access to pertinent back-ground information.

1.4.4 DISPOSITIONING OF NCR

Project Office personnel assigned the responsibility of dispositioning the NCR 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, shall reflect the accepted deviation.
- o The disposition has referenced any approved design documents, procedures, plans, work orders, etc., that are to be used to correct 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 Project Office Division Director and the Project Office Director, Quality Assurance.
- o The disposition complies with existing design documents, test plans or procedures, reports, and regulatory requirements.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	CONTROL OF NONCONFORMING ITEMS	XV-3

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

- 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 are also 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.

1.4.5 CORRECTIVE ACTION

The action taken to correct the nonconforming item is verified and documented. Repaired or reworked items are reexamined in accordance with applicable procedures and with the original acceptance criteria, unless the nonconforming item's approved NCR disposition has established alternate acceptance criteria.

1.4.6 INTERFACES

Internal interfaces between Project Office organizational units are clearly described. External interfaces between the Project Office and YMP participants are clearly described in YMP APs.

2.0 REPETITIVE NONCONFORMANCES

When repetitive or recurring nonconforming conditions are identified, an evaluation is made as to whether or not further programmatic corrective action is warranted to preclude repetition. This corrective action is beyond the scope of the action taken for the disposition on the existing NCRs and is processed as a Standard Deficiency Report (SDR) in accordance with QMP-16-03, "Standard Deficiency Reporting System."

3.0 TRENDING

Nonconformance Reports shall be periodically analyzed by the QA organization to show quality trends and to help identify root causes of NCRs. Results shall be reported to upper management for review and assessment.

4.0 DISTRIBUTION OF DOCUMENTS

Distribution of Project Office NCRs is detailed in QMP-15-01, "Control of Nonconformances." As a minimum, copies of Project Office generated nonconformance reports are sent to the respective Project Office Division Director, and the Project Office Director, Quality Assurance, upon issuance and closure. The original nonconformance reports are sent to the Project Office for evaluation, disposition, and approval as required by this section.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	CONTROL OF NONCONFORMING ITEMS	XV-4

SECTION XVI

CORRECTIVE ACTION

1.0 GENERAL

The Project Office corrective action system is defined per this section of the Project Office QAPP, and QMP-16-03, "Standard Deficiency Reporting System." The corrective action system ensures that both conditions adverse to quality and significant conditions adverse to quality are identified promptly and corrected as soon as practical.

1.1 SIGNIFICANT ADVERSE CONDITIONS

The identification, cause, and corrective action for significant conditions adverse to quality are documented and reported to immediate and upper levels of Project Office management for review and assessment as defined in QMP-16-03, "Standard Deficiency Reporting System."

A significant condition adverse to quality is one which, if not corrected, could have a serious affect 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 exists, Project Office management 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.

1.2 FOLLOW-UP ACTION

The Project Office QA Organization is responsible for documenting concurrence of the adequacy of proposed corrective actions to assure that QA requirements will be satisfied. Follow-up action is taken by the Project Office QA Organization to verify proper implementation of all corrective action and to close out the corrective action in a timely manner. Provisions for timely follow-up action are described in QMP-16-03, "Standard Deficiency Reporting System."

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	CORRECTIVE ACTION	XVI-1

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

1.3 CORRECTIVE ACTION

Corrective action, as documented on an SDR, will be periodically analyzed by the Project Office QA Organization to identify quality trends and to help identify root causes of nonconformances and programmatic deficiencies. Results are reported to Project Office upper management for review and assessment as described in QMP-16-02, "Trend Analysis."

2.0 DISTRIBUTION OF DOCUMENTS

Copies of corrective action documentation are maintained and distributed in accordance with appropriate implementing procedures. As a minimum, copies of corrective action documentation are sent to Project QA.

|2

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	CORRECTIVE ACTION	XVI-2

SECTION XVIII

AUDITS

1.0 GENERAL REQUIREMENTS

All Project Office YMP activities are subject to planned and scheduled internal audits to ensure that procedures and activities comply with the requirements of this QAPP and to determine the effectiveness of its implementation. This section of the QAPP describes a system of planned, periodic audits to provide an objective evaluation of quality related practices, procedures, instructions, activities, and items including the review of documents and records to ensure that the Project Office QA Program and YMP participant QA programs are effective and properly implemented. Tracking systems are provided 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 describes in a formal report the corrective action to be taken to address findings, and submits the report to the auditing organization and their own responsible management. Followup action, including verification of corrective action or reaudit specific areas are performed.

1.1 YMP PROJECT AUDITS

The Project Office QA Organization performs internal audits of Project Office and external audits of YMP participating organizations, NTS support contractors, and other designated Project Office suppliers in accordance with QMP-18-01, "Audit System for the Waste Management Project Office," utilizing checklists and personnel who are qualified in accordance with QMP-02-02, "Qualification of Quality Assurance Program Audit Personnel." Deficiencies identified during audits are processed as Standard Deficiency Reports (SDR) and are issued and evaluated in accordance with QMP-16-03, "Standard Deficiency Reporting." Observations and recommendations identified during audits are described in QMP-18-01, "Audit System for the Waste Management Project Office," and QMP-16-03, "Standard Deficiency Reporting System."

1.2 SCHEDULING

The Project Office QA Organization internal and external audits are scheduled in a manner that provides coverage and coordination with ongoing QA program activities. Audits are scheduled at a frequency commensurate with the status and importance of the activity and are initiated early enough in the life of the activity as practical to ensure effective QA. Audits are continued at intervals consistent with the schedule for accomplishing the activity. The audit schedule is evaluated periodically and revised as necessary to ensure that coverage is maintained current.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	AUDITS	XVIII-1

The evaluation should include an assessment of the effectiveness of the program based on (1) previous audit results and corrective actions, (2) adverse trends resulting from a series of nonconformance reports, and (3) information from other sources such as the American Society of Mechanical Engineers (ASME), and the Nuclear Regulatory Commission (NRC). Revisions to the audit schedule are documented. Regularly scheduled audits may be supplemented by supplemental audits of specific subjects when necessary to provide adequate coverage.

The Project Office, YMP participating organizations, and NTS support contractors are audited annually, as a minimum. These audits cover the entire scope of the audited organization's QAPP.

Project Office suppliers QA programs are audited at least annually or once during the life of the activity, whichever is shorter, with the exception of those activities that are less than four months in duration. Then 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 the above organizations will be documented and approved by the Project Office Director, Quality Assurance.

The scope of the audit is established by considering (1) the results of any previous audits, (2) the nature and frequency of identified deficiencies, and (3) any significant changes in personnel, organization, or in the QA program.

1.3 QUALIFICATION OF QUALITY ASSURANCE AUDIT PROGRAM PERSONNEL

The qualification of auditors, technical specialists, and lead auditors who participate in YMP audits is performed and documented in accordance with QMP-02-02, "Qualification of Quality Assurance Program Audit Personnel."

1.3.1 QUALIFICATION OF AUDITORS

Personnel selected for QA auditing assignments have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. The competence of personnel performing various auditing functions is developed by one or more of the following methods:

- o Orientation to provide a working knowledge and understanding of this document and the implementing procedures for audits and reporting results.
- o Training programs to provide general and specialized training in audit performance. General training includes fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training includes methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing audit findings.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	AUDITS	XVIII-2

- o On-the-job-training, guidance, and counseling under the direct supervision of a lead auditor. Such training includes planning, performing, reporting, and follow-up action involved in conducting audits.

1.3.2 QUALIFICATION OF LEAD AUDITORS

An individual must comply with the requirements listed below before being designated a lead auditor:

1.3.2.1 COMMUNICATION SKILLS

The prospective lead auditor must possess the capability to communicate effectively, both orally and in writing. These skills are attested to in writing.

1.3.2.2 TRAINING

Prospective lead auditors will undergo training to the extent necessary to ensure their competence in auditing skills. Training in the following areas is given based upon management evaluation of the particular needs of each prospective lead auditor:

- o Knowledge and understanding of this document, NQA-1, 10 CFR Part 60, and other nuclear and/or DOE related codes, standards, regulations, and regulatory guides, as applicable to the YMP.
- o General structure of QA programs and applicable elements as defined in this document.
- o Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.
- o Audit planning in the functions related to quality for the following activities: site characterization (scientific investigations), design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility.
- o On-the-job training to include applicable elements of the audit program.

1.3.2.3 AUDIT PARTICIPATION

The prospective lead auditor is required to participate in a minimum of five QA audits within a period of time not to exceed three years prior to the date of qualification. One of the audits will be a nuclear QA audit that was performed within the year prior to qualification.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	AUDITS	XVIII-3

1.3.2.4 EXAMINATION

The prospective lead auditor must pass an examination that evaluates his/her comprehension of and ability to apply the body of knowledge identified in the training areas listed above. The test is both oral and written. The oral and written parts of the examination questions/contents are documented and maintained on file. The integrity of the examination is maintained by confidentiality of files and, when applicable, proctoring of the examination.

1.3.3 CERTIFICATION OF QUALIFICATION

Each lead auditor is certified as being qualified to lead audits by documenting the following as a minimum:

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

1.3.4 MAINTENANCE OF QUALIFICATION

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

Lead auditors who fail to maintain their proficiency for a period of two years or more require requalification. Requalification includes retraining and reexamination in accordance with the requirements contained in this section of the QAPP and participation as an auditor in at least one nuclear QA audit.

1.4 AUDIT PREPARATION

Preparation for an audit includes the items listed below.

1.4.1 AUDIT PLAN

An audit plan is developed for each audit. The plan identifies the audit number, organization to be audited, audit scope, requirements, audit personnel including technical specialists, activities to be audited, applicable documents and procedures, schedule, and written procedures or checklists.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	AUDITS	XVIII-4

1.4.2 SELECTION OF AUDIT TEAM

The audit team is identified before the beginning of each audit and contains one or more auditors and has a qualified lead auditor. The lead auditor selects and assigns auditors who are independent of any direct responsibility for the performance of the activities that they are to audit and concurs that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. If the audit is to be an internal Project Office audit, then the personnel who have direct responsibility for performing the activities to be audited are not involved in the selection of the audit team. Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective. The lead auditor ensures that the audit team is prepared before the audit begins, organizes and directs the audit, coordinates the preparation and issuance of the audit report including any deficiencies (i.e., SDRs, NCRs), observations (potential quality problems), and recommendation, and evaluates the responses, as required.

1.5 AUDIT PERFORMANCE

Audits are performed in accordance with the audit schedule. Elements that have been selected for the audit are evaluated against specified requirements including a review of corrective actions taken on deficiencies in the areas being audited that were identified during previous audits. Objective evidence is 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 are documented by audit personnel and reviewed with the respective organization's management having responsibility for the area audited. Conditions that require prompt corrective action are reported immediately to the respective organization's management. SDRs generated during the audit are reviewed with the audited organization at a postaudit meeting.

1.6 AUDIT REPORTING

Audit reports are prepared and signed by the ATL and approved by the Verification Department Manager (SAIC) and the Project Office POM. The reports should be issued within 30 calendar days and include the following information:

- o Description of the audit scope.
- o Identification of the audit team.
- o Identification of the persons contacted during the audit.
- o Summary of the audit results, including a statement of the effectiveness of the QA program elements that were audited.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	AUDITS	XVIII-5

- o Description of each SDR, NCR, Observation, and Recommendation identified during the course of the audit including a description of the required response action for the audited organization.

1.7 AUDIT RESPONSE AND FOLLOW-UP

The ATL ensures that the audited organization's management provides an adequate response to all SDRs identified during the audit within 20 working days of the transmittal date of the SDRs. The SDR responses are evaluated to ensure that the deficiency has been investigated to determine root cause, and corrective actions including measures to prevent recurrence are identified, as appropriate. Follow-up actions are taken to verify if corrective actions have been accomplished as scheduled. Audit results are analyzed to identify adverse quality trends.

1.8 AUDIT AND PERSONNEL RECORDS

As a minimum, audit records include the following:

- o Audit plans, audit reports, written responses, and the record of completion of corrective action, and close-out of the audit.
- o Personnel qualifications for auditors and lead auditors, and technical specialists.

2.0 SURVEILLANCES

The audit program is supplemented by scheduled and unscheduled surveillance activities which are performed in accordance with QMP-18-02, "Surveillances." The purpose of a surveillance is to monitor or observe YMP items and activities, including site investigations, to verify conformance to specified requirements. Deficiencies identified during surveillances are documented as SDRs and are issued and evaluated in accordance with QMP-16-03, "Standard Deficiency Reporting System." Observations (potential quality problems) identified during surveillances are described in QMP-18-02, "Surveillances."

2.1 SURVEILLANCE PERFORMANCE

Surveillances are performed to written checklists or surveillance plans whenever practical by the Project Office QA Organization personnel who do not report directly to the immediate supervisor who is responsible for the work being surveilled. The documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of the results, of the surveillance.

Acceptance criteria related to surveillances may be as simple as "to verify proper implementation of specified procedures" or "to verify conformance to specified requirements".

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	AUDITS	XVIII-6

2.2 SURVEILLANCE OF SCIENTIFIC INVESTIGATIONS AND EXPERIMENTS

The Project Office QA Organization performs surveillances of scientific investigations and experiments, as may be deemed appropriate for the purposes and the complexity of the work. The surveillance team for a scientific investigation consists of one or more qualified technical individuals and one or more QA personnel who are familiar with the plan for the scientific investigation. The timing and the number of surveillances is determined by the Project Office QA Organization and input from the Project Office technical staff.

2.3 SURVEILLANCE RECORDS

As a minimum, Project Office surveillance records identify the following:

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	AUDITS	XVIII-7

APPENDIX A

TERMS AND DEFINITIONS

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

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

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-1

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

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 been authenticated.

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

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

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

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

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.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-2

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

- 3) The item is used in applications other than Mined Geologic Disposal Systems.

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 consequence of an event is 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.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-3

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

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

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

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

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

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

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

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

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

DEVIATION: A departure from specified requirements.

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

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

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

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

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

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.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-4

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

Existing data does not include information which is accepted by the scientific and engineering community as established facts (e.g., engineering handbooks, density tables, gravitational laws, etc.).

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

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

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

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

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

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

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

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

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

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

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

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-5

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

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.

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

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

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

NTS: Nevada Test Site

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

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

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

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

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-6

**YUCCA MOUNTAIN PROJECT-OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

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 personnel who are independent of the work being reviewed and have technical expertise in the subject matter being reviewed at least equivalent of that needed for 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.

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

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

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

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

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

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-7

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

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

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

PRIMARY DATA: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable quality assurance 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 Yucca Mountain Project AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the Yucca Mountain Project QA Program."

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

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

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.

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

QUALIFICATION TESTING: Demonstration that an item meets design requirements.

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

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-8

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

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

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

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 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.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-9

12

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

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

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

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

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

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

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

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

SITE: Location of the controlled area.

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

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-10

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

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

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

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

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

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

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

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

VALIDATION (QA RECORDS): 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.

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

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

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-11

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

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

YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE): 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 YMP.

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	TERMS AND DEFINITIONS	A-12

APPENDIX E

REQUIREMENTS FOR THE IDENTIFICATION OF ITEMS
AND ACTIVITIES SUBJECT TO QUALITY ASSURANCE REQUIREMENTS

1.0 GENERAL

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

2.0 QUALITY ASSURANCE CRITERIA FOR LICENSING

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

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

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	REQUIREMENTS FOR Q-LIST	E-1

2.2 CRITERIA FOR NON-Q-LIST ITEMS

Certain items that are not important to safety and/or waste isolation shall also be addressed in the license application to demonstrate compliance with 10 CFR Part 60 requirements such as those associated with meeting the design criteria contained in 10 CFR 60.131(a) for protection of worker health and safety. Additional guidance related to this subject can be found in NUREG-1318, (April, 1988), paragraph 5.1(b).

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

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

3.0 IDENTIFICATION OF ITEMS IMPORTANT TO SAFETY

Items important to safety are those items essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of unrestricted area at any time until the completion of permanent closure (10 CFR 60.2). The 0.5 rem value is, therefore, the threshold for determining what structures, systems, and components shall be on the Q-List as items important to safety. The rationale for placing a system, structure, or component on the Q-list is to provide added assurance, via application of rigorous QA/QC and design requirements, that they should perform their designated function.

3.1 Probabilistic Risk Analysis (PRA) may be used to the extent practicable, to support the identification of structures, systems, and components important to safety in the license application. Use of this approach for the operations phase of the HLW program is consistent with the approach prescribed by the EPA standard (40 CFR Part 191) for the overall system containment following emplacement of waste in a geologic repository. In cases where data are limited, engineering judgment and conservative bounding assumptions shall be used. Conservative assumptions shall include non-mechanistic failures where information and/or experience are not adequate to reliably determine failure modes and accident scenarios. However, non-mechanistic failures need not be considered where failure modes and mechanisms are understood and failure rates can be determined.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	REQUIREMENTS FOR Q-LIST	E-2

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

3.2 Operator actions or errors which could initiate accidents shall be identified in PRAs or other analyses. These shall be controlled in accordance with graded quality assurance requirements to minimize the probability of occurrence. Other activities which are subject to graded quality assurance requirements, such as designing, inspecting, and purchasing will not be identified in PRAs but shall also be controlled in accordance with graded quality assurance requirements.

3.3 PRAS shall utilize the following techniques:

3.3.1 System modeling to depict the combination of safety function and system successes or failures which constitute accident scenarios. Two modeling techniques which may be used are event tree analysis, which identifies the sequence of events that may result in an accident, and fault tree analysis, which determines how failures in safety systems may occur. Both techniques are analytical tools which organize and characterize potential accidents in a methodical manner.

An event-tree defines a comprehensive set of accident sequences that encompasses the effects of all realistic and physically possible potential accidents. By definition, an initiating event is the beginning point in the sequence. Hence, a comprehensive list of accident-initiating events shall be compiled to ensure that the event trees properly depict all important sequences.

A fault tree examines the various ways in which a system designed to perform a safety function can fail. Each safety system identified in the event tree as involved in an accident shall be examined to determine how failures of components within that system could cause the failure of the entire system.

If failure of a mitigating system could contribute to an off-site dose, individual components within the mitigating system shall be reviewed, using fault tree analysis, to determine the effect of their failure on performance of the overall system. For example, individual components in the ventilation system which may need to be analyzed include dampers, motors, and filters.

3.3.2 Consequence analysis of accident scenarios identified in event/fault tree analyses to determine the amount and kind of radionuclides which may reach the unrestricted area and contribute to an off-site dose. Consequence analysis includes identification of a source term for radioactive releases and evaluation of mechanisms for movement and deposition of radioactive materials released from the HLW facility. The energy, magnitude, and timing of radiological releases resulting from various accidents shall be considered in this analysis.

3.3.3 Analysis to assess the effect of uncertainties in the data base and uncertainties arising from modeling assumptions on the PRA findings. The insights gained in the analysis about features that are significant contributors to risk can provide qualitative understanding into system performance.

Additional guidance related to the assessment of pre-closure accidents can be found in NUREG 1318, (April, 1988), paragraph 5.2(a).

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	REQUIREMENTS FOR Q-LIST	E-3

3.4 REDUNDANCY

The use of redundant structures, systems, and components is a method of providing additional assurance that necessary safety functions will be performed if an accident occurs and that the accident dose limit will not be exceeded. In a redundant system, the failure of one train of the system shall not comprise or prevent the associated safety function from being performed. For the high-level waste repository, 10 CFR 60 [60.131(b)(5)(ii)] addresses requirements for redundancy. The items needed to provide redundancy of items important to safety shall also be on the Q-List.

3.5 USE OF PREVIOUSLY ESTABLISHED GUIDELINES AND STANDARDS

Many guidelines and standards have been developed in the nuclear power reactor program and other nuclear programs which may be applicable for the geologic repository program. For example, there are regulatory guides covering design basis earthquakes, floods, and tornado wind velocities which may be used in the design of the HLW facility and developing the Q-List. While some of these guidelines and standards may not be directly applicable to a geologic repository, they shall be considered to the extent practicable, to eliminate the need to develop new approaches.

3.6 RETRIEVAL

The option for retrieval of waste is addressed as a performance objective in 10 CFR 60.111(b). If retrieval is found to be necessary, analyses of retrieval operations shall be conducted at that time, to identify Q-List items.

4.0 IDENTIFICATION OF ITEMS AND ACTIVITIES IMPORTANT TO WASTE ISOLATION

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

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

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	REQUIREMENTS FOR Q-LIST	E-4

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

N-QA-045
5/89

The items and activities important to waste isolation shall include:

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

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

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

5.0 SUBMITTAL REQUIREMENTS

5.1 LICENSE APPLICATION

A description of the QA program to be applied to items important to safety and/or waste isolation shall be submitted with the license application. The

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	REQUIREMENTS FOR Q-LIST	E-5

submittal shall identify the structures, systems, and components important to safety, waste isolation and describe the analyses used in this identification. It should also identify waste isolation and the barriers important to waste isolation falling under the QA program and describe the evaluations used to identify these barriers [10 CFR 60.21(c) (1) (ii) (C)]. A Quality Activities List, as defined in Section 1.0, should also be provided listing major site characterization, isolation, operation, and performance confirmation activities under the QA program.

5.2 SITE CHARACTERIZATION PLANS

The following information related to the Q-List should be submitted in the Site Characterization Plan:

- o A description of the QA program to be applied to items and activities during the site characterization phase.
- o A preliminary Q-List identifying major structures, systems, and components important to safety, engineered barriers important to waste isolation and the methodology used to develop the list.
- o A list of major site characterization activities (Quality Activities List) and the QA requirements which apply to them.
- o A general description of the process by which the preliminary Q-List will be revised as the design advances.

Plans for development and implementation of a QA program to demonstrate that non-Q-List licensing requirements are met should also be described in the Site Characterization Plan.

6.0 GRADED APPLICATION OF QA MEASURES

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

- o The impact of malfunction or failure of the item, or the impact of erroneous data associated with data collection activities, on safety or waste isolation.
- o The complexity of design or fabrication of an item, or design and implementation of a test, or the uniqueness of an item of test.
- o The special controls and surveillance needed over processes, tests, and equipment.
- o The degree to which functional compliance can be demonstrated by inspection or test.

REV. NO.	ISSUED	SECTION TITLE	PAGE NO.
2	3/20/90	REQUIREMENTS FOR Q-LIST	E-6

**YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN**

**N-QA-045
5/89**

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

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

REV. NO. 2	ISSUED 3/20/90	SECTION TITLE REQUIREMENTS FOR Q-LIST	PAGE NO. E-7
---------------	-------------------	--	-----------------