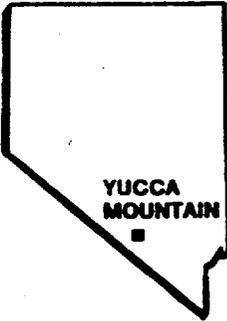


U.S. DEPARTMENT OF ENERGY

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YUCCA MOUNTAIN PROJECT



YUCCA MOUNTAIN PROJECT OFFICE

QUALITY ASSURANCE PROGRAM PLAN

AND

QUALITY MANAGEMENT PROCEDURES

Received w/Ltr Dated 4/14/89



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- REPLACE - Table of Contents, dated 4/2/89 with Table of Contents, dated 4/20/89.
- INSERT - Interim Change Notice, no. 3, dated 4/20/89, directly in front of the Interim Change Notice, no. 2, dated 4/2/89 to QMP-18-02, Surveillances.
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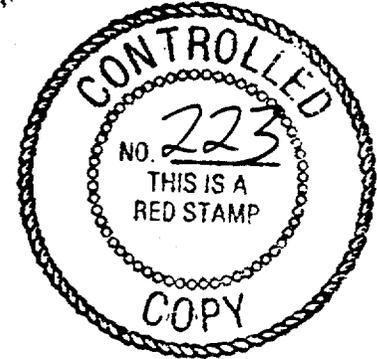
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DOE/NV

YUCCA MOUNTAIN PROJECT OFFICE

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REVISION 1

UNITED STATES DEPARTMENT OF ENERGY

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YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN

N-QA-045
10/88

DOE/NV

YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN

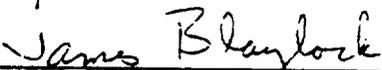
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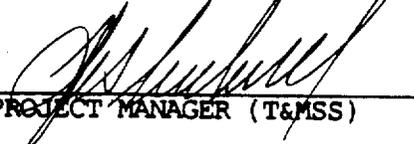
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PROJECT MANAGER, YUCCA MOUNTAIN
PROJECT OFFICE

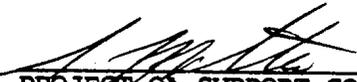
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PROJECT QUALITY MANAGER

4/13/89
DATE


PROJECT MANAGER (T&MSS)

3/20/89
DATE


PROJECT QA SUPPORT CONTRACTOR MANAGER

3/20/89
DATE

OCRWM DIRECTOR, OFFICE OF
QUALITY ASSURANCE

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YUCCA MOUNTAIN PROJECT OFFICE
QUALITY ASSURANCE PROGRAM PLAN

N-QA-045
10/88

PREFACE

This document is the fifth edition of the U. S. Department of Energy/Nevada Operations Office (DOE/NV) Yucca Mountain Project Office (Project Office) Quality Assurance Program Plan (QAPP).

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), Rev. 1. These requirements are imposed on the YMP by the Office of Civilian Radioactive Waste Management (OCRWM); the DOE/NV; 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.

On February 18, 1988, a consolidation of the Project Office QAPP, NVO-196-18, Rev. 2, and the Science Applications International Corporation (SAIC)/Technical & Management Support Services (T&MSS) QAPP, Rev. 3, was made. As directed per DOE/WMPO letter WMPO:MPK-1605, dated May 4, 1987, entitled "Quality Assurance Program Integration, Technical and Management Support Services (T&MSS), Contract DE-AC08-87NV10576 (WMPO Action Item #87-1639)," the restructuring of both the WMPO and T&MSS QA Programs into one QAPP, WMPO/88-1, Rev. 0 (formerly NVO-196-18, Rev. 2), was accomplished.

In order to support the conduct of all quality related activities, the Project Office prepares implementing procedures, either Branch Technical Procedures (BTPs) or Quality Management Procedures (QMPs) for the implementation of Project Office quality-related activities. In addition, some of the Project Office and YMP participant interface activities, which affect quality, are described in YMP Administrative Procedures (APs).

The Project Office QAPP, WMPO/88-1, Rev. 1, dated 1/ /89, was reviewed against the YMP QA Plan, NNWSI/88-9, Rev. 2, dated 12/9/88, to ensure consistency of responsibilities and requirements and resolution of previous comments. This revision encompasses all of the requirements in the current YMP QA Plan which apply to Project Office activities.

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POLICY STATEMENT

It is the policy of the U. S. Department of Energy, Nevada Operations Office (DOE/NV) that the achievement of quality in fulfilling the responsibilities for 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 documentation of quality. The establishment and implementation of the Yucca Mountain Project Office (Project Office) Quality Assurance Program Plan (QAPP) will provide DOE/NV, Project Office, and Science Applications International Corporation/ Technical and Management Support Services (SAIC/T&MSS) management with the controls necessary to verify compliance with the licensing and regulatory commitments that govern the YMP.

In order to meet our management responsibilities for achieving and ensuring quality, the DOE/NV 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 this QAPP in accordance with the Project Charter, Project Management Plan, and the YMP QAP.

The Project Office has developed the Project Office QAPP, WMPO/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 apply to all DOE/NV matrix support, Project Office, and SAIC/T&MSS personnel who perform quality related activities which support the YMP.



Nick C. Aquilina
Manager, DOE/Nevada Operations Office



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



N. E. Carter
Project Manager, SAIC/T&MSS

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SECTION I
ORGANIZATION

1.0 INTRODUCTION

This section of the Project Office QAPP describes the organizational responsibilities and interfaces of the Project Office, the internal DOE/NV matrix organization which supports the YMP, and the integrating contractor Science Applications International Corporation/Technical and Management Support Services (SAIC/T&MSS) who provides technical and management support services to the Project Office. SAIC/T&MSS functions under the Project Office QAPP. MAC technical Services Company (MACTECH) provides quality assurance and project management support for the Project Office. MACTECH functions under the Project Office QAPP on those assigned tasks within the scope of the Q.A. Program. It also describes the responsibilities and interfaces of each of the YMP participants as they interface with the Project Office. Project Office and those organizations who provide matrix support to Project Office, including SAIC/T&MSS, are required to implement the Project Office QAPP. An organizational chart depicting the YMP organization is provided in Figure 1.

2.0 DEPARTMENT OF ENERGY (DOE)

The Secretary, U. S. Department of Energy/Headquarters (DOE/HQ), was given the responsibility to carry out the Nuclear Waste Policy Act (NWPA) of 1982, as amended. This responsibility has been delegated by the DOE Secretary to the Office of Civilian Radioactive Waste Management (OCRWM) for the integration of QA and management policies and requirements for the overview of the activities performed by DOE field operations offices. The DOE/NV Operations Office has been delegated the responsibility for the implementation of the technical and QA activities of the YMP.

2.1 DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)

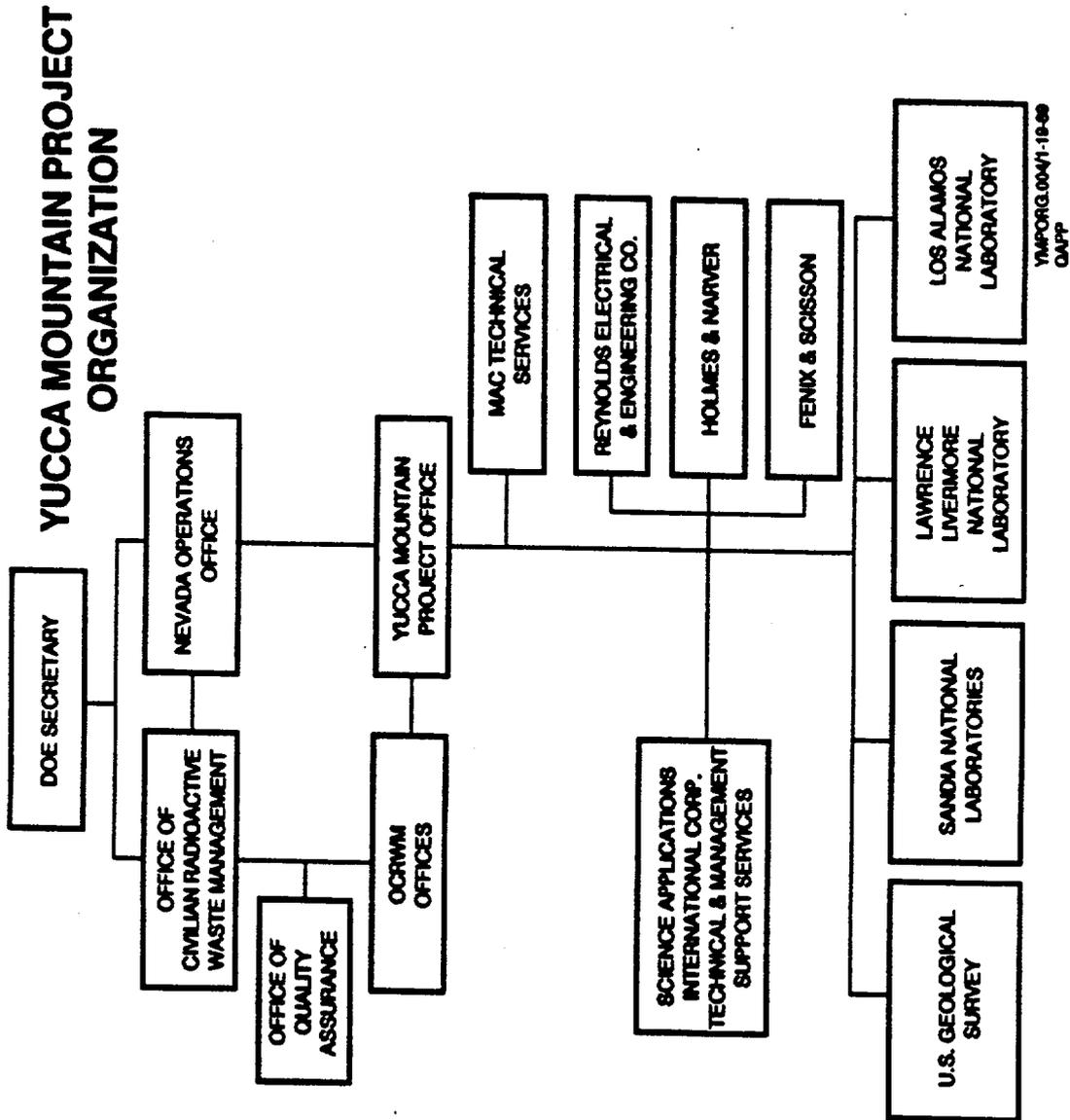
The U. S. Department of Energy Headquarters (DOE/HQ), OCRWM, provides programmatic and policy guidance to the Project Office to assure that adequate QA and technical objectives of the program are achieved.

2.1.1 OCRWM OFFICES

The OCRWM is comprised of the following offices: Program Administration and Resources Management, Facilities Siting and Development, Systems Integration and Regulation, and External Relations and Policy. These OCRWM offices provide direction to Project Office for the implementation of the OCRWM program objectives.

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Figure 1



YMFORG.00471-19-88
 OAPP

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OCRWM OFFICE OF QUALITY ASSURANCE

The OCRWM Office of Quality Assurance provides QA guidance and overview to the YMP by (1) review and approval of the YMP QA Plan and the Project Office QAPP; (2) specifying applicable requirements which are contained in the OCRWM QAR; and (3) performance of QA audits and surveillances of the Project Office.

2.2 DOE/NV OPERATIONS OFFICE

The DOE/NV Manager has the ultimate responsibility and accountability for the YMP in the Nevada Operations Office. The Project Office has been established within the DOE/NV organization for the management of the YMP. The Project Office operates as a part of the DOE/NV under the programmatic direction of the DOE/HQ OCRWM. In matters of Department policy, DOE/NV works and cooperates with DOE/HQ OCRWM in establishing a consistent QA approach for accomplishing the objectives of the Geologic Repository Program managed by the DOE/HQ OCRWM.

2.3 YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE)

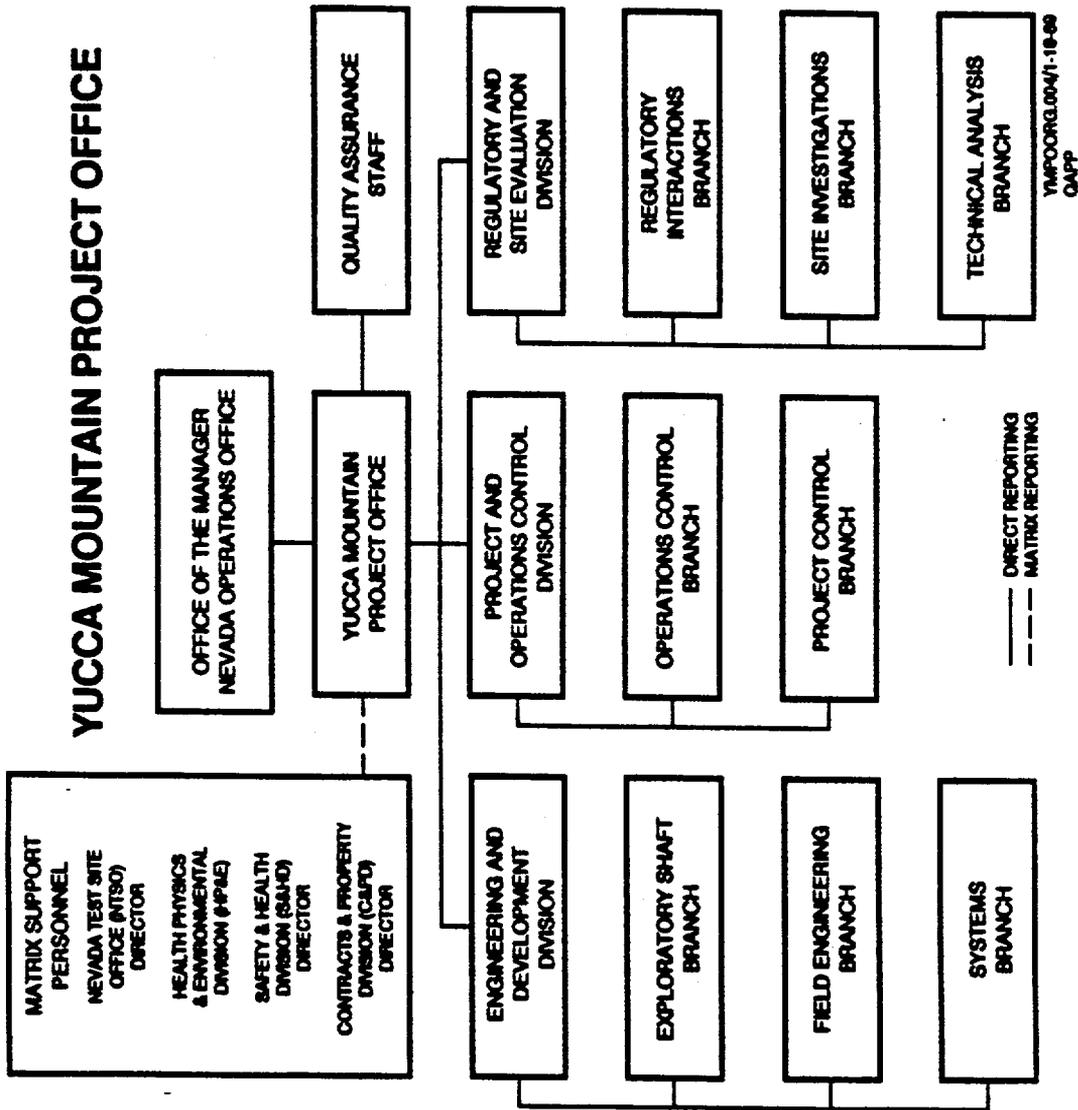
The Project Office has sole responsibility and authority for authorization of work and management and technical direction of the activities of the participating organizations and NTS support contractors through the issuance of technical and programmatic guidance, technical integration of the Project, 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. An organizational chart depicting the Project Office organization is provided in Figure 2.

The Project Manager, Project Office is responsible for the YMP management which encompasses: (1) planning and directing activities; (2) establishing goals and objectives, and assessing progress toward the attainment of those goals; (3) administration and procurement of materials and services; (4) preparation and issuance of technical and programmatic guidance; (5) organization and conduct of peer reviews; (6) compliance with laws, regulations, and DOE policies; and (7) other administrative duties. In addition, the Project Manager, Project Office is responsible for ensuring implementation of the Project Office QA program for the conduct of Project Office quality related activities and the implementation of corrective actions.

The technical responsibilities of the Project Office focus in three areas, each under the direction of a Division Director. Each Division Director is responsible for implementing the QA program in his/her area of responsibility. The QA responsibilities of the Project Office are accomplished through the efforts of the Project Office QA Organization which is comprised of the Project Office Project Quality Manager (PQM) and the SAIC/T&MSS YMP QA Support Contractor. The overall responsibility to ensure that quality assurance control and documentation is maintained throughout the Project is retained by the Project Office.

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Figure 2



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The Project Office utilizes a matrix management organizational concept to support YMP activities. The administrative responsibility for DOE/NV personnel supporting the YMP remains with the respective DOE/NV organizational element, while the functional responsibility of DOE/NV personnel performing YMP activities is to the Project Office. The organization of Project Office with the major DOE/NV divisions that provide matrix support staff is shown in Figure 2. The DOE/NV staff assists the Project Manager, Project Office by providing reviews, recommendations, and expertise on various aspects of the YMP in terms of their respective responsibilities as established in accordance with the matrix management approach. Personnel from participating organizations and NTS support contractors may also be matrixed to the Project Office. Matrix support personnel work under the implementing procedures of the Project Office QAPP.

SAIC/T&MSS is the integrating contractor for Project Office and provides broad technical, operational, and managerial support for YMP activities. SAIC/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. SAIC/T&MSS assists the Project Office in such areas as (1) the identification and analysis of, and compliance with applicable statutory, regulatory, and program requirements, (2) the Project Procedure Preparation development and execution of Project management plans and strategies, (3) 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, (4) the preparation of assigned management, technical, and scientific reports and studies, (5) presentations to the public, the program office, and affected federal, state, and other agencies on Project positions, plans, and other Project related information, (6) the execution, on an assigned basis, of any of the activities specified by the OCRWM approved work breakdown structure, (7) primary data-gathering activities in such areas as socioeconomics, meteorology, radiological monitoring and air quality, and (8) quality assurance.

2.3.1 REGULATORY AND SITE EVALUATION DIVISION

The Regulatory and Site Evaluation Division is responsible for (1) Site Characterization in field and laboratory activities (including geology, hydrology, geochemistry, geophysics, drilling, seismology, radiation safety, climate, meteorology, in-situ testing in the Exploratory Shaft Facility (ESF), and sample management facilities); (2) performance assessment (including code development, analysis, and radionuclide release calculations); (3) Nuclear Regulatory Commission (NRC) interactions (including site visits, work shops, Appendix 7 meetings, and reviews of regulations); (4) preparation of project documents required by the Nuclear Waste Policy Act and the NRC (including preparation of the Site Characterization Plan (SCP), SCP progress reports, study plans, technical input to the Environmental Impact Statement (EIS) and license application, project position papers, and prelicensing topical reports for use in the support of license application to NRC); (5) site investigation documents - evaluation and approval of reports that contain data and interpretations from site characterization; and (6) review and approval of

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YMP quality related documents as defined in QMP-06-03, "Document Review/Acceptance/Approval."

2.3.2 ENGINEERING AND DEVELOPMENT DIVISION

The Engineering and Development Division is responsible for (1) systems description, analysis, and integration; (2) waste package design and development; (3) design, construction and operation of major test facilities; (4) operational safety; (5) repository engineering including conceptual design, rock mechanics, and borehole sealing; (6) instrument and equipment development; (7) exploratory shaft design, construction, and operation; (8) engineering and technical support for Project plans, reports, and presentations; and (9) review and approval of YMP quality related documents as defined in QMP-06-03, "Document Review/Acceptance/Approval."

2.3.3 PROJECT AND OPERATIONS CONTROL DIVISION

The Project and Operations Control Division is responsible for (1) administration and management support to integrate and control the YMP including preparation of networks, monitoring milestones, and overseeing issuance of Project documentation; (2) records management system/information management system; (3) quality assurance records administration; (4) configuration management; (5) transportation; (6) socioeconomics; (7) institutional liaison; (8) Project training; (9) review and approval of YMP quality related documents as defined in QMP-06-03, "Document Review/Acceptance/Approval"; (10) environmental regulatory compliance monitoring, analysis, permitting and support, in the areas of meteorology air quality, radiological studies, and studies in the areas of archaeology, biology, Native American studies and water resources; (11) land acquisition; and (12) coordination of NTS support of YMP activities.

2.3.4 PROJECT QUALITY MANAGER (PQM)

The Project Office PQM is responsible for directing and managing the overall YMP QA Program and has appropriate organizational position, responsibilities, and authority to exercise proper control over the Project Office QA Program. The Project Office PQM is a "full-time" dedicated position and no other duties shall be assigned that would prevent full attention to YMP QA responsibilities or that would conflict with the reporting and resolution of QA issues and problems related to the YMP. This position is occupied by an individual with appropriate QA knowledge and experience. The PQM reports to the Project Manager, Project Office for the maintenance and implementation of the YMP QAP and the Project Office QAPP. The PQM is at the same or higher organizational level as the highest line manager responsible for activities affecting quality and is sufficiently independent from cost and schedule considerations. The PQM has effective communication channels with other senior management positions.

Support by the PQM to the YMP includes (1) approval of the YMP QAP, (2) approval of quality related YMP administrative procedures (APQs) (3) approval of YMP Participant QAPPs and changes thereto, (4) the approval of the Project Office QAPP, WMPO/88-1, its implementing procedures, and all changes thereto,

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(5) the responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA program implementation by the Project Office and YMP participants through the direction of audits and surveillances, and (6) coordination of Project Office QA activities. The PQM is supported by his staff of DOE employees and the SAIC/T&MSS YMP QA Support Contractor to conduct these activities. These staff positions are full time dedicated positions as defined above.

The YMP QA organizational structure is such that if disputes in QA arise between the PQM and others (e.g., Division Directors, Project participants, etc.), the disputes will be directed to the Project Manager, Project Office for arbitration. If not satisfied with the decision, the PQM has the authority to have the DOE/NV Manager arbitrate. The DOE/NV Manager may ask for assistance from the DOE/NV Quality Assurance Director (QAD) for resolution. If still not satisfied with the resolution of the problem, the PQM has the responsibility to notify OCRWM.

2.3.4.1 YMP QUALITY ASSURANCE SUPPORT CONTRACTOR

The Project Office QA Organization functions are performed by the SAIC/T&MSS YMP QA Support Contractor. The responsibilities of the Project Office QA organization are to provide for the development, maintenance, documentation, administration, and implementation of the YMP QAP and the Project Office QAPP. Project Office QA Organization activities include conducting and participating in QA audits; overview; QA surveillance and monitoring of Project Office integrated technical activities; policy guidance; review of the QAPPs prepared by the participating organizations and NTS support contractors for compliance to the YMP QA Plan; and review of YMP quality related documents as defined in QMP-06-03, "Document Review/ Acceptance/Approval," for compliance to Project QA requirements.

2.4 NEVADA TEST SITE OFFICE (NTSO)

The NTSO provides matrix support personnel functionally responsible to the Project Office for field direction and coordination of the 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.

2.4.1 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 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.

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2.4.2 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.

2.4.3 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/BQ 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.

3.0 SAIC/T&MSS ORGANIZATION

The SAIC/T&MSS organization is comprised of four Offices of Assistant Project Managers a Project Institutional Relations Office and a Senior Staff reporting administratively to the Project Manager. In order to ensure independence, the T&MSS YMP QA Support Contractor reports administratively to the Manager, Space Energy and Environment Sector and functionally to the Project Office QA Manager. The following section describes the organization, relationships, responsibilities, and authorities of the T&MSS organization in its role as the integrating contractor for the Project Office in support of the YMP. An organization chart depicting the SAIC/T&MSS organization down to the office level is shown in Figure 3.

3.1 PROJECT MANAGER (T&MSS)

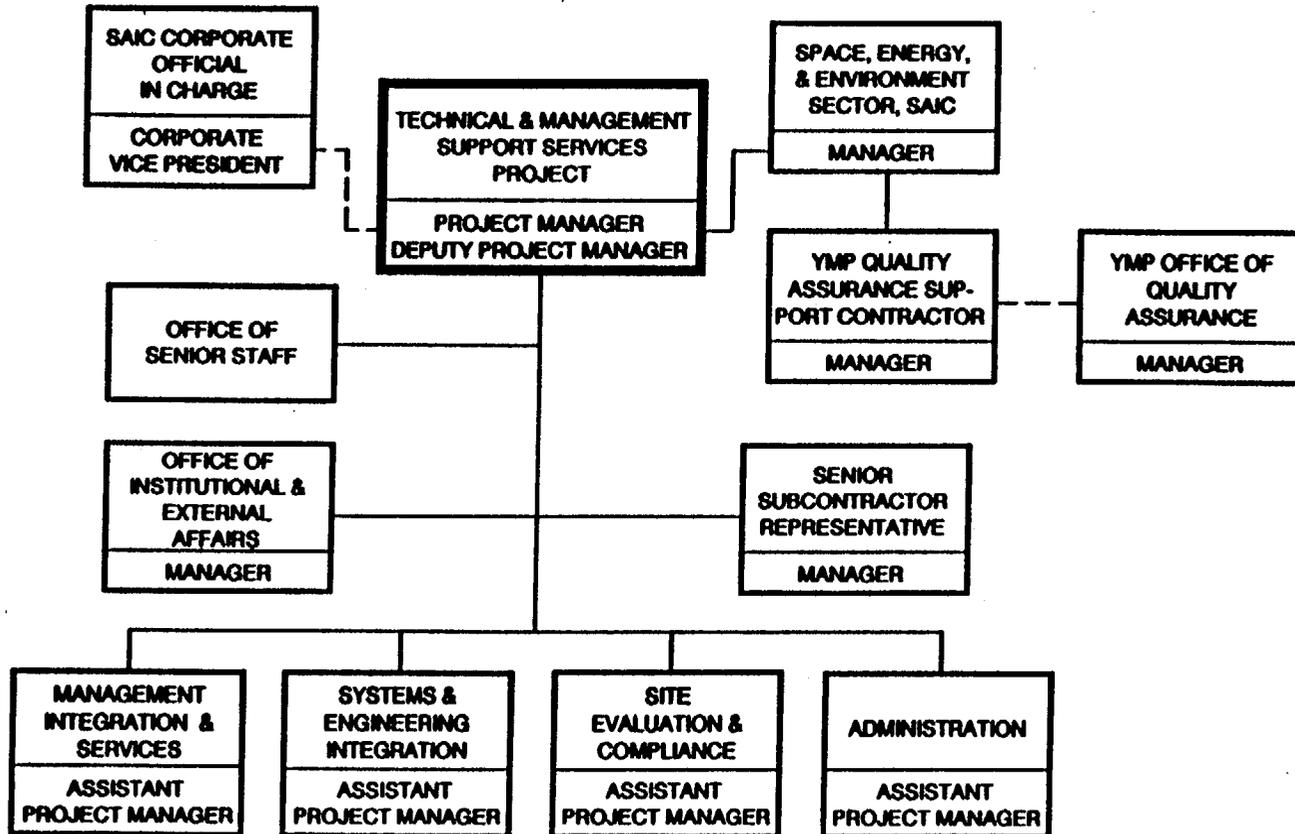
The Project Manager (T&MSS) reports directly to the Project Manager, Project Office. He has authority over all T&MSS personnel assigned to the YMP, with the exception of the T&MSS YMP QA Support Contractor, as noted in Paragraph 3.0 above, and is responsible for the management and performance of T&MSS activities in support of the Project Office.

The Project Manager (T&MSS) is responsible for ensuring implementation of the Project Office QAPP and its implementing procedures for the conduct of all T&MSS quality related activities. He is also responsible for meeting the requirements of tasks performed by T&MSS for the Project Office. These requirements include staffing, control of costs, meeting schedules, and approval of deliverables. The Project Manager (T&MSS) is the primary contact with the Project Office and the primary spokesman for T&MSS. He is also responsible for the implementation of corrective actions in cases of deficiencies in the quality of T&MSS activities or items, as documented in

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Figure 3

TECHNICAL AND MANAGEMENT SUPPORT SERVICES (T&MSS) ORGANIZATION CHART



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audits and surveillances by the Project Office QA Organization or other organizations.

3.2 DEPUTY MANAGER (T&MSS)

The Deputy Manager (T&MSS) reports to the Project Manager (T&MSS) and is delegated to act for the Project Manager (T&MSS) in his absence. He is responsible for assisting the Project Manager (T&MSS) in the implementation of the Project Office QAPP and its implementing procedures thru coordination of the activities of the SAIC/T&MSS Department Managers in the performance of their respective functions.

3.3 OFFICE OF MANAGEMENT INTEGRATION & SERVICES

The Office of Management Integration & Services provides management integration and services to the Yucca Mountain Project in the areas of (1) management interface and coordination; (2) management systems, documentation and reporting; (3) management plans and procedures; (4) planning and analysis; and (5) performance measurement and evaluation. The office also operates and integrates an authorized records management department.

3.4 OFFICE OF SYSTEMS & ENGINEERING INTEGRATION

The office of Systems and Engineering Integration provides (1) overall technical integration for the YMP in systems, waste package, repository, exploratory shaft facility, and test facilities; including engineering documentation and design reviews specifically related to waste package, repository and exploratory shaft facility designs; (2) transportation studies, (3) Project Configuration Management Support and (4) Technical data base management.

3.5 OFFICE OF SITE EVALUATION & COMPLIANCE

The office of Site Evaluation and Compliance provides technical and management support to the Project in the areas of Yucca Mountain Site Evaluation, Compliance, and Evaluation for the purpose of ensuring the complete integration of technical site evaluation programs including both surface based and ESF in-situ testing studies and those related to the compliance programs.

The office provides resources to plan and accomplish technical field programs to acquire, analyze, and report site evaluation data in the areas of the Yucca Mountain environment, climate and meteorology, radiological setting, regional and local economics, and archaeological and cultural conditions, both current and anticipated. It provides recommended mitigation actions to minimize risks and impacts to the environment and regional culture. The office operates the Project Sample Management Facility (SMF) which provides assistance in field drilling/mining program sample acquisition and management. The office provides for primary support and interface with applicable regulatory

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agencies, nuclear and environmental, ensuring technical programs are developed and executed in accordance with regulations and in fulfillment of appropriate legislated requirements necessary for successful defense of the licensing application.

3.6 OFFICE OF ADMINISTRATION

The Office of Administration provides (1) T&MSS administrative support, including personnel services and support to and coordination with Sector contract administration; (2) computer services, including software development and support, operations, and systems support; (3) publication services, including technical editing, word processing, and graphics; (4) facilities services; and (5) operates the training center which provides training services to the Yucca Mountain Project and to T&MSS.

3.7 OFFICE OF INSTITUTIONAL & EXTERNAL AFFAIRS

The office of Institutional & External affairs provides support in DOE interactions with the State of Nevada and other affected public parties.

3.8 YMP QUALITY ASSURANCE SUPPORT CONTRACTOR

The YMP Quality Assurance support contractor provides (1) quality assurance overview; (2) quality assurance implementation support, including plans and review and/or approval of procedures; and (3) audits and surveillances of Project activities. The department's function and organizational structure are further described in paragraph 5.3 of this section.

4.0 PARTICIPATING ORGANIZATIONS AND NTS SUPPORT CONTRACTORS

This QAPP identifies the major organizations participating in the Project, the designated functions of these organizations and their relationship with the Project Office. Participating organizations and NTS support contractors are responsible to the Project Office for technical activities assigned to them as specified in the YMP WBS Dictionary and Project-specific technical plans. The technical activities are to be accomplished in accordance with the QA requirements in the YMP QAP and their respective QAPPs when approved by the Project Office.

4.1 NTS SUPPORT CONTRACTORS

4.1.1 FENIX AND SCISSON, INC. (F&S)

Fenix and Scission, Inc. is the Exploratory Shaft Facility (ESF) Architect-Engineer (A-E) for drilling and mining for the YMP. Responsibilities also include surveillance & inspection of drilling & mining and subsurface facilities construction and testing.

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4.1.2 HOLMES AND NARVER, INC. (H&N)

Holmes and Narver, Inc. is the ESF A-E responsible for the design of the underground support systems and the above ground facilities. Responsibilities include surveillance and inspection of facilities construction. Additionally, they provide Material Test Laboratory support, nondestructive examination services, field surveying services, microfilming, and archival storage of YMP records.

4.1.3 REYNOLDS ELECTRICAL AND ENGINEERING COMPANY (REECO)

Reynolds Electrical and Engineering Company is the prime support contractor for subsurface and surface construction, drilling, and mining. REECO assists in the operation and maintenance of the site facilities and provides procurement and logistical activities for the YMP, when requested.

4.2 PARTICIPATING ORGANIZATIONS

4.2.1 LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL)

Lawrence Livermore National Laboratory is responsible for the development of the waste package for emplacement in tuff, which includes the definition of the package environment, material development and testing, package design, performance analysis, and testing; and provides assistance to other YMP participants in areas of specialized expertise.

4.2.2 LOS ALAMOS NATIONAL LABORATORY (LANL)

Los Alamos National Laboratory is responsible for nuclide migration, geochemistry, mineralogy, and petrology studies. Los Alamos acts as the lead technical organization for the coordination and scheduling of the exploratory shaft testing program. Los Alamos also provides assistance to other YMP participants in areas of specialized expertise.

4.2.3 SANDIA NATIONAL LABORATORIES (SNL)

Sandia National Laboratories is responsible for (1) repository systems development; (2) data management and analysis; (3) systems performance assessment of the repository; (4) conceptual design of the repository; (5) thermal and mechanical properties of the host rock; (6) repository sealing performance requirements, materials, evaluation, design, and testing; and provides assistance to other YMP participants in areas of specialized expertise.

4.2.4 U. S. GEOLOGICAL SURVEY (USGS)

The USGS is responsible for (1) site characterization of geology, hydrology, tectonism, volcanism, and seismicity; (2) acts as lead technical participant for the site characterization drilling activities; and (3) provides assistance to other YMP participants in areas of specialized expertise.

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4.2.5 MAC TECHNICAL SERVICES COMPANY (MACTEC)

MACTEC provides quality assurance and project management support for the Project Office. These services include providing assistance as requested in the development and implementation of the YMP Quality Verification Program and YMP Quality Assurance Program, and the assessment and implementation of the YMP Management Systems, Engineering Systems, Licensing Systems and processes for Project Management and Information Resources Management. MACTEC provides similar support services when requested by the Project Office to other YMP participants in areas of specified expertise. Support is provided in accordance with a Project Office approved Work Authorization, which also identifies a Project Office point of contact to provide direction for the authorized work. MACTEC implements the project QMPs and Administrative Procedures for their work within the scope of the QAPP.

5.0 PROJECT OFFICE QUALITY ASSURANCE RESPONSIBILITIES

As a YMP participant, the Project Office is responsible for the establishment and execution of the QAPP. The Project Office may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the QA program, or any part thereof, but retains the responsibility thereof. The delegation of execution of the QAPP requirements is documented. The Project Office organizational structure, lines of communication, authority and duties of persons and organizations performing activities affecting quality have been clearly established and delineated throughout this QAPP. While the Project Office Division organizations are responsible for performing these activities properly, the Project Office QA organization verifies the proper performance of work through implementation of appropriate QA controls.

5.1 PROJECT OFFICE QA ORGANIZATION FUNCTIONS

The Project Office QA Organization functions are those of ensuring that the Project Office QA program is established and executed effectively and of verifying, such as by overview, monitoring, auditing, and surveillance, that activities affecting quality functions have been performed correctly. The Project Office PQM and the Project QA Department personnel have sufficient authority, access to work areas, independence from cost and schedule, and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions through designated channels; to verify implementation of the solutions; and to ensure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. This includes the ability to stop (or cause to be stopped) unsatisfactory work through established channels. The Project Office PQM has direct access to responsible Project Office and DOE management at such levels where appropriate action can be effected.

5.2 PROJECT OFFICE QA AUTHORITY

Authority for the resolution of disputes involving quality arising from a difference of opinion between Project QA Department personnel and others is handled through the respective individual's immediate QA supervisor. Should

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this channel not provide satisfactory resolution of the dispute, then the issue is brought to the attention of the Project QA Support Contractor Manager. Should these avenues still prove unsatisfactory, then the issue is discussed with the Project Office PQM for final resolution.

5.3 PROJECT OFFICE QA ORGANIZATIONAL STRUCTURE

The Project Office QA Organization responsibilities are as described below. An organizational chart depicting the Project Office QA Organization is provided in Figure 4.

The Project Office PQM is responsible for implementation and maintenance of the Project Office QAPP and its implementing procedures for all activities affecting quality performed by the Project Office. Detailed description of the PQM's functions are contained in Paragraph 2.3.4 above.

The Project Office QA Organization functions are performed by the SAIC/T&MSS YMP QA Support Contractor, as described in Paragraph 2.3.4.1 above.

YMP QA Support Contractor Manager reports administratively to the Manager, SE&E Sector, functionally to the Project Office PQM, and interfaces with other DOE/Project Office management personnel as required to ensure implementation of the Project Office QAPP. He has overall responsibility for the management and direction of the QASC staff. The YMP QASC Deputy Manager reports to the QASC Manager and is delegated to act for him in his absence. He is responsible for assisting with the coordination of QASC activities to ensure implementation of the Project Office QAPP.

6.0 QUALITY ASSURANCE PROGRAM PLAN

The Project Office Quality Assurance Program Plan (QAPP) applies to all Quality Level I and II items and activities affecting quality on a graded basis. The Project Office organizational structure and the responsibility of assignments has been clearly established such that certain results, as described below, are obtained.

6.1 ACHIEVEMENT AND MAINTENANCE OF QUALITY

It is the policy of the Project Office that quality is achieved and maintained by those who have been assigned responsibility for performing work. Project Office quality related activities are performed in accordance with approved QMPs, BTPs, or quality related YMP APQs.

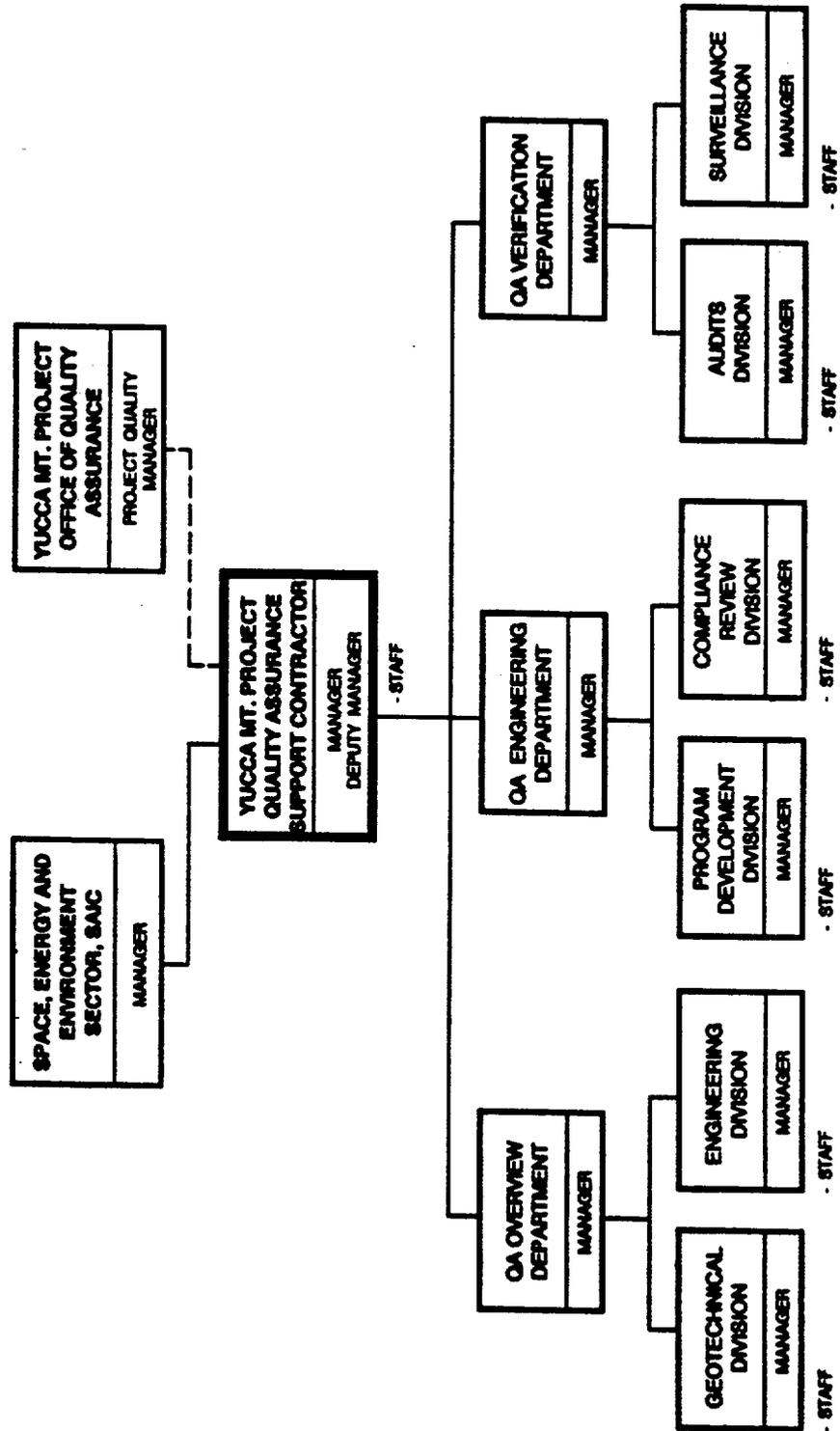
6.2 VERIFICATION OF QUALITY

Verification of conformance to established requirements (acceptance) is accomplished by individuals or groups within the Project Office QA Organization, who are not directly responsible for performing the work, unless specifically exempted elsewhere in this document.

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Figure 4

YUCCA MOUNTAIN PROJECT OFFICE QA ORGANIZATION



7.0 ORGANIZATIONAL INTERFACES

The external interfaces between the Project Office and the participating organizations and the NTS support contractors and the internal interfaces between the DOE/NV and Project Office organizational units are documented in Paragraph 2.0 of this Section. All Project Office interface responsibilities have been defined and documented in this QAPP and appropriate implementing procedures. From an overall YMP standpoint, these interfaces are exchanges of technical requirements of work to be performed and liaison until completion of work. The YMP Administrative Procedures (APs) provide the implementing interface controls utilized between Project Office and the YMP participants while Project Office QMPs and BTPs describe the methods of conducting interorganizational interfaces.

The organizational structure for executing the Project Office QA program has been described in this section of the QAPP. The Project Manager, Project Office, is responsible for ensuring that the Project activities for which the Project Office is responsible are performed in accordance with this QAPP and its respective implementing procedures which are consistent with the requirements of the YMP QA Plan.

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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 Project Quality Manager (PQM); the Project Quality Assurance Department Manager; and the Project Manager, T&MSS, prior to implementation. The Project Office QAPP is also submitted to DOE/OCRWM for review and approval.

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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 Project Quality Manager.

1.3 BRANCH TECHNICAL PROCEDURES (BTP)

These procedures govern the conduct of QA Level I or II technical (i.e., engineering, scientific, or research) activities (i.e., operation, task, function, service, or process). These procedures which are prepared at the division level describe the responsibilities of a single organization involved in a specific activity. These procedures are approved by the responsible Project Office Division Director, Assistant Project Manager, and the Project Office PQM.

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.

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Specific methods for acceptance of this information are contained in the AP 5.9Q, "Acceptance of Data and Data Interpretations 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 assigned a QA level that is consistent with its potential impact or importance, or both, in terms of radiological health and safety, waste isolation, nonradiological health and safety, the U.S. Nuclear Regulatory Commission (NRC) licensing requirements, the operability and maintainability of the repository, costs, and schedules. The Project Office is responsible for identifying the appropriate quality assurance levels and 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.

Once assigned, the QA level for a particular item or activity is applied by all YMP Participants involved in the activity.

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

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accomplishing the activity, and assurance that all prerequisites for the given activity have been satisfied. The Project Office QA Program takes into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection, test, peer review, or a combination 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 QA level assignments or 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 QA level assignments or grading. The Project Office has developed YMP Administrative Procedures for the identification of QA Levels and 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 QA Level assignment and grading. Requests for exemptions are documented and contain sufficient justification to support the exemption request. Such exemptions are approved by the Project Office PQM.

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.

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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 specified in this section are to be used to apply the graded quality philosophy to all YMP items and activities for which the Project Office is responsible.

2.2.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QA REQUIREMENTS

The appropriate QA level and grading for any item or activity shall be determined by the application of decision criteria as provided by the YMP APs. The basis for the selection of a QA level and assigned QA requirements is documented. The assigned QA levels and QA requirements must be reviewed and approved within the Project Office in accordance with the applicable YMP APs.

2.2.2 SELECTION OF SPECIFIC QA LEVELS

This approach incorporates three quality assurance levels (QA level) of which one will be assigned to each technical task that affects the quality of the YMP. The definition, application, and assignment to each of the three QA levels are described per the following:

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

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barriers to inhibit the release of radionuclides. The criteria for items or activities important to safety and waste isolation are found in 10 CFR 60, and 40 CFR 191.

2.2.2.2 QA Level II - those activities and items related to the systems, structures, and components which require a level of quality assurance sufficient to provide for reliability, maintainability, public and repository worker nonradiological health and safety, repository worker radiological health and safety and other operational factors that would have an impact on DOE and Project Office concerns, and the environment.

2.2.2.3 QA Level III - those activities and items affecting quality, not classified as QA Levels I or II.

2.2.3 APPLICATION OF LEVELS

2.2.3.1 QA LEVEL I

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

QA Level I shall be applied for near-term safety as well as long term isolation as per the following:

- o Where items and activities could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, result in, or mitigate the consequences of an accident that could result in a radiation dose, either to the whole body or to any organ, of 0.5 rem or greater, either at or beyond the nearest boundary of the unrestricted area, at any time until the permanent closure of the repository.
- o Where items and activities will provide primary data which will be relied on for performance assessment of the repository system. This data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of meeting the performance objectives for waste containment and isolation. This includes all experiments and research which have a significant impact to site-characterization or are an essential part of the data base that directly support the final design of the repository and waste package performance.

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- o Where activities could adversely impact the waste isolation capabilities of the engineered and natural barriers.
- o Where items are relied on to meet the postclosure performance objectives of the engineered barriers of the repository system.
- o Where items and activities having failed, could cause a failure of a QA Level I item, or irretrievable loss of QA Level I data.
- o The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) will be assigned a QA Level of I. One of the purposes of this design phase is to define items that will be procured and/or constructed as a result of the design activity. The definition of items includes a detailed description of their function and interrelationships. As the design phase proceeds, and the QA level for items is identified and approved, design procurement and construction activities will be governed by the QA level assigned to the item.

2.2.3.2 QA LEVEL II

QA Level II is the second highest level of quality assurance. QA Level II controls and documentation are applied to the YMP activities and items that are specifically concerned with nonradiological operation of the exploratory shaft facilities and repository, and the radiological safety of the repository worker. Additionally, activities that have a major impact on project costs or schedules that could delay the achievement of DOE/Office of Civilian Radioactive Waste Management (OCRWM) milestones must be appropriately controlled. Therefore, Quality Assurance Level II must be applied to activities and items as follows:

- o Where items and activities that are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and could have a major impact on the nonradiological health and safety of the public and repository worker and the environment.
- o Where items and activities which having failed or which are performed inadequately would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10 CFR 20.
- o Where items and activities could affect the retrievability of waste up to the time of repository closure.
- o Where items and activities involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components.
- o The design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/method/equipment is preferred, will be assigned a QA Level of II prior to execution. Where a particular item can be identified and defined during this phase, a separate QA level assignment may be made for that item. Once the QA level for such an item is identified and approved, design

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procurement and construction activities will be governed by the QA level assigned to the item.

- o Where items and activities, having failed, could result in a major cost overrun.
- o Where items and activities, if failed or not under control, could result in a major schedule slippage.

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

2.2.3.3 QA LEVEL III

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

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

2.2.4 GENERAL REQUIREMENTS

The requirements contained in this document apply to QA Level I and II items and activities unless otherwise noted herein. The requirements imposed for QA Level III items and activities are those managerial, administrative, scientific, engineering and commercial practices that are commonly used by the Project Office. Deviations within applicable criteria are permissible for Level I and Level II items and activities provided that adequate justification has been documented and approved by the Project Office PQM and the respective Project Office Division Director. Regardless of which QA level is selected, all work efforts should utilize good engineering and scientific practices consisting of selection of materials, instruments, and procedures commensurate with national, industry wide standards; documenting the sequence of steps used in the work effort; documenting the results; and any variances from the expected results.

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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."

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.

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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.

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)

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- 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 Management Project Personnel."

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.

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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 which will be used in support of the scientific investigation, including the identification of the Quality Assurance (QA) levels, or QA controls, under which 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 level 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.

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1.2 ASSIGNMENT OF QUALITY ASSURANCE LEVELS

1.2.1 ASSIGNMENT

Once a Scientific Investigation Planning Document has been developed, the QA levels 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 levels to items and activities that were identified prior to implementation of the graded QA approach. Therefore, the QA level assignments are not a part of the plans themselves, even though they would normally accompany those plans and go through the same review and approval process.

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 Quality Manager (PQM). 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 PQM, 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

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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

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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. 1.6.3.1. 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. 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.
- o Mandatory verification points.

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- 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.

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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.

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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 associated QA level assignments.

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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.

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.

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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 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.

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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 QA levels and for grading ESF items and activities as delineated in YMP APs.

2.2 QUALITY ASSURANCE LEVEL ASSIGNMENTS

All ESF design phases will be assigned a QA level prior to execution in accordance with YMP AP-5.4Q "Assignment of Quality Assurance Levels."

2.3 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.

2.4 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

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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).

2.5 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 consistent 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,

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"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."

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

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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.
- 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;

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- 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.

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 Assurance (QA) Level I and II 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.

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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 QA Level I or II 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.

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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.

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- 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 QA Level I or II 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."

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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."

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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 QA Level I and II Project Office activities in accordance with QMP-06-02, "Document Control." Controlled copies of these documents are provided to the Project Office PQM and the YMP QA Support Contractor Manager, and other appropriate staff members.

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SECTION VI

DOCUMENT CONTROL

1.0 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

1.1 METHODS

The preparation, review, approval, and issuance of Project Office documents including changes thereto, is controlled through the implementation of approved procedures and QMP-06-02, "Document Control," which require that only correct documents are used. Document control measures are applied to the following:

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

The QA organization provides an appropriate review and concurrence with the quality-related aspects of documents to ensure inclusion of quality requirements

1.2 IMPLEMENTATION

The Project Office document control system provides for the following:

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

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2.0 DOCUMENT CHANGES

2.1 MAJOR CHANGES

Changes to Project Office generated documents, other than those defined as minor changes, are considered as major changes and are reviewed and approved by the same Project Office organizations that performed the original review and approval, unless the Project Office has specifically designated another organization to perform this review. This designation is documented. The organization performing the review has access to pertinent background data or information upon which to base their approval and shall specifically consider whether the changes have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities.

2.2 MINOR CHANGES

Minor changes to Project Office generated documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval shall be defined in appropriate implementing procedures by the organization responsible for the respective document. Minor changes to quality related documents must be approved by the Project Office QA organization.

3.0 DISTRIBUTION OF DOCUMENTS

3.1 DOCUMENT CONTROL SYSTEM

The Project Office document control system ensures that documents requiring verification are not released prior to verification or, if they must be released before verification, they are uniquely identified as such and controlled in accordance with Paragraph 1.2 of this section. A master list or equivalent used to identify the correct, current, and updated versions of documents is distributed to the Project Office POM, and the YMP QA Support Contractor Manager as a minimum.

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SECTION VII

CONTROL OF PROJECT OFFICE PURCHASED ITEMS AND SERVICES

1.0 GENERAL REQUIREMENTS

Measures are established to ensure that Project Office purchased material, equipment, and services conform to Project Office procurement documents. These measures include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, audit, and examination of products upon delivery. Where required by code, regulation, or contract requirement, documentary evidence that material and equipment conform to the procurement requirements is available at the location where the material or equipment is to be used, prior to installation or use of such material and equipment. This documentary evidence is retained under the control of the Project Office information management system and is sufficient to identify the specific requirements, such as codes, standards, or specifications, that are to be met by the purchased material and equipment. Specific requirements for the control of Project Office purchased items and services are listed below and are implemented in accordance with QMP-07-03, "Control of Purchased Items and Services."

1.1 PROCUREMENT PLANNING

1.1.1 GENERAL

Project Office procurement activities are planned and documented to ensure a systematic approach to the procurement process. Procurement planning is conducted in accordance with QMP-07-03, "Control of Purchased Items and Services," which provides documented identification of Project Office procurement methods and Project Office organizational procurement responsibilities. Project Office QA Organization participation is provided for the evaluation and selection of suppliers, and verification of supplier's activities in accordance with QMP-04-01 or QMP-04-02, Procurement Document Control," as appropriate, and QMP-07-03, "Control of Purchased Items and Services." Procurement planning determines the following:

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

1.1.2 PROCUREMENT TIMING

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

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1.1.3 PROCUREMENT METHODS

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

- o Procurement document preparation, review, and change control.
- o Selection of procurement sources.
- o Project Office control of supplier performance.
- o Verification (surveillance, inspection, or audit) activities by Project Office, including notification for hold-and-witness points.
- o Control of nonconformances.
- o Corrective action.
- o Acceptance of item or service.
- o QA records.

1.2 SOURCE EVALUATION AND SELECTION

1.2.1 SELECTION OF SUPPLIERS

The selection of suppliers is based on an evaluation of their capability to provide items or services in accordance with the requirements of the procurement documents before the award of contract. These activities are accomplished in accordance with QMP-07-03, "Control of Purchased Items and Services," and QMP-07-04, "Supplier Surveys."

1.2.2 SOURCE EVALUATION AND SELECTION MEASURES

Procurement source evaluation and selection measures are implemented by the Project Office and shall provide for identification of the Project Office organizational responsibilities for determining supplier capability. These activities are to be accomplished in accordance with QMP-07-03, "Control of Purchased Items and Services," and QMP-07-04, "Supplier Surveys."

1.2.3 MEASURES FOR EVALUATION AND SELECTION OF PROCUREMENT SOURCES

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

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

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

1.3 BID EVALUATION

1.3.1 EXTENT OF CONFORMANCE

The Project Office bid evaluation process shall determine the extent of conformance to the Project Office procurement documents. This evaluation is conducted and documented in accordance with QMP-07-03, "Control of Purchased Items and Services," by Project Office technical and Project Office QA Organization personnel, or other designated organizations, to evaluate the following subjects, as applicable to the type of procurement:

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

1.3.2 RESOLUTION OF UNACCEPTABLE QUALITY ASSURANCE CONDITIONS

Before the award of the contract, the Project Office resolves or obtains commitments to resolve unacceptable quality assurance conditions resulting from the bid evaluation. These activities are documented per QMP-07-03, "Control of Purchased Items and Services."

1.4 SUPPLIER PERFORMANCE EVALUATION

1.4.1 INTERFACE MEASURES

The Project Office has established measures to interface with its suppliers, as defined per the Project Office QMPs. These procedures include the following:

- o Documentation of the agreements between the Project Office and its supplier of the provisions and specifications of the procurement documents.

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- o Requiring the supplier to identify techniques and processes to be utilized in fulfilling procurement document requirements.
- o Reviewing supplier documents that are generated or processed during activities which fulfill procurement document requirements.
- o Identifying and processing necessary change information. Measures to control changes in procurement documents have been established, implemented and documented in accordance with the requirements of this QAPP, QMP-04-01 or QMP-04-02, "Procurement Document Control," as appropriate, and QMP-07-03, "Control of Purchased Items and Services."
- o Establishing methods of document information exchange between the Project Office and its supplier.

1.4.2 VERIFICATION MEASURES

1.4.2.1 Extent of Verification

As detailed in QMP-07-03, "Control of Purchased Items and Services," QMP-18-01, "Audit System for the Waste Management Project Office," and applicable BTPs, the Project Office has established measures to verify its supplier's performance, as may be deemed necessary. These procedures describe the extent of the Project Office source surveillance and inspection activities and provide for the planning, conduct, documentation and follow-up of these activities.

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

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

1.4.2.2 Record of Verification Activities

Activities performed to verify conformance to requirements of procurement documents (i.e., source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions) are documented and evaluated to determine the effectiveness of the supplier's

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QA program in accordance with QMP-07-03, "Control of Purchased Items and Services," QMP-15-01, "Control of Nonconformances," QMP-18-01, "Audit System for the Waste Management Project Office," as appropriate, or the specific Project Office BTPs which govern the activity. These completed documents are considered QA records and are controlled in accordance with QMP-17-01, "Record Source and Record User Responsibilities."

1.5 CONTROL OF DOCUMENTS GENERATED BY SUPPLIERS

Documents that are generated by suppliers and submitted to the Project Office are controlled in accordance with QMP-04-01 or QMP-04-02, "Procurement Document Control," as appropriate, and QMP-07-03, "Control of Purchased Items and Services." Measures are established to ensure that the submittal of these documents is accomplished in accordance with the procurement document requirements. These measures provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data against acceptance criteria.

1.6 ACCEPTANCE OF ITEMS AND SERVICES

1.6.1 METHODS FOR ACCEPTANCE

Requirements and methods are established for the acceptance of an item or service being furnished by a supplier. These requirements and methods are described and implemented in accordance with QMP-07-03, "Control of Purchased Items and Services." Prior to offering the item or service for acceptance, the supplier verifies that the item or service being furnished complies with the procurement requirements. The methods used by the Project Office to accept an item or related service from a supplier is either by a supplier certificate of conformance, a source verification, a receiving inspection or post-installation test at the facility site, or a combination thereof. Requirements applicable to these methods of acceptance are listed below. Personnel selected to conduct acceptance activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities. When required, personnel shall also be indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are applicable.

1.6.1.1 Certificate of Conformance

When a certificate of conformance is used, the following minimum criteria are to be met:

- o The certificate identifies the purchased material or equipment, such as by the purchase order number.
- o The certificate identifies the specific procurement requirements met by the purchased material or equipment, such as codes, standards, or other specifications. This may be accomplished by including a list of the specific requirements or by providing at the point of receipt, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate.

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The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

- o The certificate identifies any procurement requirements that have not been met, together with an explanation and the means by which to resolve the nonconformances.
- o The certificate is attested to by a person who is responsible for this QA function and whose function and position are described in the Project Office or supplier's QA program.
- o The certificate system, including the procedures to be followed in filling out a certificate and the administrative procedures for the review and approval of the certificates, is described in the Project Office or supplier QA program.
- o Means are provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification is conducted by the Project Office at intervals commensurate with the supplier's past quality performance.

1.6.1.2 Source Verification

If source verification is used, it is performed at intervals that are consistent with the importance and complexity of the item or service and it is implemented to monitor, witness, or observe activities. Source verification includes the performance of inspections, examinations, or tests, at predetermined points. Upon the Project Office QA Organization's acceptance of source verification, documented evidence of this acceptance is furnished to the receiving destination of the item, to the responsible Project Office Division Director, and to the supplier.

1.6.1.3 Receiving Inspection

When receiving inspection is used, Project Office purchased items are inspected to verify their conformance to specified requirements, by taking into account source verification, audit documentation and the demonstrated quality performance of the supplier. Receiving inspection is performed by the Project Office in accordance with Project Office BTPs to verify by objective evidence such features as: (1) proper configuration; (2) identification; (3) dimensional, physical, and other characteristics; (4) freedom from shipping damage; and (5) cleanliness. Receiving inspection is coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

1.6.1.4 Post Installation Testing

When post installation testing is used, post installation test requirements and acceptance documentation are established mutually by both the Project Office and the supplier. Acceptance and verification of post installation test results is documented by the Project Office.

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1.7 ACCEPTANCE OF SERVICES ONLY

1.7.1 PROCUREMENT OF SERVICES ONLY

In certain cases involving procurement of services only, such as third party inspections, engineering & consulting, installation, repair, overhaul, or maintenance work, the Project Office may accept the service by any one, or by any combination, of the following methods:

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

The acceptance of services by the Project Office is described in QMP-07-03, "Control of Purchased Items and Services," which includes the requirements described above.

1.8 CONTROL OF SUPPLIER NONCONFORMANCES

1.8.1 METHODS

The Project Office and its supplier(s) will establish and document methods for disposition of items and services that do not meet procurement document requirements. These methods are detailed in QMP-07-03, "Control of Purchased Items and Services," and QMP-15-01, "Control of Nonconformances," which includes the following provisions:

1.8.1.1 Evaluation

Provisions for evaluation of nonconforming items.

1.8.1.2 Submittal

Provisions for submittal of nonconformance notice (reports) to the Project Office by the supplier is as directed by the Project Office. These submittals include supplier recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to Project Office procurement requirements or to Project Office approved documents, which consist of one or more of the items listed below, are submitted to the Project Office. Approval of the recommended disposition is in accordance with QMP-15-01, "Control of Nonconformances."

- o Technical or material requirement is violated.
- o Requirement in supplier documents, which has been approved by the Project Office, is violated.

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- o Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.
- o The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

1.8.1.3 Disposition

Provisions for Project Office disposition of supplier's recommendation.

1.8.1.4 Verification

Provisions for verification of implementation of the disposition.

1.8.1.5 Records Maintenance

Provisions for maintenance of records of nonconformances that are submitted by the supplier.

2.0 COMMERCIAL-GRADE ITEMS

2.1 ALTERNATIVES

If a design requires commercial-grade items, then the following requirements are an acceptable alternative to other requirements of this Section, except as noted in Paragraph 2.1.2 below and the requirements of Section IV of this QAPP.

If a scientific investigation requires commercial-grade items they may be controlled by the use of the following requirements (except Paragraph 2.1.1) and Section IV of this QAPP as delineated in QMP-03-02, "Scientific Investigation Control."

2.1.1 IDENTIFICATION OF COMMERCIAL-GRADE ITEMS

Where the commercial-grade item is to be used as an integral part of the designed facility, it is identified in an approved design or design output document. An alternate commercial-grade item may be supplied if the Project Office provides verification that the alternate commercial-grade item will perform the intended function and will meet the requirements applicable to both the replaced item and its application. Project Office verification is documented in accordance with QMP-07-03, "Control of Purchased Items and Services."

2.1.2 SOURCE EVALUATION AND SELECTION

Source evaluation and selection is conducted in accordance with QMP-07-03, "Control of Purchased Items and Services, and QMP-07-04, "Supplier Surveys," if it is determined necessary by the Project Office, based on the complexity of the item and its importance to safety.

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2.1.3 PURCHASE ORDER

Commercial-grade items are to be identified in the purchase order by the manufacturer's published product description (e.g., the catalog number). Control of all purchase orders and subsequent changes is in accordance with QMP-04-01, and QMP-04-02, "Procurement Document Control," as appropriate.

2.1.4 RECEIPT OF COMMERCIAL-GRADE ITEM

After receipt of a commercial-grade item, the Project Office determines that the following conditions have been met:

- o Damage was not sustained during shipment.
- o The item received was the item ordered.
- o Inspection, testing, or both, is accomplished by the Project Office, in accordance with a Project Office BTP, to ensure conformance with the manufacturer's published requirements. If applicable, acceptance of the item may be accomplished via the calibration program in accordance with the requirements of Section XII of this QAPP.
- o Documentation, as applicable to the item, was received and is acceptable.

These activities are planned, conducted and documented in accordance with QMP-07-03, "Control of Purchased Items and Services."

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SECTION VIII

IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES AND DATA

INTRODUCTION

This section of the Project Office QAPP provides the requirements for the identification and control of items, samples & data and consists of three parts. The requirements for items are stated in Part A; for samples in Part B; and, for data resulting from scientific investigations in Part C. Part A applies to activities related to engineered items and does not apply to scientific investigations; Parts B and C apply to scientific investigation activities and do not apply to any engineered items.

PART A - IDENTIFICATION AND CONTROL OF ITEMS

1.0 IDENTIFICATION

Items are identified to ensure that only correct and accepted items are used or installed. Identifications are verified prior to installation or use and are maintained either on the item, on respective containers, or in documents traceable to the item from its receipt, by the Project Office, until the time it is installed. Those items that are received and installed by the Project Office are controlled by Project Office Branch Technical Procedures (BTPs).

1.1 GENERAL

Items of production (batch, lot, component, part) are identified from the initial receipt and fabrication of the items up to and including installation and use. This identification relates an item to an applicable design or other pertinent specifying document. These activities are controlled by Project Office Branch Technical Procedures which implement the requirements of Part A, Paragraphs 1.1.1 through 1.1.4, as a minimum:

1.1.1 Physical identification is used to the maximum extent possible. Where physical identification on the item is either impracticable or insufficient, physical separation, procedural control, or other appropriate means are employed.

1.1.2 Identification markings, when used, are applied using materials and methods which provide clear and legible identification and do not detrimentally affect the function or service life of the item. Markings are transferred to each part of an identified item when subdivided and are not to be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.

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1.1.3 When explicitly identified by codes, standards, or specifications that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material, heat, batch, lot, part or serial number; or specified inspection, test or other records), the program will be designed to provide such identification and traceability control.

1.1.4 Where specified, items having limited calendar operating life or cycles are identified and controlled to preclude use of items whose shelf life or operating life has expired.

2.0 CONTROL

Provisions are made for the control of item identification consistent with the planned duration and condition of storage, such as: (1) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; (2) protection of identification on items subject to excessive deterioration due to environmental exposure; and (3) provisions for up-dating existing facility records.

PART B - IDENTIFICATION AND CONTROL OF SAMPLES

Project Office BTPs will be developed and implemented to ensure that samples are identified and controlled in a manner consistent with their intended use. These procedures define the Project Office responsibilities, including any interfaces between the Project Office and YMP participants for the collection, identification, handling, storage, transportation and the generation of related records. BTPs implement the requirements detailed in Paragraphs 1.0 through 1.1.6 as follows:

1.0 IDENTIFICATION

Physical identification is used to the maximum extent possible. Where physical identification cannot be placed on the sample, appropriate alternative identification methods are described and used. All identification methods provide a means whereby identification of samples can be traced to the appropriate documentation such as drawings, specifications, drilling logs, laboratory notebooks, test records, inspection documents, and nonconformance reports.

1.1 GENERAL

Samples are identified by placing the identification directly on the sample, on its respective container or on records traceable thereto. If it is impractical to place the identification on the sample, methods are described and implemented to ensure that samples are not mixed with like samples and that the correct identification of samples is verified and documented prior to release for use.

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

1.1.2 Storage methodologies are developed and implemented to ensure that samples are maintained in predetermined physical conditions commensurate with their intended purpose. Samples intended for long term storage shall receive appropriate treatment to ensure that they do not degrade during storage. Long term is not defined herein and will be defined by the Project Office Sample Management organization in its governing BTPs; this definition is dependent upon the sensitivity of the sample to storage conditions.

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

1.1.4 Controls and responsibilities are described and implemented to ensure that sample identification is verified and maintained when handled, transported, or transferred from one organization's responsibility to another.

1.1.5 Measures are taken to maintain sample identification while in storage. These measures are consistent with the planned duration and conditions of storage and describe actions to be taken where samples may have a maximum life expectancy while in storage. Physical segregation of samples to preclude mixing with like samples is used to the maximum degree practicable.

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

1.1.7 The Project Office will develop and implement an YMP Administrative Procedure (AP) describing the ultimate curation of all types of samples including liquids, gases and solids. The AP will, as a minimum, address the transportation, handling, storage, retrievability of samples and the generation and retention of records. All records generated as a result of testing of samples are handled in accordance with QMP-17-01, "Record Source and Record User Responsibilities."

PART C - IDENTIFICATION AND CONTROL OF DATA

1.0 IDENTIFICATION

Data generated from a Project Office scientific investigation is identified in all documents, information systems, or both, in which such data appear to assist in the determination of its correct use. QMP-03-02, "Scientific Investigation Control," provides for the following requirements, as a minimum:

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1.1 GENERAL

The identification of Project Office generated data includes a reference to the origin of the data (task, test, experiment, report, publication, etc.) and an indication of the QA level assigned to the activity which produced the data.

1.1.1 Control measures are established and implemented to ensure that Project Office generated data is properly identified. These measures include verification of the identification of such data prior to release for use.

1.1.2 Where data are the results of the efforts of more than one organization, procedures describing the organizational responsibilities for that data are developed and implemented. The documentation resulting from the scientific investigation involving more than one organization is annotated to show which organization produced what portion of the data.

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SECTION IX

CONTROL OF PROCESSES

1.0 GENERAL REQUIREMENTS

The requirements of this section apply to engineered items and scientific investigations for process control. The requirements for special processes apply to engineered items only. Measures shall be established to ensure that processes that affect quality of items or services are controlled either by instruction, procedures, or other appropriate means. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination shall be accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements. The requirements for special processes apply to engineered items only and are not applicable to the Project Office scope of work.

2.0 PROCESS CONTROL

2.1 METHODS

All processes will be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall ensure that process parameters are controlled and that specified environmental conditions are maintained. These documents will be developed and controlled in accordance with Project Office Quality Management Procedures as the need for process control develops.

2.2 IDENTIFICATION OF SPECIAL PROCESSES

2.2.1 RESPONSIBILITY

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

2.2.2 QUALIFICATION REQUIREMENTS

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

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2.2.3 CONDITIONS

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

2.2.4 APPLICABLE CODES AND STANDARDS

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

2.3 QUALIFICATION OF SPECIAL PROCESS PROCEDURES

2.3.1 PROGRAM FOR QUALIFICATION

Procedures shall be qualified in accordance with applicable codes, standards, or other specifications. The program for qualification of procedures shall be specified in documents prepared by the cognizant technical organization. The responsible QA organization shall provide appropriate reviews to assure compliance with these requirements.

2.4 QUALIFICATION OF PERSONNEL PERFORMING SPECIAL PROCESSES

2.4.1 TRAINING, QUALIFICATION, AND CERTIFICATION

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

2.4.2 PROCEDURE

Qualification shall utilize the actual working procedure to the extent possible.

2.4.3 PERSONNEL QUALIFICATION REQUIREMENTS

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

2.5 SPECIAL PROCESS EQUIPMENT

Special process equipment shall be checked out, qualified, and certified in accordance with specified requirements. These requirements shall implement the requirements of applicable codes, standards, and specifications. Equipment

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checkout, qualification, and certification shall be the responsibility of the organization performing the work. The responsible QA organization shall review the procedures for qualification of equipment for compliance with requirements.

2.6 SPECIAL PROCESS RECORDS

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

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SECTION X

INSPECTION

1.0 GENERAL REQUIREMENTS

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

2.0 PERSONNEL

2.1 REPORTING INDEPENDENCE OF PERSONNEL

Inspections are performed by Project Office personnel who do not report directly to the immediate supervisor(s) who is/are responsible for performing the activity being inspected. If these personnel are not part of the Project Office QA organization, they have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems, (2) initiate, recommend, or provide solutions to quality problems through designated channels, (3) verify implementation of solutions, and (4) ensure 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 inspection activities are not part of the Project Office QA Organization (i.e., part of line management), then the quality assurance organization overviews and monitors the inspection activity.

3.0 QUALIFICATION OF INSPECTION AND TEST PERSONNEL

3.1 GENERAL

Each person who verifies conformance of work activities for purposes of acceptance is qualified to perform the assigned inspections or tests. The qualification of personnel performing inspection and test activities is documented in accordance with QMP-02-01, "Qualification, Proficiency, Indoctrination, and Training of Waste Management Project Office Personnel." Personnel selected to perform inspection and test activities have the

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experience or training commensurate with the scope, complexity, or special nature of the activities. Personnel are also indoctrinated as to the technical objectives and requirements of the applicable codes and standards and the QA program elements that are to be employed. Documentation to support the indoctrination activities is in accordance with QMP-02-01, "Qualification, Proficiency, Indoctrination, and Training of Waste Management Project Office Personnel." The following are requirements for the qualification of Project Office personnel who perform inspection and testing activities to verify conformance to specified requirements for the purpose of acceptability.

3.2 FUNCTIONAL QUALIFICATIONS

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

3.3 LEVEL I PERSONNEL CAPABILITIES

A Level I person is capable of performing and documenting the results of inspections or tests that are required to be performed in accordance with documented Project Office procedures, acceptance standards, and/or industry practices as defined in Project Office written procedures.

3.4 LEVEL II PERSONNEL CAPABILITIES

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

3.5 LEVEL III PERSONNEL CAPABILITIES

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

3.6 EDUCATION AND EXPERIENCE QUALIFICATIONS

These education and experience requirements should be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the inspection or test activity may provide reasonable assurance that a person can competently perform a particular task. Other factors which may demonstrate capability in a given job are previous

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performance or satisfactory completion of capability testing. These factors and the basis for their equivalency are to be documented.

3.6.1 LEVEL I EDUCATION AND EXPERIENCE REQUIREMENTS

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

3.6.2 LEVEL II EDUCATION AND EXPERIENCE REQUIREMENTS

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

3.6.3 LEVEL III EDUCATION AND EXPERIENCE REQUIREMENTS

- o Six years satisfactory performance as a Level II in the corresponding inspection or test category or class; or
- o High school graduation plus ten years of related experience in equivalent inspection or testing activities; or high school graduation plus eight years of experience in equivalent inspection or testing activities with at least two years associated with nuclear facilities; or, at least sufficient training to be acquainted with relevant quality assurance aspects of a nuclear facility; or
- o Completion of college level work leading to an associate degree and seven years of related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities or, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or
- o Graduation from a four-year college plus five years related experience in equivalent inspection or testing activities with at least two years of this experience associated with nuclear facilities or, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility.

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4.0 CERTIFICATION OF INSPECTION AND TEST PERSONNEL

4.1 QUALIFICATION REQUIREMENTS

The Project Office designates those inspection or test activities that require qualified inspection and test personnel and the minimum qualification requirements for such personnel as established in this Section. If a single inspection or test requires implementation by a team or a group, then personnel who do not meet the requirements of this section may be used in data taking assignments or in repository or equipment operation, provided they are supervised or overseen by a qualified individual.

4.2 PERSONNEL SELECTION

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

4.3 INDOCTRINATION

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

4.4 TRAINING

The need for a formal training program will be determined, and such training activities will be conducted as required to qualify personnel who perform Project Office inspections and tests. On-the-job training will also be included in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests. Training will also be provided with regard to those changes to the Project Office QAPP and its implementing procedures that affect previous training. This training will be completed and documented prior to initiation of any activities. Training is in accordance with QMP-02-01, "Qualification, Proficiency, Indoctrination, and Training of Waste Management Project Office Personnel."

4.5 DETERMINATION OF INITIAL CAPABILITY

The capabilities of a candidate for certification are initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration.

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4.6 EVALUATION OF PERFORMANCE

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

4.7 CERTIFICATION OF QUALIFICATION

The qualification of Project Office personnel is certified and documented and includes the following information:

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

4.8 PHYSICAL

The Project Office will identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examinations. Provisions will be established for specifying and documenting these special characteristics as they apply to an activity.

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5.0 INSPECTION HOLD POINTS

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

6.0 INSPECTION PLANNING

Planning for inspection activities is accomplished and documented in accordance with Project Office BTPs, instructions, or checklists. These inspection procedures, instructions, or checklists provide for the following:

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

6.1 SAMPLING

When sampling is used to verify acceptability of a group of items, Project Office will develop a sampling procedure which is based on recognized standard practices.

7.0 IN-PROCESS INSPECTION

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

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7.1 COMBINED INSPECTION AND MONITORING

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

7.2 CONTROLS

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

8.0 FINAL INSPECTION

Final inspection is conducted in accordance with Project Office BTPs which, as a minimum, will specify the requirements of Paragraphs 8.1 through 8.3 below. Final inspection includes a records review of the results and resolution of all nonconformances identified by prior inspections. The final inspection is planned to reach a conclusion regarding conformance of the item to specified requirements.

8.1 INSPECTION REQUIREMENTS

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

8.2 ACCEPTANCE

The item's acceptance is documented and approved by identified authorized Project Office personnel.

8.3 MODIFICATIONS, REPAIRS, OR REPLACEMENTS

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

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9.0 IN-SERVICE INSPECTION

Required in-service inspection of structures, systems, or components will be planned and executed by or for the Project Office when it is the organization responsible for operation of such structures, systems or components. In-service inspections will be performed to approved Project Office BTPs which describe the following:

9.1 METHODS

In-service inspection methods are established and executed to verify that the characteristics of an item continue to remain within specific limits. Inspection methods include evaluation of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

10.0 RECORDS

The following are the requirements for inspection records which are retained in accordance with Section XVII of this QAPP and QMP-17-01, "Record Source and Record User Responsibilities."

10.1 INSPECTION RECORDS

As a minimum, inspection records are generated and controlled in accordance with Project Office BTPs and identify the following:

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

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10.2 PERSONNEL QUALIFICATION RECORDS

Records of Project Office inspection personnel qualification are established and maintained. The actual examinations used to qualify personnel are retained as part of the record files.

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SECTION XI

TEST CONTROL

1.0 GENERAL DISCUSSION

Project Office tests, that are required to verify the conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in service, will be planned and executed. Characteristics to be tested and test methods to be employed will be specified. Project Office test procedures are to be implemented by trained and appropriately qualified personnel. The requirements of this section apply to engineered items and do not apply to scientific investigation activities.

2.0 TEST REQUIREMENTS

Test requirements and acceptance or rejection criteria, including required levels of precision and accuracy, are identified and approved by the Project Office during task plan reviews. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests will be controlled. Test requirements and acceptance or rejection criteria are based upon specified requirements contained in applicable design or other pertinent technical documents that are approved by the Project Office.

3.0 TEST PROCEDURES

3.1 TEST INSTRUCTIONS, PROCEDURES AND DRAWINGS

Project Office Branch Technical Procedures (BTPs), test plans, or other pertinent technical documents developed specifically for test activities are prepared in accordance with QMP-05-02, "Preparation and Control of Branch Technical Procedures." The specific Project Office BTPs and test plans developed for a test activity, contain criteria for determining when a test is required and how the test is to be performed.

3.2 TEST PREREQUISITES

Project Office test plans and procedures include or reference test objectives and address provisions for ensuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites include the following, as applicable: (1) calibrated instrumentation, (2) appropriate equipment, (3) completeness of item to be tested, (4) trained or appropriately qualified personnel, (5) condition of test equipment and the item to be tested, (6) suitable and controlled environmental conditions, (7) provisions for data acquisition and storage, (8) mandatory hold points, (9) methods of documenting test data and results, and (10) methods of data analysis.

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3.3 REVIEW OF PROCEDURES

Test plans and procedures used for qualification tests shall be reviewed in accordance with design verification requirements (see Section III of this document). They shall prescribe mandatory inspection hold points (as required), methods of documenting test data and results, and methods of data analysis.

3.4 POTENTIAL SOURCES OF ERROR

The potential sources of uncertainty and error in Project Office test plans and procedures which must be controlled and measured are identified to ensure that tests are well controlled.

3.5 ALTERNATIVES

In lieu of specifically prepared written test procedures, appropriate sections of related documents, such as American Society for Testing and Materials (ASTM) methods, approved Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents must include adequate instructions and qualitative/quantitative acceptance criteria to ensure the required quality of work has been achieved.

4.0 TEST RESULTS

Test results are documented and their conformance with established and approved acceptance criteria are evaluated by a responsible authority, within the Project Office, to ensure that specified test requirements have been satisfied. Documentation is in accordance with Project Office BTPs and include the provisions of Paragraph 5.0 below.

5.0 TEST RECORDS

Project Office test records, as a minimum, identify the following:

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

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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 QA Level I or II 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.

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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.

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SECTION XIII

HANDLING, SHIPPING, AND STORAGE

1.0 GENERAL REQUIREMENTS

This section of the Project Office QAPP establishes the requirements for controlling the packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration. Handling, storage, and shipping of items is conducted in accordance with established Project Office Branch Technical Procedures (BTPs), drawings, specifications, shipment instructions, or other pertinent documents specified for use in conducting the activity; specific requirements are listed in Paragraphs 1.1 through 1.5 below and are included in one or more of these documents.

1.1 SPECIAL EQUIPMENT AND PROTECTIVE ENVIRONMENTS

When required for particular items, special equipment (e.g., containers, shock absorbers, and accelerometers) and special protective environments (e.g., an inert gas atmosphere, specific moisture content levels, and temperature levels) is specified and provided in the appropriate Project Office technical document. As a minimum, these documents are reviewed for compliance with the requirements of this Section and verified for implementation by the Project Office QA Organization.

1.2 SPECIFIC PROCEDURES

When required for critical, sensitive, perishable, or exceptionally expensive articles, specific Project Office procedures for handling, storage, packaging, shipping, and preservation are used. These procedures are developed in accordance with QMP-05-02, "Preparation and Control of Branch Technical Procedures."

1.3 INSPECTION AND TESTING OF SPECIAL TOOLS AND EQUIPMENT

Special handling tools and equipment are utilized and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with Project Office BTPs at specified time intervals, so as to verify that the tools and equipment are maintained adequately.

1.4 OPERATORS OF SPECIAL EQUIPMENT

Operators of special handling and lifting equipment are experienced or trained to use the equipment; related training activities are conducted and documented in accordance with QMP-02-01, "Qualification, Proficiency, Indoctrination, and Training of Waste Management Project Office Personnel."

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1.5 MARKING AND LABELING

Project Office BTPs used for marking, labeling, packaging, shipment, handling, and storage of items include provisions addressing the adequate identification, maintenance, and preservation of the items including indication of the presence of special environments or the need for special controls.

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SECTION XIV

INSPECTION, TEST, AND OPERATING STATUS

The corresponding section in the YMP QAP applies to engineered items and does not apply to scientific investigations. Therefore, this section does not apply to the Project Office scope of responsibility.

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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:

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

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

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approved disposition by authorized personnel. Distribution of nonconformance documentation is to all affected organizations.

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 PQM, 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 PQM 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 PQM.
- o The disposition complies with existing design documents, test plans or procedures, reports, and regulatory requirements.

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- 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, the Project Office PQM, and the Project Office of QA (Quality Engineering Department) Manager upon issuance and closure. The original nonconformance reports are sent to the Project Office for evaluation, disposition, and approval as required by this section.

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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."

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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 the Project QA Engineering Department Manager.

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SECTION XVII

QUALITY ASSURANCE RECORDS

1.0 GENERAL REQUIREMENTS

Project Office Records that furnish documentary evidence of quality are specified, prepared, and maintained in accordance with YMP APQs, Project Office BTPs, and Project Office QMPs which meet the requirements of this Section. In addition, the Project Office is responsible for the processing and storage of validated records submitted by each YMP participant.

1.1 DEFINITION

A document or item is not considered to be a QA record until it satisfies the definition of a Quality Assurance Record as defined below. The term records, as used throughout this Section, is to be interpreted as Quality Assurance Records. Quality Assurance Records include: (1) individual documents that have been executed, completed, and approved and that furnish evidence of the quality and completeness of data (including raw data), and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents, such as plans, correspondence, documentation of telecons, specifications, technical data, books, maps, papers, photographs, and data sheets; (5) magnetic media; and (6) other materials that provide data and document quality, regardless of the physical form or characteristic. A completed record is a document that will either receive no more entries or whose revision would normally consist of the reissue of the document; and is signed and dated by the originator and, as applicable, by personnel authorized to approve the document. YMP records are distributed, handled and controlled in accordance with AP-1.7Q, "NWSI Project Records Management," and other appropriate implementing procedures.

1.2 RECORDS MANAGEMENT

A records management system has been established by the Project Office for the collection and processing of YMP records and is defined, implemented and enforced in accordance with records management instructions and procedures. The records management activities to be performed by the Project Office when processing records are detailed in appropriate implementing procedures.

The Project Office has a YMP records management plan which includes the following:

- o Identifies the types of records to be generated, purchased, or maintained, including all records referenced in pertinent final reports and other documents.
- o Identifies the methods to be used to comply with all applicable records requirements, including those to be used to control in-process records.

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- o Identifies and define the responsibilities of pertinent organizations, including the QA organization.

Consistent with applicable regulatory requirements, the Project Office has established requirements concerning record types and retention that include duration, location and assigned responsibility.

1.2.1 MINIMUM RECORDS

Sufficient records are specified, prepared, and maintained to furnish documented evidence of activities that affect quality. The records include at least the following: operating logs, the results of reviews, inspections, tests, audits, monitoring of work performance, and material analyses. Also, the records include closely related data such as qualifications of personnel, procedures, and equipment. A list of typical records is contained in Appendix B of the QAPP.

1.2.2 CONTROL OF RECORDS

Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition of records are established and documented. Measures are established for the prevention of delays between record completion and storage at the Project records center.

1.3 PRESERVATION OF RECORDS

Implementing procedures define the implementation of the record system and identifies measures to be implemented for the preservation and safe-keeping of the records at the Project records center.

1.4 RETENTION CLASSIFICATION

For purposes of record retention, all YMP records are classified as lifetime records and are required to be retained for the life of the Project.

2.0 GENERATION OF RECORDS

2.1 RECORDS SPECIFICATION

The applicable design specifications, procurement documents, Project Office BTPs, Project Office QMPs, or other Project Office generated documents specify the records to be generated or maintained by the Project Office. The Project Office maintains all YMP records submitted by YMP participants, in accordance with appropriate implementing procedures.

2.1.1 QUALITY OF RECORDS

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

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2.1.2 COMPLETION OF RECORDS

Project Office generated documents that are designated to become records are completed in accordance with the methods specified in the YMP APs, Project Office BTPs, and Project Office QMPs.

3.0 VALIDATION OF RECORDS

3.1 METHODS OF VALIDATION

Project Office generated documents are considered valid records only if stamped, initialed, or signed, and dated by authorized Project Office personnel, or otherwise authenticated in accordance with approved Project Office procedures. These records may be originals or reproduced copies. Authentication may take the form of a statement by the responsible Project Office individual. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting Project Office individual.

3.2 AUTHENTICATION LIST

The Project Office maintains a list which contains the signature and initials of the Project Office personnel authorized to authenticate Project Office generated Project records.

4.0 RECEIPT OF RECORDS

4.1 RECEIPT CONTROL

The Project Office is responsible for organizing and implementing a system of receipt control of validated Project Office and YMP participant records submitted for permanent and temporary storage. The receipt control system is structured to permit a current and accurate assessment of the status of records during the receiving process. As a minimum, the receipt control system includes the following:

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

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4.2 PROTECTION OF RECORDS

The Project Office is responsible for receiving records and providing protection from damage, deterioration, or loss during the time that the records are in its possession.

5.0 RECORDS IDENTIFICATION

5.1 IDENTIFICATION DESIGNATION

Records or indexing systems, or both, provide sufficient information to permit identification between the record and the items or activities to which it applies. Records are clearly identified by a unique number or other designation which is directly traceable to controlling programmatic information (e.g., project, contract number, task number, preparing organization, author, date, title, subject, etc.). This unique identification number or other designation shall not be repeated anywhere in the YMP. The Project Office reviews and approves the records identification system of all its contractors and subcontractors to ensure consistency.

5.2 INDEXING SYSTEM

YMP records are indexed. As a minimum, the indexing system or systems include the location of the record within the YMP records management system. YMP APs and appropriate implementing procedures describe the details of the indexing system that is implemented by the Project Office.

6.0 PERMANENT STORAGE FACILITY

YMP records are controlled from the time they are complete until the time they are stored in a permanent storage facility. Temporary storage, preservation, safe keeping, and retrievability of completed records is in accordance with the requirements applicable to the permanent storage for YMP records. The use of dual storage facilities is an acceptable alternative to a single fire-rated, controlled facility.

6.1 STORAGE LOCATION

YMP records are stored in a predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies.

6.2 STORAGE PROCEDURE

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

- o A description of the storage facility.

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- o The filing system to be used.
- o Methods for verifying that the records received are legible and are in agreement with the transmittal document.
- o Methods of verifying that the records are those designated (see Paragraph 4.1 of this section).
- o The rules governing access to and control of the files.
- o Methods for maintaining control of and accountability for records removed from the storage facility.
- o Methods for filing supplemental information.

7.0 PRESERVATION

Records are stored in a manner approved by the Project Office. In order to preclude deterioration of the records, the following requirements apply:

- o Provisions are made in the storage arrangement to prevent damage from moisture, temperature, and pressure.
- o Records are firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers.
- o Provisions are made for special processed records (e.g, radiographs, photographs, negatives, microfilm, magnetic material, etc.) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.

8.0 SAFEKEEPING

8.1 MEASURES TO PRECLUDE ENTRY

Measures are established to preclude the entry of unauthorized personnel in the records storage area and prevent larceny and vandalism.

8.2 REPLACEMENT, RESTORATION, OR SUBSTITUTION

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

9.0 CORRECTED INFORMATION IN RECORDS

9.1 METHOD

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YMP records may be corrected in accordance with implementing procedures that provide for appropriate review or approval by the originating organization. The correction shall include the date and identification of the person authorized to issue such correction and shall not obliterate the corrected data.

10.0 STORAGE FACILITY

The following requirements apply to both permanent and temporary record storage facilities and are described in appropriate implementing procedures.

10.1 CONSTRUCTION AND MAINTENANCE OF FACILITY

Records are stored in single or dual storage facilities constructed and maintained in a manner that minimizes the risk of damage or destruction from natural disasters, such as winds, floods, or fires; environmental conditions such as high and low temperatures and humidity; and infestation of insects, mold, or rodents. Specific requirements for each type of facility are as follows:

10.1.1 SINGLE FACILITY

Design and construction of a single record storage facility meets the following criteria:

- o It has reinforced concrete, concrete block, masonry, or equal construction.
- o It has a floor and roof with drainage control and if a floor drain is provided, then a check valve (or equivalent device) shall be included.
- o It has doors, structures and frames, and hardware that shall be designed to comply with the requirements of a minimum two-hour fire rating.
- o Sealant is applied over walls as a moisture or condensate barrier.
- o Surface sealant is placed on the floor to provide a hard wearing surface to minimize concrete dusting.
- o It has foundation sealant and provisions for drainage.
- o It has forced-air circulation with a filtration system.
- o It has a fire protection system.
- o Only those penetrations used exclusively for fire protection, communication, lighting, or temperature and humidity control are allowed. All such penetrations are sealed or dampered to comply with the minimum two-hour fire protection rating.
- o The construction details are reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire

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protection and fire extinguishing.

- o If the facility is located within a building or structure, then the environment and construction of that building can provide a portion or all of these criteria.

10.1.2 ALTERNATE SINGLE FACILITIES

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

- o Two-hour fire rated vault that meets National Fire Protection Association (NFPA) 232-1975.
- o Two-hour fire rated Class B file containers that meet the requirements of NFPA 232-1975.
- o Two-hour fire rated file room that meets the requirements of NFPA 232-1975 with the following additional provisions:
 - An early-warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station.
 - Records storage in fully enclosed metal cabinets.
 - Adequate access and aisle ways.
 - Work that is not associated directly with record storage or retrieval shall be prohibited in the file room.
 - Smoking, eating, or drinking is prohibited in the file room.
 - Two-hour fire rated dampers or doors in all boundary penetrations.

10.1.3 DUAL FACILITIES

If storage at dual facilities for each record is provided, then the facilities are at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Neither facility is required to satisfy the requirements of Paragraphs 10.1.1 or 10.1.2 but must meet the other requirements of this document.

11.0 RETRIEVAL

11.1 PROVISIONS

The records management system provides for retrieval of information in accordance with planned retrieval times based upon the record type. Final reports contain a listing, by unique number or other designation, that enables prompt retrieval of all documents used to compile or evaluate the report. This listing includes, as a minimum, all referenced documents, peer review or

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other review documents, computer codes, data sheets, procedures, and test plans. All documents referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineers handbook, etc., are retrievable from the records management system.

11.2 PERSONNEL

A list is maintained that designates those personnel who have access to the record files.

12.0 DISPOSITION

12.1 ACCESSIBILITY AT VARIOUS LOCATIONS

Records that are accumulated at various locations, prior to transfer, must be made accessible to the Project Office either directly or through the Project Office authorized procuring organization.

12.2 CUSTODIAN

The custodian inventories the submittals, acknowledges receipt, and processes these records in accordance with procedures which implement the requirements of this QAPP.

13.0 LIST OF TYPICAL RECORDS

The YMP records period is defined as lifetime. Records will be submitted to the YMP records center by the Project Office in accordance with QMP-17-01, "Record Source and Record User Responsibilities." A listing of typical records is provided in Appendix B of this QAPP. Actual record types are defined in record management procedures and other implementing procedures.

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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.

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)

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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 PQM.

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.
- 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

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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.

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

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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 lead auditor, and approved by the Audits and Surveillances Division Manager (T&MSS) 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.
- 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.

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1.7 AUDIT RESPONSE AND FOLLOW-UP

The lead auditor 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".

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

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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.

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APPENDIX A

TERMS AND DEFINITIONS

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

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

ACTIVITIES THAT AFFECT QUALITY: Deeds, actions, work, or performance of a specific function or task. The 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).

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

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

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

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

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

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

CONSEQUENCE ANALYSIS: A method by which the 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.

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

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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. 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.).

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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.

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.

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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.

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.

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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.

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.

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PRIMARY DATA: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable Quality Assurance Level I requirements and is necessary for the resolution of the NRC performance objectives of 10CFR60 in accordance with the Yucca Mountain Project Issues Resolution Strategy. This includes information that has been qualified and accepted in accordance with 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.

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

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

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

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

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

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

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

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

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

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

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

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

REPOSITORY: See Geologic Repository Operations Area.

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

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

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

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

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

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

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SITE: Location of the controlled area.

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

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

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

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.

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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.

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.

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APPENDIX B

LIST OF TYPICAL QA RECORDS

The following is a list of typical QA records. The nomenclature of these may vary for each Participating Organization and NTS Support Contractor. The YMP retention period is defined as lifetime. (1) QA records will be submitted to the Project Records Center in accordance with approved procedures.

1.0 SITE CHARACTERIZATION

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

2.0 DESIGN RECORDS

- o Applicable codes and standards used in design.
- o Design drawings.

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

3.0 PROCUREMENT RECORDS

- o Procurement specifications.
- o Purchase order including amendments.

4.0 MANUFACTURING RECORDS

- o Applicable code data reports.
- o As-built drawings and records (Note: As-built drawings and records shall correctly identify the installed condition of the item. The type of as-built drawings and records to be maintained shall be specified).
- o Certificate of compliance.
- o Electrical control verification tests results.
- o Liquid penetrant examination final results.
- o Location of weld filler material.
- o Magnetic particle examination final results.
- o Major defect repair records.
- o Material properties records.
- o Nonconformance reports.

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- o Performance test procedure and results records.
- o Pressure test (hydrostatic or pneumatic).
- o Radiographs (for in-service inspection applications).
- o Radiograph review records.
- o Ultrasonic examination final results.
- o Welding procedures.

5.0 INSTALLATION AND CONSTRUCTION RECORDS

5.1 RECEIVING AND STORAGE - NONCONFORMANCE REPORTS

5.2 CIVIL

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

5.3 WELDING

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

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- o Radiograph review records.
- o Weld location diagrams.
- o Weld procedures.

5.4 MECHANICAL

- o Cleaning procedures and results.
- o Installed lifting and handling equipment procedures, inspection, and test data.
- o Lubrication procedures.
- o Pipe hanger and restraint data.

5.5 ELECTRICAL AND INSTRUMENTATION AND CONTROL

- o Cable pulling tension data.
- o Cable separation data.
- o Cable splicing procedures.
- o Cable terminating procedures.
- o Cable test reports.
- o Relay test procedures.

5.6 GENERAL

- o As-built drawings and records.
- o Final inspection reports and releases.
- o Nonconformance reports.
- o Specifications and drawings.
- o Details of equipment, methods, progress, and sequence of work.
- o Construction problems.

6.0 PRE-OPERATIONAL AND START-UP TEST RECORDS

- o Final system adjustment data.
- o Pre-operational test procedures and results.

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7.0 OPERATION RECORDS

- o Records and drawing changes that identify repository design modifications made to systems and equipment described in the Final Safety Analysis Report.
- o Radioactive waste inventory, emplacement location, and transfer records.
- o Environmental monitoring survey records.
- o Waste shipment records.
- o Repository radiation and contamination survey results.
- o Radiation exposure records for individuals entering radiation control areas.
- o Records of transient or operational cycles for those repository components designed for a limited number of transients or cycles.
- o Training and qualification records for members of the repository operating staff.
- o In-service inspection records.
- o Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments.
- o Meeting minutes of the Repository Nuclear Safety Committee and licensee nuclear review board.
- o Surveillance activities, inspections, and calibrations required by the technical documents.
- o Records of repository tests and experiments.
- o Changes made to Operating Procedures.
- o Sealed source leak-test results.
- o Records of annual physical inventory of all sealed source material.
- o Logs of repository operation.
- o Records and logs of maintenance activities, inspection, repair, and replacement of principal items of structures, systems, and components
- o Fire protection records.
- o Nonconformance reports.
- o Repository equipment operations instructions.

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- o Security plan and procedures.
- o Emergency plan and procedures.
- o Quality Assurance and Quality Control Manuals.
- o Applicable records noted in other section of this appendix for any modification or new construction applicable to structures, systems, or components.
- o Evaluation of results of reportable safety concerns as required by regulations.
- o Annual environmental operating report.
- o Annual repository operating report.
- o Location and description of dewatering systems.

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APPENDIX C

REQUIREMENTS FOR QUALIFICATION OF EXISTING DATA NOT GENERATED
UNDER A QA PROGRAM MEETING THE REQUIREMENTS OF 10 CFR 60, SUBPART G

1.0 GENERAL

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

2.0 METHODS FOR QUALIFICATION OF EXISTING DATA

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

- a. The execution of the peer review process in accordance with the requirements of Appendix J of this QA Plan.
- b. The use of corroborating data which is defined as existing data used to support or substantiate other existing data. Inferences drawn to corroborate the existing data shall be clearly identified, justified, and documented. The level of confidence associated with corroborating data is related to the quality of the program under which it was developed and the number of independent data sets. The amount of corroborating data needed shall be dealt with on a case-by-case basis in the documented reviews for qualification.
- c. The use of confirmatory testing which is defined as testing conducted under a 10CFR60, Subpart G QA program which investigates the properties of interest (e.g., physical, chemical, geologic mechanical) of an existing data base. One example of confirmatory testing is testing conducted under the same environmental conditions and with similar or the same procedures, test material, and equipment as the original test which generated the existing data. Another type of confirmatory testing is testing conducted by different test methods and equipment but which still investigates the same parameter of interest. The amount of confirmatory testing required shall be dealt with on a case-by-case basis in the documented reviews for qualification.
- d. Demonstrating that the existing data was collected under a QA program which is equivalent to a 10 CFR 60, Subpart G QA program.

3.0 SELECTION AND DOCUMENTATION OF QUALIFICATION METHODOLOGY

3.1 When the methods indicated in Sections 2.1b, 2.1c, and 2.1d are utilized to qualify existing data, a technical review shall be conducted to support the quality of the data.

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Additional confidence/credibility can be achieved when a combination of methods is used.

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

- a. Qualifications of personnel or organizations generating the data are comparable to qualification requirements of personnel generating similar data under the approved 10 CFR 60, Subpart G program.
- b. The technical adequacy of equipment and procedures used to collect and analyze the data.
- c. The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).
- d. The environmental conditions under which the data were obtained if germane to the quality of data.
- e. The quality and reliability of the measurement control program under which the data were generated.
- f. The extent to which conditions under which the data were generated may partially meet Subpart G.
- g. Prior uses of the data and associated verification processes.
- h. Prior peer or other professional reviews of the data and their results.
- i. Extent and reliability of the documentation associated with the data.
- j. Extent and quality of corroborating data or confirmatory testing results.
- k. The degree to which independent audits of the process that generated the data were conducted.
- l. The importance of the data to showing that the proposed repository design meets the performance objectives of 10 CFR 60, Subpart E.
- m. Replication of test results.

Note: Additional guidance related to this subject can be found in NUREG-1298 "QUALIFICATION OF EXISTING DATA FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES" (February, 1988).

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APPENDIX D

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

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

1.0 OBJECTIVES

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

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

2.0 APPLICABILITY

The detailed requirements set forth in this appendix apply to computer software used to produce or manipulate data which is used directly in site characterization, and the design, analysis, performance assessment, and operation of repository structures, systems, and components. The extent to which these requirements apply is related to the nature, complexity, and importance of the software application. The application of specific requirements is prescribed in the Project Office "Software QA Plan" and in Project Office Quality Management Procedures.

3.0 TERMS AND DEFINITIONS

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

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4.0 SOFTWARE LIFE CYCLE

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

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

Requirements

Design

Implementation

Test

Installation
and Checkout

Operation and
Maintenance

4.1 SOFTWARE QA PLAN

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

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

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

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- o Required documentation.
- o The required software reviews.

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

4.1.2 Within the Software QA Plan, software lifecycle management shall be described. The Software QA Plan shall present the specific software lifecycle controls that apply. The following lifecycle elements shall apply, as appropriate, for the specific lifecycle model defined, interpreted, and described.

4.1.2.1 Requirements Phase

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

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

4.1.2.2 Design Phase

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

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

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

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4.1.2.3 Implementation Phase

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

Verification and validation activities during this phase shall consist of:

- o The possible modification of test cases necessary due to design changes made during coding.
- o The examination of source code listings to assure adherence to coding standards and conventions.

4.1.2.4 Testing Phase

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

Verification and validation activities during this phase shall consist of:

- o The evaluation of the completed software to assure adherence to the requirements.
- o The preparation of a report on the results of software verification and validation.

4.1.2.5 Installation and Checkout Phase

During this phase the software becomes part of a system incorporating other software components, the hardware, and production data. The process of integrating the software with other components may consist of installing hardware, installing the program, reformatting or creating databases, and verifying that all components have been included.

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

4.1.2.6 Operations and Maintenance Phase

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

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5.0 SOFTWARE VERIFICATION AND VALIDATION

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

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

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

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

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

5.1 VERIFICATION

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

5.2 VALIDATION

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

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

6.0 SOFTWARE CONFIGURATION MANAGEMENT

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

6.1 CONFIGURATION IDENTIFICATION

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

A labeling system for configuration items shall be implemented that:

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

6.2 CONFIGURATION CHANGE CONTROL

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

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6.3 CONFIGURATION STATUS ACCOUNTING

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

7.0 DOCUMENTATION

Minimum acceptable lifecycle documentation of computer software developed or modified for use by the Yucca Mountain Project Office is specified in the Project Office Software QA Plan. The documentation provided shall describe the following, as applicable. Additional documentation may also be identified in the Project Office Software QA Plan.

7.1 SOFTWARE REQUIREMENTS SPECIFICATION

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

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

7.2 SOFTWARE DESIGN DOCUMENTATION

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

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

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- o A description of the allowable and tolerable ranges for inputs and outputs.
- o The design described in a manner that is easily traceable to the software requirements.
- o Code assessment and support documentation and descriptions of mathematical models and numerical methods as required by NRC publication NUREG-0856.
- o Continuing documentation, code listings, and software summary forms as required by NUREG-0856.

7.3 SOFTWARE IMPLEMENTATION DOCUMENTATION

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

7.4 SOFTWARE VERIFICATION AND VALIDATION DOCUMENTATION (TEST)

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

7.5 USER DOCUMENTATION

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

- o Program considerations, options, and initialization procedures.
- o Anticipated error situations and how the user can correct them.
- o Internal and external data files, their input sequence, structures, units, and ranges.
- o Input and output options, defaults, and formats.

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- o System interface features and limitations.
- o Information for obtaining user and maintenance support.
- o Sample problems.

8.0 REVIEWS

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

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

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

8.1 SOFTWARE REQUIREMENTS REVIEW

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

8.2 SOFTWARE DESIGN REVIEW

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

8.3 SOFTWARE IMPLEMENTATION REVIEW

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

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8.4 SOFTWARE VERIFICATION AND VALIDATION REVIEW

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

9.0 DISCREPANCY REPORTING AND CORRECTIVE ACTION

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

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

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

10.0 MEDIA CONTROL AND SECURITY

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

11.0 ACQUIRED SOFTWARE

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

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

12.0 COMPUTER SOFTWARE APPLICATIONS

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

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

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

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

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

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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 Level I requirements of this QA Plan specify the QA program for these items and related activities important to safety and/or waste isolation to assure that their characterization, design, construction, and operation comply with the requirements of 10 CFR Part 60.

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

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

2.2 CRITERIA FOR NON-Q-LIST ITEMS

Certain items that are not important to safety and/or waste isolation shall also be addressed in the license application to demonstrate compliance

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with 10 CFR Part 60 requirements such as those associated with meeting the design criteria contained in 10 CFR 60.131(a) for protection of worker health and safety. While these items are not subject to the QA Level I requirements of this QA Plan, QA Level II requirements shall be applied. Additional guidance related to this subject can be found in NUREG-1318, (April, 1988), paragraph 5.1(b).

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.

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 QA Level I requirements to minimize the probability of occurrence. Other

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activities which are subject to QA Level I requirements, such as designing, inspecting, and purchasing will not be identified in PRAs but shall be controlled in accordance with QA Level I requirements.

3.3 PRAS shall utilize the following techniques:

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

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).

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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).

The items and activities important to waste isolation shall include:

- o Components of the engineered barrier system relied on to meet the performance objectives.

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

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

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

5.0 SUBMITTAL REQUIREMENTS

5.1 LICENSE APPLICATION

A description of the QA program to be applied to items important to safety and/or waste isolation shall be submitted with the license application. The submittal shall identify the structures, systems, and components important to safety, waste isolation and describe the analyses used in this identification. It should also identify waste isolation and the barriers important to

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

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

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APPENDIX F

REQUIREMENTS FOR PEER REVIEW

1.0 General

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

2.0 APPLICABILITY OF PEER REVIEW

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

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

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

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

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3.0 STRUCTURE OF PEER REVIEW GROUP

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

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

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

4.0 ACCEPTABILITY OF PEERS

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

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

5.0 PEER REVIEW PROCESS

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

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5.2 The peer review group shall evaluate and report on:

- a. Validity of assumptions.
- b. Alternate interpretations.
- c. Uncertainty of results and consequences if incorrect.
- d. Appropriateness and limitations of methodology and procedures.
- e. Adequacy of application.
- f. Accuracy of calculations.
- h. Adequacy of requirements and criteria.
- g. Validity of conclusions.

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

6.0 PEER REVIEW REPORT

6.1 A report documenting the results of the peer review shall be prepared and issued. The peer review report shall include the following:

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

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

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APPENDIX G

FORMAT AND CONTENT REQUIREMENTS FOR SCP STUDY PLAN

1.0 Purpose and Objectives of Studies:

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

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

2.0 Rational for Selected Study:

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

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

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

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

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

3.0 Description of Tests and Analyses:

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

- a) Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g., spatial location relative to the site, ESF elements, repository layout, stratigraphic units, depth, and test location);
- b) Summarize the test methods. Reference any standards procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA level 1. Reference the applicable specific QA requirements that will be applied to the test;
- c) Specify the tolerance, accuracy, and precision required in the test, where appropriate;
- d) Indicate the range of expected results of the test and the basis for those expected results;
- e) List the equipment required for the test and describe briefly any such equipment that is special;
- f) Describe techniques to be used for data reduction and analysis of the results;

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- g) Discuss the representativeness of the including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results;
- h) Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests, and
- i) Relationship of the test to the set performance goals and confidence levels.

3.2 For each type of analysis:

- a) State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;
- b) Describe the methods of analysis including any analytical expressions and numerical models that will be employed;
- c) Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA level 1. Reference the applicable QA requirements.
- d) Identify the data input requirements of the analysis;
- e) Describe the expected output and accuracy of this analysis; and
- f) Describe the representativeness of the analytical approach (e.g., with respect to spatial variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.

4.0 Application of Results:

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

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

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

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

Schedule and Milestones:

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

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

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

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WMPO Quality Management Procedures (QMPs)

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QMP No.	ICN No.	QMP Title	Revision No.
QMP-01-01		WMPO Organization	1 (5/27/88)
QMP-01-02		Stop Work	0 (4/11/88)
QMP-02-01		Qualification, Proficiency, Indoctrination, and Training of Waste Management Project Personnel	1 (9/2/88)
QMP-02-02		Qualification of Quality Assurance Audit Personnel	1 (2/22/88)
QMP-02-03		Quality Assurance Management Assessment	In Preparation
QMP-02-08		Technical Assessment Review	0 (8/8/88)
QMP-02-08	1		(2/7/89)
QMP-02-09		Development and Conduct of Training	0 (3/31/89)
QMP-03-01		Peer Reviews	1 (1/11/89)
QMP-03-02		Scientific Investigation Control	In Preparation
QMP-03-03		Use of Software	In Preparation
QMP-03-04		Software Design, Development and Documentation	In Preparation
QMP-03-05		Verification and Validation of Software	In Preparation
QMP-03-06		Software Configuration Management	In Preparation
QMP-03-07		Software Approval	In Preparation
QMP-04-01		Procurement Document Control	0 (4/11/88)
QMP-04-02		Procurement Document Control (Project Office Initiated)	In Preparation

Date: April 20, 1989

QMP No.	ICN No.	QMP Title	Revision No.
QMP-05-01		Preparation and Control of Quality Management Procedures	1 (4/11/88)
QMP-05-02		Preparation and Control of Branch Technical Procedures	0 (5/27/88)
QMP-05-03		Preparation and Control of the NNWSI Project QAP and the WMPO QAPP	0 (5/27/88)
QMP-06-02		Document Control	1 (12/1/88)
QMP-06-02	1		(4/2/89)
QMP-06-03		Document Review/Acceptance/Approval	1 (2/22/88)
QMP-06-03	1		(5/5/88)
QMP-06-03	2		(8/1/88)
QMP-07-03		Control of Purchased Items and Services	0 (4/11/88)
QMP-07-04		Supplier Surveys	To be Developed
QMP-15-01		Control of Nonconformances	1 (5/27/88)
QMP-16-01		Corrective Action	0 (12/10/88)
QMP-16-02		Trend Analysis	2 (5/27/88)
QMP-16-03		Standard Deficiency Reporting System	0 (3/27/87)
QMP-17-01		Record Source and Record User Responsibilities	0 (1/11/89)
QMP-18-01		Audit System for the Waste Management Project Office	3 (10/3/88)
QMP-18-02		Surveillances	1 (5/27/88)
QMP-18-02	1		(2/6/89)
QMP-18-02	2		(4/2/89)
QMP-18-02	3		(4/20/89)
QMP-18-02	4		(4/20/89)

Date: April 20, 1989 |

INTERIM CHANGE NOTICE

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ICN Number:

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4/20/89

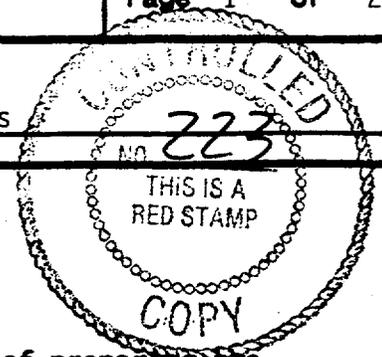
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Applies to QMP:

Number 18-02

Rev. 1

Title Surveillances



REQUIRED CHANGES:

QMP SECTION

CHANGE TO

5.1.2

Surveillance personnel have the option of preparing the Surveillance Checklist (see Figure 2, Surveillance Checklist) or a Surveillance Plan, as appropriate, that identifies elements of the activity to be observed. The Surveillance Checklist or the Surveillance Plan shall identify characteristics, methods, and acceptance criteria; shall provide for recording objective evidence of results and accuracy of the equipment necessary to perform a surveillance. The Surveillance Checklist or the Surveillance Plan shall be signed and dated by the originating personnel. Applicable reference documents shall be reviewed prior to the start of the surveillance to determine specific requirements to be observed during the surveillance. Requirements documents used to conduct the surveillance shall be listed in the surveillance report. It should be noted that in some cases a verification surveillance may be conducted without either a Surveillance Checklist or a Surveillance Plan (i.e., verification of committed remedial and corrective action).

5.2.4

The surveillance team for a scientific investigation shall consist of one or more qualified technical individuals and one or more QA personnel who are familiar with the plan for the scientific investigation. Surveillance personnel shall not report directly to the immediate supervisors who are responsible for the work being surveilled.

5.3.4

As a minimum, surveillance reports shall identify the following:

1. Date of surveillance.
2. Name of individual(s) performing the surveillance.
3. Identification of the organization(s), activities, or items surveilled, including the name(s) of personnel contacted.

APPROVALS

Project Manager, T&MSS

W Macnath
Date April 19, 1989

Project Quality Manager

James Blaylock
Date 4/20/89

Project Manager

Carl [Signature]
Date 4/20/89

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REQUIRED CHANGES:

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4. Description of deficiencies, nonconformances, and potential quality problems identified during the surveillance.
5. Surveillance criteria.
6. Equipment used during the surveillance.
7. Results.
8. Acceptance statement.

Figure 2

Revise form N-QA-054, dtd. 2/88.

Add "Prepared By _____ Date _____"

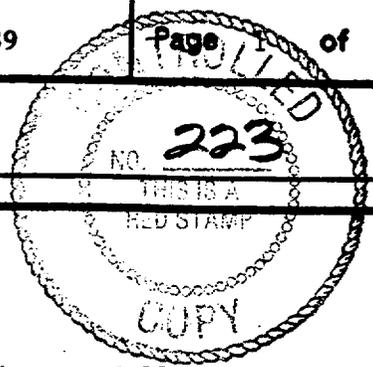
above "Surveillance Checklist No. _____".

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Applies to QMP:
Number 18-02 Rev. 1 Title Surveillances



REQUIRED CHANGES:

QMP SECTION

Paragraph 5.3.2.1.

CHANGE TO

Change this section as follows:

"The surveillance report shall be submitted to the YMPO PQM for review and approval within 20 calendar days from the date the surveillance was performed. Issuance of the report shall be within 25 calendar days."

APPROVALS

Project Manager, T&MSS <i>W Macnatt</i> Date <i>April 14, 1989</i>	Project Quality Manager <i>James Blaylock</i> Date <i>APRIL 14, 1989</i>	Project Manager <i>[Signature]</i> Date <i>4/14/89</i>
--------------------------------------------------------------------------	--------------------------------------------------------------------------------	--------------------------------------------------------------