

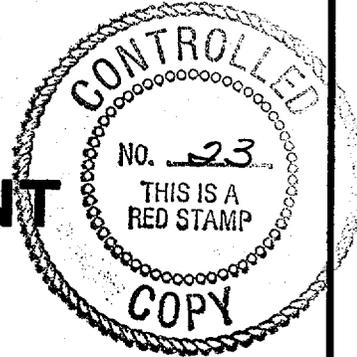
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Nevada Nuclear Waste Storage Investigations Project

WASTE MANAGEMENT PROJECT OFFICE



QUALITY ASSURANCE PROGRAM PLAN & QUALITY MANAGEMENT PROCEDURES

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Box 10

Nevada Operations Office

UNITED STATES DEPARTMENT OF ENERGY



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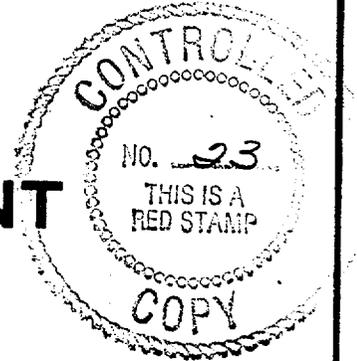
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WASTE MANAGEMENT PROJECT OFFICE



QUALITY ASSURANCE PROGRAM PLAN & QUALITY MANAGEMENT PROCEDURES

Nevada Operations Office

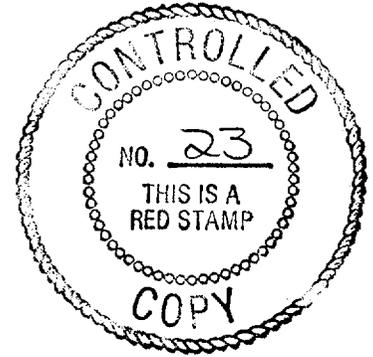
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WMPO QAPP

N-QA-045
1/87



DOE/NV

WASTE MANAGEMENT PROJECT OFFICE

QUALITY ASSURANCE PROGRAM PLAN

WMPO/88-1

(FORMERLY NVO-196-18)

REVISION 0

UNITED STATES DEPARTMENT OF ENERGY

NEVADA OPERATIONS OFFICE

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APPROVAL/SIGNATURE PAGE


PROJECT MANAGER, WMPO

2/18/88
DATE


WMPO PROJECT QUALITY MANAGER

2/18/88
DATE


PROJECT MANAGER (T&MSS)

2/12/88
DATE


PROJECT QA DEPARTMENT MANAGER

2/12/88
DATE

ASSOCIATE DIRECTOR, OGR

DATE

Effective Date: 2/18/88

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PREFACE

This document is the third edition of the U. S. Department of Energy/Nevada Operations Office (DOE/NV) Waste Management Project Office (WMPO) Quality Assurance Program Plan (QAPP). The QAPP has been renumbered, effective with this revision, to WMPO/88-1, Rev. 0, from its previous numbering as NVO-196-18, Rev. 2.

The WMPO QAPP was developed from the Quality Assurance (QA) requirements which are described in the Nevada Nuclear Waste Storage Investigations (NNWSI) Project Quality Assurance Plan (QAP), Rev. 5. These requirements are imposed on the NNWSI Project 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 WMPO in performing its functions and responsibilities for the NNWSI Project.

This revision represents a consolidation of the WMPO QAPP, NVO-196-18, Rev. 2, and the Science Applications International Corporation (SAIC)/Technical & Management Support Services (T&MSS) QAPP, Rev. 3. 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), has been accomplished by issuance of this revision. Per DOE/WMPO direction, the T&MSS QAPP and procedures have been phased out and both the quality consolidation activities at the Project level and the technical activities performed by the T&MSS at the participant level will be conducted in accordance with the WMPO QAPP. In order to support the conduct of all quality related activities, the WMPO prepares implementing procedures, either Branch Technical Procedures (BTPs) or Quality Management Procedures (QMPs) for the implementation of WMPO quality-related activities. In addition, some of the WMPO and NNWSI Project participant interface activities, which affect quality, are described in NNWSI Project Administrative Procedures (APs).

This revision encompasses all of the requirements in the NNWSI QAP, Rev. 5, which apply to WMPO activities. The changes made to this document are so extensive that line-by-line revision indicators have not been used.

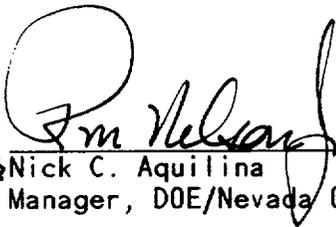
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POLICY STATEMENT

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 Nevada Nuclear Waste Storage Investigations (NNWSI) Project 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 Waste Management Project Office (WMPO) Quality Assurance Program Plan (QAPP) will provide DOE/NV, WMPO, 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 NNWSI Project.

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

The WMPO has developed the WMPO QAPP, WMPO/88-1 (formerly NVO-196-18), in accordance with the requirements of the NNWSI QAP. To meet NNWSI Project QA requirements this document establishes a framework for consistency in the development of quality related implementing procedures at all levels within the WMPO. The requirements of this document apply to all DOE/NV matrix support, WMPO, and SAIC/T&MSS personnel who perform quality related activities which support the NNWSI Project.



Nick C. Aquilina
Manager, DOE/Nevada Operations Office



Carl P. Gertz
Project Manager, WMPO



Michael E. Spaeth
Project Manager, T&MSS

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SECTION I

ORGANIZATION

1.0 INTRODUCTION

This section of the WMPO QAPP describes the organizational responsibilities and interfaces of the WMPO, the internal DOE/NV matrix organization which supports the NNWSI Project, and the integrating contractor Science Applications International Corporation/Technical and Management Support Services (SAIC/T&MSS) which, with the issuance of this document, will function under the WMPO QAPP. It describes the responsibilities and interfaces of each of the NNWSI Project participants as they interface with the WMPO.

Effective with the issuance of WMPO/88-1, Rev. 0 (formerly NVO-196-18), the Quality Assurance (QA) Programs of the WMPO and the SAIC/T&MSS are consolidated into one QA program. References to the WMPO will, as of this revision, include all SAIC/T&MSS personnel. NNWSI Project quality related activities performed by all T&MSS personnel will be conducted by implementing the WMPO QAPP, its respective Quality Management Procedures (QMPs), WMPO Branch Technical Procedures (BTPs), and those NNWSI Project Administrative Procedures (APs) which govern related activities. SAIC/Quality Assurance Support Contractor (QASC) personnel will continue to work under the scope of the WMPO QA Program and function as a part of the WMPO QA Organization. Detailed responsibilities of the integrated WMPO and T&MSS organizations are discussed within this Section, and others, as part of the applicable WMPO Branch responsibilities. An organizational chart depicting the NNWSI Project 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. 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 NNWSI Project.

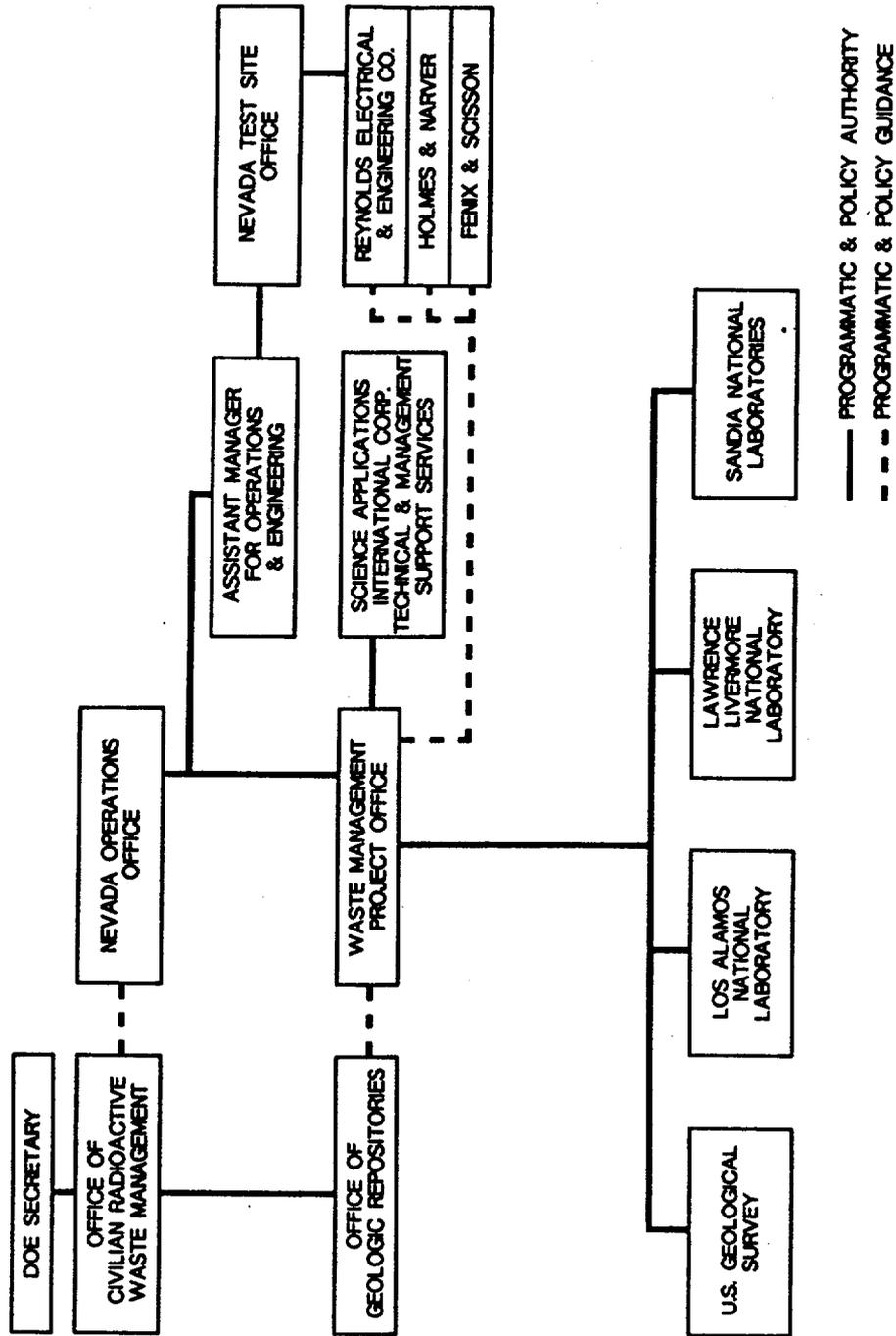
2.1 DOE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)

The U. S. Department of Energy Headquarters (DOE/HQ), OCRWM, provides programmatic and policy guidance and QA overview through the Office of Geologic Repositories (OGR) to ensure that adequate NNWSI Project QA programs are established, implemented, and maintained.

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Figure 1

MNWSI PROJECT ORGANIZATION



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2.2 DOE OFFICE OF GEOLOGIC REPOSITORIES (OGR)

The DOE/HQ, OGR, provides QA guidance and overview to the NNWSI Project by (1) review and approval of the NNWSI Project Quality Assurance Plan (QAP) and the WMPO QAPP; (2) specifying applicable requirements which are contained in the OGR QAP, OGR/B-3; and (3) performance of QA audits of the WMPO.

2.3 DOE/NV OPERATIONS OFFICE

The DOE/NV Manager has the ultimate responsibility and accountability for the NNWSI Project in the Nevada Operations Office. The WMPO has been established within the DOE/NV organization for the management of the NNWSI Project. The WMPO 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.

2.4 WASTE MANAGEMENT PROJECT OFFICE (WMPO)

The WMPO 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 WMPO is responsible for conducting the technical activities described under the responsibilities of the appropriate WMPO Branch Chief. An organizational chart depicting the WMPO organization is provided in Figure 2.

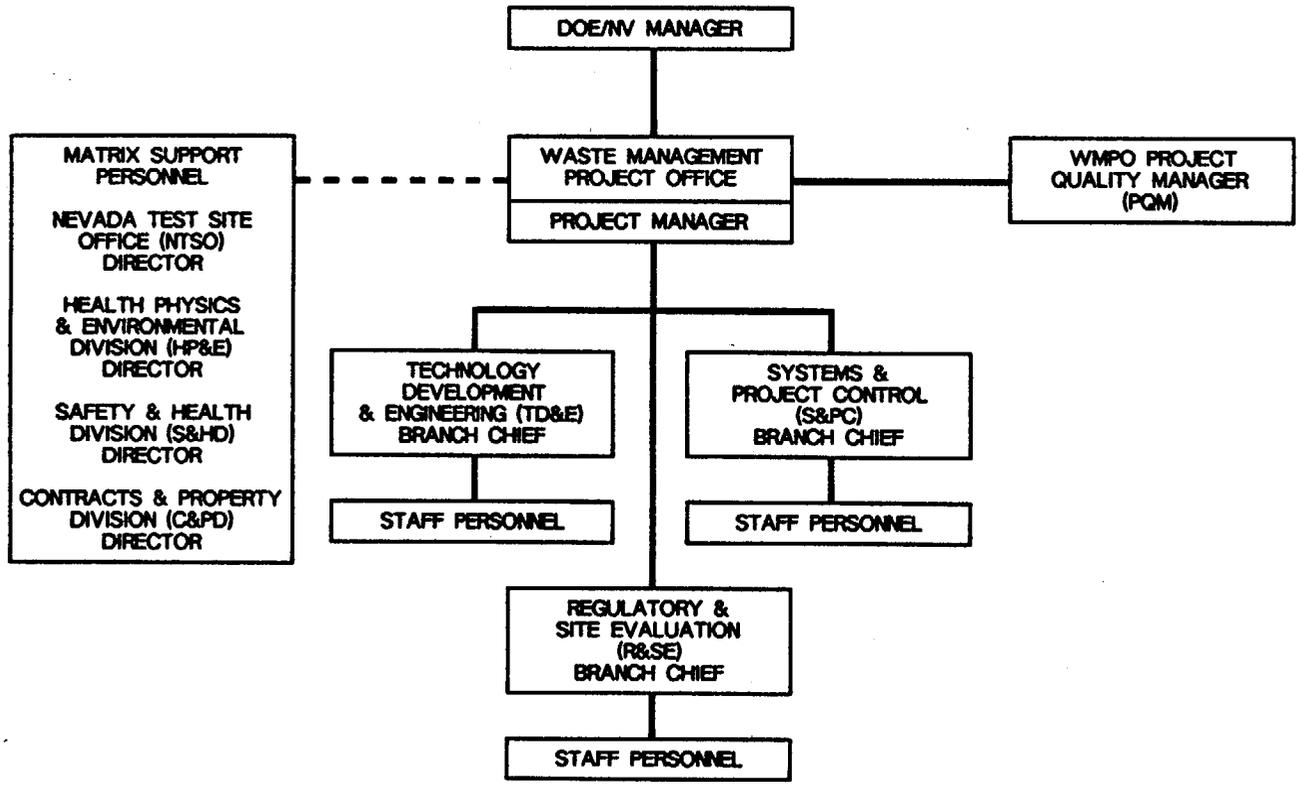
The Project Manager, WMPO is responsible for the NNWSI Project management which encompasses: (1) planning and directing activities; (2) establishing goals and objectives, and assessing progress toward the attainment of those goals; (3) administration and procurement of materials and services; (4) preparation 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, WMPO is responsible for ensuring implementation of the WMPO QA program for the conduct of WMPO quality related activities and the implementation of corrective actions.

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

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WMPO ORGANIZATION



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Figure 2

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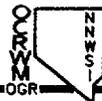
The WMPO utilizes a matrix management organizational concept to support NNWSI Project activities. The administrative responsibility for DOE/NV personnel supporting the NNWSI Project remains with the respective DOE/NV organizational element, while the functional responsibility of DOE/NV personnel performing NNWSI Project activities is to the WMPO. The organization of WMPO with the major DOE/NV divisions that provide matrix support staff is shown in Figure 2. The DOE/NV staff assists the Project Manager, WMPO by providing reviews, recommendations, and expertise on various aspects of the NNWSI Project 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 WMPO. Matrix support personnel work under the implementing procedures of the WMPO QAPP.

SAIC/T&MSS is the integrating contractor for WMPO and provides broad technical, operational, and managerial support for NNWSI Project 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, and regulatory licensing and institutional activities related to the NNWSI Project. SAIC/T&MSS assists the WMPO in such areas as (1) the identification and analysis of, and compliance with applicable statutory, regulatory, and program requirements, (2) the 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, and (7) quality assurance.

2.4.1 REGULATORY AND SITE EVALUATION BRANCH

The Regulatory and Site Evaluation Branch 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 updates, study plans, technical input to the Environmental Impact Statement (EIS) and license application, project position papers, and prelicensing topical reports for use in the 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 NNWSI Project quality related documents as defined in WMPO QMP-06-03, "Document Review/Acceptance/Approval."

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2.4.2 TECHNOLOGY DEVELOPMENT AND ENGINEERING BRANCH

The Technology Development and Engineering Branch 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 NNWSI Project quality related documents as defined in WMPO QMP-06-03, "Document Review/Acceptance/Approval."

2.4.3 SYSTEMS AND PROJECT CONTROL BRANCH

The Systems and Project Control Branch is responsible for (1) administration and management support to integrate and control the NNWSI Project including preparation of networks, monitoring milestones, and overseeing issuance of Project documentation; (2) records 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 NNWSI Project quality related documents as defined in WMPO QMP-06-03, "Document Review/Acceptance/Approval"; (10) environmental monitoring, analysis, and support, including meteorological, air quality, and radiological; (11) land acquisition; and (12) coordination of NTS support of NNWSI Project activities.

2.4.4 PROJECT QUALITY MANAGER (PQM)

The WMPO PQM is responsible for directing and managing the overall NNWSI Project QA Program and has appropriate organizational position, responsibilities, and authority to exercise proper control over the WMPO QA Program. This position is occupied by an individual with appropriate QA knowledge and experience. The PQM reports to the Project Manager, WMPO for the maintenance and implementation of the NNWSI Project QAP and the WMPO 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 NNWSI Project includes (1) approval of the NNWSI Project QAP, (2) approval of quality related NNWSI Project administrative procedures (APQs) (3) approval of NNWSI Project Participant QAPPs and changes thereto, (4) the approval of the WMPO QAPP, WMPO/88-1 (formerly NVO-196-18), its implementing procedures, and all changes thereto, (5) the responsibility and authority to verify the adequacy and effectiveness of QA plans, requirements, and QA program implementation by the WMPO and NNWSI Project participants through the direction of audits and surveillances, and (6) coordination of WMPO QA activities. The PQM is supported by the SAIC/T&MSS Project QA Department to conduct these activities.

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The NNWSI Project QA organizational structure is such that if disputes in QA arise between the PQM and others (e.g., Branch Chiefs, Project participants, etc.), the disputes will be directed to the Project Manager, WMPO 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 OGR.

2.4.4.1 WMPO QUALITY ASSURANCE (QA) ORGANIZATION

(FORMERLY REFERRED TO AS: QUALITY ASSURANCE SUPPORT CONTRACTOR/QASC)

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

2.5 NEVADA TEST SITE OFFICE (NTSO)

The NTSO provides matrix support personnel functionally responsible to the WMPO 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 WMPO and provides assistance to other Project participants in areas of specialized expertise.

2.5.1 HEALTH PHYSICS AND ENVIRONMENTAL DIVISION (HP&ED)

Upon the request of WMPO, the HP&ED may provide matrix support personnel to WMPO 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 WMPO and provides document reviews, advice, and assistance to WMPO.

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2.5.2 SAFETY AND HEALTH DIVISION (S&HD)

Upon the request of WMPO, the S&HD may provide matrix support personnel to WMPO and are 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 WMPO and provides document reviews, advice, and assistance to the WMPO.

2.5.3 CONTRACTS AND PROPERTY DIVISION (CPD)

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

3.0 SAIC/T&MSS ORGANIZATION

The SAIC/T&MSS organization is comprised of six major operating departments and a Project Institutional Relations Office reporting to the Project Manager. In addition, the Project Quality Assurance (QA) Department reports administratively to the Project Manager (T&MSS) and functionally to the WMPO Project Quality Manager to ensure independence. The following section describes the organization, relationships, responsibilities, and authorities of the T&MSS organization in its role as the integrating contractor for the WMPO in support of the NNWSI Project. An organization chart depicting the SAIC/T&MSS organization down to the department level is shown in Figure 3.

3.1 The Project Manager (T&MSS) reports directly to the Project Manager, WMPO. He has authority over all T&MSS personnel assigned to the NNWSI Project and is responsible for the management and performance of T&MSS activities in support of the WMPO.

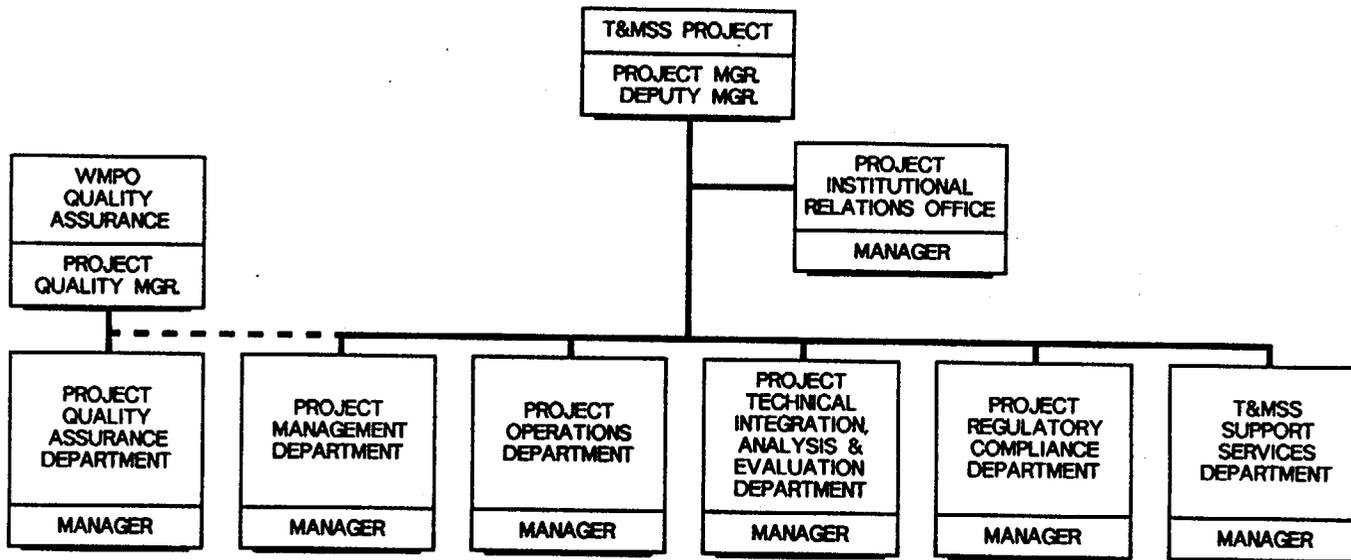
The Project Manager (T&MSS) is responsible for ensuring implementation of the WMPO QAPP and its implementing procedures for the conduct of all T&MSS quality related activities. He is also responsible for meeting the requirements of tasks performed by T&MSS for the WMPO. These requirements include staffing, control of costs, meeting schedules, and approval of deliverables. The Project Manager (T&MSS) is the primary contact with the WMPO 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 audits and surveillances by the WMPO QA Organization or other organizations.

3.2 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 WMPO QAPP and its implementing procedures thru coordination of the activities of the six SAIC/T&MSS Department Managers in the performance of their respective functions.

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SAIC/T&MSS ORGANIZATION



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Technical & Management Support Services
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3.3 Project Management Department

The Project Management Department provides (1) overall management and integration for NNWSI Project management and Project Control WBS elements, management of T&MSS and Project plans and procedures, training of staff in both Project and T&MSS procedures and technical subject matter, and quick response support to client requests (e.g., briefings to outside organizations and DOE/HQ); (2) management analysis and evaluation, including performance evaluation/reporting and performance measurement; (3) information management (including system operations, information integration, information systems development, and technical data management); and (4) Project configuration management support.

3.4 Project Operations Department

The Project Operations Department provides (1) engineering documentation and design reviews specifically related to waste package, repository, and exploratory shaft facility designs; (2) geotechnical services, including operation of the NNWSI Project Sample Management Facility and various field studies; (3) regional studies, including transportation, land access, and socioeconomics; and (4) environmental programs, including environmental and radiological field programs.

3.5 Project Technical Integration, Analysis, and Evaluation Department

The Project Technical Integration, Analysis, and Evaluation Department provides (1) technical integration across the NNWSI Project in systems, waste package, site, repository, regulatory and institutional, exploratory shaft facility, and test facilities; and (2) technical evaluation and analysis of the site characterization plans and other technical documents.

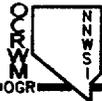
3.6 Project Regulatory Compliance Department

The Project Regulatory Compliance Department provides (1) nuclear regulatory compliance support, including regulatory interaction and planning and regulatory review; and (2) environmental regulatory compliance support, including permitting and planning.

3.7 Project Quality Assurance Department

The Project Quality Assurance Department provides (1) quality assurance overview; (2) quality assurance implementation support, including plans and procedures; and (3) audits and surveillances of all Project activities. The department's function and organizational structure are further described in paragraphs 2.4.4.1 and 5.3 of this section.

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3.8 T&MSS Support Services Department

The T&MSS Support Services Department 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; and (3) publication services, including technical editing, word processing, and graphics.

3.9 Project Institutional Relations Office

The Project Institutional Relations Office provides support in DOE interactions with the State of Nevada and other affected public parties.

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 WMPO. Participating organizations and NTS support contractors are responsible to the WMPO for technical activities assigned to them as specified in the NNWSI Project WBS Dictionary and Project-specific technical plans. The technical activities are to be accomplished in accordance with the QA requirements in the NNWSI Project QAP and their respective QAPPs when approved by the WMPO.

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 NNWSI Project. Responsibilities also include surveillance & inspection of drilling & mining and subsurface facilities construction and testing.

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 NNWSI Project records.

4.1.3 Reynolds Electrical and Engineering Company (REECO)

Reynolds Electrical and Engineering Company is the prime support contractor support 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 NNWSI Project, 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 NNWSI Project participants in areas of specialized expertise.

4.2.2 Los Alamos National Laboratory (Los Alamos)

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 NNWSI Project 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 NNWSI Project 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 NNWSI Project participants in areas of specialized expertise.

5.0 QUALITY ASSURANCE RESPONSIBILITIES OF THE WMPO

As a Nevada Nuclear Waste Storage Investigations (NNWSI) Project participant, the WMPO is responsible for the establishment and execution of this QAPP, WMPO/88-1 (formerly NVO-196-18). The WMPO 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 WMPO 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 WMPO Branch organizations are responsible for performing these activities properly, the WMPO QA Organization verifies the proper performance of work through implementation of appropriate QA controls.

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5.1 QA ORGANIZATION FUNCTIONS

The WMPO QA Organization functions are those of ensuring that the WMPO 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 WMPO PQM and the Project QA Department personnel have sufficient authority, access to work areas, and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions through designated channels; to verify implementation of 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 WMPO PQM has direct access to responsible WMPO and DOE management at such levels where appropriate action can be effected.

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

5.3 ORGANIZATIONAL STRUCTURE

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

5.3.1 The WMPO PQM is responsible for implementation and maintenance of the WMPO QAPP and its implementing procedures for all activities affecting quality performed by the WMPO. Detailed description of the PQM's functions are contained in Paragraph 2.4.4 above.

5.3.2 The WMPO QA Organization functions are performed by the SAIC/T&MSS Project QA Department, as described in Paragraph 2.4.4.1 above.

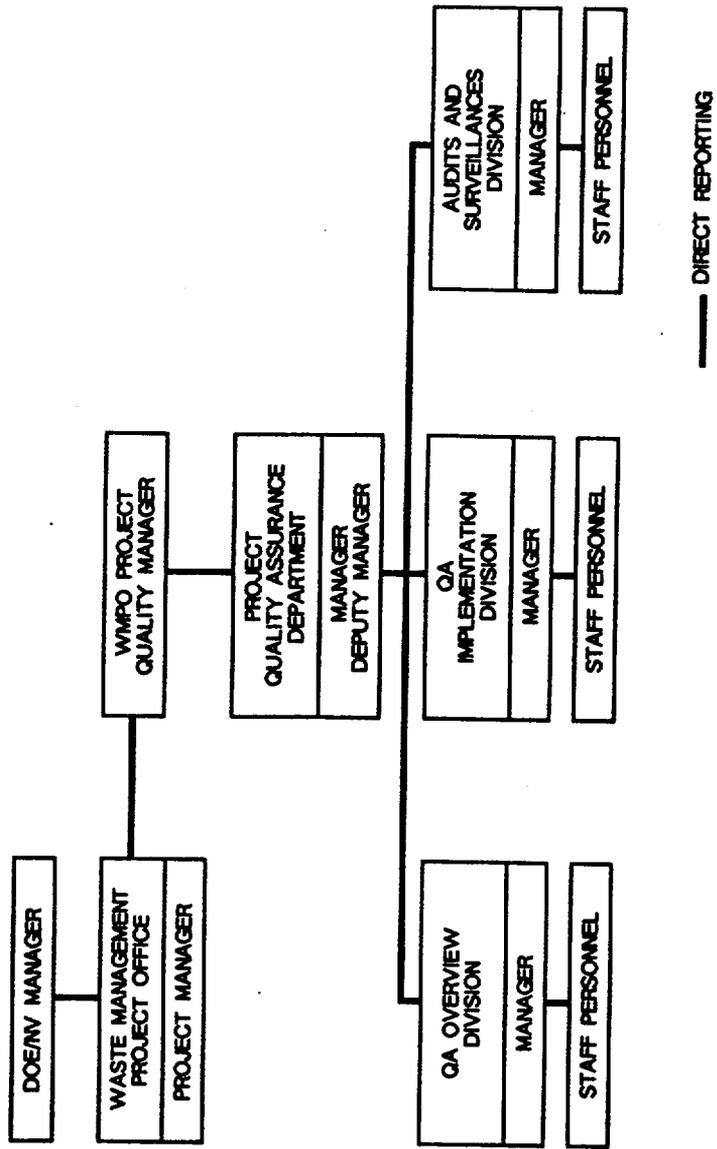
5.3.2.1 The Project QA Department Manager reports administratively to the Project Manager (T&MSS), functionally to the WMPO PQM, and interfaces with other DOE/WMPO management personnel as required to ensure implementation of the WMPO QAPP. He has overall responsibility for the management and direction of the Project QA Department staff.

5.3.2.2 The Deputy Project QA Department Manager reports to the Project QA Department Manager and is delegated to act for him in his absence. He is responsible for assisting with the coordination of Project QA Department activities to ensure implementation of the WMPO QAPP.

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Figure 4

WMPO QA ORGANIZATION



[WMPOQA.ORG:12/17/87]



6.0 QUALITY ASSURANCE PROGRAM PLAN

The WMPO Quality Assurance Program Plan (QAPP) applies to all Quality Level I and II items and activities affecting quality. The WMPO 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

Quality is achieved and maintained by those who have been assigned responsibility for performing work. WMPO quality related activities are performed in accordance with approved QMPs, BTPs, or quality related NNWSI Project APQs.

6.2 VERIFICATION

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

7.0 ORGANIZATIONAL INTERFACES

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

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

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SECTION II

WMPO QUALITY ASSURANCE PROGRAM

1.0 EXTENT OF THE QUALITY ASSURANCE PROGRAM

The Waste Management Project Office (WMPO) Quality Assurance (QA) Program for the NNWSI Project consists of the WMPO Quality Assurance Program Plan (QAPP), WMPO Quality Management Procedures (QMP), Branch Technical Procedures (BTP), and quality related NNWSI Project Administrative Procedures (APQs).

The WMPO QAPP is submitted to WMPO and Science Applications International Corporation/Technical Management Support Services (SAIC/T&MSS) management for review and approval prior to implementation. The WMPO QAPP is reviewed and approved by the Project Manager, WMPO; the WMPO Project Quality Manager (PQM); the Project Quality Assurance Department Manager; and the Project Manager (T&MSS). The WMPO QAPP, is also be submitted to DOE/OGR for review and approval.

1.1 THE WMPO QA PROGRAM PLAN

The WMPO 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 NNWSI Project QA requirements defined in the NNWSI QAP. A checklist based on the NNWSI Project QAP has been completed which identifies how and where each requirement is addressed within this document. The WMPO QAPP includes consideration of the technical aspects of those activities affecting quality that are the responsibility of the WMPO and has been developed by the WMPO QA Organization with assistance from the WMPO technical staff. The WMPO QAPP provides instruction for implementing and applying the QA requirements to the technical activities of the NNWSI Project that are within the WMPO scope of work. The WMPO QAPP is implemented and maintained in accordance with the NNWSI Project QAP requirements. WMPO management regularly receives information as to the scope, status, adequacy, compliance, etc. of the QA program.

1.2 QA CRITERIA

The QA criteria and specific requirements associated with these criteria have been adapted to the NNWSI Project activities through the NNWSI Project QAP, and are addressed in the WMPO QAPP. QA criteria not applicable to a WMPO activity is noted in this QAPP with justification of its exception.

1.3 CONTENTS OF THE QA PROGRAM

The WMPO Quality Assurance Program consists of this QAPP and implementing procedures required to provide control over activities affecting quality. The control is consistent with the importance of the activity as evidenced by its

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assigned quality level. These procedures (WMPO BTPs, WMPO QMPs, and quality related NNWSI Project APs) are developed by qualified personnel and reviewed and approved by the WMPO QA Organization prior to implementation to ensure that they meet all the requirements of this QAPP.

1.4 QAPP VERIFICATION

Assurance that the QA requirements have been adequately addressed and effectively implemented will be provided by the WMPO 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 WMPO program and ensure its effective implementation. These activities are conducted and documented in accordance with WMPO Quality Management Procedures.

1.5 USE OF DATA NOT GENERATED UNDER QA CONTROLS

The WMPO 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 NNWSI Project QAP. Specific methods for acceptance of this information are contained in the NNWSI Project AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the NNWSI Project QA Program." These provisions apply to the items listed below. Once accepted, this data is classified as "primary data" for licensing purposes.

1.5.1 DATA GENERATED PRIOR TO NNWSI PROJECT QAP, REV. 0

Data or data interpretations and reports that were generated by the NNWSI Project participants, predecessor organizations, or their subcontractors involved in siting the NNWSI Project Yucca Mountain Mined Geologic Disposal System (MGDS) prior to implementation of a QA program meeting the requirements of the NNWSI Project QAP, Rev. 0.

1.5.2 DATA NOT GENERATED BY THE NNWSI PROJECT

Data from reports, books, and theses generated by non-NNWSI Project participants.

1.5.3 DATA FROM TECHNICAL JOURNALS

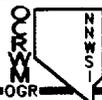
Data or data interpretations from a technical journal.

1.6 METHODOLOGY FOR FORMULATING THE "Q" LIST

1.6.1 DEFINITION OF THE "Q" LIST

The "Q" List is a list of geologic repository structures, systems, components, and activities that have been determined to be important to safety or waste isolation or both, and are thereby subject to the highest Quality Assurance level (Quality Level I) of the formal NNWSI Project QA Program.

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1.6.2 DETERMINATION OF ITEMS TO BE INCLUDED ON THE "Q" LIST

The WMPO is responsible for preparing NNWSI Project AP 5.12Q, "Methodology for Development of the Project Q-List," for determining the items and activities to be placed on the Project Q-List. This procedure will be consistent with the guidance contained in the OGR QA Plan (OGR B/3), Supplement 3, Attachment A.

1.7 APPROACH TO QA

The NNWSI Project 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. A participating organization or the WMPO identifies the appropriate quality assurance levels for all 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. Once assigned, the QA level for a particular item or activity is applied by all NNWSI Project Participants involved in the activity. The WMPO assigns quality assurance levels to items and activities that affect quality in accordance with WMPO QMP-02-06, "Assignment of QA Levels."

1.8 APPLICATION OF QA

The WMPO QAPP will be applied throughout the life of the NNWSI Project in accordance with the established policies, procedures, and instructions. The WMPO QAPP applies to all items and activities affecting quality which are the responsibility of the WMPO; these activities are described in Section I.

The WMPO QAPP provides control over WMPO activities that affect the quality of the identified structures, systems and components to an extent consistent with their importance. WMPO activities that affect quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that all prerequisites for the given activity have been satisfied. The WMPO 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 WMPO QA Program provides for indoctrination and, as necessary, 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.

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The WMPO regularly assesses the status and adequacy of the QA Programs of the NNWSI Project's 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, 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. The WMPO has developed NNWSI Project AP 5.4Q, "QALAS for NNWSI Project Activities," and WMPO QMP-02-06, "Assignment of QA Levels," for the application of graded QA (assignment of QA Levels). The procedure is in consonance with the QA requirements specified herein. It may be necessary to exempt certain NNWSI Project items and activities from QA Level assignment. Requests for exemptions are documented and contain sufficient justification to support the exemption request. Such exemptions are approved by the WMPO 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.

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 WMPO 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.

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2.1.4 FLEXIBILITY OF QA LEVEL SELECTION

The graded approach set forth in this document provides for selective application of the level of the quality assurance 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 NNWSI Project items and activities for which WMPO is responsible.

2.2.1 SELECTION OF QUALITY ASSURANCE LEVEL AND QA REQUIREMENTS

The appropriate QA level for any item or activity shall be determined by the application of decision criteria as provided by the NNWSI Project 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 WMPO in accordance with QMP-02-06, "Assignment of QA Levels," prior to implementation or use.

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 NNWSI Project. 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 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 WMPO concerns, and the environment.

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2.2.2.3 QA Level III - those activities and items 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 material (waste) at the geologic repository. QA Level I control and documentation must be applied to 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 must 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 site characterization data. Site characterization data is 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 providing long-term waste containment and isolation. This includes all tests, 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 as well as the assessment of repository performance. It also includes those activities (e.g., tests, experiments, and research) that are one of several independent activities contributing to a single base of information that is considered in formulating the repository design or performance assessment of the engineered or natural barriers.
- o Where items and activities could affect the retrievability of waste until the time of repository closure.
- o Where activities are intended to provide the primary data which will be utilized to support public radiologic health and safety issues for a license application.
- 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.

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- 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 NNWSI Project activities and items that are specifically concerned with nonradiological operation of the exploratory shaft facilities and repository, and the radiological safety of the repository worker. Additionally, activities that have a major impact on project costs or schedules that could delay the achievement of DOE/Office of Geologic Repositories (OGR) 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.
- 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 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 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, could result in a major schedule slippage.

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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 NNWSI Project AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the NNWSI Project QA Program."

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 NNWSI Project QAP may be used in the licensing process as background or corroborative information.

2.2.4 GENERAL

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 WMPO. 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 WMPO PQM and the respective WMPO Branch Chief. 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.

3.0 QA ACTIVITIES

3.1 OVERVIEW

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

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

3.2 REVIEW AND APPROVAL OF PARTICIPANT QA PROGRAMS

WMPO QMP-06-03, "Document Review/Acceptance/Approval," has been established for the review of NNWSI Project participant QA program documents for adequacy, completeness and relevance. In addition, this QMP identifies the types of documents to be submitted by the NNWSI Project 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 WMPO QA Program are conducted by the WMPO at least annually in order to determine:

1. The effectiveness of the WMPO 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 WMPO QA Program.

WMPO 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 WMPO 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. Copies of the WMPO management assessment are provided to the Project Manager, WMPO; the WMPO PQM; and DOE/OCRWM.

5.0 PERSONNEL SELECTION, INDOCTRINATION, AND TRAINING PROCEDURES

5.1 GENERAL

Requirements for the selection, indoctrination, and training of WMPO personnel performing or verifying activities that affect quality are contained in this

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section of the QAPP. The implementation and documentation of these requirements is performed and maintained in accordance with WMPO QMP-02-01, "Indoctrination and Training of Personnel Performing Quality Related Activities." 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 for each WMPO position involved in the performance of activities that affect quality.

5.1.2 PERSONNEL QUALIFICATION EVALUATION

Personnel selected to perform an activity must have education and experience commensurate with the minimum requirements specified in position descriptions. Relevant education and experience is 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 are performed by those managers or supervisors responsible for the activities to be performed.

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 NNWSI Project QA Plan
- o NNWSI Project Administrative Procedures (Quality Related)
- o WMPO QA Program Plan, WMPO/88-1 (formerly NV0-196-18)
- o WMPO Quality Management Procedures
- o WMPO Branch Technical Procedures
- o Federal Regulations
- o Project Level Documents
- o Other Appropriate Project Documents (applicable to an individual's responsibilities/work functions)

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5.1.4 TRAINING

Prior to assigning personnel to perform quality affecting activities that are complex in nature (i.e., assignments where it is deemed necessary to develop and demonstrate initial proficiency), training is conducted to gain the required proficiency. The training (in-depth instruction) includes the principles, techniques, and requirements of the activity. Such in-depth instruction may be internal or external classroom sessions, classroom sessions supplemented by hands-on workshops, on-the-job training, other instructional methods, or combinations thereof.

5.1.5 PROFICIENCY EVALUATION

After the initial personnel qualification evaluation, the job proficiency of WMPO 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 WMPO QMP-17-01, "QA Records." 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 WMPO scientific investigation, the responsible WMPO Principal Investigator (PI) develops a Scientific Investigation Plan (SIP) for that investigation. Such plans are developed in accordance with WMPO QMP-03-02, "Scientific Investigation and Design Control," 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 including a discussion of the overall purpose for the work. References to any applicable regulations, requirements, performance criteria, key issues, issues, information needs, higher level scientific investigation planning documents, or Work Breakdown Structure (WBS) items, for which the work is to be performed is also be provided. This discussion identifies all of the factors and concerns that are important for the planning or performance of the scientific investigation.

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.

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.

1.2 ASSIGNMENT OF QUALITY ASSURANCE LEVELS

1.2.1 ASSIGNMENT

Once a SIP has been developed, the QA levels for all of the items and activities which are associated with that work, may be assigned. Assignment of QA levels is in accordance with WMPO QMP-02-06, "Assignment of QA Levels." 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,

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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 WMPO conducts a technical review of WMPO generated SIPs. 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 WMPO 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. This review is accomplished in accordance with WMPO QMP-06-03, "Document Review/Acceptance/Approval."

1.3.2 REVIEW OF WMPO GENERATED SIPS

The WMPO PQM and the appropriate WMPO Branch Chief review and approve WMPO generated SIPs prior to implementation in accordance with WMPO QMP-03-02, "Scientific Investigation Control and Design Control."

1.3.3 PEER REVIEW

Peer reviews of WMPO SIPs will be conducted, when deemed necessary by the WMPO Branch Chief in accordance with WMPO QMP-03-01, "Peer Reviews."

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

1.4.1 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 both, in their work. Alternatively, the technical implementing procedure system will generally be used when qualified technicians are performing repetitive work which does not include the use of professional judgement 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. 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

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control over all other aspects of the work. The specific method chosen for the documentation of WMPO scientific work is stipulated in the WMPO scientific planning document per WMPO QMP-05-02, "Preparation and Format of WMPO Branch Technical Plans and Procedures."

1.4.2 SCIENTIFIC NOTEBOOKS

Scientific notebooks along with other appropriate documents are used to document WMPO 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.

1.4.3 TECHNICAL IMPLEMENTING PROCEDURES AND SUPPORTING DOCUMENTATION

Detailed WMPO Branch Technical Procedures are used whenever the work is repetitive. WMPO Branch Technical Procedures are developed in accordance with the requirements specified WMPO QMP-05-02, "Preparation and Format of WMPO Branch Technical Procedures and Plans."

1.4.4 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, WMPO logbooks or notebooks will document the following:

1.4.4.1 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.
- 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 Dated signature of the individual or individuals making the initial entries.

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1.4.4.2 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 experiment/researcher could repeat the experiment or research. This information includes:

- o Date and name of individual making the entry.
- 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 1.4.4.1 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.
- o Final results and a summary of the outcome of the experiment or research. This includes a discussion of whether the experiment's objectives as outlined in the initial entries were achieved. This is accomplished by inclusion of completed report or entry of information into the notebook. If the report is used, it becomes a part of the notebook.

1.4.4.3 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.

1.5 CHANGE CONTROL

All changes to WMPO generated SIPs shall go through the same review and approval process as specified in Paragraph 1.3 of this Section. The WMPO is responsible for evaluating the impacts of such changes on the associated QA level assignments. This review and approval plus the evaluation for impact of changes to the QA level assignment is documented in accordance with WMPO QMP-03-02, "Scientific Investigation Control and Design Control."

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1.6 INTERFACE CONTROL

1.6.1 COORDINATION

Internal and external scientific investigation interfaces are identified and scientific investigation efforts are coordinated among and within the responsible WMPO 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 WMPO and any affected participating organization(s) for the review, approval, release, distribution, and revision of documents involving scientific investigation interfaces. Interfaces between scientific investigations, or between a scientific investigation and any other Project activity including design activities, are coordinated among Project participants in accordance with NNWSI Project APs established by the WMPO. In addition, interfaces between the WMPO and its suppliers are also be controlled in accordance with NNWSI Project APs.

1.6.2 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 WMPO Branch Technical Procedures.

1.7 REPORTS, CONCLUSIONS, AND RECOMMENDATIONS

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

1.8 CLOSE OUT VERIFICATION

The WMPO 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 WMPO Quality Management Procedures.

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2.0 DESIGN CONTROL

2.1 DEFINITION OF WMPO RESPONSIBILITIES

The WMPO holds no responsibilities for the performance of design activities, however, the WMPO 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 WMPO is responsible for the assignment of QA levels for ESF items and activities.

2.2 QUALITY ASSURANCE LEVEL ASSIGNMENTS

All ESF design phases will be assigned a QA level prior to execution in accordance with WMPO QMP-02-06, "Assignment of QA Levels." QA levels for the repository and waste package design phases will be assigned by the participating organizations responsible for those designs.

2.3 DESIGN INTERFACE CONTROL

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

2.4 DESIGN OUTPUT DOCUMENT REVIEWS

The WMPO 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 WMPO. 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 WMPO review and acceptance of design output documents is performed in accordance with WMPO QMP-06-03, "Document Review/Acceptance/Approval." The WMPO acceptance of design output documents is done on an acceptance of Architect/Engineer (A/E) services basis. The acceptance does not include the actual approval, analysis, and verification of the output documents.

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3.0 PEER REVIEWS

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

3.1 APPLICABILITY

The requirements of the following paragraphs are applicable to all peer reviews. Peer reviews should not be confused with technical reviews. (See Appendix A, Terms and Definitions).

3.2 GENERAL REQUIREMENTS

Peer reviews are required for activities that support a license application and involve use of data collection or analysis procedures and methods that are untried or beyond the state of the art or where detailed technical criteria and requirements do not exist or are being developed. Other instances where a peer review should be considered in lieu of a technical review include situations in which:

- o Analytical modeling techniques are (or will be) applied to a range of conditions outside of their normally accepted boundaries.
- o Data collection results are not predictable with a high degree of certainty.
- o Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.
- o Decisions or interpretations having significant impact on performance assessment conclusions will be made.
- o Results of tests are not reproducible or repeatable.
- o Data or interpretations are ambiguous.
- o Data adequacy is questionable, i.e., data may not have been collected in conformance with an established QA program.

3.3 PEER REVIEW GROUP SELECTION

The WMPO's peer review program, is conducted in accordance with WMPO QMP-03-01, "Peer Reviews," which defines the selection process for a peer review group. A peer review group is comprised of individuals who have qualifications at least equivalent to those required for performance of the original work and who are independent of the work being reviewed. The peer reviewer's qualifications are documented and verified by the organization requesting the peer review.

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3.3.1 The establishment of a peer reviewer's independence includes:

- a. The peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being performed.
- b. The peer to the extent practical, has sufficient freedom from funding considerations to ensure the work is impartially reviewed.

3.3.2 In some cases it may be difficult to meet the independence criteria without reducing the technical quality of the peer review. In those cases where independence cannot be met, a documented rationale should be placed in the peer review report.

3.4 PERFORMANCE

3.4.1 SCOPE

Peer reviews should address the following areas as applicable:

- o Validity of assumptions or functional requirements.
- o Alternate interpretations.
- o Appropriateness and limitations of methodology and procedures.
- o Uncertainty of results and consequences if incorrect.
- o Adequacy of application.
- o Verification of calculations or computer software.
- o Adequacy of requirements and criteria.
- o Validity of conclusions.

3.4.2 WRITTEN PROCEDURES

Peer reviews are conducted in accordance with WMPO QMP-03-01, "Peer Reviews," and address the following:

- o The review process and reviewer responsibilities.
- o Handling of comment resolution.
- o Reporting of minority positions.
- o Involvement of the QA organization.
- o Changes to previously peer reviewed documents.
- o Re-review of revised documents.

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- o Records of the review including written meeting minutes and deliberations.
- o Peer review reports are signed by all peer review group members.

3.4.3 RE-REVIEW OF PEER REVIEWED DOCUMENTS

Re-review of previously peer reviewed documents is performed whenever the technical content or results presented in the documents are significantly revised. Justification for not providing re-review by a peer group is to be documented. As a minimum, this justification is reviewed and approved by the same organizations who were involved in the original peer review.

3.5 QA RECORDS

Peer review records include personnel qualifications of the reviewers, results of the review, and disposition or replies to reviewer comments. Peer review records are retained commensurate with the retention requirements of the data or document which they support. QA records are processed in accordance with WMPO QMP-17-01, "QA Records."

4.0 SOFTWARE QUALITY ASSURANCE REQUIREMENTS

4.1 COMPUTER SOFTWARE DOCUMENTATION AND CONTROL

Scientific and engineering computer software used to support a high-level nuclear waste repository license application is documented and controlled. Methods for this documentation and control are contained in the NNWSI Project AP 5.5Q, "Software QA," and WMPO QMP-03-03, "Use and Control of Computer Programs." 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."

4.2 DOCUMENTATION OF COMPUTER SOFTWARE

WMPO documentation of computer software includes the following, as a minimum:

- o Software summary.
- o Description of mathematical models and numerical methods.
- o User's manual.
- o Code assessment and support.
- o Continuing documentation and code listings.

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4.3 SOFTWARE CONFIGURATION MANAGEMENT

The WMPO has instituted a software configuration management program appropriate to the activities it conducts and provides documentation of this program to the records management system. The minimum requirements for this 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 WMPO software configuration management program is documented and controlled in accordance with NNWSI Project AP 5.5Q, "Software QA," WMPO QMP-03-03, "Use and Control of Computer Programs," WMPO QMP-03-04, "Software Development and Maintenance," and WMPO QMP-03-06, "Verification and Validation of Computer Programs."

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SECTION IV

PROCUREMENT DOCUMENT CONTROL

1.0 REQUIREMENTS

1.1 MEASURES TO ENSURE ADEQUATE QUALITY FOR WMPO PROCURED EQUIPMENT, ITEMS, AND SERVICES

Measures have been established, per WMPO QMP-04-01, "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 Level I and II material, equipment, and services utilized by the WMPO on the NNWSI Project. To the extent necessary, WMPO procurement documents require subtier contractors to provide a Quality Assurance (QA) program that is consistent with the pertinent provisions of the WMPO QAPP, as required by the specified QA level of the item or activity procured.

WMPO initiated procurements for equipment, items and services 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 WMPO procures services from contractors or requests services from national laboratories and supporting federal agencies, the WMPO prepares work agreements, memos of understanding, interagency agreements, management agreements, or other suitable documents. These documents are considered to serve the same function as a "procurement document," as referenced throughout this QAPP, and meet the requirements established in the following paragraphs.

2.0 ADDITIONAL REQUIREMENTS FOR QA LEVEL I ACTIVITIES

2.1 CONTENT OF PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement include provisions for the items listed below, as deemed necessary by the WMPO:

2.1.1 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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2.1.2 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 services to be furnished. The procurement documents provide for identification of test, inspection, and acceptance requirements of the WMPO for monitoring and evaluating the supplier's performance.

2.1.3 QA REQUIREMENTS

2.1.3.1 WMPO procurement documents require that the supplier have a documented QA program that implements either specific portions or all of the requirements of the NNWSI QA Plan. Quality Assurance Program Plans (QAPPs) and documents of subcontractors for QA Level I purchases are reviewed and approved in accordance with WMPO QMP-06-03, "Document Review/Acceptance/Approval." Those which do not adequately define the QA requirements established by the WMPO are corrected prior to initiation of activities specified in the procurement document. The extent of the program required depends upon the type and use of the item or service being procured. The WMPO procurement documents require the supplier to incorporate appropriate QA program requirements in subtier procurement documents.

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

2.1.4 RIGHTS OF ACCESS

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

2.1.5 DOCUMENTATION REQUIREMENTS

WMPO procurement documents, and those of its suppliers/subcontractors, identify the documentation required to be submitted to the WMPO. The time of submittal is also established. If the WMPO 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.

2.1.6 NONCONFORMANCE

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

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2.1.7 SPARE AND REPLACEMENT PARTS

WMPO 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. The evaluation is documented in accordance with a WMPO QMP.

2.2 PROCUREMENT DOCUMENT REVIEW

A review of WMPO procurement documents and changes thereto is made 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. The review is performed and documented, per WMPO QMP-04-01, "Procurement Document Control," prior to contract award. Procurement document reviews are performed by WMPO personnel who have access to pertinent information and who have adequate understanding of the requirements and intent of the procurement documents. As a minimum, the review includes the cognizant WMPO Technical Branch and the WMPO QA Organization. The review by the WMPO QA Organization ensures that the following requirements are met:

- o QA requirements are correctly stated, inspectable, and controllable.
- o Technical requirements, as stated below, are correctly translated into the procurement document.
- o Procurement documents have been prepared, reviewed, and approved in accordance with the QA requirements of this QAPP.

The WMPO technical review shall ensure that the following requirements are met:

- o Technical requirements are correctly stated.
- o There are adequate acceptance and rejection criteria established.
- o Appropriate standards, codes, regulations, procedures or instructions, including revisions thereto, that describe the items or services to be furnished are referenced.
- o Procurement documents contain sufficient technical information (i.e., design drawings, specifications, etc.).
- o Identification of WMPO test, inspection and acceptance requirements that will be utilized for monitoring and evaluating the supplier's performance.

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2.2.1 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 WMPO QMP-04-01, "Procurement Document Control." This review includes the following considerations:

- o Appropriate requirements are included in procurement documents as specified by Paragraph 2.1 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 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.

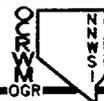
2.3 PROCUREMENT DOCUMENT CHANGES

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

2.4 DISTRIBUTION OF PROCUREMENT DOCUMENTS

When purchases involve QA Level I items or services, the originating WMPO Branch is required to forward an "as-issued" copy of purchase documents, and any subsequent changes, to the WMPO QA Organization. Only those procurement documents which identify the supplier/vendor, describe the scope of work, and detail when work is to start are required to be submitted to the WMPO QA Organization. Copies of WMPO procurement documents are maintained in accordance with WMPO QMP-17-01, "QA Records."

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SECTION V

INSTRUCTIONS, PROCEDURES, PLANS, AND DRAWINGS

1.0 GENERAL

WMPO activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, plans, or drawings, of a type appropriate to the circumstances. 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. WMPO generated documents which are covered by this Section include:

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

2.0 REVIEWS

A review of all instructions, procedures, plans, and drawings is performed in accordance with WMPO QMP-06-03, "Document Review/Acceptance/ Approval," to assure technical adequacy and inclusion of appropriate quality requirements.

3.0 INSTRUCTIONS FOR SCIENTIFIC NOTEBOOKS

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

4.0 DISTRIBUTION

The WMPO maintains controlled distribution of all implementing procedures, plans, instructions and drawings used for QA Level I and II WMPO activities in accordance with WMPO QMP-06-02, "Document Control." Controlled copies of these documents are provided to the WMPO PQM and the Project QA Department Manager.

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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 WMPO documents including changes thereto, is controlled through the implementation of WMPO QMP-06-03, "Document Review/Acceptance/Approval," and WMPO QMP-06-02, "Document Control," which ensures 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.

1.2 IMPLEMENTATION

The WMPO 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 WMPO generated documents, other than those defined as minor changes, are considered as major changes and are reviewed and approved by the same WMPO organizations that performed the original review and approval, unless the WMPO 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.

2.2 MINOR CHANGES

Minor changes to WMPO 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 may 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 WMPO QA organization.

3.0 DISTRIBUTION OF DOCUMENTS

3.1 DOCUMENT CONTROL SYSTEM

The WMPO 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 WMPO PQM, the Project QA Department Manager, and all other controlled document holders.

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SECTION VII

CONTROL OF WMPO PURCHASED ITEMS AND SERVICES

1.0 GENERAL REQUIREMENTS

Measures are established to ensure that WMPO purchased material, equipment, and services conform to WMPO 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 WMPO 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 WMPO purchased items and services are listed below and are implemented in accordance with WMPO QMP-07-03, "Control of Purchased Items and Services."

1.1 PROCUREMENT PLANNING

1.1.1 GENERAL

WMPO procurement activities are planned and documented to ensure a systematic approach to the procurement process. Procurement planning is conducted in accordance with WMPO QMP-07-03, "Control of Purchased Items and Services," which provides documented identification of WMPO procurement methods and WMPO organizational procurement responsibilities. WMPO QA Organization participation is provided for the evaluation and selection of suppliers, and verification of supplier's activities in accordance with WMPO QMP-04-01, "Procurement Document Control," and WMPO 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 WMPO 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 WMPO control of supplier performance.
- o Verification (surveillance, inspection, or audit) activities by WMPO, 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 WMPO QMP-07-03, "Control of Purchased Items and Services," and WMPO QMP-07-04, "Supplier Surveys."

1.2.2 SOURCE EVALUATION AND SELECTION MEASURES

Procurement source evaluation and selection measures are implemented by the WMPO and shall provide for identification of the WMPO's organizational responsibilities for determining supplier capability. These activities are be accomplished in accordance with WMPO QMP-07-03, "Control of Purchased Items and Services," and WMPO 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, 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 WMPO bid evaluation process shall determine the extent of conformance to the WMPO procurement documents. This evaluation is conducted and documented in accordance with WMPO QMP-07-03, "Control of Purchased Items and Services," by WMPO technical and WMPO 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 WMPO resolves or obtains commitments to resolve unacceptable quality assurance conditions resulting from the bid evaluation. These activities are documented per WMPO QMP-07-03, "Control of Purchased Items and Services."

1.4 SUPPLIER PERFORMANCE EVALUATION

1.4.1 INTERFACE MEASURES

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

- o Documentation of the agreements between the WMPO 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, WMPO QMP-04-01, "Procurement Document Control," and WMPO QMP-07-03, "Control of Purchased Items and Services."
- o Establishing methods of document information exchange between the WMPO and its supplier.

1.4.2 VERIFICATION MEASURES

1.4.2.1 EXTENT OF VERIFICATION

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

The extent of WMPO's 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 WMPO 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 WMPO's 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 QA program in accordance with WMPO QMP-07-03, "Control of Purchased Items and Services," WMPO QMP-15-01, "Nonconformance Control," WMPO QMP-18-01, "Audit System for the Waste Management Project Office," as appropriate, or the specific WMPO BTPs which govern the activity. These completed documents are considered QA records and are controlled in accordance with WMPO QMP-17-01, "QA Records."

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1.5 CONTROL OF DOCUMENTS GENERATED BY SUPPLIERS

Documents that are generated by suppliers and submitted to the WMPO are controlled in accordance with WMPO QMP-04-01, "Procurement Document Control," and WMPO 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 WMPO 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 WMPO 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.

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. 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 WMPO's or supplier's QA program.

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- 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 WMPO's or supplier's 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 WMPO 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 WMPO QA Organization's acceptance of source verification, documented evidence of this acceptance is furnished to the receiving destination of the item, to the responsible WMPO Branch Chief, and to the supplier.

1.6.1.3 Receiving Inspection

When receiving inspection is used, WMPO 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 WMPO in accordance with WMPO 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 WMPO and the supplier. Acceptance and verification of post installation test results is documented by WMPO.

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 WMPO may accept the service by any one, or by any combination, of the following methods:

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- 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 WMPO is described in WMPO 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 WMPO 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 WMPO QMP-07-03, "Control of Purchased Items and Services," and WMPO QMP-15-01, "Nonconformance Control," 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 WMPO by the supplier is as directed by the WMPO. These submittals include supplier recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to WMPO procurement requirements or to WMPO approved documents, which consist of one or more of the items listed below, are submitted to the WMPO. Approval of the recommended disposition is in accordance with WMPO QMP-15-01, "Nonconformance Control."

- o Technical or material requirement is violated.
- o Requirement in supplier documents, which has been approved by the WMPO, is violated.
- o Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.
- o The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

1.8.1.3 Disposition

Provisions for WMPO 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 WMPO QMP-03-02, "Scientific Investigation and Design Control."

2.1.1 IDENTIFICATION OF COMMERCIAL-GRADE ITEMS

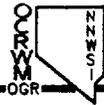
Where the commercial-grade item is to be used as an integral part of the designed facility, it is identified in an approved design or design output document. An alternate commercial-grade item may be supplied if the WMPO provides verification that the alternate commercial-grade item will perform the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

2.1.2 SOURCE EVALUATION AND SELECTION

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

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 WMPO QMP-04-01, "Procurement Document Control."



SECTION VIII
IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES AND DATA

INTRODUCTION

THIS SECTION OF THE WMPO 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 WMPO, until the time it is installed. Those items that are received and installed by WMPO are controlled by WMPO 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 WMPO 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

WMPO 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 WMPO responsibilities, including any interfaces between the WMPO and NNWSI Project 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 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 WMPO 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 WMPO 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 WMPO 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 The WMPO will develop and implement an NNWSI Project 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 WMPO QMP-17-01, "QA Records."

PART C - IDENTIFICATION AND CONTROL OF DATA

1.0 IDENTIFICATION

Data generated from a WMPO 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. WMPO QMP-03-02, "Scientific Investigation Control and Design Control," provides for the following requirements, as a minimum:

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1.1 GENERAL

The identification of WMPO 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 WMPO 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 of the WMPO QAPP apply to scientific investigations for process control. Measures will be established to ensure that processes that affect quality of items or services are controlled either by instruction, procedures, or other appropriate means. The requirements for special processes apply to engineered items only and are not applicable to the WMPO 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 will ensure that process parameters are controlled and that specified environmental conditions are maintained. These documents will be developed and controlled in accordance with WMPO Quality Management Procedures as the need for process control develops.

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SECTION X

INSPECTION

1.0 GENERAL REQUIREMENTS

Measures have been established by the WMPO 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 WMPO 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 WMPO BTPs. The requirements of this section apply to WMPO engineered items and do not apply to WMPO scientific investigation activities. WMPO BTPs which specify the conduct of inspections address the requirements of this section.

2.0 PERSONNEL

2.1 REPORTING INDEPENDENCE OF PERSONNEL

Inspections are performed by WMPO 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 WMPO 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 WMPO 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 WMPO QMP-02-07, "Qualification of Inspection and Test Personnel." Personnel selected to perform inspection and test activities have the 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

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indoctrination activities is in accordance with WMPO QMP-02-01, "Indoctrination and Training of Personnel Performing Quality Related Activities." The following are requirements for the qualification of WMPO 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 WMPO 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 WMPO procedures, acceptance standards, and/or industry practices as defined in WMPO 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 performance or satisfactory completion of capability testing. These factors and the basis for their equivalency are be documented.

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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 a 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 WMPO designates those inspection or test activities that require qualified inspection and test personnel and the minimum qualification requirements for such personnel. The WMPO has established WMPO QMP-02-07, "Qualification of Inspection and Test Personnel," to ensure that only those personnel who meet the established requirements are permitted to perform inspection and test activities. 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 WMPO 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 WMPO 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 WMPO 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 WMPO 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 WMPO QMP-02-01, "Indoctrination and Training of Personnel Performing Quality Related Activities."

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 WMPO 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 WMPO 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 WMPO 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 WMPO's designated representative who is responsible for such certification.
- o Dates of certification and certification expiration.

4.8 PHYSICAL

The WMPO 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 hold points are established as necessary. When such hold points are established, work may not proceed without the specific consent of the responsible WMPO representative. These hold or witness points are indicated in appropriate documents controlling the activity. Specified hold points may not be waived without documented consent.

6.0 INSPECTION PLANNING

Planning for inspection activities is accomplished and documented in accordance with WMPO 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, WMPO 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 WMPO 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 WMPO 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 WMPO 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 WMPO 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 WMPO when it is the organization responsible for operation of such structures, systems or components. In-service inspections will be performed to approved WMPO 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 WMPO QMP-17-01, "QA Records."

10.1 INSPECTION RECORDS

As a minimum, inspection records are generated and controlled in accordance with WMPO 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.
- 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 WMPO inspection personnel qualification are established and maintained. The actual examinations used to qualify personnel are retained as part of the record files. Documentation is maintained in accordance with WMPO QMP-02-07, "Qualification of Inspection and Test Personnel."

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SECTION XI

TEST CONTROL

1.0 GENERAL DISCUSSION

WMPO 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. WMPO test procedures are to be implemented by trained and appropriately qualified personnel.

2.0 TEST REQUIREMENTS

Test requirements and acceptance or rejection criteria, including required levels of precision and accuracy, are identified and approved by the WMPO 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 WMPO.

3.0 TEST PROCEDURES

3.1 TEST INSTRUCTIONS, PROCEDURES AND DRAWINGS

WMPO 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 Format of WMPO Branch Technical Plans and Procedures." The specific WMPO 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

WMPO 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 POTENTIAL SOURCES OF ERROR

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

3.4 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 WMPO, to ensure that specified test requirements have been satisfied. Documentation is in accordance with WMPO BTPs and include the provisions of Paragraph 5.0 below.

5.0 TEST RECORDS

WMPO 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 WMPO QAPP establishes the requirements necessary to ensure that tools, gages, instruments, and other measuring and test equipment (M&TE) used in WMPO 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 WMPO Branch Chief(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 WMPO QA Level I or II activities. The methodology for the control of this equipment is described in WMPO 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 WMPO 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. 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.

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2.2 CALIBRATION

M&TE is calibrated against certified equipment having known valid relationships to the National Bureau of Standards or other nationally recognized standards and is calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the basis for calibration will be documented.

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 WMPO NCR in accordance with WMPO QMP-15-01, "Nonconformance Control," 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 WMPO Branch.

2.6 RECORDS

Records are maintained and equipment is suitably marked to indicate calibration status. WMPO BTPs and WMPO QMP-17-01, "QA Records," 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 WMPO 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 WMPO 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 WMPO technical document. As a minimum, these documents are reviewed for compliance with the requirements of this Section and verified for implementation by the WMPO QA Organization.

1.2 SPECIFIC PROCEDURES

When required for critical, sensitive, perishable, or exceptionally expensive articles, specific WMPO procedures for handling, storage, packaging, shipping, and preservation are used. These procedures are developed in accordance with WMPO QMP-05-02, "Preparation and Format of Branch Technical Plans and 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 WMPO 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 WMPO QMP-02-01, "Indoctrination and Training of Personnel Performing Quality Related Activities."

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1.5 MARKING AND LABELING

WMPO 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 NNWSI Project QAP applies to engineered items and does not apply to scientific investigations. Therefore, this section does not apply to the WMPO scope of responsibility.

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SECTION XV
CONTROL OF NONCONFORMING ITEMS

1.0 GENERAL REQUIREMENTS

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

WMPO initiated nonconformance reports which are generated on items that are the responsibility of a participating organization or an NTS support contractor are processed in accordance with the requirements of NNWSI Project APs and the respective NCR procedures of the affected organization.

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 WMPO NCR number. The NCR number is a sequential number preceded by the WMPO acronym (e.g, WMPO-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 WMPO 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. If work on a nonconforming item must be continued (conditional release) prior to implementation of the disposition, the responsible WMPO Branch Chief and the WMPO 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 WMPO maintains a nonconformance control log to track nonconforming items. This log contains the following information:

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

1.3 SEGREGATION

1.3.1 HOLD AREA

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

1.3.2 ALTERNATIVE

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

1.4 DISPOSITION

1.4.1 NONCONFORMANCE CHARACTERISTICS

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

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1.4.2 RESPONSIBILITY AND AUTHORITY

The responsibility and authority for the evaluation and disposition of all nonconforming items includes the respective WMPO Branch Chief and the WMPO PQM, or their respective designees, as a minimum. WMPO QA Organization responsibilities relating to nonconformances are defined in WMPO QMP-15-01, "Nonconformance Control." 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 WMPO Branch Chief and the WMPO PQM approve NCR dispositions involving "repair" or "use-as-is" determinations and conditional release recommendations.

1.4.3 PERSONNEL

WMPO 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 background information.

1.4.4 DISPOSITIONING OF NCR

WMPO 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 authorized WMPO personnel.
- o The disposition complies with existing design documents, test plans or procedures, reports, and regulatory requirements.
- o If a change to reflect the as-built condition is appropriate, then the disposition addresses action to change the existing design documents, test plans or procedures, reports, etc. Any documents changed are also cross-referenced on the NCR.

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- 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.
- o The cause of the nonconforming condition has been described.
- o Action needed to preclude recurrence has been documented, if appropriate.

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 WMPO organizational units are clearly described. External interfaces between the WMPO and NNWSI Project participants are clearly described in NNWSI Project 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 WMPO QMP-16-03, "Standard Deficiency Reporting System."

3.0 UNUSUAL OCCURRENCES

The WMPO QMP-15-02, "Unusual Occurrences," has been developed for the reporting of unusual occurrences. This procedure meets the requirements of U.S. Department of Energy (DOE/NV) Order 5000.3, "Unusual Occurrence Reporting System." WMPO generated NCRs and SDRs are evaluated by the WMPO QA Organization to determine if further processing as an unusual occurrence is required. WMPO generated unusual occurrence reports are submitted to the DOE/NV office and copies are provided to the WMPO PQM.

4.0 DISTRIBUTION OF DOCUMENTS

Distribution of WMPO NCRs is detailed in WMPO QMP-15-01, "Nonconformance Control." As a minimum, copies of WMPO generated nonconformance reports are sent to the respective WMPO Branch Chief, the WMPO PQM, and the Project QA Department Implementation Division Manager upon issuance and closure. The original nonconformance reports are sent to the WMPO for evaluation, disposition, and approval as required by this section.

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SECTION XVI
CORRECTIVE ACTION

1.0 GENERAL

The WMPO corrective action system is defined per this section of the WMPO QAPP, WMPO QMP-15-01, "Nonconformance Control," and WMPO 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. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability. Significant conditions include, but are not limited to breakdowns in the WMPO QA Program and repetitive nonconformances.

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 WMPO management for review and assessment as defined in WMPO QMP-16-03, "Standard Deficiency Reporting System."

1.2 FOLLOW-UP ACTION

The WMPO 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 WMPO 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 both WMPO QMP-15-01, "Nonconformance Control," and WMPO QMP-16-03, "Standard Deficiency Reporting System."

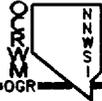
1.3 CORRECTIVE ACTION

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

1.4 CORRECTIVE ACTION DOCUMENTATION EVALUATION

The WMPO is responsible for evaluating corrective action documentation to determine if further processing is required as an unusual occurrence in accordance with WMPO QMP-15-02, "Unusual Occurrences."

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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 Department Implementation Division Manager.

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SECTION XVII

QUALITY ASSURANCE RECORDS

1.0 GENERAL REQUIREMENTS

WMPO Records that furnish documentary evidence of quality are specified, prepared, and maintained in accordance with NNWSI Project APs, WMPO BTPs, and WMPO QMPs which meet the requirements of this Section. In addition, the WMPO is responsible for the processing and storage of validated records submitted by each NNWSI Project 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, documentation of telecons, specifications, technical data, books, maps, 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. NNWSI Project records are distributed, handled and controlled in accordance with NNWSI Project AP-1.7Q, "NNWSI Project Records Management," and other appropriate implementing procedures.

1.2 RECORDS MANAGEMENT

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

The WMPO has a NNWSI Project records management plan which was submitted to HQ/OGR for review and approval. The records management plan:

- o Identifies the types of records to be generated, purchased, or maintained, including all records referenced in pertinent final reports and other documents.

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- o Identifies the methods to be used to comply with all applicable records requirements, including those to be used to control in-process records.
- o Identifies and define the responsibilities of pertinent organizations, including the QA organization.

Consistent with applicable regulatory requirements, the WMPO 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 Paragraph 13.0 of this section.

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 NNWSI Project 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, WMPO BTPs, WMPO QMPs, or other WMPO generated documents specify the records to be generated or maintained by the WMPO. The WMPO maintains all NNWSI Project records submitted by NNWSI Project participants, in accordance with appropriate implementing procedures.

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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.

2.1.2 COMPLETION OF RECORDS

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

3.0 VALIDATION OF RECORDS

3.1 METHODS OF VALIDATION

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

3.2 AUTHENTICATION LIST

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

4.0 RECEIPT OF RECORDS

4.1 RECEIPT CONTROL

The WMPO is responsible for organizing and implementing a system of receipt control of validated WMPO and NNWSI Project 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.

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4.2 PROTECTION OF RECORDS

The WMPO 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 NNWSI Project. The WMPO reviews and approves the records identification system of all its contractors and subcontractors to ensure consistency.

5.2 INDEXING SYSTEM

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

6.0 PERMANENT STORAGE FACILITY

NNWSI Project 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 NNWSI Project records. The use of dual storage facilities is an acceptable alternative to a single fire-rated, controlled facility.

6.1 STORAGE LOCATION

NNWSI Project 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:

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- o A description of the storage facility.
- 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 WMPO. 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.

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9.0 CORRECTED INFORMATION IN RECORDS

9.1 METHOD

NNWSI Project records may be corrected in accordance with implementing procedures that provide for appropriate review or approval by the originating organization.

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.

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- 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 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.

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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 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 WMPO either directly or through the WMPO 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 NNWSI Project records period is defined as lifetime. Records will be submitted to the NNWSI Project records center by the WMPO in accordance with WMPO QMP-17-01, "QA Records."

13.1 SITE CHARACTERIZATION

The following is a list of typical records:

- o Surveys of the underground facility excavations, shafts, and boreholes referenced to readily identifiable surface features.
- o Description of the materials encountered.

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- o Geologic maps and geologic cross section.
- o Locations and amounts of seepage.
- o Instrument locations, readings, analysis, and reports for in situ testing.
- o Technical specifications.
- o Sample extraction location maps.
- 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
 - Geoengineering
 - Hydrology
 - Geochemistry
 - Climatology and Meteorology
- o Environmental Impact Statement.
- o Environmental Report.

13.2 DESIGN RECORDS

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

13.3 PROCUREMENT RECORDS

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

13.4 MANUFACTURING RECORDS

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

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- 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.

13.5 INSTALLATION AND CONSTRUCTION RECORDS

13.5.1 RECEIVING AND STORAGE - NONCONFORMANCE REPORTS

13.5.1.1 CIVIL

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

13.5.1.2 WELDING

- o Ferrite test results.
- o Heat treatment records.
- o Liquid penetrant test final results.

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

13.5.1.3 MECHANICAL

- o Cleaning procedures and results.
- o Code data reports.
- o Installed lifting and handling equipment procedures, inspection, and test data.
- o Lubrication procedures.
- o Material properties records.
- o Pipe and fitting location reports.
- o Pipe hanger and restraint data.
- o Pressure test results (hydrostatic or pneumatic).
- o Safety valve response test procedures.

13.5.1.4 ELECTRICAL AND INSTRUMENTATION AND CONTROL

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



13.5.1.5 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.
- o Anomalous conditions encountered.

13.6 PREOPERATIONAL AND START-UP TEST RECORDS

- o Automatic emergency power source transfer procedures and results.
- o Final system adjustment data.
- o Pressure test results (hydrostatic or pneumatic).
- o Instrument alternating current (AC) systems and inverters test procedures and reports.
- o Offsite power source energizing procedures and test reports.
- o Onsite emergency power source energizing procedure and test reports.
- o Preoperational test procedures and results.

13.7 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 Offsite 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.

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- o Records of gaseous and liquid radioactive material released to the environment.
- 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 Operational, shift supervisor, and control-room logs.
- o Licensee event reports.
- o Fire protection records.
- o Nonconformance reports.
- o Repository equipment operations instructions.
- o Security plan and procedures.
- o Emergency plan and procedures.
- o Quality Assurance and Quality Control Manuals.
- o Records of activities required by the security plan and procedures.

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- 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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SECTION XVIII

AUDITS

1.0 GENERAL REQUIREMENTS

All WMPO NNWSI Project 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 WMPO QA Program and NNWSI Project participant QA programs are effective and properly implemented.

1.1 NNWSI PROJECT AUDITS

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

1.2 SCHEDULING

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

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WMPO suppliers QA programs are audited at least annually or once during the life of the activity, whichever is shorter, with the exception 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 WMPO 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 and lead auditors who participate in NNSWI Project audits is performed and documented in accordance with WMPO QMP-02-02, "Qualification, Certification, and Training of 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 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.

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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 NNWSI Project.
- 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.

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.

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- 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 WMPO's 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.

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 WMPO 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,

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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 WMPO PQM. 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.

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.

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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.

2.0 SURVEILLANCES

The audit program is supplemented by scheduled and unscheduled surveillance activities which are performed in accordance with WMPO QMP-18-02, "Surveillances." The purpose of a surveillance is to monitor or observe NNWSI Project 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 WMPO QMP-16-03, "Standard Deficiency Reporting." Observations (potential quality problems) identified during surveillances are described in WMPO QMP-18-02, "Surveillances."

2.1 SURVEILLANCE PERFORMANCE

Surveillances are performed to written checklists or surveillance plans whenever practical by the WMPO QA Organization personnel who do not report directly to the immediate supervisor who is responsible for the work being surveilled.

2.2 SURVEILLANCE OF SCIENTIFIC INVESTIGATIONS AND EXPERIMENTS

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

2.3 SURVEILLANCE RECORDS

As a minimum, WMPO surveillance records identify the following:

- o Date of surveillance.
- o Name of individual(s) performing the surveillance.



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- 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.
- o Specification of recommended and/or approved corrective action resulting from the surveillance.

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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: Activities that have impact on the validity of information or data reported to NNWSI Project participants or to agencies designated to receive Project output on functions of structures, systems, or components that are important to operator safety and that could cause undue risk to the health or safety of the public. These activities may include planning, researching, developing, demonstrating, investigating, characterizing, designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, decontaminating, decommissioning, dismantling, etc.

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

AP - NNWSI Project 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.

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

BRANCH TECHNICAL PROCEDURE (BTP): A WMPO technical implementing procedure which describes and governs the conduct of a technical (i.e., engineering, scientific or research) activity (i.e., operation, task, function, service or process).

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.

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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.

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.

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.

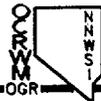
CONTROLLED AREA: The surface location, which is to be marked by suitable monuments, that extend horizontally no more than 5 kilometers in any direction from the outer boundary of the underground facility and the underlying subsurface, which is an area that has been committed to use as a geologic repository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

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

CORROBORATIVE DATA: Information that may or may not have been acquired and controlled in a manner consistent with QA Level I requirements and may be used as background, or corroborative support to primary data.

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.

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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.

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

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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.

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, service, structure, subassembly, subsystem, system, unit, and prototype hardware. This term includes magnetic media, and other materials that retain or support data.

LABORATORY LOGBOOK: A document which may be used to provide a written record of repetitive activities performed in accordance with technical implementing procedures. Examples include calibration, data runs, inventory of controlled materials, etc.

LIFETIME RECORDS: QA records that furnish evidence of the quality and completeness of data, items, and activities affecting quality. All NNWSI 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 NNWSI 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 so that conformance to specified requirements can be verified.

NNWSI PROJECT PARTICIPANTS: An all inclusive term used to describe (generically) the various organizations involved in the NNWSI Project. This term includes the WMPO, participating organizations, and NTS support contractors. These organizations are required to have a WMPO approved Quality Assurance Program Plan for the conduct of their activities.



NNWSI PROJECT PERSONNEL: All U.S. Department of Energy, participating organizations, and NTS support contractor personnel involved in NNWSI Project activities.

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

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

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) government agencies external to the DOE, (2) national laboratories, and (3) organizations participating directly in NNWSI Project activities.

PEER REVIEW: A documented critical review performed by personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Peer reviews are in-depth, critical reviews and evaluations of documents, material or data that require interpretation or judgement 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.

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

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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 NNWSI Project participant.

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

PRIMARY DATA: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable QA Level I requirements and is necessary for the resolution of the NRC performance objectives of 10 CFR 60. This includes information that has been qualified and accepted in accordance with NNWSI Project AP 5.9Q, "Acceptance of Data and Data Interpretations not Developed Under the NNWSI 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, waste isolation, or both, and a list of activities that will provide site characterization data which will be used to assess the performance of natural barriers. The items and activities on this list are subject to the highest QA level (QA Level I) of the formal QA Plan.

QUALITY MANAGEMENT PROCEDURE (QMP): An implementing procedure which identifies the control methods that meet Project QA requirements and is utilized by WMPO, WMPO matrix support, and SAIC/T&MSS personnel.

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

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

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

QUALITY ASSURANCE RECORD: An individual document or other item that has been executed, completed, and approved and that furnishes evidence of (1) the quality and completeness of data (including raw data), items, and activities affecting quality; (2) documents prepared and maintained to demonstrate implementation of quality assurance programs (e.g., audit, surveillance, and inspection reports); (3) procurement documents; (4) other documents such as plans, documentation of telecons, specification, technical data, books, maps, 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 10 CFR 60, and 40 CFR 191.

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 WMPO concerns, and the environment.

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

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QUALITY ASSURANCE PROGRAM PLAN (QAPP): The document, NVO-196-18, that describes the WMPO Quality Assurance Program. This document, in conjunction with WMPO Quality Management Procedures (QMPs) Branch Technical Procedures (BTPs), and quality related NNWSI Project Administrative Procedures (APs), implement the quality assurance requirements delineated in the NNWSI Project QAP, NVO-196-17, that apply to the scope of activities performed by the WMPO.

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

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

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.

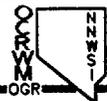
RIGHT OF ACCESS: The right of a purchaser or designated representative to enter the premises of a supplier for the purpose of inspection, surveillance, or QA audit.

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

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

SERVICE: The performance of activities that include but are not limited to site characterization, design, fabrication, investigation, inspection, non-destructive 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 situ testing at depth as needed to determine the suitability of the site for a geologic repository. It does not include preliminary borings and geophysical testing needed to decide whether or not site characterization should be undertaken.

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

SUPPLIER: Any individual or organization under contract to provide items or services to the DOE/NV, to a participating organization, or to an NTS support contractor for NNWSI Project activities.

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

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

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

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

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

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

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

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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.

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

WAIVER: Documented authorization to depart from specified requirements.

WASTE MANAGEMENT PROJECT OFFICE (WMPO): 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 NNWSI Project.

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

WMPO QA ORGANIZATION: Consists of the WMPO PQM and the SAIC/T&MSS Project QA Department personnel.

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

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WMPO Quality Management Procedures (QMPs)

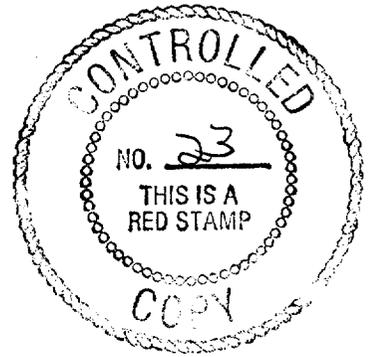


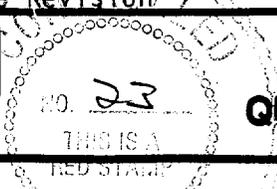
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QMP-02-02	Qualification of Quality Assurance Audit Personnel	1
QMP-03-01	Peer Review	0
QMP-05-01	QMP Format and Preparation	0
QMP-06-03	Document Review/Acceptance/Approval	1
QMP-15-01	Nonconformance Control	0
QMP-16-01	Corrective Action	0
QMP-16-02	Trend Analysis	1
QMP-16-03	Standard Deficiency Reporting System	0
QMP-18-01	Audit System for the Waste Management Project Office	2
QMP-18-02	Surveillance	0

Date: February 22, 1988



QUALITY MANAGEMENT PROCEDURE



<p>Title</p> <p>QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL</p>	<p>No. QMP-02-02 Rev. 1</p> <p>Effective Date 2/22/88</p> <p>Page 1 of 19</p>
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1.0 PURPOSE AND SCOPE

This procedure defines the Waste Management Project Office (WMPO) requirements, responsibilities, and methodology for the qualification of personnel who direct or participate in WMPO Quality Assurance (QA) audits; and, the requirements for the use of Technical Specialists to accomplish the QA audit.

2.0 APPLICABILITY

This procedure applies to the indoctrination, training, orientation, examination, and qualification (including the certification) of personnel who plan, perform, report the results of, and/or evaluate corrective action relating to QA audits conducted by WMPO. In addition, this procedure applies to individuals designated as Technical Specialists for QA audits conducted by WMPO.

3.0 DEFINITIONS

3.1 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 documents; and the effectiveness of implementation.

3.2 AUDITOR

An individual qualified in accordance with this procedure to participate in a QA audit.

3.3 CERTIFICATION

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

APPROVED BY

Project Manager, 78-MSS
[Signature]
Date **2/19/88**

WMPO Project Quality Manager
[Signature]
Date **2/19/88**

WMPO Project Manager
[Signature]
Date **2/19/88**

**QUALITY MANAGEMENT PROCEDURE**

Title

QUALIFICATION OF QUALITY ASSURANCE
PROGRAM AUDIT PERSONNELNo. QMP-02-02 Rev. 1
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Page 2 of 19**3.4 LEAD AUDITOR**

An individual who is qualified in accordance with this procedure to organize, perform, and direct a QA audit; report audit findings, and evaluate related corrective actions. The Lead Auditor (LA) may be referred to as the Audit Team Leader.

3.5 TECHNICAL SPECIALIST

An individual assigned by the Project QA Department (PQAD) Manager to provide advice to Auditor(s) and/or the LA in the preparation or performance of a QA audit when it is determined that the scope, complexity, and/or special nature of the activities to be audited warrant the need of a Technical Specialist to assure an adequate audit.

4.0 RESPONSIBILITIES**4.1 PROJECT MANAGER, Technical and Management Support Services (T&MSS)**

The Project Manager, T&MSS is responsible for certifying and recertifying the PQAD Manager as a LA or Auditor, as appropriate, in accordance with this procedure.

4.2 PROJECT QUALITY ASSURANCE DEPARTMENT (PQAD) MANAGER

The PQAD Manager is responsible for evaluating training needs of prospective Auditors and LAs, ensuring prospective auditing personnel are adequately trained, certifying and recertifying Auditors and LAs, administering the LA examinations(s), assigning Technical Specialists to QA audits, and ensuring adequate QA Records are generated and maintained.

4.3 LEAD AUDITORS

LAs are responsible for issuing letters upon the completion of QA audits to document audit participation by qualified personnel in order to provide evidence of maintaining qualification proficiencies.

5.0 PROCEDURE**5.1 GENERAL**

Personnel selected for QA auditing assignments shall have sufficient experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.



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5.2 QUALIFICATION OF AUDITORS

5.2.1 The PQAD Manager shall ensure personnel participating in QA audits have been provided appropriate training or orientation to develop their competence for performing required QA audits. Competence of personnel in regard to the performance of various auditing functions shall be developed by one or more of the following methods:

1. Orientation to provide a working knowledge and understanding of Nevada Nuclear Waste Storage Investigations (NNWSI)/88-9, NNWSI Project QA Plan; WMPO/88-1, WMPO QA Program Plan; QMP-18-01, Audit System for the WMPO; and, QMP-16-03, Standard Deficiency Reporting System.
2. Training programs to provide general and specialized training in audit performance. General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.
3. On-the-job-training, guidance, and counseling under the direct supervision of a LA. Such training shall include planning, performing, reporting, and follow-up actions involved in conducting audits.

5.2.2 Based upon the requirements of QMP-02-01, Indoctrination and Training of Personnel Performing Quality Related Functions, and this procedure the PQAD Manager shall evaluate the previous experience and training of a prospective Auditor to identify the additional required indoctrination, training, and/or orientation that shall be provided to the prospective Auditor to develop his/her competence for performing required QA audits.

5.2.3 The PQAD Manager shall document the results of this evaluation including the identification of required additional indoctrination, training, and/or orientation of the prospective Auditor. This indoctrination, training, and orientation shall be conducted and documented in accordance with procedure QMP-02-01 and this procedure.

5.2.4 Upon the satisfactory completion of the indoctrination, training, and/or orientation of a prospective Auditor as identified in Section 5.2.3 the PQAD Manager shall review the related documentation required by QMP-02-01 and this procedure for the individual; and, as appropriate, certify the individual as an Auditor. This certification of an Auditor's qualification shall be documented on Figure 1, Record of Auditor/Lead Auditor Qualification.

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5.3 QUALIFICATION OF LEAD AUDITORS

In addition to the requirements of Section 5.2 a prospective LA shall meet the requirements of Sections 5.3.1 through 5.3.5 prior to being certified as a LA.

5.3.1 Communication Skill

The prospective LA shall have the capability to communicate effectively both in writing and orally. These skills shall be demonstrated to the satisfaction of the PQAD Manager who shall, as appropriate, attest to the effectiveness of these skills on Figure 1.

5.3.2 Training

5.3.2.1 Based upon a documented evaluation by the PQAD Manager of the particular needs of each prospective LA, additional required training shall be identified and provided to the extent necessary to assure competence in auditing skills. Training in the following areas shall be required of the prospective LA, as appropriate:

1. Knowledge and understanding of NNWSI/88-9; WMPO/88-1; 10 CFR Part 60, Disposal of High Level Radioactive Waste in Geologic Repositories; and other nuclear and/or DOE related codes, standards, orders, regulations, and regulatory guides, as applicable to the NNWSI Project.
2. General structure of Quality Assurance programs as a whole and applicable elements as defined in NNWSI/88-9 and WMPO/88-01.
3. Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings as delineated in QMP-16-03 and QMP-18-01.
4. Audit planning in the functions related to quality for the following activities: 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.
5. On-the-job training to include applicable elements of the WMPO QA Audit Program.

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5.3.2.2 The training identified in Section 5.3.2.1 shall be conducted and documented in accordance with QMP-02-01 and this procedure.

5.3.3 Audit Participation

The prospective LA shall have participated in a minimum of five QA audits within a period of time not to exceed three years from the date of qualification. One of the audits shall be a nuclear QA audit conducted within a year prior to qualification.

5.3.4 Examination

The prospective LA shall pass an examination that shall evaluate his/her comprehension of and ability to apply the body of knowledge identified in Section 5.3.2. The test may be oral, written, practical, or any combination of the three types as determined by the PQAD Manager. The minimum acceptable score for the LA examination is 80 percent correct regardless of the type of examination given.

5.3.5 Education and Experience

The PQAD Manager shall document the prospective Lead Auditor's qualification on Figure 1, and, as necessary, Figure 2, Record of Auditor/Lead Auditor Qualification Continuation Sheet. A minimum of 10 credits, which are awarded for qualification in the areas of education, experience, professional competence, and demonstrated audit skills, are required. The PQAD Manager shall ensure verifiable evidence, as appropriate, exists and is adequate to support awarding credits as follows:

1. Education (maximum of four points may be awarded):
 - a. Award one credit for an associate degree from an accredited institution, or two credits if the degree is in engineering, physical sciences, mathematics, or quality assurance.
 - b. Award two credits for a bachelor's degree from an accredited institution, or three credits if the degree is in engineering, physical sciences, mathematics, or quality assurance.
 - c. Award one credit for a master's degree from an accredited institution if the degree is in engineering, physical sciences, business management or quality assurance.
2. Experience (maximum of nine credits may be awarded):
 - a. Award one credit for each full year of experience in engineering,

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manufacturing, construction, operation or maintenance with a maximum of five credits.

- b. Award one additional credit if two years of the technical experience have been in the nuclear field, or
- c. Award two additional credits if two years of the technical experience have been in quality assurance; or,
- d. Award three additional credits if two years of the technical experience have been in auditing; or,
- e. Award three additional credits if two years of the technical experience have been in nuclear quality assurance; or
- f. Award four additional credits if two years of experience have been in nuclear quality assurance auditing.

3. Professional Competence (maximum of two credits may be awarded):

Award two credits for certification of competency in engineering, science, or quality assurance specialties issued and approved by a state agency or a national professional society.

4. Rights of Management (maximum of two credits may be awarded):

Award up to two credits for other performance factors applicable to auditing which may not be explicitly delineated in this procedure. Justification for awarding the additional credits shall be documented on Figure 1. Examples of performance factors are: leadership, maturity, sound judgement, tenacity, analytical ability, past performance, and QA training courses.

5.3.6 Certification of Lead Auditors

When the prospective LA meets the requirements of Sections 5.2 and 5.3.1 through 5.3.5, the PQAD Manager shall certify on Figure 1 that the individual is qualified as a LA.

5.4 MAINTENANCE OF PROFICIENCY

5.4.1 LAs and Auditors shall maintain their proficiency through performance of the following activities: participation in at least one QA audit per year (LAs shall participate in at least one QA audit a year either as a LA or Auditor); review and study of codes, standards, procedures, instructions, and other documents related to QA program and program auditing;

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and participation in training programs, as directed by the PQAD Manager. The activities performed by LAs and Auditors to maintain their proficiency shall be listed on Figure 2 by the PQAD Manager for each LA and Auditor, and shall be used as the basis for demonstrating adequate maintenance of proficiency. Based upon the results of annual assessments of documented evidence the PQAD Manager may extend the certification, require retraining, or require requalification. Figure 2 shall identify the activity performed, the date(s) the activity was performed, and the type of proficiency maintenance activity (i.e., audits performed, reviews/studies conducted, or participation in training programs) for each activity performed. The PQAD Manager's dated signature on Figure 1 shall indicate that the results of the evaluation are satisfactory and the certification is extended for a period of one year from the date of the evaluation.

5.4.2 LAs and Auditors who fail to maintain their proficiency for a period of one year and one month or more shall require requalification. Requalification shall include retraining in accordance with the requirements of Section 5.2 (Auditors only) or 5.3.2 (LAs only); reexamination (LAs only) in accordance with Section 5.3.4, and participation as an Auditor (LAs only) in at least one nuclear QA audit. The recertification in regard to the requalification of an individual shall be documented by the PQAD Manager on Figure 1.

5.5 NON-WMPO STAFF PERSONNEL PARTICIPATION IN QA AUDITS

The PQAD Manager may certify personnel external to WMPO staff as Auditors for the purpose of participating in QA audits conducted by WMPO. This certification shall be based on the PQAD's documented review and verification of objective evidence that demonstrates the prospective WMPO Auditor is currently certified as an Auditor in accordance with a Department of Energy (DOE) Headquarters, Office of Civilian Radioactive Waste Management (OCRWM), Office of Geologic Repositories (OGR), or WMPO approved/accepted auditor qualification program.

5.6 TECHNICAL SPECIALISTS

5.6.1 Technical Specialists shall be assigned by the PQAD Manager for use in QA audits as advisors in technical matters when the scope, complexity, and/or special nature of the activities to be audited warrant the need of a Technical Specialist to assure an adequate audit.

5.6.2 Technical Specialists may be Auditors qualified in accordance with Section 5.2 who participate in the preparation and conduct of the QA audit. Technical Specialists who are not qualified Auditors shall be required to receive training identified in QMP-02-01, and shall be required to read Figure 3, Audit Guide For Technical Specialists, prior to the QA audit. This



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guide addresses the basics of the QA audit process and the conduct of personnel during the QA audit, and identifies applicable QA auditing related documents. The Audit Guide for Technical Specialists shall be signed and dated by the Technical Specialist and the PQAD Manager prior to the QA audit.

5.7 RECORD OF AUDIT PARTICIPATION

5.7.1 Upon the completion of each QA audit performed by WMPO the appropriate LA shall prepare a letter to the PQAD Manager that identifies the QA audit number, date(s) of the QA audit, the title or name of the audited organization, and the name of each Auditor participating in the QA audit.

5.7.2 A listing of each QA audit (see Figure 4, Record of Audit Participation) in which a LA or Auditor participates shall be maintained by the PQAD Manager and shall be updated upon receipt of the letter(s) (see Section 5.7.1) documenting participation in a QA audit.

5.7.3 A file for each LA, Auditor, and Technical Specialist shall be established and maintained by the PQAD Manager and shall contain a copy of the individual's resume, documentation relating to or supporting the individual's qualifications, educational degree(s), training course certificates, training attendance records, audit participation records, and applicable examination results.

5.7 ADMINISTRATIVE REQUIREMENTS

5.7.1 The LA examination(s) shall be developed and administered by the PQAD Manager to evaluate the prospective LA's comprehension of and ability to apply the knowledge identified in Section 5.3.2.1.

5.7.2 Integrity of the LA examination(s) shall be maintained by the PQAD Manager through appropriate confidentiality of files containing LA examination(s) and proctoring of LA examinations, where applicable.

6.0 REFERENCES*

- 10 CFR 60 Disposal of High-Level Radioactive Waste in Geologic Repositories
- NNWSI/88-9 NNWSI Project Quality Assurance Plan
- WMPO/88-1 WMPO Quality Assurance Program Plan
- QMP-02-01 Indoctrination and Training of Personnel Performing Quality Related Functions

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QMP-16-03 Standard Deficiency Reporting System

QMP-17-01 QA Records

QMP-18-01 Audit System for the WMPO

*Latest Revision

7.0 APPLICABLE FORMS

Figure 1 Record of Auditor/Lead Auditor Qualification

Figure 2 Record of Auditor/Lead Auditor Qualification Continuation Sheet

Figure 3 Audit Guide for Technical Specialists

Figure 4 Record of Audit Participation

NOTE: Figures listed in this section shall be utilized for individuals being initially qualified or requalified, or having their qualifications extended in accordance with this QMP. Figures completed in accordance with the previous revision of this QMP for prospective Auditors and LAs shall remain in effect prior to the individuals being initially qualified or requalified, or the individuals qualifications being extended in accordance with this QMP.

8.0 QA RECORDS

The PQAD Manager shall ensure the following QA Records resulting from implementation of this procedure are maintained in the WMPO QA Organization Personnel Qualification File for each Technical Specialist, Auditor, and Lead Auditor; and, are processed and maintained in accordance with QMP 17-01, Quality Assurance Records:

1. Records of Auditor/Lead Auditor Qualification (see Figures 1 and 2);
2. Completed Audit Guides for Technical Specialists (see Figure 3);
3. Records of Audit Participation (see Figure 4);
4. LAs' letters of audit participation;
5. Evaluations to determine training needs for prospective Auditors and LAs;



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6. LA examination(s) and results;
7. Annual assessments of Auditors and LAs;
8. Resumes of Auditors and LAs;
9. Training records supporting the qualifications of Auditors and LAs;
and,
10. Documentation relating to the verification of the adequacy of
non-WMPO staff personnel qualification records.



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WASTE MANAGEMENT PROJECT OFFICE RECORD OF AUDITOR/LEAD AUDITOR QUALIFICATION		N-QA-042 2/88			
1. Name: _____		Date: _____			
Employer: _____					
QUALIFICATION CREDIT REQUIREMENTS					
2. EDUCATION - University/Degree/Date ● Undergraduate Level ● Graduate Level		4 Credits Max.			
3. EXPERIENCE - Company/Dates ● Technical (0-5 credits) and ● Nuclear Industry (0-1 credit), or ● Quality Assurance (0-2 credits), or ● Auditing (0-4 credits)		9 Credits Max.			
4. PROFESSIONAL ACCOMPLISHMENT - Certificate/Date ● Professional Engineer ● Society		2 Credits Max.			
5. MANAGEMENT - Justification/Evaluator/Date Explain: _____		2 Credits Max.			
Evaluated By (Name and Title) _____		Date _____			
6. CREDITS AWARDED		Total Credits _____			
7. AUDIT COMMUNICATION SKILLS Evaluated By (Name and Title) _____					
Date _____					
8. AUDITOR TRAINING COURSES					
Course Title or Topic: 1. _____		Date _____			
2. _____		Date _____			
9. ON-THE-JOB TRAINING and/or ORIENTATION (Explain)					
1. _____		Evaluated By (Signature and Date) _____ _____ _____ _____			
2. _____					
3. _____					
4. _____					
5. _____					
10. AUDIT PARTICIPATION (See Attached)					
11. EXAMINATION <input type="checkbox"/> Passed					
Administered By _____		Date of Examination _____			
(Name and Title)		Date _____			
12. QUALIFICATION					
<input type="checkbox"/> Auditor					
Certified By _____		Date _____			
(Signature and Title)		Date _____			
<input type="checkbox"/> Lead Auditor					
Certified By _____		Date _____			
(Signature and Title)		Date _____			
13. ANNUAL EVALUATION (Signature and Date)					

Figure 1 Record of Auditor/Lead Auditor Qualification



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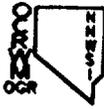
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1. NAME/EMPLOYER/DATE Enter the name of the individual to be certified, the employer of the individual, and the date the form is completed.
2. EDUCATION Enter the name of university(ies) attended, degree(s) obtained, date(s) of degree(s), and number of credits awarded.
3. EXPERIENCE Indicate employment experience (i.e., company(ies) and date(s)). Attach resume or additional sheets, if needed. Indicate the number of credits awarded.
4. PROFESSIONAL ACCOMPLISHMENT Enter type of certification of competency, specialty (i.e., engineering, or QA), name of awarding agency or society, date of certification, and number of credits awarded.
5. MANAGEMENT Provide a statement regarding special performance factors applicable to auditing, e.g., leadership, maturity, sound judgment, tenacity, analytical ability, past performance, QA training courses, etc. Indicate number of credits awarded. (Use continuation sheet if necessary.) Evaluator shall sign and date.
6. CREDITS AWARDED Enter total number of credits awarded.
7. AUDIT COMMUNICATION SKILLS Indicate evaluation and acceptability of communication skills. Evaluator shall sign and date.
8. AUDITOR TRAINING COURSES Enter course(s), title(s), and attendance date(s).
9. ON-THE-JOB TRAINING AND/OR ORIENTATION List type of on-the-job training and/or orientation completed satisfactorily, e.g., preparation of audit plan, knowledge and understanding of NNWSI/88-9, etc. Instructor, Auditor or Lead Auditor who conducted training or orientation shall sign and date.
10. AUDIT PARTICIPATION Enter organization audited, location, date, and audit number on continuation sheet.
11. EXAMINATION Check block if the Lead Auditor's examination was passed and the date of the examination. The individual who administered the examination shall sign and date.
12. QUALIFICATION Check type of qualification. The individual responsible for certification shall sign and date.
13. ANNUAL EVALUATION Evaluator shall sign and date to indicate annual evaluation was satisfactory. Certification of Lead Auditors or Auditors is extended for a period of one year from the date of the evaluation.

Figure 1 Record of Auditor/Lead Auditor Qualification (cont'd)



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AUDIT GUIDE FOR TECHNICAL SPECIALISTS

Technical Specialist

Date

Audits & Surveillances Division Manager

Date

Figure 3 Audit Guide for Technical Specialist



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I. Introduction

This document is written on the basis of the current requirements of NNWSI/88-9, NNWSI Project Quality Assurance Plan, that relate to QA audits, and QMP-18-01, Audit System for the Waste Management Project Office. These requirements apply to the preparation, performance, reporting, and follow-up of QA audits.

The purpose of this document is to provide sufficient basic information to Technical Specialists so that they can effectively advise audit team members and make optimum contributions to the QA audit. The established methods and requirements for QA audits are delineated in QMP-18-01.

QA audits are unique opportunities to gain in-depth understanding of non-technical activities which are not normally related to the Technical Specialist's work. The management systems, procedures, work controls, and other mechanisms which are included in the audit scope are frequently unfamiliar because of the pressures of day-to-day problems in one's own discipline. The QA audit experience provides an opportunity to participate in an orderly analysis of such systems. Therefore, time spent in preparation for participation in a QA audit can be worthwhile and can significantly improve the overall value of the QA audit.

You are urged to take sufficient time prior to the first meeting of the audit team to become as familiar as possible with the information provided herein. If you have questions about the audit process, talk to the audit team leader before the QA audit.

II. The Audit Process

As an advisor to the audit team, you will be primarily concerned with the preparation and performance of the audit. You may also participate in writing the report as directed by the Audit Team Leader. The audit follow-up is the responsibility of the Audit Team Leader.

The first audit function in which you may participate is the development of the audit plan. This plan will identify the audit scope, which activities are to be audited, the applicable documents to be audited against, the audit schedule, and the written checklists to be utilized by the Auditors.

One of the major activities in planning the audit will be a review of deficiencies or problems reported during previous audits or past experience with the audited organization. The past audit records and other related reports provide information pertaining to both past problems for which corrective action has been established and for open items which have not yet been closed out.

Figure 3 Audit Guide for Technical Specialist (cont'd)



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The Audit Team Leader will conduct a pre-audit team meeting to discuss details of the audit plan and establish individual responsibilities. A pre-audit conference will be conducted with the audit team and representatives of the audited organization in attendance to outline the audit scope, the audit plan, and other details of the audit. The pre-audit conference will also introduce the Auditors to the audited organization personnel with whom the Auditors will work. The proposed sequence of events for the audit will be reviewed, and tentative plans for the exit interview will be made.

During the conduct of the audit, it may be advantageous to split the audit team into several groups. The Technical Specialist of the audit team will be in a group which includes the Audit Team Leader or another Auditor. This will assist the Technical Specialist in concentrating on his/her specialized areas.

The principal audit method is to verify compliance with the Quality Assurance Program and other stated requirements. Objective evidence may take the form of records such as, drawings, specifications, logs, data sheets, test results, or other documents which will assist the Auditor in drawing meaningful conclusions in regard to effective implementation of applicable requirements. The Audit Team Leader should be kept fully aware of any needs for special information and should be advised if it is necessary to talk to people or examine records outside the scope of the audit as originally planned.

Whenever deficiencies are identified or suspected during an audit, they should be pursued to the point of a thorough understanding. Whenever possible, the Auditors should determine the cause of such deficiencies and evaluate their effect on other work. When possible, it is good practice to determine the extent of corrective action required. However, it is not the function of the audit team to initiate the corrective action. The deficiency should be pointed out to the responsible members of the organization being audited. It is their function to take proper corrective action. The audit team should maintain cognizance of such corrective action since it will have a bearing on the exit interview and the audit report.

The purpose of the exit interview is to review the audit findings with responsible management of the audited organization. This is essential so that if there are any misunderstandings based on insufficient or incorrect information, they can be clarified. In addition, the exit interview gives the audited organization a good understanding of the overall findings so that appropriate corrective action can be initiated as expeditiously as possible - often even before the audit report is returned to the audited organization for formal acknowledgement.

Figure 3 Audit Guide for Technical Specialist (cont'd)



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After the QA audit has been completed, the audit team usually meets one or more times to develop the audit report. This report will be prepared in accordance with QMP-18-01 and be signed by the Audit Team Leader. It will include a summary of the findings and a statement of effectiveness of the QA Program audited. Standard Deficiency Reports (SDRs), which identify deficiencies noted during the audit, will be issued prior to the audit report in accordance with QMP-16-03, Standard Deficiency Reporting System, and are attached to the audit report for information purposes. The audit report is to be issued by the audit team within 25 days of completion of the audit.

III. Personal Conduct

One subject of prime importance is the matter of personal conduct of the audit team members. Audits will have various degrees of personal involvement on the part of the Auditors and the members of the organization being audited.

Conflicts of opinion are frequently unavoidable; however, conflicts of personalities can almost always be avoided by a skillful Auditor. The point to constantly remember is that an audit evaluates the performance of others. To a varying degree, difference of opinion is almost always a factor in the Auditor-auditee relationship. Consequently, it is imperative that an Auditor be fully aware of the sensitivity of his/her position. The following guidelines are provided to minimize the impact of personal involvements in the audit process.

1. The audit or checklist should be used as a guide and should not restrict the audit investigation. Departure from the audit checklist should be discussed with the Audit Team Leader.
2. Be objective and listen carefully to responses. Remember that the audited organization will normally understand its system better than you will.
3. Avoid personal accusations in audit-related conversations with the audited organization.
4. Arguments with the audited organization should be avoided. If you feel you are correct, accurately document the finding. Next, summarize the audited organization's opinion and read it back for concurrence.
5. Tentatively classify each adverse finding at the time it is found in accordance with QMP-16-03. The reason(s) which prompted the classification should be carefully noted for future reference.
6. Record names, titles, places, etc. of individuals you engage during the audit. Material which will be required to support findings should be reproduced, if possible, or its identity carefully recorded.

Figure 3 Audit Guide for Technical Specialist (cont'd)



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7. An adverse finding which is deemed severe enough to warrant immediate action should be brought to the attention of the Audit Team Leader.

IV. References*

These references provide more detailed information relative to QA audits and should be consulted for answers to specific problems. The Audit Team Leader can direct you to the reference which addresses your question.

1. NNWSI/88-9 NNWSI Project QA Plan
2. QMP-02-02, Qualification of QA Program Audit Personnel
QMP-16-03, Standard Deficiency Reporting System
QMP-18-01, Audit System for the WMPO
WMPO/88-1, Quality Assurance Program Plan
3. 10 CFR 60-Subpart G - Quality Assurance
10 CFR 50-Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
OGR/B-3 - Quality Assurance Plan For High-Level Radioactive Waste Repositories
DOE 5700.6 - Quality Assurance
NV 5700.6 - Quality Assurance
DOE/RW-0005 - Mission Plan

*Latest applicable revision

Figure 3 Audit Guide for Technical Specialist (cont'd)

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1.0 PURPOSE AND SCOPE

1.1 This procedure specifies the responsibilities and prescribes the methods for the review, acceptance, or approval of documents and revisions thereto that: affect the quality of Nevada Nuclear Waste Storage Investigations (NNWSI) Project items or activities or; contribute to the assessment or attainment of NNWSI Project goals or; represent the result of services performed on the behalf of the Waste Management Project Office (WMPO).

2.0 APPLICABILITY

2.1 The responsibilities and methods stated herein apply to WMPO, Department of Energy Nevada Operations Office (DOE/NV), Science Applications International Corporation/Quality Assurance (SAIC/QA) Support Contractor (QASC), and Technical and Management Support Services (T&MSS) Contractor personnel with regard to the review, acceptance, or approval of documents and revisions thereto listed in Exhibit 1. WMPO personnel serving in the position of Branch Chief or higher may elect to apply this procedure to documents other than those listed in Exhibit 1 (See section 5.1).

2.2 This procedure shall apply upon receipt of a draft document and a written request for acceptance or approval from the organization originating

APPROVED BY

Project Manager T&MSS

Michael Lopez

Date 1/20/88

WMPO Project Quality Manager

James Braylock

Date 1/20/88

WMPO Project Manager

Carl [Signature]

Date 1/20/88

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the document. Once implementation of the procedure is initiated on a document, it shall remain effective throughout the necessary review cycle(s) until the document is accepted, approved, or withdrawn by the author(s) or the originating organization's Technical Project Officer (TPO).

3.0 DEFINITIONS

(For additional definitions refer to the Appendix A of the NNWSI Quality Assurance Plan, NVO 196-17)

3.1 Acceptance, Acceptable, or Accepted - These terms are used by the WMPO to indicate that technical documents and revisions thereto, which contribute to the satisfaction of a Nevada Nuclear Waste Storage Investigation (NNWSI) Project or Office of Civilian Radioactive Waste Management (OCRWM) milestone, are suitable for use by NNWSI Project personnel. Acceptance of a technical document by the WMPO does not indicate authentication of the technical data or interpretations contained in the document, nor does acceptance relieve the author(s) of responsibility for the defense of technical data or interpretations contained therein. Exhibit 1 contains a list of documents to which these terms apply.

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3.2 Approval or Approved - These terms are used by the DOE/NV and the WMPO to indicate agreement with the form, tenor, and details of administrative and management documents and revisions thereto. Use of this term does not relieve the document originator of the responsibility to fulfill contractual obligations. Exhibit 1 contains a list of documents to which these terms apply.

3.3 Concurrence - This term is used by the Office of Geologic Repositories (OGR) to indicate agreement that a document is suitable for use by the NNWSI Project personnel and is used by the DOE/NV Assistant Manager Administration Technical (AMAT) to indicate that an AMAT review of a document has been satisfactorily completed and the document is suitable for publication and release to the public.

3.4 DOE/NV and WMPO Authorities - The DOE/NV and WMPO personnel who are designated as responsible for the acceptance or approval of documents as indicated in Exhibit 1.

3.5 Document Review - A documented traceable review of documents, material, or data that may consist of a technical review, peer review, AMAT review, regulatory review, QA review, and/or management review.

3.6 AMAT Review - This review is required for all documents intended for publication and release to the general public and authored by U.S.

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governmental agencies or organizations under direct contract to the DOE Nevada Operations Office (DOE/NV). It is an examination of a document to determine compliance with established DOE policies; (e.g., DOE Orders 1430.1 and 1430.2) evaluate eligibility for a patent and; determine a security classification commensurate with the document's effect on national security. National laboratories have been delegated responsibility and authority to perform these reviews.

3.7 Regulatory Review - An examination of a document to determine its value and appropriate use in supporting a Nuclear Regulatory Commission (NRC) license, environmental regulatory requirements, or its appropriateness for supporting the preparation of NNWSI Project Regulatory Topical Reports and Issue Resolution Reports. Documents are to be reviewed for consistency or inconsistency with current NNWSI Project views as expressed in the Environmental Assessment (EA), the Site Characterization Plan (SCP), other previously published documents, and the Project technical data bases. A recommendation to conduct a technical or peer review may result from a regulatory review.

3.8 QA Review - An examination of a document to determine its compliance with DOE Orders relating to Quality Assurance (DOE/NV 5700.6B) and the NNWSI Project Quality Assurance Plan (NVO-196-17) as well as NNWSI Project quality-related Administrative Procedures.

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3.9 Management Review - An examination of a document to determine its compliance with requirements established by approved NNWSI Project management plans, procedures, and DOE policies adopted by the WMPO, as directed by DOE/NV, the Office of Geologic Repositories (OGR), or OCRWM. This review includes an examination to determine if the document fulfills the established milestone criteria. A recommendation to conduct a technical or peer review may result from a management review.

3.10 Major Comments - Comments that, in the opinion of the reviewer, identify and describe areas in the text of a document that represent significant conflicts with, or deviation from, existing approved NNWSI Project policy, quality assurance, programmatic, management requirements, or technical positions. Omissions of pertinent or significant information or disagreement with the technical facts or positions presented in the document are included within the scope of major comments.

3.11 Editorial/Grammatical Comments - Comments that are identified by the reviewer as editorial or grammatical errors. Reviewers are encouraged to identify editorial/grammatical comments, however it will be at the discretion of the author(s) or originating organization's TPO to resolve them.

3.12 Suggestions - Comments that are identified by the reviewer, which are made with the understanding that these comments are not expected to be resolved by the author(s) or originating organization's TPO.

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4.0 RESPONSIBILITIES**4.1 DOE/NV and WMPO Authorities**

4.1.1 It is the responsibility of the WMPO Project Manager to ensure the implementation of the requirements of this procedure for the DOE/NV on the NNWSI Project. The WMPO Project Manager is responsible for acceptance, approval, or concurrence of documents for the NNWSI Project within his delegated contract authority for Project participants and contractors, including other federal agencies and the national laboratories.

4.1.2 WMPO staff and DOE/NV matrix support staff are responsible for performing reviews in accordance with this procedure and documenting their comments on Document Review Sheet(s) (DRS, Exhibit 3 and 4), and accepting or rejecting resolutions proposed by document originators. Signature of acceptance or approval either on the document or in related correspondence serves to indicate satisfactory completion of the resolution of comments.

4.1.3 WMPO Branch Chiefs or designee are responsible for determining when a Technical, Management, Regulatory, QA, AMAT, or Peer review is required for documents not included in Exhibit 1. WMPO Branch Chiefs or designee are responsible for resolving disputes concerning comments and resolutions with the appropriate personnel.

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4.1.4 AMAT is responsible for coordinating the AMAT review for DOE/NV and preparing correspondence for the appropriate Contracting Officers Technical Representative (COTR) or Contracting Officer (CO).

4.2 Technical and Management Support Services (T&MSS) Contractor

4.2.1 The T&MSS contractor is responsible for providing qualified personnel to conduct Management, Regulatory, Technical, and QA reviews in accordance with this procedure.

4.2.2 The T&MSS contractor is responsible for obtaining Peer reviews when requested by the WMPO.

4.2.3 The Technical Integration and Support Division (TISD) of the T&MSS contractor is responsible for coordinating the document review process on behalf of the WMPO. The TISD is also responsible for establishing and maintaining a document review status system.

4.3 Project Participants

4.3.1 NNWSI Project Participants are responsible for submitting appropriate documents to WMPO for review, acceptance/approval, or concurrence in



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accordance with NNWSI Project Administrative Procedure (AP-1.3Q) and resolving comments that have been generated as a result of implementation of QMP-06-03.

5.0 PROCEDURE

(See Exhibit 2 "Document Review/Acceptance/Approval Flowchart")

5.1 Initiating the Review of a Document

5.1.1 The WMPO Project Manager, the Project Quality Manager (PQM), AMAT, DOE/NV Manager, and each WMPO Branch Chief shall provide the T&MSS TISD with a distribution list indicating which DOE/NV personnel, WMPO personnel, AMAT personnel, and/or T&MSS manager(s) are responsible for review of each document or document type.

5.1.2 The T&MSS TISD shall establish and maintain a document review status system such that the status of each document in the review/acceptance/approval cycle can be readily ascertained.

5.1.3 Following the receipt of a draft document, the T&MSS TISD shall initiate the document review cycle. Using Exhibit 1, or specific directions

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from the WMPO for documents that are not included in Exhibit 1, the T&MSS TISD shall determine which types of reviews are necessary for each draft document, prepare the necessary Document Review Sheet(s) (DRS, Exhibits 3 and 4) and distribute to the appropriate staff the draft document, the request for acceptance or approval, and the DRS.

5.2 Document Review

5.2.1 The WMPO Project Manager, the PQM, AMAT, DOE/NV Manager, and each WMPO Branch Chief shall develop, maintain, and provide to designated reviewers (See sections 5.1.1 above) written instructions that establish criteria that reviewers shall use to evaluate a document during a review. Such instructions shall be consistent with the definitions given for document reviews in Section 3.0 of this procedures.

5.2.2 Personnel performing document reviews (reviewers) shall document their comments on the Document Review Sheets (DRS, Exhibits 3 and 4). If the reviewer listed in Exhibit 1 delegates additional staff within the reviewer's organization to perform the review, it shall be the responsibility of the reviewer listed in Exhibit 1 to consolidate comments on to a single DRS using additional Document Review Continuation Sheets as necessary. This consolidation shall include resolving any conflicting comments generated by the



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reviewer's staff. Upon completion of the review, the reviewer listed in Exhibit 1 shall sign and date the DRS.

5.2.3 When the review does produce comments, the reviewer shall identify each comment as either a "Major Comment," Editorial/Grammatical Comment," or "Suggestion" as shown in Exhibits 3 and 4.

5.2.4 Personnel performing Regulatory and Management reviews shall indicate on the DRS any recommendation for a Technical or Peer review of the subject document.

5.2.5 Personnel performing Technical reviews shall indicate on the DRS any recommendation for a Peer review of the subject document.

5.2.6 Following completion of the DRS(s), the reviewer(s) shall forward the DRS(s) to the T&MSS TISD.

5.3 Action Subsequent to Review

5.3.1 Following receipt of the completed DRS(s), the T&MSS TISD shall review the DRS(s) to determine the extent of the comments and to assure that the DRS(s) conform to the requirements of this procedure. In addition, the T&MSS TISD shall review the DRS(s) received from the Management and Regulatory

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review to determine if a recommendation was made for a Technical or Peer review. The T&MSS TISD shall review the DRS(s) received from a Technical review to determine if a recommendation was made for a Peer review. If recommendation was made for a Technical or Peer review, the T&MSS TISD shall forward the DRS(s) and the document to the WMPO authorities to approve the need for a Technical or Peer review (see Section 5.6).

5.3.2 Subsequent to the successful conclusion of a Technical or Peer review, the document and completed DRS(s) shall be returned to the T&MSS TISD.

5.3.3 If no comments exist, the T&MSS TISD shall complete a transmittal slip (Exhibit 5) and forward it, the DRS(s), and the document to the WMPO. The WMPO shall prepare an approval letter for the WMPO Project Manager signature and forward the approval letter, the DRS(s), and the document to the DOE/NV and WMPO authorities for disposition regarding acceptance/approval, the determination of the need for OGR review/acceptance/approval and/or an AMAT review (see Section 5.6).

5.3.4 If major comments, editorial/grammatical comments, or suggestions exist, the T&MSS TISD shall complete a transmittal slip (Exhibit 5) and forward the transmittal slip and the DRS(s) to the WMPO. The WMPO shall prepare a letter for the WMPO Project Manager signature to transmit the DRS(s) to the originating organization's TPO for disposition.

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5.4 Disposition of Comments by the Author(s) or Originating Organization's TPO

5.4.1 Following the receipt of the DRS(s), the author(s) or the originating organization's TPO may, at their discretion elect to resolve the comments as described in Section 5.5 below or withdraw the document from the review/acceptance/approval cycle. When a document is withdrawn, the originating organization's TPO shall provide the T&MSS TISD and the WMPO with written notice of this action and provide the reason for the withdrawal of the document.

5.5 Resolution of Comments

5.5.1 Resolution of major comments shall be accomplished by the author(s) or the originating organization's TPO or his/her designee and the reviewer(s). In the event that the reviewer is unavailable for resolution, the reviewing organization shall designate a replacement to resolve the comments or the appropriate DOE/NV and WMPO authorities shall serve to resolve the comments.

5.5.2 Resolution of editorial/grammatical comments or suggestions shall be accomplished by the author(s) or the originating organization's TPO or his/her designee at their discretion. The resolution of these comments are not required to be documented on the DRS(s).

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5.5.3 The resolution of major comments shall be documented by the author(s), the originating organization's TPO or his/her designee adjacent to the comments on the same DRS(s) on which the comments appear. The reviewer shall indicate his/her agreement or disagreement with the resolution of these comments in the column on the DRS provided for this purpose (see Exhibits 3 and 4).

5.5.4 Following the completion of the resolution of comments on the DRS, the author(s) or the originating organization's TPO or his/her designee shall revise the document if necessary and submit the document to the WMPO and the T&MSS TISD, along with the completed DRS package.

5.5.5 Following the receipt of the document, the completed DRS package, and a written request for acceptance/approval the T&MSS TISD shall evaluate the DRS package to determine if all comments have been resolved in accordance with this procedure. If deficiencies in the DRS(s) exist, the DRS package shall be returned to the author(s) or originating organization's TPO for correction.

5.5.6 If no deficiencies in the DRS(s) exist and the DRS(s) contains major comments, the T&MSS TISD shall distribute the DRS(s) and the revised document to the reviewer and the T&MSS TISD shall initiate the document review cycle as described in section 5.1 of this procedure. In this portion of the review cycle, each reviewer shall review their own set of completed DRS(s) so that

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they may verify if the revised document compliments the resolutions described by the DRS(s). This verification process occurs only once if the reviewer determines that the revised document compliments the resolution described by the DRS(s).

5.5.7 Subsequent to completion of Section 5.5.6, if major comments have not been resolved, the T&MSS TISD shall forward the document and DRS package to the appropriate DOE/NV and WMPO Authorities for resolution of the dispute(s) (see Section 5.8).

5.5.8 If only editorial/grammatical comments or suggestions exist on the completed DRS(s), the T&MSS TISD shall complete a transmittal slip (Exhibit 5) and forward it, the DRS(s), and the document to the WMPO. The WMPO shall prepare an approval letter for the WMPO Project Manager signature and forward the approval letter, the DRS(s), and the document to the DOE/NV and WMPO authorities for disposition regarding acceptance/approval, the determination of the need for OGR review/acceptance/approval and/or AMAT review (see Section 5.6).

5.5.9 Subsequent to completion of Section 5.5.6 and if all major comments, including disputes, have been resolved, the T&MSS TISD shall complete a transmittal slip (Exhibit 5) and forward it, the DRS(s) and the document to the WMPO. The WMPO shall prepare an approval letter for the WMPO Project Manager signature and forward the approval letter, the DRS(s), and the

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document to the DOE/NV and WMPO authorities for disposition regarding acceptance/approval, the determination of the need for OGR review/acceptance/approval and/or and AMAT review (see Section 5.6).

5.6 Technical, Peer, AMAT Reviews and OGR Review/Acceptance/Approval

5.6.1 Technical reviews and AMAT reviews shall be accomplished in accordance with the requirements of this procedure, Sections 5.2, 5.3, 5.4, 5.5, and

5.6. Peer reviews shall be accomplished in accordance with QMP-03-01, "Peer Review."

5.6.2 If a Technical review is deemed necessary by the WMPO, the WMPO authorities shall direct the T&MSS TISD to reissue the document for a Technical review in accordance with this procedure. If a Peer review is deemed necessary by the WMPO, the WMPO authorities shall initiate a Peer review in accordance with QMP-03-01.

5.6.3 If a Technical or Peer review is not necessary or following the satisfactory conclusion of a Technical or Peer review, the document shall be considered for OGR review/acceptance/approval in accordance with the requirements of Exhibit 1 or as directed by WMPO. The WMPO Project Manager may release the document for NNWSI Project use if an AMAT review is not required prior to receiving OGR acceptance/approval.

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5.6.4 Following acceptance or approval by OGR or as described by the WMPO Project Manager, the document shall be considered for an AMAT review in accordance with the requirements of Exhibit 1 or as directed by the WMPO. If an AMAT review is necessary, the DOE/NV and WMPO authorities will initiate the review in accordance with appropriate DOE Orders.

5.6.5 If an AMAT review is not required or following the satisfactory completion of an AMAT review, the DOE/NV and WMPO authorities shall document their acceptance or approval of the document, secure the concurrence of AMAT (if required, see Exhibit 1), and notify the originating organization's TPO of the acceptance/approval.

5.7 Action Subsequent to Acceptance/Approval by the DOE/NV and WMPO

5.7.1 Subsequent to acceptance/approval by the DOE/NV and WMPO authorities, the DOE/NV and WMPO authorities shall direct the T&MSS TISD to issue the document for NNWSI Project use by taking one of the following actions:

- o Enter the document into the Project Baseline per NNWSI Project AP-3.3Q, "Baseline Change Process."
- o Enter the document into controlled distribution.

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- o Return the document to the originating organization's TPO for distribution and/or publication.

5.8 Resolution of Disputes

5.8.1 Differences of opinion (disputes) that occur between the reviewer(s) and the author(s) shall be documented on the DRS(s) in accordance with the requirements of Section 5.5.3 of this procedure.

5.8.2 Disputes shall be resolved by the appropriate DOE/NV and WMPO authorities. The DOE/NV and WMPO authorities shall make the final disposition decision. The final disposition action may include, but is not limited to: development of an agreeable compromise; or appointment of an independent panel of qualified personnel to resolve the matter (this would include peer reviews in accordance with QMP-03-01).

5.8.3 The resolution of disputes shall be documented by the DOE/NV and WMPO authorities in correspondence traceable to the DRS(s). Correspondence related to disputes shall include a complete description of the resolution, the justification for the resolution and the DRS(s) on which the dispute appears. Such correspondence shall be made available to the author(s), originating organization's TPO and the reviewer.

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5.8.4 If resolution of a dispute requires revision to the document, the document shall be returned to the originating organization's TPO through the T&MSS TISD. The author shall revise the document in accordance with the resolution of the dispute and return the revised document to the T&MSS TISD. This procedure shall repeat from Section 5.5.9.

5.8.5 If resolution of a dispute does not require revision to the document, the WMPO shall prepare an approval letter for the WMPO Project Manager's signature and forward the approval letter, the DRS(s), and the document to the DOE/NV and WMPO authorities for disposition regarding acceptance/approval, the determination of the need for OGR review/acceptance/approval and/or an AMAT review (see Section 5.6).

6.0 REFERENCES

- o NVO-196-17, NNWSI Project Quality Assurance Plan
- o QMP-03-01, WMPO Quality Management Procedure, "Peer Review"
- o QMP-17-01, WMPO Quality Management Procedure, "Quality Assurance Records"
- o NNWSI Project Administrative Procedure 1.3Q, "Documents Requiring WMPO Review and Approval"
- o NNWSI Project Administrative Procedure 3.3Q, "Baseline Change Process"

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7.0 RECORDS

- o Documents listed in Exhibit 1 that are authored by the WMP0, the completed DRS(s), documentation indicating the acceptance/approval of documents, and correspondence related to the resolution of disputes shall be considered QA Records. These records shall be maintained in accordance with the requirements of QMP-17-01, "Quality Assurance Records."
- o The T&MSS TISD shall assure that the documents listed in Section 7.0 are provided to the NNWSI Project Records Center.

8.0 EXHIBITS

- o Exhibit 1 - Document Review/Acceptance/Approval
- o Exhibit 2 - Document Review/Acceptance/Approval Flow Chart
- o Exhibit 3 - Document Review Sheet
- o Exhibit 4 - Document Review Continuation Sheet
- o Exhibit 5 - Transmittal Slip



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Document	Review type	Review staff ^a	Action	Level
1. NNWSI Project Plan	Management	C, D, & E	Approval	WMPO Project Manager, DOE/NV Manager, OGR Assoc. Director
2. NNWSI Project Management Plan	Management	C, D, & E	Approval Concurrence	WMPO Project Manager, DOE/NV Manager OGR Associate Dir.
3. NNWSI Quality Assurance Plan	Management Quality Assurance	C, D, & E G & H	Approval	WMPO Project Manager, PQM, OGR Assoc. Director
4. ESF Management Plan	Management Quality Assurance	C, D, & E G	Approval	WMPO Project Manager
5. Systems Engineering Management Plan	Management Quality Assurance Regulatory	C, D, E, H G D	Approval	WMPO Project Manager OGR Assoc. Director
6. Configuration Management Plan	Management Quality Assurance Regulatory	C, D, & E G D	Approval	WMPO Project Manager
7. Exploratory Shaft Test Plan	Management Quality Assurance Regulatory	C, D G D	Acceptance	WMPO Project Manager



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Document	Review type	Review staff ^a	Action	Level
8. Field Activities Plan	Management	C, D	Approval	WMPO Project Manager
9. Environmental Impact Statement Management Plan	Management Regulatory Quality Assurance	C, D, & E D G	Approval	WMPO Project Manager
10. Tourism Data Report	Management AMAT	D, E, & F F	Approval Concurrence	WMPO Project Manager AMAT
11. Demographic Data Report	Management AMAT	E F	Approval Concurrence	WMPO Project Manager AMAT
12. Environmental Regulatory Compliance Plan	Management Regulatory Quality Assurance	D, E & F D G	Approval	WMPO Project Manager
13. Horizontal Waste Emplacement Equipment Development Plan	Management Quality Assurance	C G	Approval	WMPO Project Manager
14. Records Management Plan	Management Quality Assurance	C, D, & E G	Approval	WMPO Project Manager
15. Reference Information Base	Management Quality Assurance	C, D G	Approval	WMPO Project Manager



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Document	Review type	Review staff ^a	Action	Level
16. Retrievalability Compliance Strategy Plan	Management Quality Assurance	C G	Approval	WMPO Project Manager
17. Technical Data Base Management Plan	Management Quality Assurance	C, D, & E G	Approval	WMPO Project Manager
18. NNWSI Training Plan	Management Quality Assurance	C, D, & E G	Approval	WMPO Project Manager
19. NNWSI Outreach and Participation Plan	Management	E	Approval	WMPO Project Manager
20. Environmental Program Plan	Management Quality Assurance AMAT	E G F	Approval Concurrence	WMPO Project Manager AMAT
21. Socioeconomic Monitoring and Mitigation Plan	Management Quality Assurance Regulatory AMAT	D G D F	Approval Concurrence	WMPO Project Manager AMAT
22. Environmental Monitoring and Mitigation Plan	Management Quality Assurance Regulatory AMAT	E G D F	Approval Concurrence	WMPO Project Manager AMAT



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23. Transport Studies Plan	Management	E	Approval	WMPO Project Manager
	Quality Assurance	G		
	Regulatory	D		
24. Radiological Monitoring Plan	Management	E	Approval	WMPO Project Manager
	Quality Assurance	G		
	Regulatory	D	Concurrence	AMAT
	AMAT	F		
25. Decommissioning Plan	Management	C	Approval	WMPO Project Manager
	Quality Assurance	G		
	Regulatory	D	Concurrence	AMAT
	AMAT	F		
26. Regulatory Compliance Plan	Management	D	Approval	WMPO Project Manager
	Quality Assurance	G		
	Regulatory	D	Concurrence	AMAT
	AMAT	F		
27. Waste Package Strategy Document	Management	C & H	Approval	WMPO Project Manager, OGR Assoc. Director
	Quality Assurance	G		
	Regulatory	D		
28. Repository Sealing Plan	Management	C	Approval	WMPO Project Manager
	Quality Assurance	G		
	Regulatory	D	Concurrence	AMAT
	AMAT	F		



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Document	Review type	Review staff ^a	Action	Level
29. SCP Management Plan	Management Quality Assurance Regulatory	D G D	Approval	WMPO Project Manager
30. Regulatory Topical Reports	Management Regulatory Quality Assurance	C, D, E, & F D G	Approval	WMPO Project Manager
31. Issues Resolution Reports	Management Regulatory	C,D,E,H & F D	Approval	WMPO Project Manager
32. Safety Analysis Report	Management Quality Assurance Regulatory	C, D, E & H G D	Approval	WMPO Project Manager, OGR Assoc. Director
33. Yucca Mountain MGDS System Requirements Documents	Management Quality Assurance Regulatory	C, D & H G D	Approval	WMPO Project Manager, OGR Assoc. Director
34. Subsystem Design Requirements Documents	Management Quality Assurance Regulatory	C & H G D	Approval	WMPO Project Manager, OGR Assoc. Director
35. NNWSI MGDS Description	Management Quality Assurance Regulatory	C & H G D	Approval	WMPO Project Manager, OGR Assoc. Director



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Exhibit 1. Document review/acceptance/approval (page 6 of 7)

Document	Review type	Review staff ^a	Action	Level
36. WMPO Quality Assurance Program Plan and Interim Change Notices	Management Quality Assurance	C,D,E,I,J,K,L, M, & N G & H	Approval	WMPO Project Manager, WMPO PQM, T&MSS Project Manager, T&MSS QA Manager, OGR Assoc. Director
37. WMPO Quality Management Procedures and Interim Change Notices	Management Quality Assurance	C,D,E,I,J,K,L, M, & N G	Approval	WMPO Project Manager, WMPO PQM, T&MSS Project Manager
38. WMPO Branch Technical Procedure	Management Quality Assurance	C,D, or E as appropriate; J,K,L,M or N as appropriate G	Approval	WMPO Branch Chief, WMPO PQM, T&MSS Department Manager
39. Participant Quality Assurance Program Plans	Quality Assurance	G	Approval	WMPO PQM
40. Quality Assurance Level Assignment Sheets	Management Quality Assurance	C,D or E as appropriate G	Approval	WMPO PQM, WMPO Branch Chief



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Document	Review type	Review staff ^a	Action	Level
41. Scientific Investigations Plans	Management	C,D or E as appropriate	Approval	WMPO PQM, WMPO Branch Chief
	Quality Assurance	G		
42. Design Drawings and Specifications, QA Level I and II	Management	C	Acceptance	WMPO Branch Chief TD&E
	Quality Assurance	G		
43. Review Sheets for Acceptance of Data Interpretations Not Generated under the NNWSI Project QA Plan	Management	C,D or E as appropriate	Acceptance	WMPO PQM WMPO Branch Chief
	Quality Assurance	G		
44. Technical Reports and Publications	Management	C,D or E	Acceptance	WMPO Project Manager
	Quality Assurance	G	Concurrence	AMAT (as needed)
	Regulatory AMAT	D (as needed) F (as needed)		

^aLegend for Review Staff assigned:

- | | |
|--------------------------------------|---|
| A = WMPO Project Manager | I = T&MSS Project Manager |
| B = DOE/NV Manager Staff | J = T&MSS Project Management Department Manager |
| C = TD&E Branch Staff (and/or T&MSS) | K = T&MSS Project Operations Department Manager |
| D = R&SE Branch Staff (and/or T&MSS) | L = T&MSS Project Technical Integration, Analysis and Evaluation Department Manager |
| E = S&PC Branch Staff (and/or T&MSS) | M = T&MSS Project Regulatory Compliance Department Manager |
| F = AMAT Staff | N = T&MSS Support Services Department Manager |
| G = WMPO PQM and QASC Staff | |
| H = OGR Staff | |



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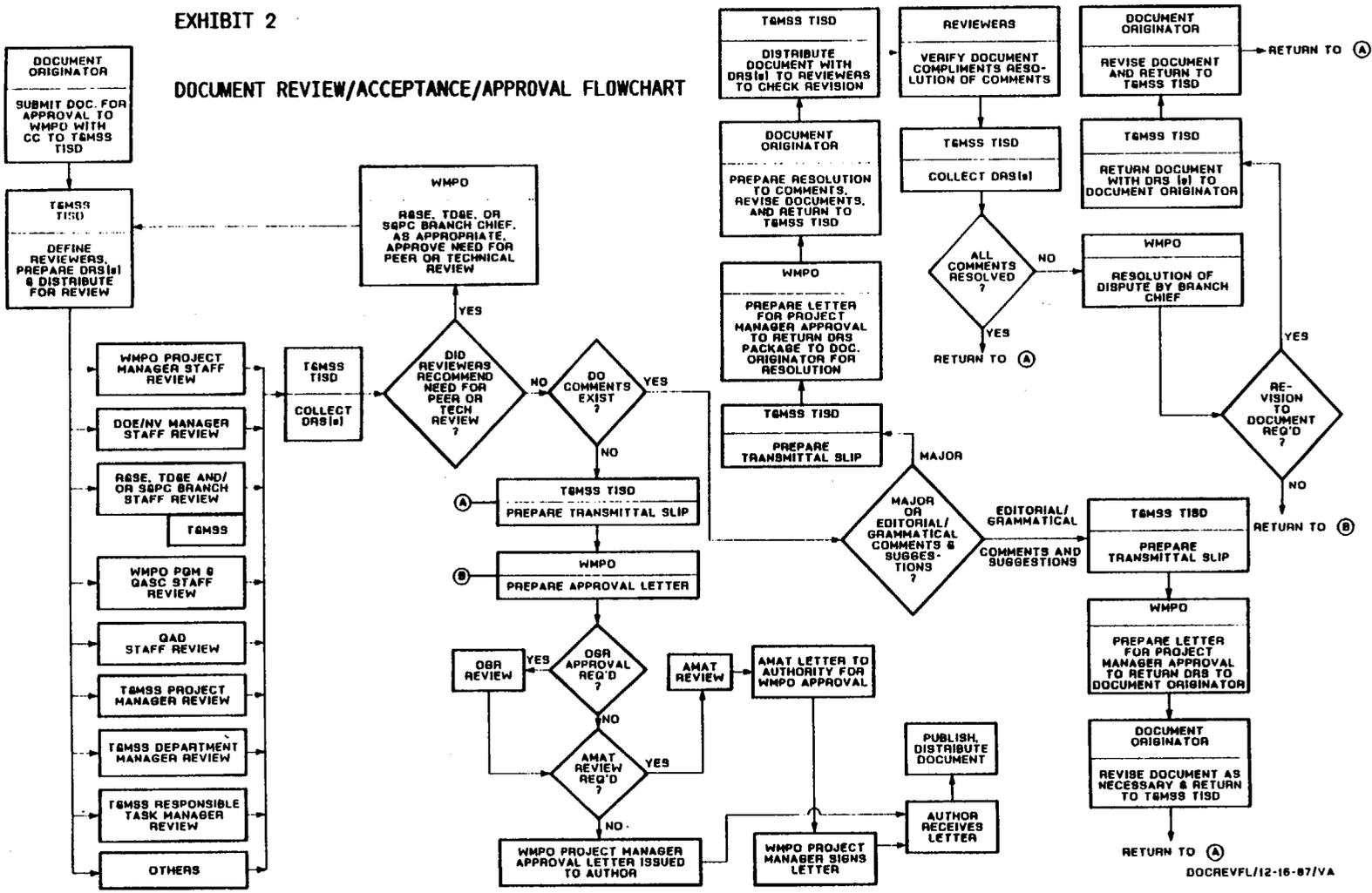
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EXHIBIT 2

DOCUMENT REVIEW/ACCEPTANCE/ APPROVAL FLOWCHART



DOCREVFL/12-16-87/VA

Exhibit 4. Document Review Continuation Sheet



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DOCUMENT REVIEW CONTINUATION SHEET N-QA-041
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Document Title Exploratory Shaft Facility Subsystem Requirements Document
 Name of Reviewer J. Doe

REVIEWER'S COMMENTS		RESOLUTION			REVIEWER'S DISPOSITION FOR MAJOR COMMENTS		
COMMENT NO. & TYPE	PAGE NO.	COMMENTS	ACCEPT	REJECT	REASONING	ACCEPT	REJECT
4 Con't.					referenced in Sec. 6.1 and currently available for use.		
5 Suggestion	28	Reword the second line of Para. 7.1.8 to address the subject "natural hazards". As it is this is not clear.	JWH 1/15/87		Agreed. This sentence will be revised accordingly.		
SAMPLE							



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TRANSMITTAL SLIP

TO: _____ DATE: _____

FROM: _____

DOCUMENT TITLE: _____

DOCUMENT ORIGINATOR: _____

ORIGINATING ORGANIZATION:

- SNL
- LANL
- LLNL
- SAIC
- USGS
- H&N
- F&S

DRS STATUS:

- NO COMMENTS EXIST
- MAJOR COMMENTS EXIST
- EDITORIAL/GRAMMATICAL COMMENTS AND/OR SUGGESTIONS EXIST
- MAJOR COMMENTS RESOLVED

ACTION REQUIRED:

- RETURN TO DOCUMENT ORIGINATOR FOR COMMENT RESOLUTION? YES NO
- WMPO APPROVAL REQUIRED? YES NO TO BE DETERMINED BY WMPO
- OGR APPROVAL REQUIRED? YES NO TO BE DETERMINED BY WMPO
- AMAT REVIEW REQUIRED? YES NO TO BE DETERMINED BY WMPO

REMARKS:



NO. 23

THIS IS A
RED STAMP

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1.0 PURPOSE AND SCOPE

The purpose of this procedure is to establish the responsibilities and methods for planning, conducting, and documenting a formal, comprehensive Waste Management Project Office (WMPO) Quality Assurance audit program in support of the Nevada Nuclear Waste Storage Investigations (NNWSI) Project.

2.0 APPLICABILITY

This procedure applies to all internal, external, and supplemental audits conducted by WMPO of quality related activities.

3.0 DEFINITIONS

3.1 AUDIT

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

3.2 AUDIT FINDING

The audit finding is any deficiency in characteristics, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

3.3 AUDIT TEAM

An audit team shall consist of one or more auditors, and shall include an individual qualified as a Lead Auditor who organizes and directs the audit. The team may include technical specialists and audit candidates.

3.4 AUDITOR

An auditor is an individual who is qualified to perform any portion of an audit under the direction of a Lead Auditor.

APPROVED BY

Project Manager, T&MSS

Date

2/19/88

WMPO Project Quality Manager

Date

2/19/88

WMPO Project Manager

Date

2/19/88

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The all inclusive term "condition adverse to quality" refers to any of the following: (1) failures, (2) malfunctions, (3) deficiencies, (4) defective items, and (5) nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.

3.6 EXTERNAL AUDIT

An external audit is an audit of those portions of another organization's quality assurance program that are neither under the direct control nor within the organizational structure of the auditing organization.

3.7 INTERNAL AUDIT

An internal audit is an audit of those portions of an organization's quality assurance program that are neither under the direct control nor within the organizational structure of the auditing organization.

3.8 LEAD AUDITOR

The Lead Auditor is an individual who is certified to develop and perform an audit; report audit findings; and to follow-up and evaluate corrective actions. The Lead Auditor is also referred to as the audit team leader.

3.9 OBJECTIVE EVIDENCE

Objective evidence is any documented statement of fact, information, or record, either quantitative or qualitative, that pertains to the quality of an item, activity, or service and that is based on verifiable observations, measurements, or tests.

3.10 OBSERVATION

The recognition by the audit team of a weakness in a quality assurance program that, if left uncorrected, could result in a condition adverse to quality.

3.11 OBSERVER

An individual who is not an active participant, but may be involved with the audit to observe how the audit is conducted or to become familiar with the auditee's organization and activities.

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3.12 ORGANIZATION

For the purpose of this procedure, organization refers to WMPO, NNWSI Project Participating organizations, and NTS Support Contractors.

3.13 STANDARD DEFICIENCY REPORT (SDR)

An SDR is a preformatted form used to document deficient, non-hardware related conditions adverse to quality, document remedial/investigative/corrective actions, document evaluation of these actions, and document verification of satisfactory completion of these actions.

3.14 SUPPLEMENTAL AUDITS

Supplemental audits are audits which are conducted in addition to regularly scheduled audits. They cover specific subjects which are selected by and deemed necessary by the WMPO PQM.

3.15 SURVEILLANCE

The act of monitoring or observing an item or activity to verify whether it conforms to specified requirements.

3.16 TECHNICAL SPECIALIST

An individual having technical expertise in the audit subject who serves as an advisor in technical matters.

4.0 RESPONSIBILITIES**4.1 WMPO PROJECT QUALITY MANAGER (PQM)**

The WMPO PQM is responsible for the maintenance of the WMPO QA Audit System which evaluates the implementation of Quality Assurance Program Plans of organizations providing items or services to the NNWSI Project. It is the responsibility of the WMPO PQM to evaluate and approve audit plans and reports prior to issuance and to ensure that conditions adverse to quality are identified and reported on Standard Deficiency Reports in accordance with QMP-16-03, Standard Deficiency Reporting System.

4.2 PROJECT QUALITY ASSURANCE DEPARTMENT MANAGER

The Project QA Department Manager, under the direction of the WMPO PQM, is responsible for the implementation of the WMPO Audit System.

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Page 4 of 22**4.3 AUDITS AND SURVEILLANCES DIVISION MANAGER**

The Audits and Surveillances Division Manager is responsible for developing and maintaining the WMPO audit schedule, selecting the Lead Auditor for each scheduled audit, reviewing and approving the audit plan and the audit report, and for directing the evaluation of remedial and corrective action response and follow-up activities, as required.

4.4 LEAD AUDITOR

The Lead Auditor is responsible for the selection of the audit team and for assuring that the audit team is prepared prior to the initiation of the audit. The Lead Auditor is responsible for the development of the audit plan, direction, and conduct of the audit, and preparation of the audit report. Additionally, the Lead Auditor is responsible for the evaluation and follow-up of remedial and corrective actions associated with the respective audit deficiencies.

4.5 AUDIT TEAM MEMBERS

The audit team members are responsible for assisting the Lead Auditor in the planning, preparation, and conduct of the audit and in the reporting of audit results.

4.6 TECHNICAL SPECIALIST

The Technical Specialist is responsible for providing technical guidance to the audit team members when auditing specific areas which require technical expertise.

5.0 PROCEDURE**5.1 AUDIT SCHEDULE**

5.1.1 The Audits and Surveillances Division Manager is responsible for audit schedule development, and implementation in support of the WMPO PQM. Sources of information available for planning purposes include:

- a. Weekly and monthly reports,
- b. approved Scientific Investigation Plans, and
- c. Quality Assurance Level Assignment Sheets.

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5.1.2 Internal and external audits shall be scheduled in a manner that shall provide coverage and coordination with ongoing QA program and technical activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity, and shall be conducted at intervals consistent with the schedule for accomplishing the activity.

5.1.3 The WMPO shall conduct internal audits, to evaluate compliance with the NNWSI Project Quality Assurance Plan, the WMPO Quality Assurance Program Plan (QAPP) and the respective implementing procedures on an annual basis.

5.1.4 Audits of Project participants shall include an annual evaluation of compliance with the applicable elements of the NNWSI Project Quality Assurance Plan and to verify the effectiveness and adequacy of the respective QAPPs and implementing procedures.

5.1.4.1 Audits of all participating organizations and NTS support contractors activities shall be performed at least annually or once during the life of the activity, whichever is the shorter period. The following are exceptions to this requirement: if the activity is less than 4 months in duration, an audit is not required to be performed unless an audit is necessary due to the complexity or importance of the activity being performed; the justification for not performing these audits must be documented. These audits may not be performed when the participating organizations and NTS Support Contractors are in a stop work situation or are not performing quality related activities.

5.1.4.2 Qualified auditors of the participating organizations or NTS support contractors, or both, may be invited to participate in a WMPO audit when the audited organization's activities are of mutual interest.

5.1.5 The Audits and Surveillances Division Manager shall develop the WMPO Audit Schedule planned for each fiscal year. The audit schedule and any subsequent changes shall be approved by the WMPO PQM and issued by WMPO as an annual planning document. The schedule shall be revised as necessary to assure coverage is maintained current. The review of the schedule should include (a) previous audit results and corrective actions; (b) nonconformance reports; and (c) information received from external sources such as NRC, OGR, etc. The schedule should include the following as a minimum:

- a. Organizations to be audited
- b. Audit number
- c. Scheduled audit date (month/year)

5.1.5.1 Audit schedules received from participants shall be considered in the WMPO audit scheduling process.

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5.2 AUDIT PREPARATION AND PLANNING

5.2.1 Planned and scheduled audits shall be performed to verify compliance with all aspects of the respective quality assurance program to determine its effectiveness. These audits shall be performed in accordance with this procedure.

5.2.1.1 Regularly scheduled audits may be supplemented by conducting surveillances in accordance with the requirements of QMP-18-02, Surveillances.

5.2.2 The audit team shall be identified prior to the beginning of each audit. The Audits and Surveillances Division Manager shall select the Lead Auditor for each scheduled audit. For internal audits, personnel having direct responsibility for audited activities, shall not be involved in the audit. The audit team will be approved by the WMPO PQM. The Lead Auditor may be selected from an organization outside of the NNWSI Project, (i.e., DCRWM, DGR, Independent consultants, etc). Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. The Lead Auditor shall ensure that the audit team is prepared prior to initiation of the audit.

5.2.3 The Lead Auditor is responsible for developing and documenting the Audit Plan (Figure 1 provides an acceptable format) for the audit to be performed. This plan is a statement of intent and shall identify the audit number, purpose and scope, the schedule, the organization to be audited, the requirements to be audited, the organizational elements or activities to be audited, procedures and documents to be used, audit checklist numbers, and the audit team members. This plan need not be revised to incorporate changes. The final audit scope and performance will be documented by the audit report. The Audit Plan is reviewed and approved by the Audits and Surveillances Division Manager and the WMPO PQM, prior to issuance. Prior to the audit, the WMPO PQM should issue a notification letter with the Audit Plan enclosed to the organization to be audited.

5.2.4 The audit team assists the Lead Auditor in the preparation of the audit checklist based upon a review of the requirements, procedures, previous audit and surveillance reports, and other technical documents. The checklist is to be developed using checklist forms equivalent to Figure 2. Checklists consist of a series of questions or statements which are to be verified by the audit team during the audit.

5.2.5 The Lead Auditor is responsible for assuring that audit team members are cognizant of pertinent practices, policies, procedures, standards, instructions, codes, regulatory requirements, commitments, and of prior audit/surveillance reports which are applicable. Audit team orientation may be

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accomplished by methods such as providing audit team members with advance copies of checklists; individual communication between the Lead Auditor and respective audit team members; and/or the conduct of preaudit team meetings. If preaudit team meetings are conducted, attendance shall be documented; each attendee must sign the Meeting Participant List (Figure 3 provides an acceptable form).

5.3 PREAUDIT CONFERENCE

5.3.1 The Lead Auditor conducts a Preaudit Conference which is attended by applicable staff members of the audited organization. Audit team members will attend at the request of the Lead Auditor. Attendance at this conference shall be documented; each attendee must sign the Meeting Participant List (Figure 3 provides an acceptable form). The purpose of this Preaudit Conference is to confirm the audit scope, discuss the audit plan, identify the auditors and counterparts, discuss audit sequence, establish a tentative time for a Post-Audit Conference and establish channels of communications.

5.4 CONDUCTING THE AUDIT

5.4.1 Upon completion of the Preaudit Conference, the audit team commences investigative activities. To ensure depth and continuity of the audit, prepared audit checklist will be utilized. Instructions for completing the checklists are contained in Figure 2. The checklist items are intended to be used as a guide and should not restrict the audit investigation. The checklists may be expanded by audit team members during the conduct of the audit to facilitate the audit process. Objective evidence shall be examined and documented for compliance with the checklist requirements in the space allotted on the checklist. Within the scope of the audit, specific attention shall be given to corrective action on program deficiencies identified during previous WMPD audits of the auditee.

5.4.1.1 The selected elements of the quality assurance and technical program shall be audited to the extent necessary to determine whether or not they are being implemented effectively. Checklist items must be annotated with comments documenting either compliance or noncompliance as they are examined. It is mandatory that every entry listed in the checklist be completed during the audit. If the item does not apply or is not audited, the N/A (not applicable) shall be entered in the appropriate space and an explanation as to why must be entered on the checklist. Reference to specific deficiencies shall be noted on the checklists by documenting the SDR number adjacent to the checklist item.

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5.4.2 Appropriate management personnel of the audited organization shall be verbally notified by the Lead Auditor of all observed conditions adverse to quality prior to the postaudit meeting. This provides management with an opportunity to implement immediate corrective action where required or to conduct further investigations to facilitate discussion at the postaudit meeting.

5.4.3. An auditor who discovers or observes a condition which requires immediate attention to avoid personnel injury or damage to equipment must immediately notify responsible management personnel.

5.5 EVALUATION AND DOCUMENTATION OF AUDIT RESULTS

5.5.1 Audit team members will provide the audit checklist to the Lead Auditor prior to the Postaudit Conference, describing their findings in the audit areas for which they were responsible. For the purpose of the Postaudit Conference, discussed below, the deficiencies, (findings) are prepared as SDR rough drafts by the Lead Auditor. They are then discussed with the audited organization with the understanding that the SDRs may be changed prior to being issued. Observations and recommendations are also discussed at the Post Audit Conference.

5.5.2 A Standard Deficiency Report (SDR) will be generated in accordance with QMP-16-03, Standard Deficiency Reporting System, for programmatic and/or implementation deficiencies which cannot be resolved during the course of the audit.

5.5.3 Observations identified during the audit are submitted with the audit report and a response is required within 25 working days from the date of the transmittal letter.

5.5.3.1 The Lead Auditor will evaluate the response for acceptability and will advise the audited organization accordingly.

5.5.3.2 If this response is not received by the required date, a follow-up letter will be prepared by the Lead Auditor for the WMPO PQM's signature and issuance.

5.5.4 Recommendations are identified in the audit report and do not require a response.

5.6 POSTAUDIT CONFERENCE

The Lead Auditor conducts the Postaudit Conference. This is a debriefing at the conclusion of the audit consisting of a discussion between the audit team and the audited organization's representatives having responsibilities in the

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areas audited. A summary of the audit results is presented to the audited organization. Each deficiency, observation, and recommendation is discussed to assure that they are clearly understood and that the audited organization's representatives have the opportunity to state their position relative to each condition adverse to quality. Attendance at the Postaudit conference shall be documented; each attendee shall sign the Meeting Participant List (Figure 3 provides an acceptable form).

5.7 STANDARD DEFICIENCY REPORTS

5.7.1 Standard Deficiency Reports shall be issued independently of the audit report and sent directly to the audited organization by transmittal letter from the WMPO PQM. The audited organization's response due date is 20 working days from the transmittal letter date, as required by QMP-16-03.

5.8 AUDIT REPORTS

5.8.1 The Lead Auditor, with the support of the audit team, prepares a formal audit report. Figure 4 provides an acceptable format to be used. The audit report shall be based on the completed checklists, discussions with the representatives of the audited organizations, and the summary of the audit team members. The report describes the audit scope, provides a synopsis of the applicable Standard Deficiency Reports for management review, summarizes the audit results (including a statement of the effectiveness of the QA program), and identifies the auditors and the persons contacted during the audit. Any observations and recommendations made by the audit team will also be included in the audit report. Copies of all applicable SDRs are attached to the audit report for information purposes.

5.8.2 The audit report is signed by the Lead Auditor and reviewed and approved by the Audits and Surveillances Division Manager; and the WMPO PQM. As a minimum, copies are transmitted by cover letter to the management of the audited organizations; QA Records Center, HQ-OGR, QAD/NV, Management Evaluation Div/NV, and other WMPO Branches and organizations, as deemed necessary. The audit report should be issued with 25 working days after the Postaudit conference.

5.8.3 The Lead Auditor will draft a cover letter for the WMPO PQM, to be forwarded to the audited organization with the audit report. This letter will state that the subject audit is considered to be completed as of the date of the letter, but any open SDRs will continue to be tracked until each one has been closed to the satisfaction of the Lead Auditor and the WMPO PQM.

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5.9 PROCESSING OF STANDARD DEFICIENCY REPORTS

5.9.1 Upon issuance of the SDR, the Lead Auditor is responsible for submitting it for entry into the SDR Status Log. The SDR Status Log provides detailed information on each SDR in the form of a computer print out. Pertinent information is taken from the SDR and entered into the computer to reflect the current status in accordance with QMP-16-03. The Lead Auditor, under the direction of the Audits and Surveillances Division Manager, is responsible for timely follow-up of open SDRs until resolution of commitments and corrective action is verified. The Lead Auditor shall provide up-to-date information for the SDR Status Log, as appropriate, until closure of the SDR is accomplished.

5.9.2 The SDR responses received from the audited organization shall be reviewed and evaluated under the direction of the Audits and Surveillances Division Manager for acceptability of all recommended action, proposed implementation, and effective date. Responses that are determined to be acceptable shall be so documented on the SDR and copies shall be transmitted by letter from WMPO advising the audited organization that verification will be performed after the scheduled implementation date.

5.9.3 Unacceptable responses and subsequent requests for extensions of the effective date for completion of committed corrective actions are dispositioned in accordance with QMP-16-03.

5.9.4 The Lead Auditor is responsible for contacting the audited organization to affirm that the corrective action has been implemented by the effective date proposed in the SDR. Upon notice of the completed implementation by the audited organization, the Audits and Surveillances Division Manager will assign a qualified auditor or surveillance person who will contact the audited organization to make arrangements required to verify whether the corrective action was properly implemented. The SDR may be closed if the results verifies proper implementation of the required corrective action to the satisfaction of the Lead Auditor. For deficiencies that address incomplete documentation, the SDR may be closed by submittal of the required documentation to the Lead Auditor. As corrective action for each open SDR is satisfactorily verified, the Lead Auditor will document the results and details of the verification on the SDR and close the SDR. After concurrence by the WMPO PQM, a copy of the completed SDR shall be forwarded to the audited organization by transmittal letter from WMPO. The SDR closure date will be entered in the SDR Status Log and the completed SDR with supporting documentation will be filed with a copy to the appropriate audit report file.

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Page 11 of 22**5.10 SUPPLEMENTAL AUDITS**

5.10.1 Regularly scheduled audits may be augmented by additional audits of specific subjects when deemed necessary by the WMPO PQM. Supplemental audits may be performed in the following cases:

5.10.1.1 When significant changes are made in functional areas of a quality assurance program such as reorganization or procedure revisions or significant changes in work assignment.

5.10.1.2 When it is suspected that the quality of an item or service is in jeopardy because of deficiencies in the quality assurance program.

5.10.1.3 When assessment of the program effectiveness is considered desirable.

5.10.1.4 To determine the capability of an organizations quality assurance program before awarding a contract or purchase order.

5.10.1.5 It is determined that there appears to be a declining trend in the performance of quality related work.

5.10.1.6 After the award of a contract, when sufficient time has elapsed for implementing the QA program to determine is effectiveness.

5.10.1.7 When it is necessary to verify implementation of required corrective actions of a complex or diversified nature.

5.10.2 The Audits and Surveillances Division Manager will designate a Lead Auditor who will select an audit team to conduct a supplemental audit. The supplemental audit shall be conducted in accordance with the requirements of this procedure.

5.11 PARTICIPATION AS OBSERVERS

5.11.1 WMPO staff personnel may participate as observers on a selective basis, in the external audits conducted by the NNWSI Project participants.

5.11.2 The Audits and Surveillances Division Manager will review the annual audit schedules provided to WMPO by the Project participants and select the audits in which WMPO will participate.

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5.11.3 The Project participants will be notified in advance of the selected audits and the names of the WMPO observers shall be provided. The observers will not be active participants in the audit process but will observe how the audit is conducted and/or become familiar with the vendor's organization and activities. A written report covering these activities will be prepared by the observer(s) and submitted to the Audits and Surveillance Division Manager and to the WMPO PQM.

5.12 AUDIT STATUS REPORT

A report on the status of audits is included as part of the monthly project report.

5.13 AUDIT RECORDS

The Lead Auditor shall be responsible for establishing an audit record file for each audit in which he participates as Lead Auditor. As a minimum the records shall include the audit plan, audit report, and copies of initial, reviewed, and final SDRs. In addition, the file will include all copies of related correspondence necessary to provide a record of completion and verification of remedial and corrective action. All QA records will be processed in accordance with QMP-17-01, QA Records.

5.14 HEADQUARTERS OFFICE OF GEOLOGIC REPOSITORIES (HQ-OGR) PARTICIPATION IN WMPO AUDITS

5.14.1 HQ-OGR participates in selected QA audits of the contractors which are conducted by WMPO for the NNWSI Project. The OGR Quality Assurance Manager will notify the Project Office of the audits selected for HQ participation and will forward the certification/qualification records for the OGR (auditor) representative. The certification/qualification records will be reviewed by the Lead Auditor prior to participation in a WMPO audit, to verify current status and proper authorization. The record will be placed in the appropriate file. The Lead Auditor will provide HQ-OGR with a copy of the audit plan, checklists, and instructions for those audits that OGR selects to be a participant.

5.15 FOLLOW-UP AND CLOSE OUT OF AUDIT FINDINGS FROM PREVIOUS WMPO AUDITS

5.15.1 Audit findings from previous WMPO audits remaining open as of the effective date of this procedure will be evaluated, verified and closed according to the following steps.

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5.15.1.1 Audit Finding Sheets (AFS) which were issued for deficiencies identified during an audit, require a written response from the audited organization within 35 days from the issuance date. The audited organization shall respond to the AFS with the cause of the finding, the proposed corrective action, the corresponding implementation date, and measures to prevent recurrence.

5.15.1.2 The WMPD PQM, with assistance from the Lead Auditor is responsible for review and approval of the proposed corrective action and implementation date that is submitted for each AFS by the audited organization.

5.15.1.3 If an AFS needs to be revised due to rejection of a response or an unsatisfactory verification, it will be "rolled-over" to an SDR in accordance with QMP-16-03.

5.15.1.4 After notification by the audited organization that approved corrective action has been implemented, a Lead Auditor is responsible for verifying that the action has been taken and evaluating its effectiveness to prevent recurrence.

5.15.1.5 Following verification and approval of the AFS, the AFS closeout date shall be entered in the AFS log and the completed AFS shall be filed with the appropriate audit report.

5.15.1.6 When all the AFSs associated with an audit are closed, the Lead Auditor shall document that the audit is closed on the Audit Log.

5.15.1.7 Audit records associated with previous WMPD audits include audit plans and reports, written replies, and completed audit finding sheets. A Lead Auditor shall assure that the audit records are complete and accurate. These records shall be processed in accordance with QMP-17-01, QA Records.

6.0 REFERENCES

- 6.1 WMPD/88-1, WMPD QAPP
- 6.2 QMP-01-02, Stop Work
- 6.3 QMP-02-02, Qualification and Certification of Auditors.
- 6.4 QMP-16-02, Trend Analysis
- 6.5 QMP-16-03, Standard Deficiency Reporting System



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6.6 QMP-17-01, QA Records

6.7 QMP-18-02, Surveillances

7.0 FIGURES

Figure 1 WMPO QA Audit Plan

Figure 2 Audit Checklist

Figure 3 Meeting Participant List

Figure 4 WMPO Quality Assurance Audit Report

8.0 QA RECORDS

QA Audits Plans

QA Audit Reports

Standard Deficiency Reports

Observations



WASTE MANAGEMENT PROJECT OFFICE

QUALITY MANAGEMENT PROCEDURE

N-QA-016
7/87

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Audit No. _____

Date _____

WMPO QUALITY ASSURANCE AUDIT PLAN

1.0 PURPOSE/SCOPE

2.0 ORGANIZATION TO BE AUDITED

3.0 AUDIT SCHEDULE

The schedule for this audit is tentatively established as follows.
This time frame may be expanded as audit programs dictate.

4.0 REQUIREMENTS TO BE AUDITED

The requirements being audited are stated in the following documents.

5.0 ACTIVITIES TO BE AUDITED

The activities to be investigated during this audit include:

6.0 AUDIT TEAM MEMBERS

7.0 AUDIT CHECKLIST NUMBER(S)

Prepared by _____
Audit Team Leader

Approved by _____
Audits and Surveillances Division Manager

Approved by _____
WMPO PQM

Figure 1



WASTE MANAGEMENT PROJECT OFFICE

QUALITY MANAGEMENT PROCEDURE

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INSTRUCTIONS FOR COMPLETING
THE WMPO AUDIT CHECKLIST

The checklist number consists of the applicable audit number followed by a (-1) for programmatic or (-2) for technical requirements. For example, 87-15-1 for a programmatic checklist on audit #87-15.

Enter the checklist number at the top of the page. Complete the forms indicated below:

1. Organization - Name of organization being audited.
2. Page - Page number of checklist.
3. Audit Item No. - Sequential item numbers assigned to each checklist entry.
4. Quality Element and Reference - Enter name or number of the auditee's quality or project document, page number, and applicable paragraph pertaining to the requirements listed in Block 5.
5. Standard Quality Requirements/Audit Guidelines - Enter NNWSI requirements document, section and/or paragraph covering the requirements to be listed for each audit team number.
6. Results - Enter "S," "X:", or "N/A."
 - a. Enter "S" if the specified requirements are being met satisfactorily.
 - b. Enter "X" if specified requirements have not been met or if some deficiency has been discovered.
 - c. Enter "N/A" if the stated requirement is not applicable (N/A) and therefore has not been audited.
7. Summary of Investigation - Summarize investigation of requirements in a brief statement, giving justification for the "results" stated in Block 6. Reference SDR number applicable to "X" entries for each item number. Provide justification or reasons why certain items were marked "N/A" and were not audited. Items which were marked "S" as being satisfactory, but which have had observations written against them will be annotated with the observation number in Block 7.
8. Person Contacted - List name of individual providing pertinent information to the auditor for each requirement.
9. Auditor Signature - Signature(s) of auditor or audit team members who completed the checklist page.
10. Date - Date of audit.

Figure 2 (cont'd)



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WMPQ QUALITY ASSURANCE AUDIT REPORT

AUDIT NUMBER: _____

CONDUCTED ON: _____

PREPARED BY _____ DATE _____
Lead Auditor

APPROVED BY _____ DATE _____
Audits & Surveillances Division Manager

APPROVED BY _____ DATE _____
PQM (WMPQ)

Figure 4



QUALITY MANAGEMENT PROCEDURE

Title

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Audit Report _____
Date _____
Page 1 of 3

1.0 INTRODUCTION

This report contains the results of a Quality Assurance Audit of:
(Name & Location)

The audit was conducted in accordance with the requirements of the WMP0
Quality Assurance Program Plan.

2.0 AUDIT SCOPE

3.0 AUDIT TEAM PERSONNEL

This audit team consisted of following members:

Lead Auditor _____ Auditors _____

4.0 SUMMARY OF AUDIT RESULTS

_____ deficiencies and _____ observations were
identified during the course of the audit. These are delineated in
Section 6.0.



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Audit Report _____
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4.0 SUMMARY OF AUDIT RESULTS (CONTINUED)

Within the scope of this audit, _____ audited areas(s)
were found to be generally in compliance. They were:

The effectiveness of the quality assurance elements that were audited is
summarized as follows:

5.0 AUDIT MEETINGS

5.1 PRE AUDIT CONFERENCE

An opening meeting was held to outline the purpose and scope of the
audit and to establish further audit activities and a tentative time
for the closing meeting.

Date _____ Time _____

Attendees and Titles:

5.2 PERSONS CONTACTED DURING THE AUDIT



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Date _____
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6.3 POST AUDIT CONFERENCE

A closing meeting was conducted to discuss the detailed audit results and resolve any possible misunderstandings prior to completion of the final audit report.

Date _____ Time _____

Attendees and Title:

6.0 SYNOPSIS OF SDRs AND OBSERVATIONS

7.0 RECOMMENDED ACTION

A written response is required for each Standard Deficiency Report and observation delineated in Part 6 above. Copies of these documents have been forwarded by mail to your Technical Project Officer. Response is due within 20 working days of the date of the transmittal letter. Upon satisfactory verification completion of all remedial and corrective action, the SDR will be closed and the Project participant will be notified by letter of the SDR closure.



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N-QA-022
11/87

PLEASE SIGN AND RETURN BY 4/5/88 Transmittal Date 3/8/88
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- Remove: WMPO QAPP, NVO-196-18, Rev. 2
- Insert: WMPO QAPP, WMPO/88-1, Rev. 0
- Remove: QMP Table of Contents, dated 4/29/87
- Insert: WMPO QMP Table of Contents, Dated 2/22/88
- Remove: QMP Revision Record
- Remove: Qualification and Certification of Auditors, QMP-02-02, Rev. 0
- Insert: Qualification of Quality Assurance Program Audit Personnel, QMP-02-02, Rev. 1
- Remove: Document Review/Approval, QMP-06-03, Rev. 0
- Insert: Document Review/Acceptance/Approval, QMP-06-03, Rev. 1
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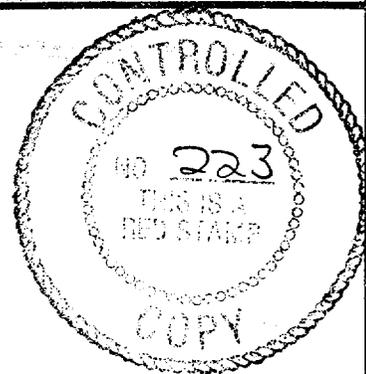
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N-QA-045
1/87



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WASTE MANAGEMENT PROJECT OFFICE

QUALITY ASSURANCE PROGRAM PLAN

WMPO/88-1

(FORMERLY NV0-196-18)

REVISION 0

UNITED STATES DEPARTMENT OF ENERGY

NEVADA OPERATIONS OFFICE

LAS VEGAS, NV

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