

**Nevada
Nuclear
Waste
Storage
Investigations**



A U.S. DOE PROJECT

UNCONTROLLED

**WASTE MANAGEMENT
PROJECT OFFICE**

**QUALITY ASSURANCE
PROGRAM PLAN**

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**UNITED STATES DEPARTMENT OF ENERGY
NEVADA OPERATIONS OFFICE
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WASTE MANAGEMENT PROJECT OFFICE

QUALITY ASSURANCE PROGRAM PLAN

REVISION 2

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FOREWORD

The Waste Management Project Office (WMPO) Quality Assurance Program Plan (QAPP) is composed of two sections. Section I - contains the WMPO QAPP and is issued as a controlled document. It contains a separate cover sheet, a revision record, and a table of contents. As revisions are issued, the Section I revision record, the table of contents, and applicable portions of the QAPP will be updated and issued to all holders of the controlled document. Section II - contains a separate table of contents, a revision record, and the effective WMPO QAPP supporting procedures that are issued as individually controlled documents. The Quality Management Procedures (QMPs) are separated by tabbed dividers, and the numbers correspond to the eighteen criteria of 10CFR50, Appendix B. When revisions to the QMPs are issued, the Section II table of contents, revision record, and affected procedures will be updated and issued to all holders of the controlled documents.

INTRODUCTION

The Waste Management Project Office (WMPO) is the organization to which the U.S. Department of Energy, Nevada Operations (DOE/NV), has assigned the responsibility of administering and coordinating the activities of the various Participating Organizations and of Nevada Test Site (NTS) Support Contractors working on the Nevada Nuclear Waste Storage Investigations (NNWSI) Project. The WMPO Quality Assurance Program Plan (QAPP), describes the policies and methods to be used by WMPO, by the DOE/NV matrix support, and by QASC personnel (also referred to as the WMPO staff) to conduct quality related activities in support of the NNWSI Project.

This QAPP provides the quality assurance program plan to implement the NNWSI Project Quality Assurance (QA) Plan, NVO-196-17. It ensures that adequate quality assurance measures are applied and that records provide traceability for those activities of the NNWSI Project that are controlled directly by the WMPO staff. It is intended that the WMPO QAPP be used to supplement the NNWSI Project QAP for the control of such activities.

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1.0 ORGANIZATION

Organizational structuring and functional responsibility assignments are based on recognition of quality assurance as an interdisciplinary function with quality-related activities being performed by organizational components and individuals from top level management down to individual contributors.

The authorities and responsibilities of individuals and organizations performing quality-related activities are established, assigned, and documented in the NNWSI Project Quality Assurance Plan (QAP). Those individuals and organizations assigned such functions are given appropriate and sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions to quality problems; to verify implementation of the solutions; and to prevent further processing, delivery, installation, or utilization of nonconforming items until proper dispositioning has been accomplished.

The organizational structure and functional responsibility assignments assure the following: (1) the attainment and maintenance of quality objectives will be accomplished by personnel who are assigned the responsibility of performing the activity; (2) the verification of conformance to established quality requirements will be accomplished by personnel who do not have the direct responsibility of specifying, producing, or expediting the products; and (3) the quality assurance functions will be performed by personnel who have direct access to responsible management.

The Director, WMPO, has the ultimate responsibility of establishing, administering, and enforcing the NNWSI Project QA Plan and as a minimum, is responsible for a yearly assessment of the NNWSI Project QA Plan. The Quality Assurance Division is responsible for providing programmatic guidance, independent overview of the WMPO Quality Assurance Program, and a Project Quality Manager (PQM) to WMPO. The PQM supports the WMPO with coordination of the Quality Assurance Support Contractor (QASC) activities. The QASC has the responsibility of assisting WMPO with the development, implementation, and maintenance of the NNWSI Project QA Plan, the QA Program Plan, and the

implementing procedures. The WMPD Branch Chiefs are responsible for meeting the requirements of the QAP by implementing the principles and procedures of this QAPP.

The WMPD organizational structure and responsibilities are detailed in QMP-01-01, WMPD Organization.

Portions of the NNWSI Project site investigation, research and development, procurement, design, construction, preoperational and functional testing, operations, decommissioning, and other activities (including the associated QA functions) may be delegated to qualified Participating Organizations, or to NTS Support Contractors as outlined in the NNWSI Project Work Breakdown Structure (WBS) Dictionary. However, WMPD retains ultimate responsibility for the entire QA Program.

2.0 QUALITY ASSURANCE PROGRAM

The function of WMPO is to administer, direct, approve, and monitor the Participating Organizations' and NTS Support Contractors' activities. Therefore, many of the requirements, as delineated in the NNWSI Project QAP, are not applicable directly to WMPO functions; instead, they are assigned to the Participating Organizations' and NTS Support Contractors' control methods.

WMPO may assign the responsibility for all or any portion of the NNWSI Project activities to the Participating Organizations and to NTS Support Contractors. The responsibilities to be assigned include technical support of and QA requirement direction for the technical activities. The planned activities assigned to the Participating Organizations and NTS Support Contractors are delineated in the NNWSI Project Work Breakdown Structure and Dictionary, and the QA requirements for controlling these technical activities are found in the NNWSI Project QA Plan. Although WMPO may assign these activities, it retains the final responsibility for the activities.

All quality-related activities conducted by WMPO, DOE/NV matrix support, and QASC personnel shall be performed in accordance with this QAPP and the implementing Quality Management Procedures. These personnel shall receive indoctrination or training to the extent necessary to perform their specific functions. The requirements are described in QMP-02-01, Indoctrination and Training, and QMP-02-02, Qualification and Certification of Auditors.

WMPO shall assure that the Participating Organizations and NTS Support Contractors have a QAPP that meets the requirements of the NNWSI Project QAP. Periodic reviews shall be conducted by WMPO to ensure that the Participating Organizations' and NTS Support Contractors' QAPPs comply with the applicable requirements of the NNWSI Project QAP. This will be accomplished by periodic audits, surveillances, and management review activities, as deemed appropriate.

3.0 DESIGN CONTROL

WMPO shall review and approve all final repository designs, test plans, and site investigation reports submitted by the Participating Organization and/or NTS Support Contractors that are to be used on the NNWSI Project. The reviews shall be documented in accordance with QMP-06-03.

WMPO shall initiate peer reviews of documents when there is a unique application of an established or standard practice, when the work documented goes beyond the existing state of the art, and when new or unusual experimental techniques are used by a Participating Organization or NTS Support Contractor. The control of a peer review is detailed in QMP-03-01, Peer Reviews.

WMPO shall participate in the Level I design verification process conducted by the Participating Organizations or NTS Support Contractors. The participation shall consist of the review, and approval of all design drawings used for the construction of the repository.

4.0 PROCUREMENT DOCUMENT CONTROL

WMPD does not perform directly any purchasing activities. The purchases for NNWSI Project activities are conducted for WMPD by the Participating Organization or by the NTS Support Contractor under their respective activities for which the purchase is required. These purchases are controlled through the use of the Federal Acquisition Regulations (FARs), the Department of Energy Acquisition Regulations (DEARs), which are found in Title 48 Code of Federal Regulations (CFRs) Chapters 1 and 9 and through the NNWSI Project Quality Assurance Plan.

DOE/NV maintains service contracts with the Participating Organizations and the NTS Support Contractors. The NNWSI activities performed by the Participating Organization and NTS Support Contractor are detailed in the NNWSI Project Work Breakdown Structure and Dictionary. These activities are conducted in accordance with the NNWSI Project QA Plan. When an NNWSI activity requires the mandate of additional technical or quality requirement, the requirements are disseminated to the Participating Organization or NTS Support Contractor through the use of plans developed by the WMPD.

5.0 INSTRUCTION, PROCEDURES, AND DRAWINGS

Activities performed by WMPO which affect quality are controlled through the use of the QMPs contained in this QAPP. These procedures are generated by the QASC and approved by the Director, WMPO, the Quality Assurance Director (QAD), and the QASC QA Manager. Revisions to these documents are approved in the same manner as is the original.

6.0 DOCUMENT CONTROL

This procedure describes the methods used to control the issuance of documents such as instructions, procedures, and drawings, including changes thereto, which prescribe activities that affect quality. These measures provide assurance that documents and changes are reviewed and approved for adequacy by authorized personnel and are distributed to and used at the location at which the prescribed activity is to be performed. Changes to documents are reviewed and approved by representatives of the same organization that performed the original review and approval. When the original reviewers are not available other organizations may be designated by the Director, WMPO, to perform the review function. The designated reviewer shall have access to pertinent background information upon which to base the review, and shall be assigned by WMPO on the basis of having an adequate understanding of the requirements and intent of the original document. The documents that require control and the control methods to be used are detailed in QMP-06-02, Document Control. The format for the preparation of quality management procedures is established in QMP-06-01.

The QASC QA Manager shall assess the NNWSI Project QAP, the Standard Operating Procedures, the WMPO Project QAPP, and the QMPs to determine their adequacy and whether or not it is necessary to change existing procedures or generate new procedures. Controlled documents shall either be revised or generated as necessary, and a summary of the update shall be noted in the QASC QA Manager's annual report to the Director, WMPO.

Participating Organizations' and NTS Support Contractors' documents that are submitted to WMPO for review or approval of technical adequacy and/or QA requirements, shall be controlled in accordance with QMP-06-03, Document Review and Approval.

The WMPO shall maintain master lists which have been submitted by the Participating Organizations and NTS Support Contractors on which is identified the instructions, procedures, drawings, and other documents that control activities classified as Quality Levels I and II. (See NVO-196-17, Rev. 2, for definitions of Quality Levels I and II).

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

WMPO shall perform a yearly evaluation of the activities performed by the Participating Organizations and NTS Support Contractors. Evaluations shall be based on the ability of the organization to meet the technical and quality requirements imposed on them and will provide a means by which to communicate to the Participating Organizations and NTS Support Contractors either satisfaction or dissatisfaction of their performance.

WMPO shall perform unannounced surveillances on the activities conducted by the Participating Organizations and NTS Support Contractors. The surveillances shall be conducted in accordance with QMP-07-01, Surveillance.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

WMPO has assigned the responsibility for the identification and control of materials, parts, and components to the Participating Organizations, and NTS Support Contractors. Their effectiveness in satisfactorily implementing this responsibility will be monitored by WMPO through audit and/or surveillance activities.

9.0 CONTROL OF PROCESSES

Processes affecting quality, which are directly performed by the WMPO staff, are controlled in accordance with the procedures contained in this QAPP.

WMPO performs no special process activities. Special processes are performed by Participating Organizations and NTS Support Contractors on the activities assigned to them by WMPO. WMPO shall review Participating Organization and NTS Support Contractor Quality Level I special process procedures in accordance with QMP-06-03, Document Review/Approval, and shall maintain an index of the Quality Level II special processes that are submitted by the Participating Organizations and NTS Support Contractors.

10.0 INSPECTIONS

WMPO does not perform first-line inspection. WMPO assigns the Participating Organizations and NTS Support Contractors with the responsibility of performing first-line inspection of the NNWSI Project quality-related activities for which they are responsible. Their effectiveness in satisfactorily implementing this responsibility will be monitored by WMPO through audit and/or surveillance activities.

11.0 TEST/EXPERIMENT CONTROL

WMPO assigns the responsibility of performance of NNWSI Project tests and experiments to the Participating Organizations and NTS Support Contractors. WMPO shall review and approve Quality level I test plans and procedures. The effectiveness of the Participating Organizations and NTS Support Contractors in satisfactorily implementing Test/Experiment control will be monitored by WMPO through audit and/or surveillance activities.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

No activities requiring control of measuring or test equipment are performed directly by WMPO. All measuring and test equipment shall be controlled by the calibration programs of the Participating Organizations and NTS Support Contractors. These programs will be monitored by WMPO through audit and/or surveillance activities.

13.0 HANDLING, STORAGE, AND SHIPPING

WMPO has assigned the responsibility of handling, storage, and shipping of samples or hardware to the Participating Organizations and NTS Support Contractors. WMPO will monitor these activities through audit and/or surveillance activities.

14.0 INSPECTION, TEST, AND OPERATING STATUS

WMPO has assigned the responsibility of inspection, test, and operating status to the Participating Organizations and NTS Support Contractors. WMPO will monitor these activities through audit and/or surveillance activities.

15.0 NONCONFORMANCES

A procedure has been established to provide control and to prevent the inadvertent use of items or activities that do not conform to specified requirements. A nonconformance report (NCR) form shall be used by WMPD, by the DOE/NV matrix support, and by QASC personnel to record information and data concerning nonconformances discovered in the course of their activities. The methods of initiation and control of all NCRs are found in QMP-15-01, Nonconformances.

16.0 CORRECTIVE ACTION

The procedure QMP-16-01, Corrective Action, describes the methods by which the WMPD staff can identify and control conditions that are adverse to quality. The procedure is to be followed when there is an identified need to issue corrective action measures to rectify conditions that are adverse to quality, that have been observed to be repetitive, and for which previous dispositions of the problem have failed to correct the nonconforming situation.

WMPD shall conduct trend analyses on various activities within the NNWSI Project, according to QMP-16-02, Trend Analysis. Trend analysis reports shall be generated periodically and shall be reviewed by WMPD management together with recommendations for any corrective action.

17.0 QUALITY ASSURANCE RECORDS

Procedures and practices have been established to ensure that the QA records generated by the WMPO staff will furnish adequate documentary evidence that an item or activity has been performed satisfactorily. These records will be stored and maintained in appropriate facilities under controlled conditions to prevent loss and deterioration and will be readily retrievable. QMP-17-01, Quality Assurance Records, describes the controls to be used for collection and storage of documents generated by the WMPO staff.

18.0 AUDITS

A comprehensive system of planned and documented internal and external audits is carried out by WMPO to verify that NNWSI Project activities are in compliance with the various aspects of the NNWSI Project QAP. The audits are performed in accordance with QMP-18-01, Audits, by appropriately trained personnel who do not have direct responsibilities in the areas being audited. The audit results are documented and transmitted to the Director, WMPO, and to the management responsible for the audited area.

External audits are performed on NNWSI Project Participating Organizations and NTS Support Contractors. When the Participating Organization is under the cognizance of another U. S. Department of Energy (DOE) field office, WMPO may delegate responsibility for the audit to the cognizant field office. If the cognizant DOE field office is unable to perform a requested audit of WMPO program activities, the audit will be performed by WMPO.

QUALITY MANAGEMENT PROCEDURES (QMPs)

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