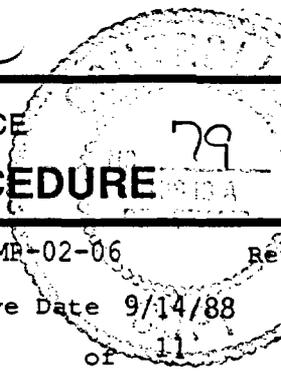




WASTE MANAGEMENT PROJECT OFFICE

QUALITY MANAGEMENT PROCEDURE

N-QA-015
6/88



Title ASSIGNMENT OF QUALITY ASSURANCE LEVELS

No. QMP-02-06 Rev. 0
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NNA-880915-0013

1.0 PURPOSE AND SCOPE

This procedure establishes the responsibilities and methodology for assigning Quality Assurance (QA) levels to Nevada Nuclear Waste Storage Investigations (NNWSI) Project items and activities that are the direct responsibility of the Waste Management Project Office (WMPO).

2.0 APPLICABILITY

This procedure is applicable to all WMPO items and activities that affect quality associated with site characterization, facility and equipment design, procurement and construction, facility operation, performance confirmation, waste retrievability if required, permanent closure, decommissioning, and dismantling of surface facilities. The preparation of administrative and management planning documents shall not require QA level assignments except for NNWSI Project level documents which are specifically required by the Nuclear Waste Policy Act of 1982, or are required for licensing, such as the Site Characterization Plan, Exploratory Shaft Test Plan, Environmental Assessment, etc.

3.0 DEFINITIONS

3.1 ACTIVITY

Any 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 Work Breakdown Structure (WBS) dictionary.

3.2 ITEM

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

3.3 TASK MANAGER (TM)

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.

APPROVED BY

Project Manager, T&MSS

Date

9/16/88

WMPO Project Quality Manager

Date

Roy S. Monte for
9/21/88

WMPO Project Manager

Date

[Signature] 9/21/88

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This term may be synonymous with Principal Investigator (PI) or Cost Account Manager (CAM) depending on the respective task.

3.4 QUALITY ASSURANCE CRITERIA

As used in this procedure, QA criteria refers to the WMPO QA Program requirements which have been established in the WMPO QAPP. Each of the 18 sections of the WMPO QAPP is titled a specific QA criteria and delineates the controls which are necessary to effectively implement the specific element of the WMPO QA Program.

3.5 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, waste retrieval 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 10CFR60, and 40CFR191.

3.6 QUALITY ASSURANCE LEVEL II

Those items and activities 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 U.S. Department of Energy/Headquarters (DOE/HQ) and WMPO concerns, and the environment.

3.7 QUALITY ASSURANCE LEVEL III

Those items and activities not classified as QA Levels I or II.

3.8 NNWSI PROJECT WBS DICTIONARY



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A product-oriented framework for organizing and defining work to be accomplished.

4.0 RESPONSIBILITIES

4.1 TASK MANAGER

The respective Task Manager (TM) is responsible for determining the QA level assignments and QA criteria applied to each item and activity that is associated with a particular WMPO task.

4.2 DEPARTMENT MANAGER

The respective Department Manager is responsible for the review and approval of QA level assignments, including changes, and QA criteria applied to items and activities.

4.3 WMPO BRANCH CHIEF

The cognizant WMPO Branch Chief is responsible for the review and approval of QA level assignments and QA criteria applied to items and activities.

4.4 WMPO PROJECT QUALITY MANAGER (PQM)

The WMPO PQM is responsible for the review and approval of QA level assignments and for ensuring that the correct QA criteria for each item and activity.

5.0 PROCEDURE

5.1 CRITERIA FOR DETERMINATION OF QA LEVEL ASSIGNMENTS

5.1.1 Characteristics of QA Level I Items and Activities

QA Level I is the most stringent level of QA. It is to be applied to those items and activities that may affect the ability of the repository to meet the preclosure and post closure performance objectives specified by the Nuclear Regulatory Commission (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.



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QA Level I control and documentation must be applied to activities, including data collection, investigation, analysis, design, construction, fabrication, operation, waste retrieval, decommissioning, or sealing when they are specifically concerned with the protection of the public's health and safety with respect to a radiological hazard. To keep radionuclides out of man's environment, a high level radioactive waste repository will utilize engineered systems, structures, and components to contain the waste and ensure the short-term safety. The repository also will utilize the natural barriers to afford long-term isolation. Within this context, QA Level I must be applied for near-term safety as well as long term isolation as per the following:

1. Where items and activities could affect the preclosure radiological health and safety of the general public. Specifically, this means items and activities that could cause, or result in, an accident that could result in a radiation dose, either to the whole body or to any organ, of 0.5 rem or greater, either at or beyond the nearest boundary of the unrestricted area, at any time until the permanent closure of the repository.
2. Where items and activities will provide site characterization data. Site characterization data are the field and laboratory data and subsequent analyses that provide the basis for determining and demonstrating that the natural and the engineered systems of the repository are capable of 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 (i.e., 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.
3. Where activities are intended to provide the primary data which will be utilized to support public radiological health and safety issues for a license application.
4. Where items and activities that, having failed, could cause a failure of QA level I item, or irretrievable loss of QA Level I data.
5. Where items and activities could affect the retrievability of waste up to the time of repository closure.



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6. The design phase that involves the preparation of detailed design documents (such as drawings, specifications, and analyses) will be assigned QA Level 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 functions and interrelationships. As the design phase proceeds, and the QA level for items is identified and approved, design, procurement, and construction activities shall be governed by the QA level assigned to the item.

5.1.2 Characteristics of QA Level II Items and Activities

5.1.2.1 QA Level II is the second highest level of quality assurance. QA Level II controls and documentation shall be applied to activities and items that are specifically concerned with nonradiological operation of the exploratory shaft facilities and repository, and the radiological safety of the repository worker. The high-level waste (HLW) repository will utilize engineered systems, structures, and components which must be designed, constructed, fabricated, tested, and operated to meet the performance objectives during the operational phase and to minimize the nonradiological hazard to the public and repository worker and the radiological hazard to the repository worker. Additionally, activities that have a major impact on project costs or schedules that could delay the achievement of DOE/Office of Civilian Radioactive Waste Management (OCRWM) milestones must be appropriately controlled. Therefore, QA Level II shall be applied to activities and items as follows:

1. Where items and activities that are essential to the design, construction, and operation of the repository or of the exploratory shaft facility, and could have a major impact on the non-radiological health and safety of the public and repository worker.
2. Where items and activities which having failed or which are performed inadequately would cause repository workers to be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10CFR20.
3. Where items and activities that involve the nonradiological operational reliability and maintainability of engineered systems, structures, or components.
4. The design phase that involves the comparative technical analysis of alternatives/methods/equipment to determine which alternative/method/equipment is preferred, shall be assigned QA Level II prior to execution.



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Where a particular item can be identified and defined during this phase, a separate QA level assignment may be made for that item. Once the QA level for such an item is identified and approved, design procurement and construction activities shall be governed by the QA level assigned to the item.

5. Where items and activities that, having failed, could result in a major cost overrun.
6. Where items and activities that, if failed, could result in a major schedule slippage.

5.1.2.2 QA Level II activities may have as much importance as QA Level I activities; however, except when used to support a QA 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 QA Level II program cannot be used subsequently to directly support QA Level I activities unless it can be substantiated that quality assurance requirements equivalent to those which would have been applied to a QA Level I activity were implemented or that a technical justification process is applied in accordance with appropriate NNWSI Project procedures.

5.1.3 Characteristics of QA Level III Items and Activities

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

5.2 PREPARATION OF QA LEVELS ASSIGNMENTS

5.2.1 When assigning QA levels, it may be necessary for the TM to subdivide each appropriate WBS Dictionary item or activity, including items and activities associated with a scientific investigation (see QMP-03-02, Control of Scientific Investigations), into sub-items or activities, and identify all such items and activities on Figure 1, WMPO QA Level Assignment Sheet (QALAS). It is important that all items and activities be addressed, not just those considered to be QA Level I and II. The purpose of assigning a QA level is to be able to provide objective evidence that each item or activity was addressed and a justifiable QA level established in accordance with this procedure.



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5.2.2.1 If an item or activity is assigned a QA level without further subdivision, all of its subparts shall have the same QA level. The justification for the QA level may be as basic as "Item does not meet any of the attributes for QA Level I or Level II." Alternatively, it may be necessary to support the QA level assignment with detailed calculations, performance assessment studies, scenarios, etc.. Supporting documentation and references shall be attached to the QALAS, as necessary.

5.2.2.2 All activities, excluding design, associated with a specific item shall be assigned the same QA level as the item. Justification to exempt a particular activity shall be documented by the TM.

5.2.3 The TM shall utilize Figure 2, QA Level Assignment Checklist, to determine the QA level for each item or activity, and record the assigned QA level on the QALAS. The QALAS shall be identified with a unique number and the proper revision indicator. The TM shall also prepare the justification for the QA level assigned to each item or activity. In addition to assigning QA levels, the TM shall determine and record on the QALAS which of the WMPO QA criteria apply to the item or activity.

5.2.3.1 The TM shall document on the QALAS the justification(s) for the WMPO QA criteria that has been determined to be not applicable to the item or activity.

5.2.3.2 The QALAS shall reference the appropriate scientific investigation planning document, including revision on the QALAS, as applicable.

5.2.4 The assignment of QA levels is based on the definitions and characteristics of QA Levels I, II, and III as they apply to each item and activity. Each item and activity shall be individually processed by the TM using this procedure and Figure 2:

1. Process each item and activity individually by responding to the questions on Figure 2. Begin with step 1 and respond to each question in sequential order until the response to the question is "Yes". The QA level that corresponds to the first question on Figure 2 for which the response of the TM is "Yes" shall be the assigned corresponding QA Level for that specific item or activity.
2. Document the assigned QA level on the QALAS adjacent to the appropriate item or activity.



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3. Document on the QALAS the justification(s) for the assigned QA level. When the justification for an item or activity is based on step 4 of Figure 2, the TM shall identify on the QALAS the QA Level I items, including data, affected by the failure.
4. Document on the QALAS applicable WMPO QA criteria which apply to the item or activity and the justification for the WMPO QA criteria which are determined not to be applicable.

5.2.5 The TM shall sign, date, and forward the completed QALAS to the appropriate Department Manager for review to determine if the assigned QA levels, applicable WMPO QA criteria and required justifications are adequate. If the QALAS is acceptable the Department Manager shall sign and date the QALAS and forward it to the WMPO PQM. If the QALAS is unacceptable, the Department Manager shall return the QALAS to the TM for resolution.

5.2.6 The WMPO PQM and the responsible WMPO Branch Chief shall review the QALAS to determine if the assigned QA levels, appropriate WMPO QA criteria, and required justifications are correct, complete and adequate; and to determine if the identification of QA Level I items, including data, as required in Section 5.2.4.3 has been completed. If the QALAS is acceptable, the WMPO PQM and WMPO Branch Chief shall sign, date, and return the QALAS to the responsible Department Manager. When the QALAS is determined to be inadequate, incorrect, or incomplete, the WMPO PQM shall return the QALAS to the responsible Department Manager for resolution.

5.4 CHANGES TO QA LEVEL ASSIGNMENTS

Changes to the assigned QA level or other contents of the QALAS shall be documented on Figure 1 and processed in the same manner as the original QALAS. The revision indicator of the QALAS being changed shall be revised to the next appropriate indicator. QA Level III items or activities cannot be upgraded to QA Levels I or II through the implementation of this procedure. When the change involves upgrading a QA Level II activity to QA Level I, the TM shall substantiate that QA requirements equivalent to those which would have been applied to a QA Level I activity were implemented. The process required to demonstrate this consists of the following:

1. The TM shall assemble adequate documentation related to the justification of upgrading the assigned QA level which provides objective evidence to demonstrate the QA Level II activities were performed in accordance with QA requirements equivalent to those which would have been applied to QA Level I activities.



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2. The revised QALAS with associated documentation shall be reviewed and approved by the responsible Department Manager, WMPO Branch Chief, and WMPO PQM.

6.0 REFERENCES*

Nuclear Waste Policy Act of 1982 as amended

NNWSI Project QA Plan*

WMPO QA Program Plan*

10CFR50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

10CFR60, Disposal of High-Level Radioactive Wastes in Geologic Repositories

40CFR191, Environmental Standards for the Disposal of Spent Nuclear Fuel, High Level and Transuranic Radioactive Wastes

10CFR20, Standards for Protection Against Radiation

QMP-03-02, Control of Scientific Investigations

QMP-17-01, Quality Assurance Records *

* Latest Revision

7.0 FIGURES

Figure 1 - WMPO Quality Assurance Level Assignment Sheet

Figure 2 - QA Level Assignment Checklist

8.0 QA RECORDS

WMPO QALASs, including revisions, and related documentation, including documented justifications as required by this procedure, shall be maintained in accordance with QMP-17-01, QA Records.



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YUCCA MOUNTAIN PROJECT OFFICE
QA LEVEL ASSIGNMENT CHECKLIST

N-QA-016
8/88

Item/Activity: _____

Step	Characteristics	Level
1.	Does the item or activity involve or affect public radiological health and safety? (Section 5.1.1.1) Yes	I
2.	Does the item or activity involve long term waste containment and waste isolation? (Para. 5.1.1.2) Yes	I
3.	Is the intended purpose of this activity to provide data for a license application? (Section 5.1.1.3) Yes	I
4.	Can the failure of the item or activity cause a failure of a QA Level I item or irretrievable loss of QA Level I data? (Section 5.1.1.4) Yes	I
5.	Does the activity involve a design phase which is to be conducted immediately prior to application for a NRC license, procurement, or construction? (Section 5.1.1.5) Yes	I
6.	Does the item or activity involve or affect retrievability of waste up to the time of the repository closure? (Section 5.1.2.3) Yes	I
7.	Can the item or activity have a major impact on non-radiological or occupational health and safety of the public and repository workers (Section 5.1.2.1) Yes	II
8.	If the item or activity were to fail or is performed inadequately could repository workers be exposed to radiation or radioactive contamination levels in excess of the limits expressed in 10 CFR 20? (Section 5.1.2.2) Yes	II
9.	Does the item or activity have a major impact on the non-radiological operation, reliability, or maintainability of engineered systems, structures or components? (Section 5.1.2.4) Yes	II
10.	Does the item or activity involve a design phase for which the principal purpose is to conduct a comparative technical analysis of alternatives? (Section 5.1.2.5) Yes	II
11.	Can the item or activity cause major cost overrun or schedule slippage? (Section 5.1.2.6 and 5.1.2.7) Yes	II
12.	When none of the responses to the above 11 steps is Yes, then the item or activity shall be assigned a QA Level III.	III

QA Level _____

Assigned By/Date _____ Dept. _____

Approval:

Task Mgr./Date _____ Dept. Mgr./Date _____

YMPO PQM/Date _____ YMPO Branch Chief/Date _____

Figure 2 - QA Level Assignment Checklist

DOCUMENT TRANSMITTAL RECORD

N-GA-022
11/87

PLEASE SIGN AND RETURN BY 9/29/88 Transmittal Date 9/15/88
TO Name SEE DISTRIBUTION LIST Organization SEE DIST.
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Document Title WMPO Quality Assurance Program Plan, WMPO/88-1 Copy No. SEE DIST.

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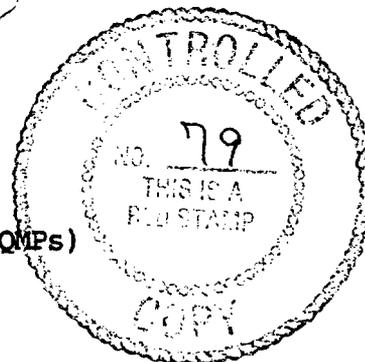
- REMOVE - QMP Table of Contents (2 pages) dated 9/2/88.
- INSERT - QMP Table of Contents (2 pages) dated 9/14/88.
- INSERT - QMP-02-06, Assignment of Quality Assurance Levels, Rev. 0, dated 9/14/88, behind last page of QMP-02-02, which is located in section 2 of the WMPO QAPP.

Please sign to indicate that the above instructions have been complied with and return transmittal to the address below:

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WMPO Quality Management Procedures (QMPs)

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QMP-02-02		Qualification of Quality Assurance Audit Personnel	1
QMP-02-06		Assignment of Quality Assurance Levels	0
QMP-02-08		Technical Assessment Review	0
QMP-03-01		Peer Review	0
QMP-03-02		Scientific Investigation Control	In Preparation
QMP-03-03		Use and Control of Computer Programs	To be Developed
QMP-03-04		Software Development and Maintenance	To be Developed
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QMP-04-01		Procurement Document Control	0
QMP-05-01		Preparation and Control of Quality Management Procedures	1
QMP-05-02		Preparation and Control of Branch Technical Procedures	0
QMP-05-03		Preparation and Control of the NNWSI Project QAP and the WMPO QAPP	0
QMP-06-02		Document Control	In Preparation

Date: September 14, 1988

QMP-06-03	1&2	Document Review/Acceptance/Approval	1
QMP-07-03		Control of Purchased Items and Services	0
QMP-07-04		Supplier Surveys	To be Developed
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QMP-16-03		Standard Deficiency Reporting System	0
QMP-17-01		QA Records	In Preparation
QMP-18-01		Audit System for the Waste Management Project Office	2
QMP-18-02		Surveillances	1

Date: September 14, 1988

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