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JAN 05 1988

Stephen H. Kale, Associate Director, Geologic Repositories, HQ (RW-20) FORS

RESOLUTION OF U.S. NUCLEAR REGULATORY COMMISSION (NRC) COMMENTS ON THE NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS (NNWSI) PROJECT QUALITY ASSURANCE PROGRAM PLAN REQUIREMENTS FOR NNWSI PROJECT PARTICIPATING ORGANIZATIONS AND NEVADA TEST SITE SUPPORT CONTRACTORS AND THEIR VENDORS, NNWSI SOP-02-01, REVISION 1 (WMPO ACTION ITEM #88-710)

Reference: Letter, Linehan to Knight, dtd. 11/21/86

The Waste Management Project Office (WMPO) has completed an evaluation of the NRC comments to the subject document that were submitted per the referenced letter. These comments, along with proposed resolutions, are contained in the enclosure to this letter. It should be noted that the majority of the NRC comments were resolved via Revision 5 to the NNWSI Project Quality Assurance (QA) Plan, NVO-196-17, which was issued for implementation on March 9, 1987. Additional clarification to address the NRC comments will be incorporated into Revision 6 of NVO-196-17, which is currently being finalized. These clarifications are as noted in the enclosure. It is suggested that a meeting be scheduled with the NRC to discuss the proposed resolutions to their comments prior to formal submittal so as to ensure agreement and understanding. This meeting should also include a discussion of the NNWSI Project resolution of the NRC comments on the NNWSI Project QA Plan, NVO-196-17, Revision 4. These resolutions were previously submitted to your office on September 22, 1987, via letter C. P. Gertz, WMPO to S. H. Kale, Headquarters dated September 16, 1987. The WMPO requests participation in this meeting, which can be scheduled at your convenience.

If you have any questions or require further information regarding this subject, please advise.

Carl P. Gertz, Project Manager
Waste Management Project Office

WMPO:JB-813

Enclosure:
Proposed Resolution of the
NRC Comments

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Proposed Resolution of the NRC Comments
Regarding the NNWSI Project QAPP Requirements
for NNWSI Project Participating Organizations
and NTS Support Contractors and their Vendors

NNWSI SOP-02-01, Revision 1

General Comments

1. The staff suggests that WMPO consider showing the tie between the document entitled "Nevada Nuclear Waste Storage Investigations Quality Assurance Plan," NVO-196-17, and NNWSI-SOP-02-01 since both are listed as requirements documents.

Response:

This comment is no longer applicable. NNWSI SOP-02-01, Rev. 1 has been incorporated into NVO-196-17, Rev. 5, to establish a single requirements document which defines the QA requirements that are applicable to the NNWSI Project participating organizations and NTS support contractors and their vendors.

2. The "Purpose and Scope" section of NNWSI-SOP-02-01 includes a definition of Level I activities which for waste isolation is tied only to releases to the accessible environment. Activities which affect meeting the other numerical performance objectives of Subpart E of Part 60 are not included in the definition of Level I. The requirements described in the plan could under certain conditions eliminate, for example, the waste package testing and the package itself from the Level I list. The NRC staff's "Draft Generic Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to 10 CFR Part 60 Quality Assurance Requirements," Section 5.3, gives the staff position on this issue. The staff believes that all items and activities contributing to meeting the containment and isolation requirements in Subpart E Part 60 should be Level I. The plan should be revised to reflect this position.

Response:

It is not the intention of the WMPO to exclude the waste package from being assigned a QA Level I designation. NVO-196-17, Rev. 5, Section II, Para. 2.2.2.1, will be revised to clarify this issue. Specifically, in the next to the last sentence in this paragraph, the words "...from the site to the accessible environment after permanent closure..." will be deleted. This will be accomplished via Revision 6 of NVO-196-17.

3. In DOE/RW-0032, the Office of Civilian Radioactive Waste Management's "Quality Assurance Management Policies and Requirements," DOE includes ANSI/ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities," as one of the governing documents of the high-level

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radioactive waste program. The NRC has not yet endorsed use of NQA-1 in the high-level radioactive waste programs but the staff did make a cursory review of NNWSI-SOP-02-01 against the requirements of NQA-1. The last eight comments of the enclosure to this letter resulted from that review and are offered for DOE's consideration.

Response:

This comment is informational in nature. No response is required.

Specific Comments

I. Organization

A. The Quality Assurance Program Plan (QAPP) of each of the NNWSI Project participants and NTS support contractors should identify, by position title, the individual responsible for the QA program covering these activities. (1.1)* Organization charts should clearly identify the organizational elements which function under the cognizance of the QA program and, if the organizational elements are not at the same location, indicate the location of each element (1.7).

Response:

NVO-196-17, Rev. 5, Section I, Para. 2.1, requires that the person responsible for directing and managing the overall QA program be identified and have appropriate organizational position, responsibilities and authority to exercise proper control over the QA program. Para. 1.0 of this section requires that the organizational structure, lines of communication, authority, and duties of persons and organizations performing activities affecting quality be clearly established and delineated in writing. Assurance that these, as well as all other requirements, are addressed in the QAPPs of each NNWSI Project participant is achieved via WMPO review and approval of the QAPPs of each participant.

B. Each QAPP should describe how responsibility is exercised for the overall QA program of the Project participant and NTS support contractor. The extent of management responsibility and authority from the Project participant's and NTS support contractor's home office should also be described. The interface between the Project participant, support contractor, and DOE should be described in the QAPP (1.3).

Response:

The QAPP of each NNWSI Project participating organization and NTS support contractor does describe how responsibilities are exercised for the overall QA program. The NNWSI Project QA Plan, NVO-196-17, Rev. 5, Section I, Para. 1.0, requires that the organizational structure, lines of communication, authority, and duties of persons

and organizations performing activities affecting quality be clearly established and delineated in writing. Para. 3.0 of this section requires that the organizational structure and responsibility of assignments be clearly established such that quality is achieved and maintained by those who have been assigned responsibility for performing work and quality achievement is verified by persons or organizations not directly responsible for performing the work. Interfaces between the NNWSI Project participating organizations, the NTS support contractors, and the DOE are described in the introduction and shown graphically in Figure 2 of the NNWSI QA Plan (NVO-196-17). In addition, the QAPP of each NNWSI Project participant also describes their interfaces with the WMPO as well as other NNWSI Project participants, as appropriate.

C. Section 1.1.1 of the SOP indicates that each Project participant shall retain the responsibility for QA work delegated to others outside the participant's organization. Each QAPP should identify qualified individuals or organizational elements responsible for the quality of the delegated work (1.5).

Response:

NVO-196-17, Rev. 5, Section I, Para. 1.0, states that the participants may delegate to others such as contractors, agents, or consultants the work of establishing and executing the QA program or any part thereof but shall retain the responsibility therefore. Para. 4.1 of this same section states that the Technical Project Officer of the respective participating organizations and NTS support contractors are responsible to the WMPO Director to ensure that the Project activities for which they are responsible are performed to a QAPP and implementing procedures that are consistent with the NNWSI Project QA program requirements. Revision 6 of NVO-196-17 will change the title of the WMPO Director to the WMPO Project Manager.

D. Organization charts noted in A above should demonstrate that management controls and effective lines of communication exist both internally and externally to ensure direction and implementation of the QA program (1.6). The QAPPs should describe the QA responsibilities of each of the organizational elements shown on the organization charts (1.9).

Response:

NVO-196-17, Rev. 5, Section I, Para. 4.1, requires that the external interfaces between organizations and the internal interfaces between organizational units be documented. This paragraph also states that all interface responsibilities be defined and documented. Interfaces between the WMPO, the participating organizations, and the NTS support contractors, are required to be described in the QAPPs of the respective organizations. The introduction of NVO-196-17 provides a brief overview of the interfaces from an overall Project standpoint. Specific interfaces will be contained in the WMPO QAPP, NVO-196-18, and the respective QAPPs of each NNWSI Project participating organization and NTS support contractor.

E. The QAPP of each Project participant and NTS support contractor should identify a management position within its organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience, should have the following characteristics:

1. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.

2. Has effective communication channels with other senior management positions.

3. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.

4. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters. (1.10, 1.15)

Response:

NVO-196-17, Rev. 5, Section I, Para. 2.1, requires that full time dedicated positions be established by the WMPO, participating organizations, and NTS support contractors. This paragraph further requires that the person responsible for directing and managing the overall NNWSI Project participant QA program be identified and have appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. This paragraph also states that this person shall have appropriate management and QA knowledge and experience and shall be at the same or higher organizational level as the highest line manager responsible for performing activities affecting quality and sufficiently independent from cost and schedule. In addition, Paragraph 2.1 states that personnel in these positions shall have responsibility for approval of QAPPs, changes thereto, and interpretations thereof as well as implementing procedures and all changes thereto. This position is also required to have effective communication channels with other senior management positions. Finally, this paragraph concludes by stating that personnel responsible for managing and directing the overall QA program shall not be assigned duties that would prevent full attention to QA responsibilities or that would conflict with the reporting and resolution of QA issues and problems.

F. Section 1.2.2.2 of the SOP indicates that, for QA Level I activities, quality is verified by persons or organizations not directly responsible for performing the work. This quality control function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity. (1.11)

Response:

NVO-196-17, Rev. 5, Section I, Para. 3.2, requires that quality achievement is verified by persons or organizations not directly responsible for performing the work. Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization unless specifically exempted elsewhere in NVO-196-17. A change which will be reflected in Revision 6 of NVO-196-17, Section X, Inspection, provides for inspections to be performed by personnel who do not report directly to the immediate supervisor who is responsible for performing the activity being inspected. If these personnel are not part of the formal QA organization, they shall have sufficient authority, access to work areas, and organizational freedom to: (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; (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 these inspection activities are not part of the formal QA organization (i.e., part of line management) then the QA organization shall overview and monitor the inspection activity.

G. Section 1.1.2 of the SOP addresses stop work and other authority of persons performing QA functions. Each QAPP should describe how these authorized actions are accomplished, including a description of how stop work requests are initiated and completed (1.12).

Response:

NVO-196-17, Rev. 5, Section I, Para. 2.0, requires that persons and organizations performing QA functions have sufficient authority, access to work areas, and organizational freedom to identify quality problems, initiate, recommend, or provide solutions, verify implementation, and to ensure further processing or use of a nonconforming item is controlled. This responsibility will include the ability to stop or cause to be stopped unsatisfactory work through established channels. Specific details on how these stop work actions are accomplished including a description of how stop work requests are initiated and completed will be contained in the specific implementing procedures of each NNWSI Project participant.

II. Quality Assurance Program

A. The QA organization of each Project participant and NTS support contractor should review and document concurrence with the quality-related (i.e., important to safety or important to waste isolation) procedures generated or used by that Project participant and NTS support contractor relative to the QA requirements (2.4).

Response:

NVO-196-17, Rev. 5, Section V, Para. 2.0, requires that an independent technical and QA review of all instructions, procedures, plans, and drawings be performed by the originating organization. Section VI of NVO-196-17, Para. 1.1, requires that the QA organization provide the appropriate review, resolution of comments, and concurrence with respect to quality related aspects of documents that fall under the provisions of the document control system (i.e., documents containing or specifying quality requirements or documents that prescribe activities affecting quality.

B. Each QAPP should identify existing or proposed QA procedures and detailed technical procedures reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities, will be met.

Response:

The WMPO is in agreement with this comment. However, since the NNWSI Project is still in the process of identifying and developing the necessary procedures, it is inappropriate to include the identification of these procedures in the QAPPs at the present time. To do so would necessitate frequent changes to these documents. NVO-196-17, Rev. 5, Section VI, Para. 3.1, does require that a master list or equivalent which identifies the correct, current and updated versions of documents (including procedures) be provided to the WMPO. A requirement to include identification of these procedures in the QAPPs of each NNWSI Project Participant will be included in a future revision to NVO-196-17 after the QA Program matures and procedure development has stabilized.

C. The last sentence of section 2.1.1 of the SOP indicates that the participating organizations' and NTS support contractors' management shall assess the adequacy and implementation of their QAPPs on an annual basis. This requirement should extend to subtier vendors and others (such as contractors and agents) involved in the quality-related aspects of the NNWSI Project. The QAPPs should describe how management will regularly assess the scope, status, adequacy, implementation, and compliance of the QA program to Appendix B of 10 CFR 50. These measures should include:

1. Frequent contact with program status through reports, meetings, and audits, and

2. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked. (2.7)

Response:

NVO-196-17, Rev. 6, Section II, Para. 1.0, will require that management outside of the QA organization regularly receive information as to the scope, status, adequacy, compliance, etc. of the QA program. In addition, Para. 4.0 of the current revision of this section establishes requirements for management assessment and requires management assessment to be conducted annually to determine (1) the effectiveness of the system and management controls that are established to achieve and ensure quality, and (2) the adequacy of resources and personnel provided to the QA program. This paragraph also requires that management verify that the QA program is being effectively implemented and that personnel are trained to the QA requirements of the program. In addition, Para. 4.2 of this section requires that management assessments be performed by each NNWSI Project participant. Each organization is required to develop internal procedures for planning, organizing, performing, and documenting the management assessment including the analysis and reporting of the results and the tracking of recommendations. Relative to subtier vendors, NVO-196-17, Rev. 5, Section IV, Procurement Document Control, Para. 2.1.3, requires that suppliers have a documented QA program. The extent of this program depends upon the type and use of the item or service being procured, therefore the requirement to perform an annual assessment of the adequacy and effectiveness of the QA Program may or may not be imposed dependent upon the subtier vendor's work scope.

III. Design and Site Investigation Control

A. The SOP should include the definitions of design, design information, design activities, and data analysis to be consistent with regulations as follows.

Design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters (3.1).

Response:

Definitions of the terms design, design information, design activities, and data analysis have been incorporated into NVO-196-17, Rev. 5, Section III, Scientific Investigation and Design Control, Para. 2.1.1. The NVO-196-17 definitions are consistent with the definitions contained in the NRC Review Plan, Item 3.1. It should be noted, however, that data collection activities associated

with characterization of the site are controlled by the scientific investigation control requirements defined in NVO-196-17, Rev. 5, Section III, Para. 1.0. Additionally, activities associated with data collection resulting from performance verification testing of engineered items are controlled by the traditional design control and test control requirements. These requirements are presently contained in NVO-196-17, Rev. 5, Section III, Para. 2.0 and Section XI, Test Control.

B. Performance requirements should be specified for repository system components to support (1) identification of which items are important to safety and which items are important to waste isolation, (2) establishment of a graded QA approach, and (3) establishment of data gathering and analysis needs (3.2).

Response:

The preliminary requirements for each performance and design issue is found in the issue resolution strategy sections of the Site Characterization Plan. NVO-196-17, Rev. 5, Section II, Para. 1.5, establishes requirements for the formulation of a Q-List. A 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 (QA Level I) of the formal NNWSI Project QA program. Para. 2.0 of this section establishes requirements for the application of graded QA including the selection of QA levels and appropriate QA requirements.

C. Each QAPP should describe organizational responsibilities for preparing, reviewing, approving, verifying, and validating design and design information documents (3.3).

Response:

NVO-196-17, Rev. 5, Section I, Para. 1.0, requires that the organizational structure, lines of communication, authority, and duties of persons or organizations performing activities affecting quality shall be clearly established and delineated in writing. Para. 4.1 of this section states that the organizational structure for executing QA programs varies from organization to organization and each one shall be described in the individual organization's QAPP. Therefore, the QAPP of each organization involved in design activities will describe the organizational responsibilities for preparing, reviewing, approving, verifying, and validating design and design information documents.

D. Section 3.1.3 of the SOP addresses design verification. Confirmation that a correct computer code has been used is part of design verification. Design checking, which must also be performed, includes such things as confirmation of the numerical accuracy of computations and the accuracy of data input to computer codes. Design verification requires a level of skill at least equal to that of the original designer, while design checking can be performed by

less experienced persons. Design verification should be performed by persons other than those performing design checking. Sections 3.1.3 and 3.2.4.4 of the SOP indicate that those performing design verification may be from the same organization as those who performed the original design or site investigation. It is preferable to have qualified personnel not associated with the responsible design or investigation organization conduct the verification activities (3.7).

Response:

NVO-196-17, Rev. 5, Section III, Para. 2.3.3 requires that computer programs used for design analysis be verified and controlled in accordance with requirements of Para. 3.0 of this same section. Para. 3.0 requires that computer software used to support a high level nuclear waste repository license application be documented and controlled consistent with the guidance contained in NUREG 0856 "Final Technical Position on Documentation of Computer Codes for High Level Waste Management." The WMPO considers design checking to be a normal part of the evolution of the design. As such, specific requirements relative to design checking are not contained in the NNWSI Project QA Plan, NVO-196-17. However, specific requirements for design verification are contained in NVO-196-17, Rev. 5, Section III, Para. 2.4. The requirements for design verification do allow the individual or groups performing the verification to be from the design originator's same organization. This is consistent with NQA-1, 1983, Supplement 3S-1. It is recognized that it is preferable to have the original design verified by qualified personnel not associated with the responsible design organization.

E. For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants should be retained for needed expertise where required (3.8).

Response:

NVO-196-17, Rev. 5, Section III, Para. 2.1.4, requires a peer review for design activities including design output documents which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed. Peer review is subject to the requirements of Para. 4.0 including subparagraphs of this same section of the NNWSI Project QA Plan. The WMPO is responsible for development of a procedure which describes the peer review process. Appendix A of NVO-196-17, Rev. 5, defines peer

review as a documented critical review performed by personnel who are independent of those who perform the work but who have technical expertise at least equivalent to those who performed the original work. Peer reviews are indepth 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 the report go beyond the existing state-of-the-art.

VI. Document Control

A. Section 6.1.1 of the SOP identifies the scope of the document control program to include documents such as instructions, procedures, and drawings. The document control program should also cover other types of documents such as procurement documents, specifications, reports (inspection, test, nonconformance, calibration, audit, design, NDE, surveillance, inventory, and corrective action), QAPPs, manuals, computer software, certification, system descriptions, logs, etc. (6.1).

Response:

NVO-196-17, Rev. 5, Section VI, adequately describes the scope of the document control program and establishes the following parameters for documents that need to be controlled: (1) documents containing or specifying quality requirements, and (2) documents that prescribe activities affecting quality. Although certain documents listed in this comment are subject to these requirements such as procurement documents, specifications, design documents, etc., there are certain other documents listed which will not be subject to document control requirements (i.e., inspection tests, nonconformance reports, audit reports, surveillance reports, corrective action reports, logs, etc.). The current requirements for document control contained in NVO-196-17, Rev. 5, are consistent with NQA-1 requirements and adequately describe the bounds of the document control program.

B. Section 6.2.1.3 requires the review of documents concerning QA Level I activities for adequacy, completeness, and correctness before approval and issuance. This review should ensure appropriate quality requirements and the quality related aspects of documents should be reviewed and concurred in by the QA organization (6.2).

Response:

NVO-196-17, Rev. 5, Section VI, Para. 1.1, requires that the QA organization provide appropriate review, resolution of comments and concurrence with respect to quality related aspects of documents that come under the provisions of the document control program. In addition, Para. 1.2 of this same section will require that a review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements be conducted prior to approval and issuance. This will be incorporated in Revision 6 to NVO-196-17.

VII. Control of Purchased Material, Equipment, and Services

A. Each QAPP should describe the organizational responsibilities, including those of the QA organization, for the control of purchases (7.1).

Response:

As stated previously, NVO-196-17, Rev. 5, Section I, Para. 1.0, requires that the organizational structure, lines of communication, authority, and duties of persons and organizations performing activities affecting quality be clearly established and delineated in writing. In addition, Section 7.0 of this document, Para. 1.1.1, requires that procurement planning result in the documented identification of procurement methods and organizational responsibilities. Through WMPO review and approval of the QAPPs of each NNWSI Project participant, the appropriate requirements of NVO-196-17 will be translated into each respective QAPP.

VIII. Identification and Control of Materials, Parts, Components, and Samples

A. Each QAPP should describe the organizational responsibilities for the identification and control of materials, parts, components, and samples (8.1).

Response:

As stated previously, Section I of NVO-196-17, Rev. 5, establishes adequate requirements to ensure that organizational responsibilities including interface responsibilities are defined for all activities affecting quality on the NNWSI Project.

B. Section 8.1 of the SOP indicates that identification and control measures shall be designed to prevent the use of incorrect or defective items. In this regard, the SOP should require that the correct identification of materials, parts, components, and samples is verified and documented prior to release for processing, use, or analysis (8.4).

Response:

Section VIII of NVO-196-17, Rev. 5, has been restructured into three sections and retitled as "The Identification and Control of Items, Samples, and Data." Part A, Para. 1.0 requires that items be identified to ensure that only correct and accepted items are used or installed. Revision 6 to NVO-196-17 will add the requirement that the identification of the items be verified prior to installation or use. Part B requires that samples be identified and controlled in a manner consistent with their intended use. Para. 1.1 requires that the correct identification of samples be verified and documented prior to release for use. Part C applies to the identification and control of data. Para. 1.0 of this part requires

that data be identified to assist in the determination of its correct use and that the identification of such data be provided in all documents, information systems, or both in which such data appear. In addition, Para. 1.1 of Part C requires that the identification of the data be verified prior to its release for use.

IX. Control of Processes

A. Each QAPP should describe the organizational responsibilities, including those of the QA organization, for the qualification of special processes, equipment, and personnel (9.2).

Response:

As stated previously, Section I of NVO-196-17, Rev. 5, establishes adequate requirements to ensure that organizational responsibilities including interface responsibilities are defined for all activities affecting quality on the NNWSI Project.

B. Section 9.2.6 of the SOP addresses records of special process qualifications. It should also address records of special process implementation which provide evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel (9.4).

Response:

NVO-196-17, Rev. 5, Section IX, Para. 2.6, requires that records be maintained for the qualified personnel, procedures, and equipment of each special process and requirements for maintenance of these records be specified. This paragraph also requires that special process verification methods and criteria be documented and retained. This information will be contained in the implementing procedures of each organization involved in the performance of special processes.

X. Inspection

A. Section 10.1.1 of the SOP refers to "repository hardware." This term needs to be defined such that the scope of the inspection is clear. Procedures should provide criteria for determining when inspections are required, and each QAPP should describe the QA organization's participation in establishing the criteria and the procedures (10.1).

Response:

NVO-196-17, Rev. 5, Section X, Para. 1.0, states that the inspection requirements apply to engineered items and do not apply to scientific investigation activities. This should not be construed to mean that receipt inspection associated with items that are used in the performance of scientific investigations are excluded from the appropriate requirements of this section. Additionally, this paragraph requires that measures be established to provide for the

identification of criteria for determining when inspections are required or how and when inspections are to be performed. Responsibilities of the QA organization as well as other organizations involved in inspection activities will be detailed in the QAPPs or implementing procedures of those organizations involved in inspection activities.

B. Organizational responsibilities, including those of the QA organization, for inspection should be described in each QAPP. The inspection function may be part of the line organization provided that the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activity (10.2).

Response:

As stated previously, Section I of NVO-196-17, Rev. 5, establishes adequate requirements to ensure that organizational responsibilities including interface responsibilities are defined for all activities affecting quality on the NNWSI Project. NVO-196-17, Rev. 5, Section I, Para. 3.2, requires that quality achievement is verified by persons or organizations not directly responsible for performing the work. Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization unless specifically exempted elsewhere in NVO-196-17. A change which will be reflected in Revision 6 of NVO-196-17, Section X, Inspection, provides for inspections to be performed by personnel who do not report directly to the immediate supervisor who is responsible for performing the activity being inspected. If these personnel are not part of the formal QA organization, they shall have sufficient authority, access to work areas, and organizational freedom to: (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) 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 these inspection activities are not part of the formal QA organization (i.e., part of line management) then the QA organization shall overview and monitor the inspection activity.

C. Inspection procedures, instructions, or checklists (and the inspection records referred to in Section 10.2.7 of the SOP) should provide for the following:

1. Identification of characteristics and activities to be inspected.

2. A description of the method of inspection.

3. Identification of the individuals or groups responsible for performing the inspection operation.

4. Acceptance and rejection criteria.

5. Identification of required procedures, drawings, and specifications and revisions.

6. Recording inspector or data recorder and the results of the inspection operation.

7. Specifying necessary measuring and test equipment including accuracy requirements.

Response:

Although NVO-196-17, Rev. 5, Section X, Para. 4.0, is consistent with the NRC requirements regarding the content of inspection procedures, instructions, or checklists, this paragraph will be modified in Rev. 6 of NVO-196-17 to clarify the specific content of these inspection documents. Para. 9.1 of Section X adequately describes the content of inspection records at the present time.

XI. Test and Experiment/Research Control

A. Test, experiment, and research plans, procedures, and results should be reviewed by qualified personnel other than the originator or the originator's supervisor. The reviewer should have a level of skill at least equal to the originator. Peer reviews should be conducted if the test, experiment, or research involves state-of-the-art activities or where detailed technical criteria do not exist or are being developed. Each involved QAPP should identify procedures which describe the responsibilities of the reviewer(s) the areas and features to be reviewed, the pertinent considerations to be reviewed, and the extent of review documentation (11.2, 11.5).

Response:

NVO-196-17, Rev. 5, Section XI, Para. 3.3, requires that test plans and procedures be reviewed in accordance with the verification requirements defined in Section 3.0, Para. 2.4. Para. 2.1.4 of Section 3.0 requires that design activities including design output documents which involved the use of untried or state-of-the-art testing and analysis procedures and methods be subject to peer review. Para. 2.4.6.1 of Section 3.0 provides minimum considerations for the performance of design reviews which are consistent with NRC Standard Review Plan requirements relative to this item.

B. Test, experiment, and research plans and procedures should identify the potential sources of uncertainty and error and parameters which must be controlled and measured (11.3).

Response:

NVO-196-17, Rev. 5, Section XI, Para. 3.4, requires that the potential sources of uncertainty and error in test procedures be controlled and measured to ensure the tests are well controlled. It should be noted that the title of this section has been changed to Test Control. Requirements associated with scientific investigation control are contained in Section III.

C. Test, experiment, and research plans and procedures (and the records referred to in Section 11.2.4 of the SOP) should provide for the following:

1. The requirements and acceptance limits contained in applicable documents, including precision and accuracy.

2. Instructions for performing the activity.

3. Prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.

4. Provisions for assuring prerequisites have been met.

5. Mandatory inspection hold points (as required).

6. Acceptance and rejection criteria, including required levels of precision and accuracy.

7. Methods of data analysis.

8. Methods of documenting or recording data and results. (11.4)

Response:

Specific requirements relative to the content of test plans and procedures and associated records are contained in NVO-196-17, Rev. 5, Para. 2.0, 3.1, 3.2, and 3.3. These requirements are consistent with the NRC Standard Review Plan item relative to this subject.

XII. Control of Measuring and Test Equipment

A. Organizational responsibilities, including those of the QA organization, for establishing, implementing, and assuring the effectiveness of the calibration program should be described in each QAPP (12.2).

Response:

NVO-196-17, Rev. 5, Section XII, Para. 1.3, requires that the responsibility of all organizations be described for the establishment, implementation, and assurance that the calibration program is effective. These organization responsibilities will be defined in detailed implementing procedures of each NNWSI Project participant involved in calibration activities.

B. Measuring and test equipment should be labeled, tagged, or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data (12.4).

Response:

NVO-196-17, Rev. 5, Section XII, Para. 2.3, requires that measuring and test equipment be labeled, tagged, or otherwise documented to indicate the due date of the next calibration and provide traceability of calibration data.

XV. Control of Nonconforming Items

A. Nonconformance documentation should identify and describe the nonconformance, should show the disposition of the nonconformance, and should include authorized signature approval of the disposition (15.3).

Response:

NVO-196-17, Rev. 5, Section XV, Para. 1.4.4, requires that nonconformance documentation adequately identify and describe the nonconformance. In addition, this paragraph requires that the disposition of the nonconformance be documented. Para. 1.4.2 of Section XV requires that the personnel assigned signature approval of the disposition be identified and that QA responsibilities relating to nonconformances be described.

B. Nonconformance reports should be periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances, and the significant results should be reported to upper management for review and assessment (15.4).

Response:

NVO-196-17, Rev. 5, Section XV, Para. 4.0, requires that nonconformance reports be periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances. The results are required to be reported to upper management for review and assessment.

XVI. Corrective Actions

A. Procedures for the establishment of an effective corrective action program should be reviewed by and have the documented concurrence of the involved QA organization (16.1). The QA organization should also be involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied (16.2).

Response:

NVO-196-17, Rev. 5, Section V, Para. 2.0, requires that an independent QA review be performed of all instructions, procedures, plans, and drawings. In addition, Section VI, requires that the QA organization provide appropriate review, resolution of comments, and concurrence with respect to quality related aspects of documents. Section XVI, Para. 1.2, requires that the QA organization shall document concurrence with the adequacy of proposed corrective actions to ensure that QA requirements will be satisfied.

B. The follow-up of corrective action required by the last sentence of SOP Section 16.1 should be the responsibility of the QA organization (16.3).

Response:

NVO-196-17, Rev. 5, Section XVI, Para. 1.2, requires that follow-up action be taken by the QA organization to verify proper implementation of corrective action and to close out corrective action.

XVII. Quality Assurance Records

A. Section 17 of the SOP limits records to paperwork. QA records should be expanded to include samples associated with site characterization (17.1).

Response:

NVO-196-17, Rev. 5, Section XVII, Para. 1.1, provides the NNWSI Project definition of QA Records. It includes other materials that provide data and document quality regardless of the physical form or characteristic. Specific requirements associated with samples are contained in Section VIII.

B. Each QAPP should describe the organizational responsibilities, including those of the QA organization, for the definition and implementation of activities related to QA records (17.2).

Response:

As stated previously, the NNWSI Project QA Plan, NVO-196-17, Section I, Para. 1.0, requires that the organizational structure, lines of communication, authority, and duties of persons and organizations performing activities affecting quality be clearly established and delineated in writing.

XVIII. Audits

A. Audit data should be analyzed by the QA organization and the results of these analyses should be reported to responsible management for review, assessment, and appropriate action (18.4).

Response:

NVO-196-17, Rev. 5, Section XVIII, Para. 1.7, requires that analysis of audit results be performed to identify quality trends. This paragraph will be clarified in Rev. 6 of NVO-196-17 to specifically require that the results of these analyses be reported to responsible management for review, assessment, and appropriate action.

B. A tracking system for audit findings should be established to help assure that all findings are appropriately addressed and to trend audit findings (18.6).

Response:

NVO-196-17, Rev. 5, Section XVIII, Para. 1.0, requires that tracking systems be instituted for audit findings to ensure all findings are appropriately addressed and to identify quality trends.

C. Section 18.2.5 of the SOP describes the required response to adverse audit findings. In resolving such findings, the root cause should be identified and corrected (18.8).

Response:

NVO-196-17, Rev. 5, Section XVIII, Para. 1.6, requires that management of the audited organization or activity investigate adverse audit findings, determine root cause, schedule corrective actions, including measures to preclude recurrence.

D. Both technical and QA programmatic audits should be performed to:

1. Provide a comprehensive independent verification and evaluation of procedures and activities affecting quality.

2. Verify and evaluate supplier's QA programs, procedures, and activities.

Response:

NVO-196-17, Rev. 5, Section XVIII, does not specifically differentiate between technical and QA programmatic audits. Para. 1.2 of this section requires that internal and external QA audits be scheduled in a manner that provides coverage and coordination with ongoing QA program activities. This paragraph also requires that audits be scheduled with a frequency commensurate with the status and importance of the activity. Para. 1.2.1 of this section requires that elements of an organization's QAPP be audited at least annually. In practice, the WMPO is conducting a program of technical audits as well as QA programmatic audits on a selected basis. Relative to Item 2 of this comment, it is the WMPO position that requirements relative to evaluation of supplier's QA programs are governed by requirements of Section VII of NVO-196-17 which provides for other methods, besides audits, of verifying that the suppliers performance is adequate.

E. Audits should be led by appropriately trained, qualified, and certified audit personnel. The audit team should include personnel (not necessarily from the QA organization) having technical expertise in the areas being audited. The audit program should include audits which examine in detail the technical adequacy of products. Such audits should be conducted by personnel having technical expertise and direct experience in areas being reviewed.

Response:

NVO-196-17, Rev. 5, Section XVIII, Para. 1.3.3, requires that all audits have an individual qualified as a lead auditor who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates the responses. Specific requirements for qualification and certification of audit personnel are contained in Appendix F of NVO-196-17. Para. 1.3.3 of Section XVIII also requires that the audit team leader identify the technical specialists that will participate in the audit and must include this information in the audit plan.

NQA-1 Requirements

1. The SOP defines commercial grade item as "...an item which is not part of a basic component design or specification requirements used in the construction or operation of the geologic repository licensed pursuant to 10 CFR 60. These items are to be ordered from the manufacturer's published product description." (page 67) NQA-1 (1a-83) defines commercial grade item as "an item satisfying (a), (b), and (c) below:

   a. not subject to design or specification requirements that are unique to nuclear facilities;

   b. used in applications other than nuclear facilities;

c. is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, catalog)."

Explain, justify, and/or eliminate this difference.

Response:

NVO-196-17, Rev. 5, Appendix A, provides a definition of commercial grade items that is consistent with the definition per NQA-1. The only exception is that the term "nuclear facilities" has been changed to "mined geologic disposal systems" in order to be more specific to the high-level waste repository program.

2. Section 3.2.4.4.4 of the SOP states that test results shall be evaluated by the responsible "technical" organization, while Section 4.2.3 of Supplement 3S-1 of NQA-1 states that test results shall be evaluated by the responsible "design" organization. Explain, justify, and/or eliminate this difference.

Response:

NVO-196-17, Rev. 5, Section III, Para. 2.4.6.3, requires that test results be documented and evaluated by the responsible design organization, therefore the difference has been eliminated.

3. Section 3.2.7 of the SOP addresses documentation and records of designs and site investigations. This section should include the requirement of Section 7 of Supplement 3S-1 of NQA-1 that the documentation shall include not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design.

Response:

NVO-196-17, Rev. 5, Section III, Para. 2.8, requires that design documentation, including design inputs, analyses, drawings, specifications, approved changes thereto, evidence of design verification, and records confirming interface control, be collected, controlled, stored, and maintained as QA records. This is consistent with NQA-1 requirements.

4. Section 6.0 of the SOP should include the requirement of Section 3.1 of Supplement 6S-1 of NQA-1 that the organization that reviews major changes of documents shall have access to pertinent background data or information upon which to base approval.

Response:

NVO-196-17, Rev. 5, Section VI, Para. 2.1, requires that the reviewers of major changes to documents have access to pertinent background data or information upon which to base their approval.

5. Section 8.2.2.3 of the SOP should include the requirement of Section 3.3 of Supplement 8S-1 of NQA-1 for protection of identification on items subject to deterioration due to environmental exposure.

Response:

NVO-196-17, Rev. 5, Section VIII, Para. 2.0, requires that provisions be made for the control of item identification including protection on items subject to excessive deterioration due to environmental exposure.

6. Section 9.2.2 of the SOP specifies that it is the responsibility of the participating organization of NTS support contractor that is performing the work to identify which portions of its activities involve the use of special processes. This responsibility should be extended to subtier organizations.

Response:

Requirements relative to the control of suppliers are contained in Sections IV and VII of NVO-196-17. Section IV, Para. 2.1.3, requires that the supplier have a documented QA program that implements either portions or all the requirements of NVO-196-17. This paragraph also requires that procurement documents require the supplier to incorporate appropriate QA program requirements into subtier procurement documents.

7. The SOP should reflect the definition of nonpermanent records and the requirement for establishing in writing the retention period for nonpermanent records in accordance with Sections 2.7.2 and 2.8, respectively, of Supplement 17S-1 of NQA-1. The last paragraph of Section 6 of the same supplement also specifies requirements for nonpermanent records that should be incorporated into the SOP.

Response:

NVO-196-17, Rev. 5, Section XVII, Para. 1.4, states that all NNWSI Project records are classified as lifetime records and are required to be retained for the life of the Project. There will be no nonpermanent records specified for the NNWSI Project, therefore, requirements related to nonpermanent records do not apply.

8. The SOP should reflect the requirements of Section 4.3 of Supplement 17S-1 of NQA-1 which states that measures shall be established to preclude the entry of unauthorized personnel into the record storage area and that these measures shall guard against larceny and vandalism.

Response:

NVO-196-17, Rev. 5, Section XVII, Para. 8.0, requires that measures be established to preclude the entry of unauthorized personnel in the storage area and that these measures guard against larceny and vandalism.

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SEP 22 1987

Stephen H. Kale, Associate Director, Geologic Repositories, HQ (RW-20) FORS

RESOLUTION OF U.S. NUCLEAR REGULATORY COMMISSION (NRC) COMMENTS ON THE NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS (NNWSI) PROJECT QUALITY ASSURANCE (QA) PLAN, NVO-196-17, REVISION 4 (WMPO ACTION ITEM #87-2535)

Reference: Letter, Linehan to Purcell, dtd 8/25/86

The Waste Management Project Office (WMPO) has completed an evaluation of the NRC comments to the NNWSI Project QA Plan, NVO-196-17, Revision 4, that were submitted per the referenced letter. These comments, along with proposed resolutions, are contained in the enclosure to this letter. It should be noted that the majority of the NRC comments were resolved via Revision 5 to the NNWSI Project QA Plan, NVO-196-17, which was issued for implementation on March 9, 1987. Additional clarification to address the NRC comments will be incorporated into Revision 6 to NVO-196-17, which is currently being prepared. These clarifications are as noted in the enclosure. It is suggested that a meeting be scheduled with the NRC to discuss the proposed resolutions to their comments prior to formal submittal so as to ensure agreement and understanding. The WMPO requests participation in this meeting, which can be scheduled at your convenience.

If you have any questions or require further information regarding this subject, please advise.

Carl P. Gertz, Project Manager
Waste Management Project Office

WMPO:JB-2772

Enclosure:
WMPO Evaluation of NRC Comments to the NNWSI Project QA Plan, NVO-196-17, Rev. 4

cc w/encl:
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Proposed Resolution of the NRC Comments
NVO-196-17, Revision 4
Effective January 14, 1986

General Comments

1. The staff suggests that WMPO consider revising the title to "Nevada Nuclear Waste Storage Investigations Quality Assurance Requirements" to more appropriately describe the content. It will be less confusing if there is a clear distinction between documents which contain only requirements and documents which contain QA plans (i.e. details of how requirements will be met).

   The staff reviewers had difficulty reviewing the NVO-196-17 document as strictly a requirements document since some of the information provided is "how to" meet the NRC requirements. As an example, on page 4 under 1.0 Organization, a full description of how DOE headquarters and the WMPO organize to conduct the waste management program is provided. Some of the staff comments and questions appended to this letter are related to "how to" meet the requiremtns and will be useful to the DOE in its critique of NVO-196-18 now in preparation by the WMPO.

Response:

The WMPO disagrees with this comment. It is felt that NVO-196-17 adequately establishes that NVO-196-17 is a requirement document. This is stated in the preface (page iii). A title change to NVO-196-17 would impact too many additional NNWSI Project documents which reference the NNWSI Project QA Plan.

2. The "Policy" section of the NNWSI QA plan includes a definition of Level I activities which for waste isolation is tied only to releases to the accessible environment. Activities which affect meeting the other numerical performance objectives of Subpart E of Part 60 are not included in the definition of Level I. The requirements described in the plan could under certain conditions eliminate, for example, the waste package testing and the package itself from the Level I list. The NRC staff's letter to Mr. James Knight of DOE dated March 7, 1986 provided the staff's position on this issue (see response to question 3.1 in the attachment to that letter). The staff believes that all items and activities contributing to meeting the containment and isolation requirements in Subpart E Part 60 should be Level I. The plan should be revised to relect this position.

Response:

It is not the intention of the WMPO to exclude the Waste Package from being assigned a QA Level I designation. NVO-196-17, Rev. 5, Section 2, Paragraph 2.2.2.1 will be revised to clarify this issue. Specifically in the next to the last sentence of this paragraph the words "from the site to the accessible environment after permanent closure" will be deleted.

3. The plan states that Level I activities provide the basis for the NRC to

approve a license for DOE. The plan also states that Level II activities do not support licensing efforts. We disagree. Level II is defined in the plan as including certain NRC licensing-related activities such as radiological health and safety of workers under 10 CFR Part 20. the plan states that Level II activities are not subject to NRC inspection and enforcement. Although classification of these activities as Level II is permissible, certain of them will be reviewed by the staff and findings made by the staff before a license can be issued to DOE. The plan should be revised to relfect this fact. It should also be noted that all activities in the DOE program (Levels I, II, and III) are subject to NRC inspection, if only to assure that activities are correctly classified.

Response:

The statement that Level II activities do not support licensing has been removed. The relationship between QA Level I and QA Level II relative to licensing are presently defined in NVO-196-17, Rev. 5, Section 2, Paragraph 2.2.3. The WMPO acknowledges that all activities in the DOE program (i.e., QA Levels I, II, and III) are subject to NRC inspection if only to assure that activities are correctly classified.

4. The plan states that Level III activities cannot subsequently be used to support Level I activities. No exceptions appear to be permitted by the plan. Although the staff believes that it is not prudent to classify activities as Level III if there is a possibility that they may later be used in licensing, a number of Level III activities have already been performed but could be useful in licensing if their quality can be adequately demonstrated. It is possible that some activities classified as Level III could be qualified for licensing using methods described in the staff's position entitled "Draft Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." The staff therefore suggests the sentence be changed to "...are not expected to be used..."

Response:

The statement that Level III activities can not be used to support Level I activities has been removed in NVO-196-17, Rev. 5. The requirement in NVO-196-17 is that all activities be assigned a QA Level to properly classify this work prior to the start of the work. However, we do keep open the option to process Level III information in accordance with requirements that are consistent with the NRC generic technical position.

5. Figure 3 lists a hierarchy of *criteria* for the NNWSI QA program. In this hierarchy, internal DOE documents are given status equal to NRC requirements and guidance. The process by which conflicts between DOE internal criteria and NRC criteria are identified and resolved needs to be discussed.

Response:

NVO-196-17, Section 2, Paragraph 1.0, states that NVO-196-17 takes

precedence over the documents listed in the hierarchy described in Figure 1. Conflicts between the NNWSI Project QA Plan and NRC criteria will be resolved via the review/comment process between DOE and NRC consistent with what is occuring on Rev. 4 of NVO-196-17. Conflict resolution will be finalized via NRC acceptance of NVO-196-17.

Specific Comments

1. The first sentence of Section 1.4 of the QAP states that the DOE/NV Manager has the ultimate organizational responsibility for the NNWSI Project in the DOE/NV, and Section 1.5 states that the WMPO Director is responsible for the NNWSI Project management (emphasis added). Identify by position title who is responsible for the overall NNWSI program. (1.1)

   Resolution:

   This has been clarified in NVO-196-17, Rev. 5, Policy statement (page xiii) and the Introduction (page xix) paragraphs 2.4 and 2.5. These sections clearly assign responsibility to the DOE/NV Manager for the ultimate responsibility and accountability for the NNWSI Project. However, this responsibility has been delegated to the WMPO Director for the management direction of the NNWSI Project.

2. Discuss how SAI, serving both as a Participating Organization and as DOE/NV's QA Support Contractor, avoids any potential conflict of interest. (1.3)

   Resolution:

   DOE/NV has recognized the perception of a conflict of interest. As a result, DOE is in the process of consolidating the DOE program with the existing T&MSS QA Program so that SAIC will be working under the DOE Program. Accordingly, SAIC will be providing internal Quality Assurance for DOE WMPO/T&MSS activities as well as external Quality Assurance overview of NNWSI Project participant activities.

3. Describe how DOE/NV evaluates the performance of work delegated to others. QAP Section 18.2.1 states that Participating Organizations and NTS Support Contractors shall be audited "periodically." Provide the frequency of such audits or describe how the frequency is determined. (1.4)

   Resolution:

   This item has been clarified in NVO-196-17, Rev. 5, Section XVIII, paragraph 1.2.2. This paragraph requires that an external organizations QA Program be audited a least annually or once during the life of the activity, which ever is shorter. However, for clarity, Section XVIII, paragraph 1.1.1 of NVO-196-17, Rev. 5, will be clarified. In addition, specific details on how WMPO accepts services performed by contractors will be defined in WMPO Procedure QMP-06-03.

4. Show the DOE/DGR on Figure 1 and identify the onsite and offsite organizational elements which function under QA Program controls or justify not doing so. (1.7)

Resolution:

Figure 2 in the Introduction to NVO-196-17, Rev. 5, depicts the NNWSI Project organization. The WMPO organization is described in Figure 3 of the Introduction. All organizations working under the WMPO QA Program are described in the text. These descriptions are also contained in the Introduction to NVO-196-17, Revision 5.

5. Describe measures which ensure that DOE/NV's QAD Director and Project Quality Manager (PQM) are involved in the aspects of the NNWSI that affect safety and waste isolation and that the extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation. (1.8)

Resolution:

The DOE/NV QA Director provides overview of the NNWSI Project for compliance with DOE Order 5700.6B. He also provides review/concurrence of NVO-196-17, and NVO-196-18. The NNWSI Project PQM with support from the Quality Assurance Support Contractor provides direct QA overview of the Participating Organizations and NTS Support Contractors. Paragraph 2.10 of the Introduction to NVO-196-17, discusses the PQM responsibilities. Detailed responsibilities for the PQM are contained in specific implementing procedures and NVO-196-18.

The method for assigning Quality Assurance Levels on the NNWSI Project ensures that the QA staff in combination with the line staff assign the QA Levels in accordance with complexity and the importance to safety or waste isolation. Specific details for assignment of quality assurance levels are currently contained in NNWSI-SOP-02-02.

6. Identify a management position within DOE/NV, each Participating Organization, and each NTS Support Contractor that retains overall authority and responsibility for the applicable QA program. Describe the management, QA, and technical experience and knowledge requirements for these positions. Verify that these positions have the following characteristics:

   a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurements, manufacturing, etc.) and is sufficiently independent from cost and schedule.

   b. Has effective communication channels with other senior management positions.

   c. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.

   d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters. (1.10)

Resolution:

The specific management position with overall responsibility for the QA program for DOE/NV, each Participating Organization, and each NTS Support Contractor is found in the QAPPs of each organization and WMPO. NVO-196-17 Section I, Organization, Paragraph 2.1, specifically requires that this information be contained within each participant's QA Program Plan. Education and experience requirements are mandated by NVO-196-17, Rev. 5, Section 2, Quality Assurance Program, Page 10, Paragraph 5.0.

7. Identify QA Level I activities (if any beyond the exceptions allowed in guidance items 3.7, 10.2, and 11.3 of the NRC Review Plan) where verification of performance to established requirements is accomplished by individuals or groups outside the QA organization. (1.11)

Resolution:

At the present time there are no QA Level I activities that go beyond the exceptions allowed in Sections 3.7, 10.2, and 11.3 of the NRC Review Plan where verification of performance to established requirements is accomplished by individuals or groups outside the QA organization. The requirement for independent verification is presently contained in NVO-196-17, Rev. 5, Section I, Organization, Paragraph 3.2.

8. The last paragraph in Section 1.6 addresses the resolution of disputes which "arise between the PQM and the WMPO Director." Since the PQM reports functionally to the WMPO Director per Figure 1, we would expect disputes to arise between the PQM and others who also report functionally to the WMPO Director (i.e., at the peer level), between the PQM and Participating Organizations, or between the PQM and NTS Support Contractors. Only when the WMPO Director could not resolve such disputes to the PQM's satisfaction would the PQM be required to seek satisfaction through the QAD Director. Clarify the last paragraph in Section 1.6 accordingly or justify not doing so. Also clarify whether DOE/NV's QAD Director and/or PQM have appeal rights into the OGR/OCRWM QA organization. (1.13)

Resolution:

Questions relative to disputes have been clarified in NVO-196-17, Rev. 5, Introduction, Paragraph 2.10.

9. The last 2 paragraphs of the QAP Policy address rationale for assigning Quality Assurance Levels. Clarify whether these rationale include system analyses and whether numerical performance objectives and standards are defined. Justify why not if not. Identify items and activities covered by the QA program. (2.1)

Resolution:

Specific details regarding the assignment of Quality Assurance Levels are contained presently in NNWSI-SOP-02-02. This procedure is scheduled to be

converted into an NNWSI Project Administrative Procedure (AP) in the near future. NVO-196-17, Rev. 5, Section I, Organization, Paragraph 3.0 requires that the QA Program apply to all items and activities affecting quality. Section II of NVO-196-17, Rev. 5, Paragraph 1.5, establishes the methodology for formulating the Q List. Revision 6 to NVO-196-17 will reference the attachment to OGR Supplement 3 of the OGR QA Plan for further guidance.

10. Identify existing or proposed DOE/NV QA procedures reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities, will be met. Appendix D of the QAP appears inadequate to satisfy this. (2.6)

    Resolution:

    DOE/NV QA Procedures are, in actuality, WMPO QA Procedures. These procedures are contained as part of NVO-196-18. These procedures are numbered consistent with the 18 criterion format of 10 CFR 50, Appendix B, however, all 18 elements may not apply to the WMPO.

11. Describe how DOE/NV management (above or outside the QA organization) regularly assess the scope, status, adequacy, and compliance of the QA program to 10 CFR Part 50, Appendix B. These measures should include:

    a. Frequent contact with program status through reports, meetings, and/or audits.

    b. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked. (2.7)

    Resolution:

    Part A of this item will be resolved via Revision 6 to NVO-196-17. This revision will require management outside of QA to receive information as to the scope, status, compliance, etc., of the QA Program. This requirement will be added to Section II, paragraph 1.0.

    Part B of this item is adequately covered in NVO-196-17, Revision 5, Section II, QA Program, Paragraph 4.0.

12. QAP Section 2.4 addresses personnel proficiency. Clarify that indoctrination, training, and qualification programs are established such that:

    a. Personnel responsible for performing quality-related activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

    b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.

c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and the date of attendance.

d. Appropriate management monitors the performance of individuals involved in activities affecing quality and determines the need for retraining and/or replacement. A system of annual appraisal and evaluation can satisfy this criterion.

e. Qualified personnel are certified in accordance with applicable codes and standards. (2.12)

Resolution:

NVO-196-17, Rev. 5, Section II, Quality Assurance Program, Paragraph 5.0, describes the NNWSI Project requirements for personnel selection, indoctrination, and training. Requirements for personnel performing quality related activities to be instructed as to the purpose, scope, and implementation of the quality program are contained in Paragraph 5.1.3. Requirements for personnel verifying activities affecting quality are contained in Paragraph 5.1.1 and 5.1.2. Requirements for documentation of training and qualification programs are contained in Paragraph 5.1.6.2 and Paragraph 5.1.6.3. Requirements for management involvement in monitoring the performance of individuals performing activities affecting quality are contained in Paragraph 5.1.5. Requirements for personnel to be certified in accordance with applicable codes and standards are contained in Paragraph 5.1.

13. Consistent with 10 CFR 60 and the Atomic Energy Act of 1954, modify and expand the definitions of QAP Appendix B as follows:

a. Design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design).

b. Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis.

c. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters. (3.1)

Resolution:

The definitions of design, design information, and design activities are presently contained in NVO-196-17, Rev. 5, Section III, Paragraph 2.1.1. It should be noted, however, that data collection activities associated

with characterization of the site are controlled by the scientific investigation control requirements defined in NVO-196-17, Rev. 5, Section III, Paragraph 1.0. Additionally, activities associated with data collection resulting from performance verification testing of engineered items are controlled by the traditional design control and test control requirements. These requirements are contained in NVO-196-17, Rev. 5, Section III, Paragraph 2.0 and Section XI of NVO-196-17, Test Control.

14. Describe measures which ensure that performance goals are specified for repository subsystems and components to support the establishment of data gathering and analysis needs. Discuss the timeliness of specifying these requirements. At the latest, planned performance allocation should be addressed in the SCP consistent with agreements reached in NRC/DOE meetings of April 17, 1981, and September 26 and 27, 1985, on this matter. (3.2)

Resolution:

The preliminary requirements for each performance and design issue is found in the issue resolution strategy sections of the Site Characterization Plan.

15. Describe measures which ensure that (1) errors and deficiencies in approved design and design information documents are documented and (2) action is taken to ensure that all errors and deficiencies are corrected. (3.4)

Resolution:

Requirement that errors and deficiencies in approved design and design information documents be documented and corrected is contained in NVO-196-17, Section III, Paragraph 2.5.1. Specific details on how this is accomplished will be contained in the Quality Assurance Program Plans and implementing procedures of each NNWSI Project participant that performs design activities.

16. Describe interface controls among organizations or groups involved in design development and other design activities. (3.5)

Resolution:

Requirements for interface control are contained in NVO-196-17, Rev. 5. The interface control requirements for Scientific Investigations are established by Section III, Paragraph 1.7. Interface control requirements for the control of design activities are established by Section III, Paragraph 2.6. Specific details on implementation of these interface requirements will be contained in the Quality Assurance Program Plans and implementing procedures of each NNWSI Project participant.

17. Describe measures which ensure that design drawings, specifications, criteria, and analyses are reviewed by the QA organization to ensure that

the documents have been prepared, reviewed, and approved in accordance with documented procedures and QA requirements. (3.6)

Resolution:

Requirements for quality assurance review of various design documents are contained in NVO-196-17, Revision 5, Section III. Paragraph 2.2.1 of Section III, establishes the requirement for QA to be involved in the review of design inputs. Paragraph 2.3.2, establishes requirements for QA to be involved in the review of design analysis. Paragraph 2.7.1.3 of Section III establishes requirements for QA review of design output. As stated previously, specific implementation details of these requirements will be contained in the Quality Assurance Program Plans and the implementing procedures of each NNWSI Project participant involved in design activities.

18. QAP Section 3.3 addresses Peer Reviews. Describe measures which ensure that peer reviews are conducted of designs or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed. Also describe the selection process for a peer group, the expertise of peer group members, and the process by which the peer group conducts its review. A peer review is a critical review performed by personnel who are independent of, but have expertise at least equivalent to, those who performed the work. Outside consultants should be retained for needed expertise where required. (3.8)

Resolution:

Paragraph 2.1.1.4 of NVO-196-17, Rev. 5, Section III, establishes requirements for peer review of design activities which involve use of untried or state of the art testing and analysis, procedures, and methods or where detailed technical criteria and requirements do not exist. Additional requirements regarding peer review group selection, performance, etc., are contained in Paragraph 4.0 of Section III of NVO-196-17, Rev. 5. Specific details on implementation of these requirements will be contained in implementing procedures.

19. Describe measures which ensure that procedures identify the responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the documentation required. (3.9)

Resolution:

Requirements governing design verification are established by NVO-196-17, Rev. 5, Section III, Paragraph 2.4. Specific details for implementation of these requirements will be contained in implementing procedures of the organization which has responsibility for design.

20. QAP Section 3.1.1 indicates that design verifications ensure changes are controlled and approved by the originating organization. Clarify whether a configuration control system is in place such that design changes, including field changes, are analyzed to ensure they are required, are subject to the same design controls as the original design, are communicated to all affected groups and individuals, and are considered for changes to procedures and training. (3.10)

Resolution:

Requirements for control of design changes including field changes are contained in NVO-196-17, Rev. 5, Section III, Paragraph 2.5.1. Requirements for document control of these design changes are established by Section VI of NVO-196-17. Paragraph 5.1.3 of Section II of NVO-196-17, Rev. 5, will be revised to include the requirement that training be conducted on changes to procedures.

21. Section 3.2 requires a documented plan prior to the start of a site investigation and requires WMPO approval of the plan prior to use. Describe the PQM's responsibilities regarding WMPO review and approval of such plans. Section 3.2 also requires a technical review of the plan by the responsible Participating Organization. Clarify how the responsible Participating Organization's QA organization is to be involved in the development/technical review of the plan. Similarly, Section 3.4 requires criteria letters and/or work requests for work done at the NTS by NTS Support Contractors. Describe QA involvement in the development/review of these documents. (1.1)

Resolution:

Requirements for WMPO review and approval of Scientific Investigation Plans are contained in Section III, Paragraph 1.3.1.2 of NVO-196-17, Rev. 5. Paragraph 2.0 of Section V of NVO-196-17, establishes the requirement for QA review of these documents. Specific details for QA involvement in the review of criteria letters and/or work requests will be contained in NNWSI Project APs.

22. Describe QA and other organizational responsibilities (for DOE/NV, Participating Organizations, and NTS Support Contractors) for (1) procurement planning; (2) the preparation, review, approval,and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. (4.2)

Resolution:

QA and other organizational responsibilities for procurement planning are contained in NVO-196-17, Rev. 5, in the following Sections: Section IV, Paragraph 2.1.3 and Paragraph 2.2; and Section VII, Paragraph 1.1.1 and Paragraph 1.3.1.

23. Describe the scope of the DOE/NV document control program and identify the types of documents controlled by this program. QAP Section 6.0 describes what WMPO required of Participating Organizations and NTS Support Contractors in the area of document control. Clarify that WMPO requires the same of DOE/NV. (6.1)

Resolution:

NVO-196-17, Rev. 5, Section VI, Paragraph 1.1, establishes the scope and types of documents that are controlled by the document control system. Applicability of these requirements to the WMPO are established via Section II, Paragraph 1.0. It should be noted that DOE/NV is, in fact, the WMPO.

24. Describe measures which ensure that the QA organization reviews and concurs with documents controlled in accordance with the document control system with respect to quality-related aspects. (6.2)

Resolution:

Requirements for QA review of documents controlled in accordance with the document control system are established via Section V of NVO-196-17, Rev. 5, Paragraph 2.0.

25. Describe measures which ensure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner. (6.4)

Resolution:

Requirements to ensure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas are contained in Section VI of NVO-196-17, Rev. 5, Paragraph 1.2. Specific control measures will be defined in each organizations implementing procedures.

26. Describe measures which ensure that documents which require verification are not released prior to verification or that if they are released prior to verification they are so identified and controlled. (6.6)

Resolution:

Requirements to ensure that documents which require verification are not released prior to verification are contained in Section VI, Paragraph 3.1 of NVO-196-17, Rev. 5. Specific control measures will be defined in each organization's implementing procedures.

27. Describe measures which ensure that organizations providing items or services to DOE/NV also provide the following related records:

    a. Documentation that identifies the purchased item or service and the specific procurement requirements (e.g., codes, standards, and specifications) met.

b. Documentation identifying any procurement requirements that have not been met.

c. A description of those nonconformance from the procurement requirements dispositioned "accept as is" or "repair."

Describe DOE/NV's procedure for review and acceptance of these documents. (7.3)

Resolution:

Requirements related to procurement records that are required to be provided to the WMPO are contain in Section VII of NVO-196-17, Rev. 5. The requirement for documentation that identifies the purchased item or service and the specific procurement requirements to be met are contained in Paragraph 1.6 of this Section. Requirements for documentation to identify any procurement requirements that have not been met are contained in Paragraph 1.8.1. Requirements that a description of nonconformance from the procurement requirements be provided are contained in Paragraph 1.8.1.2 of Section VII. The WMPO methods for review and acceptance of these documents will be contained in specific implementing procedures.

28. Describe measures which ensure that suppliers' certificates of conformance are periodically evaluated by audits, independent inspections, or tests to ensure they are valid and the results documented. (7.4)

Resolution:

Requirements relative to supplier certificates of conformance are contained in NVO-196-17 Rev. 5, Section VII, Paragraph 1.6.1.1. Specific requirements governing the periodic evaluation of supplier certificates of conformance will be contained in implementing procedures of each organization.

29. Describe measures which ensure that, in developing QA requirements for data collection test equipment and other equipment, consideration is given to whether proper performance of a test can be determined during or after testing (i.e., whether failure or malfunction of test equipment can be detected). Where no specific QA controls are found to be necessary, special quality/performance verification requirements are established and described in procedures governing the use of the equipment. (7.5)

Resolution:

The requirements governing the acceptance of an item for use on the NNWSI Project are contained in Section VII of NVO-196-17, Rev. 5. Paragraph 1.6 of this section identifies the various methods of acceptance. In addition, if the item is measuring and test equipment the requirements of Paragraph 2.3 of Section XII also apply to insure proper calibration prior to and post use.

30. Describe measures which ensure the correct identification of materials, parts, components (including core, cuttings, and other field and laboratory samples) is verified and that the verification is documented prior to release for use or analysis. (8.4)

Resolution:

Requirements governing the identification of material, parts, and components, including core, cuttings, and other field and laboratory samples are contained in Section VIII of NVO-196-17, Rev. 5. The requirement that data be verified prior to its release for use are established by Paragraph 1.1, Part B of this Section. Requirements that the identification of samples be verified prior to release are contained in Paragraph 1.1.1 of Part C of Section VIII. Paragraph 1.0 of Part A of Section VIII will be revised to require the verification of the identification of items prior to installation or use.

31. QAP Section 9.4 indicates that special process procedures will be forwarded to WMPO for review and approval prior to use. Clarify that WMPO approval must be obtained prior to use. Describe DOE/NV QA and other organizational responsibilities for qualification of special processes, equipment, and personnel. Provide examples of processes during site characterization that will be classified as special processes and those which will not. (9.2)

Resolution:

The WMPO is no longer responsible for the approval of NNWSI Project participant implementing procedures prior to use. It is the responsibility of the QA organization of each NNWSI Project participant to review and approve their implementing procedures prior to use. The WMPO shall ensure the adequacy of these procedures during audit and surveillance activities. Responsibilities of WMPO QA and other organizations relative to the qualification of special process equipment and personnel will be defined in each NNWSI Project participant's QA Program Plan or implementing procedures if they perform these activities. It should be noted that NVO-196-17, Rev. 5, Section IX, Paragraph 1.0 states that the requirements for special processes apply to engineered items only.

32. Describe measures which ensure that evidence is recorded of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel. (9.4)

Resolution:

NVO-196-17, Rev. 5, Section IX, Paragraph 2.6, requires that records shall be maintained for qualified personnel, procedures, and equipment of each special process and that the requirements for maintenance of these records shall be specified. NVO-196-17, Rev. 5, Section V, Paragraph 1.0, requires that instructions, procedures, and plans, used to implement activities affecting quality shall include a section that identifies the

QA records which are generated during implementation of the activity. Implementing procedures of each NNWSI Project participant who perform special processes shall contain detailed methodology for meeting these requirements.

33. QAP Section 10.0 addresses inspections by "individual participants." Clarify whether this includes inspections by WMPO personnel. Indicate how the WMPO technical branches, the QASC, and the WMPO Project Quality Manager participate in determining when inspections are required and in defining how and when inspections are performed. (10.1)

Resolution:

NVO-196-17, Rev. 5, Section X, Paragraph 1.0, states that inspection requirements apply to engineered items only and do not apply to Scientific Investigations. Specific details for WMPO inspection planning activities will be contained in the WMPO Quality Management Procedures (QMPs). The responsibilities of the WMPO, the technical branches, the QASC, and the PQM will be described in these procedures. These procedures will govern the inspection activities for which WMPO is responsible.

34. Guidance item 10.2 in Appendix A of the NRC QA Review Plan indicates that individuals performing inspections should be part of the QA organization with provisions for other individuals being used for inspections requiring special expertise provided the independence of the inspection function is maintained. We note that QAP Section 1.4 indicates that the WMPO Technology Development and Engineering Branch and the WMPO Geological Investigations Branch are responsible for quality control, and it is not clear whether guidance item 10.2 is being met by WMPO, Participating Organizations, and NTS Support Contractors. If the quality control function is part of the line organization, clarify that the QA organizations perform periodic surveillances to confirm that inspection personnel are sufficiently independent from the individuals performing the activity being inspected. (10.2)

Resolution:

The Quality Control (QC) function is presently a line responsibility on the NNWSI Project. WMPO shall ensure during audit and surveillance activities that a review is performed to ensure that independence exists. NVO-196-17, Rev. 5, Section X, Paragraph 2.1, requires that the QA organization verify independence and the need for special expertise.

35. Clarify that qualification programs for inspectors are established and documented, and the qualifications and certifications of inspectors are kept current. (10.3)

Resolution:

NVO-196-17, Rev. 5, Section X, Paragraph 2.2, requires that each person who verifies conformance of work activities for purposes of acceptance

shall be qualified and that this qualification shall be certified in writing. Appendix C to NVO-196-17, Rev. 5, establishes the specific qualification requirements that apply to inspection personnel.

36. QAP Section 10.3 indicates some specific information that will be included on inspection documents. Clarify that this will include the following as well.

    a. A description of the method of inspection.

    b. Identification (including applicable revision) of required procedures, drawings, and specifications. (10.4)

    Resolution:

    NVO-196-17, Rev. 5, Section X, Paragraph 9.1, specifies the minimum information that must be included on inspection records. Item 5 of this paragraph requires a description of the type of observation. This item will be modified to include "method of inspection." Item 6 requires that the inspection criteria be recorded. Item 6 will be modified in Rev. 6 to NVO-196-17 to require the identification of drawings, specifications, etc., that were used to perform the inspection (including revisions).

37. Describe measures which ensure that procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector. (10.5)

    Resolution:

    NVO-196-17, Rev. 5, Section X, Paragraph 3.0, establishes the requirements for inspection hold points. This paragraph requires that hold or witness points be indicated in appropriate documents controlling the activity.

38. Describe measures which ensure that the acceptability of inspection results is determined and documented by a responsible individual. (10.6)

    Resolution:

    NVO-196-17, Rev. 5, Section X, Paragraph 6.1, establishes inspection requirements including the requirement that quality records be examined for adequacy and completeness. Paragraph 9.1 of Section X of NVO-196-17, Rev. 5, specifies the requirements for the content of inspection records. Appendix C, Paragraph 2.0 to NVO-196-17, Rev. 5, establishes the functional qualifications for various levels of inspection personnel including determining the acceptability of inspection results.

39. Describe measures which ensure that procedures (1) provide criteria for determining when a test, an experiment, or research is required and (2) require such activities to be performed by appropriately trained and qualified personnel. (11.1)

Resolution:

NVO-196-17, Rev. 5, Section XI, Paragraph 3.1, establishes the requirement that test procedures or instructions contain criteria for determining when a test is required. Paragraph 1.0 and 3.2 of this section of NVO-196-17, Rev. 5, establish the requirement that such activities be performed by appropriately trained and qualified personnel.

40. Describe measures which ensure that test, experiment, and research plans, procedures, and results are reviewed in accordance with the verification requirements for designs and relate to allocation of performance to various components of repository systems. (See guidance items 3.7, 3.8, and 3.9 of the NRC Review Plan.) (11.2 and 11.5)

Resolution:

NVO-196-17, Rev. 5, Section XI, Paragraph 3.3, establishes the requirement that test plans and procedures be reviewed in accordance with the verification requirements defined in paragraph 2.4 of Section III of NVO-196-17. It should be noted that requirements for research and experiment plans are covered by the Scientific Investigation requirements of Section III of NVO-196-17, Rev. 5.

41. Describe measures which ensure that identification of (1) potential sources of uncertainty and error in test, experiment, and research plans and procedures and (2) parameters which must be controlled and measured. (11.3)

Resolution:

NVO-196-17, Rev. 5, Section XI, Paragraph 3.4, requires the identification of potential sources of uncertainty and error in test procedures which must be controlled and measured to ensure that tests are well controlled. It should be noted that this paragraph applies to test plans only. Controls on research and experiment activities are contained in Section III of NVO-196-17, Rev. 5. Requirements for parameters which must be controlled and measured are contained in NVO-196-17, Rev. 5, Section XI, Paragraph 3.2, which establishes requirements for test prerequisites, including the requirement that test procedures include or reference test objectives and provisions for ensuring that prerequisites for the given test have been met.

42. Describe measures which ensure that test, experiment, and research procedures or instructions provide for the following:

    a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy.

    b. Instructions for performing the activity.

c. Prerequisites such as calibrated instrumentation, adequate equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for test data collection and storage.

d. Mandatory inspection hold points (as required).

e. Acceptance and rejection criteria, including required levels of precision and accuracy.

f. Methods of data analysis.

g. Methods of documenting or recording test data and results.

h. Provisions for assuring prerequisites have been met. (11.4)

Resolution:

Specific requirements relative to test procedures or instructions which address the NRC concerns in this area are contained in NVO-196-17, Rev. 5, Section XI, in the following paragraphs.

a. Paragraph 2.0,

b. Paragraph 3.1,

c. Paragraph 3.2,

d. Paragraph 3.3,

e. Paragraph 2.0,

f. Paragraph 3.3,

g. Paragraph 5.0, and

h. Paragraph 3.2.

It should be noted that the requirements of Section XI do not apply to experiment and research activities. These activities are controlled by the scientific investigation control requirements of Section III of NVO-196-17, Rev. 5.

43. Describe QA and other organizations' responsibilities for establishing, implementing, and assuring effectiveness of the calibration program. (12.2)

Resolution:

NVO-196-17, Rev. 5, Section XII, Paragraph 1.3, establishes the requirement that the responsibilities of all organizations involved in the establishment, implementation, and assurance that the calibration program is effective be described. Specific responsibilities will be contained in

the implementing procedures of the organizations responsible for performing calibration activities.

44. Describe measures which ensure that measuring and test equipment is calibrated at specified intervals based on required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions which would affect measurement. (12.5)

Resolution:

NVO-196-17, Rev. 5, Section XII, Paragraph 2.3, establishes the requirements for determining the calibration interval. This paragraph will be modified in Rev. 6 to NVO-196-17, to add that precision and degree of usage be considered when establishing a calibration interval.

45. QAP Section 15.1 indicates that nonconformances shall be reviewed and dispositioned by the involved Participating Organization or NTS Support Contractor. Identify to a lower organizational level those authorized to dispose of and close out nonconformances. (15.1)

Resolution:

NVO-196-17, Rev. 5, Section XV, Paragraph 1.4.2, requires that the responsibility and authority for the evaluation and disposition of nonconforming items be defined and documented. The implementing procedures of the NNWSI Project participants will define the specific responsibilities relative to nonconformance control.

46. Describe QA responsibilities within WMPO, Participating Organizations, and NTS Support Contractors related to nonconformance control. (15.2)

Resolution:

See the response to NRC comment 45. Specific WMPO responsibilities for nonconformance control shall be contained in the WMPO Quality Management Procedures.

47. Describe measures which ensure that nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of nonconformances and that significant results are reported to upper management for review and assessment. (15.4)

Resolution:

NVO-196-17, Rev. 5, Section XV, Paragraph 4.0, establishes the requirement that nonconformance reports be analyzed by the QA organization for quality trends and to identify the root causes of nonconformances and that these results be reported to upper management for review and assessment. Specific methodology for accomplishing this trending will be contained in the implementing procedures of the NNWSI Project participants.

48. Describe measures which ensure that corrective action is documented and initiated following a nonconformance to preclude recurrence, that a QA organization is involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied, that corrective action is accomplished in a timely manner, and that the responsibility for follow-up action mentioned in 16.2 is assigned to a QA organization. (16.2 and 16.3)

Resolution:

NVO-196-17, Rev. 5, Section XV, Paragraph 2.0, requires that when repetitive or recurring nonconforming conditions are identified an evaluation be made to determine whether further programmatic action is warranted to preclude repetition. This corrective action shall be beyond the scope of the action taken for the disposition on the existing NCR and shall be controlled in accordance with the corrective action procedures developed by each NNWSI Project participant. Requirements for corrective action are defined in Section XVI of NVO-196-17, Rev. 5. This section will be rewritten in Rev. 6 of NVO-196-17, to address the NRC concerns in this area.

49. Clarify that "appropriate management" referred to in 16.2 includes both the management responsible for accomplishing the corrective action and upper levels of management responsible for review and assessment. (16.4)

Resolution:

See response to NRC comment 48.

50. Describe the scope of the QA records program in more detail, i.e., identify the types of records to be maintained. (17.1)

Resolution:

NVO-196-17, Rev. 5, Section XVII, Paragraph 1.1, defines the scope of the QA records program. Appendix E to NVO-196-17, Rev. 5, establishes a list of typical QA records to be maintained. NVO-196-17, Rev. 5, Section V, Paragraph 1.0, requires that instructions, procedures, and plans used to implement activities affecting quality contain a section which identifies the QA records which are generated during implementation of the activity.

51. Describe the responsibilities of WMPO's QA and other organizations for the definition and implementation of activities related to QA records. Identify the organization responsible for the Records Management Plan. Provide the reporting relationship of the Project Records Center. (17.2)

Resolution:

The QA responsibilities as well as the responsibilities of other organizations related to QA records will be described in the Information Management System Plan (IMS Plan) which is currently being developed.

52. Describe requirements for the facilities used for the storage of records. (17.4)

Resolution:

NVO-196-17, Rev. 5, Section XVII, Paragraph 10.0, establishes the requirements that apply to both permanent and temporary records storage facilities.

53. QAP Section 18.1.1 indicates audits are scheduled and performed on the basis of "impact to the Project." Clarify that "impact to the Project" relates to the status and safety importance of the activities being performed and that audits are initiated early enough to ensure effective QA. (18.2)

Resolution:

NVO-196-17, Rev 5, Section XVIII, Paragraph 1.2, establishes the requirement that audits be scheduled at a frequency commensurate with the status and importance of the activity. This paragraph will be modified via Rev. 6 to NVO-196-17, to require that these audits be initiated early enough to assure effective QA.

54. Describe measures which ensure that audits include an objective evaluation of the quality-related practices, procedures, instructions, activities, and items and the review of documents and records to ensure that the QA program is effective and properly implemented. (18.3)

Resolution:

NVO-196-17, Rev. 5, Section XVIII, Paragraph 1.0, establishes requirements that audits include an objective evaluation of the quality related practices, procedures, instruction, activities, and items and a review of documents and records to ensure that the QA program is effective and properly implemented.

55. Describe measures which ensure that audit data are analyzed by the QA organization and the results are reported to responsible management for review, assessment, and appropriate action. (18.4)

Resolution:

NVO-196-17, Rev. 5, Section XVIII, Paragraph 1.0, establishes the requirement that audit results shall be documented, reported to, and reviewed by responsible management. Paragraph 1.7, of this section requires that audit results be analyzed to identify quality trends.

56. Describe measures which ensure that audits are led by appropriately qualified and certified personnel from the QA organization, that the audit team membership includes personnel (not necessarily QA organization

personnel) having technical expertise in the areas being audited, and that technical and QA programmatic audits are performed to provide a comprehensive independent verification and evaluation of procedures and activities affecting quality.

Resolution:

NVO-196-17, Rev. 5, Section XVIII, Paragraph 1.3.2, requires that the qualifications of QA audit personnel be in accordance with Appendix F. Appendix F contains specific requirements for the qualification and certification of QA audit personnel. Paragraph 1.3.3 of this section will be modified in Rev. 6 to NVO-196-17 to require that the audit team leader identify the technical specialists who will participate in the audit and that this information be included in the audit plan. Paragraph 1.2 of this section requires that all elements of an organizations QA Program Plan be audited at least annually.

57. Describe measures which ensure that a tracking system for audit findings is established to help assure that all findings are appropriately addressed and to trend audit findings. (18.6)

Resolution:

NVO-196-17, Rev. 5, Section XVIII, Paragraph 1.0, establishes the requirement for tracking systems to be instituted for audit findings to help assure that all findings are appropriately addressed and to trend audit findings. Specific methodology to implement these requirements will be contained in the implementing procedures of each NNWSI Project participant.

58. Describe measures which ensure that the root cause of each adverse audit finding is identified and corrective action for it is described. (18.8)

Resolution:

NVO-196-17, Rev. 5, will be modified to require the identification of root cause for audit findings. Specific methodology will be contained in the implementing procedures of each NNWSI Project participant. This requirement will be added to Paragraph 1.6 of NVO-196-17, Rev. 5, Section XVIII.

59. QAP Appendix C provides modifications to ANSI/ASME NQA-1 for Level I program considerations. Clarify whether items II.A, IV.A through E, V.A, XI.A through E of Appendix C are replacements or additions to NQA-1.

Resolution:

Item II.A. This item exceeded the requirement of NQA-1 and therefore was deleted in NVO-196-17, Rev. 5.

Item IV.A. This item represents an addition to NQA-1 supplement 3S1. This information is presently found in Appendix B to NVO-196-17, Rev. 5.

Item IV.B. The requirements for use of the immediate supervisor to do design verification are as per NQA-1, 1983, as modified by the NRC Standard Review Plan, June 1984. These requirements are contained in NVO-196-17, Rev. 5, Section III, Paragraph 2.4.5.3.

Item IV.C. This represents an addition to NQA-1 in order to satisfy the NRC Standard Review Plan requirement 3.8. This requirement is found in NVO-196-17, Rev. 5, Section III, Paragraph 4.0.

Item IV.D. This item exceeded the requirements of NQA-1 and therefore was deleted in Rev. 5 of NVO-196-17. However, NVO-196-17, Rev. 5, Section XV, Paragraph 1.4.4, describes the "as built records" to be generated as a result of nonconformance disposition. Normal design changes are governed through the design change control requirements specified in Section III of NVO-196-17, Rev. 5.

Item IV.E. This item exceeded the requirements of NQA-1 and therefore was deleted. However, the requirements in NVO-196-17, Rev. 5, are consistent with the NRC Standard Review Plan requirements relative to evaluating design changes.

Item V.A. This is an addition to NQA-1 and exceeds the requirements of NQA-1. These requirements are contained in NVO-196-17, Rev. 5, Section IV, Paragraph 2.1.7.

Item XI.A. This represents an addition to NQA-1. These requirements are contained in NVO-196-17, Section XVIII, Paragraph 1.2.1.

Item XI.B. This represents an addition to NQA-1. These requirements are contained in NVO-196-17, Rev. 5, Section XVIII, Paragraph 1.2.2.

Item XI.C. This item exceeded the requirements of NQA-1 and therefore has been deleted. Audits are performed based on the importance of the activity.

Item XI.D. This item relates to requirements contained in a nonmandatory appendices of supplement 18A-1 of NQA-1. These requirements have been retained in Section XVIII to NVO-196-17, Rev. 5, although they have been modified to some extent.

Item XI.E. This represents an addition to NQA-1 and therefore was deleted. NVO-196-17, Rev. 5, Section XVIII, Paragraph 1.8 is consistent with supplement 18S-1 of NQA-1 relative to audit records.

60. Identify and justify differences between the guidance in the NRC QA Review Plan, "Quality Assurance programs for Site Characterization of High-Level Nuclear Waste Repositories," and the DOE positions in the NNWSI QA Plan. In cases where NQA-1 provides more detailed guidance than the NRC QA Review Plan but does not contradict it, no justification need be provided.

Resolution:

The NNWSI Project QA Plan, NVO-196-17, Rev. 5, is consistent with the NRC Standard Review Plan with the exception of item 3.1. See response to NRC comment 13.

61. Section 1 of the NNWSI QA Plan describes the DOE/NV matrix organization for managing the NNWSI project. The NRC staff has recommended against the use of such matrix organizations based on the results of the congressionally mandated study concerning the quality and QA in the design and construction of nuclear power plants. (See NUREG 1055.) Discuss how DOE/NV will overcome the shortcomings of this type of organization.

Resolution:

It is the opinion of the NNWSI Project that the NRC has revised their position on the use of matrix organizations since this type of organization was evaluated during the recent NRC audit of LANL and no deficiencies were noted concerning the use of the matrix type organization. Therefore, no further response to this item is required.

Editorial Comments

1. A list of abbreviations should be included.

Response:

All acronyms are spelled out at the point of first usage, therefore, a list of abbreviations is not required.

2. The last sentence of the second paragraph of the Policy refers to the NRC licensing "process." It appears that reference to the NRC licensing "requirements" would be more appropriate. Clarify.

Response:

Agree. NVO-196-17, Rev. 5, Section 2, Paragraph 1.6, will be revised to read "licensing requirements," in lieu of "licensing process."

3. Since DOE/NV stands for the Nevada Operations Office of DOE, "Operations Office" should follow "Nevada" in the heading of Section 1.4.

Response:

This has been corrected in NVO-196-17, Rev. 5, Introduction, Paragraph 2.4.

4. Section 1.10.2.3 states: "SNL is responsible for .... thermal and mechnical properties of the host rock...." Clarify that this responsibility is for determining (or measuring or verifying or whatever) these properties.

Response:

Agreed. NVO-196-17, Rev. 5, Introduction, Paragraph 2.16.2.3, item 5 will be modified to indicate that the SNL responsibility is to determine the properties of the host rock.

5. It appears that the word "drawings" at the end of QAP Section 3.1.3 should be "drawings and specifications." Clarify.

Response:

NVO-196-17, Rev. 5, Section 3, Paragraph 2.7.1.3, defines the WMPO participation in the design verification process of design output documents. Design output documents are defined in Appendix A to NVO-196-17.

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