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Mr. Robert R. Loux
Executive Director
Agency for Nuclear Projects
Nuclear Waste Project Office
Capital Complex
Carson City, Nevada 89710

NOV 25 1988

Dear Mr. Loux:

The purpose of this letter is to provide the Nuclear Regulatory Commission (NRC) staff's comments on the Nuclear Waste Project Office Quality Assurance Manual (NWPO QA Manual) dated June 10, 1988. The NWPO QA Manual is comprised of 4 sections, namely, the Statement of Quality Assurance Policy, Quality Assurance Program, Quality Assurance Procedures, and the Glossary of Definitions.

The purpose of our review is to determine whether the NWPO QA Manual contains adequate requirements and controls to address the appropriate criteria of Appendix B to 10 CFR Part 50 and thus serve as the framework to develop specific policies, plans, and procedures to implement the NWPO QA Manual. The criteria for our review were 10 CFR Part 60, Subpart G and various staff guidance documents and consensus standards. These included: the "NRC Review Plan - Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories;" staff technical positions on "Peer Review" (NUREG-1297); "Documentation of Computer Codes for High-Level Waste Management" (NUREG-0856); ANSI/ASME NQA-1-1986; and Regulatory Guide 1.28 (endorses ANSI/ASME NQA-1-1983).

As a result of our review, a Request for Additional Information is enclosed. The staff believes a working meeting between the NWPO personnel and NRC staff would be beneficial to develop a firm understanding of the functioning QA relationships and QA responsibilities of the NWPO and its contractors and to discuss the staff's comments. It is suggested this meeting take place within the next few weeks after receipt of this letter. Should you have any questions concerning our review, please contact Bill Belke of my staff at (301) 492-0445. Should you agree that a meeting would be useful, please call Joe Holonich of my staff at (301) 492-3403.

Sincerely,

ORIGINAL SIGNED BY

John J. Linehan, Acting Director
Repository Licensing Project Directorate
Division of High-Level Waste Management

Enclosure: As stated

cc: S. Zimmerman, State of Nevada

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State of Nevada
Agency for Nuclear Projects
Nuclear Waste Project Office
QA Program Review
Requests for Additional Information

The following Requests for Additional Information were generated as a result of staff review of the NWPO QA Manual:

GENERAL COMMENTS

A. On page 1 of the Table of Contents for the NWPO QA Manual, it is indicated that the NWPO QA Manual is comprised of 4 sections namely, Statement of Quality Assurance Policy, Quality Assurance Program, Quality Assurance Procedures, and Glossary. These four sections of the NWPO QA Manual have formed the basis for the staff's review and a determination of whether the NWPO QA Manual meets the staff review criteria. Consequently, provisions should be included in the NWPO Manual to notify the staff of any changes that reduce the commitments in the NWPO QA Manual.

C. Page 17-2 of the QA Manual, item 8 lists "topical reports" as a quality assurance record. Clarification or a definition should be provided on what a "topical report" is.

SPECIFIC COMMENTS

1. The QA Program consistently references its application to "significant activities performed by the Agency for Nuclear Projects/Nuclear Waste Project Office...". The Glossary Section of the QA Manual defines "significant activity" as, "A technical or administrative activity which has important impact on NWPO's technical goals and objectives, synonymous with the words, "important activity".

   A clarification of the definition for "significant activity" would assist the staff in understanding the scope of the program's application and the specific types of activities that are included. The Compliance Demonstration Report states, on Page 01-9, "...NWPO considers all NWPO-sponsored activities equally significant for purposes of QA control...". Since this is not clearly defined in the QA Program manual and the Compliance Demonstration Report is not identified as part of the QA Manual, clarification of the term 'significant activity' should be added to the QA Program Manual. Clarify how the Compliance Demonstration Report will be used in the overall structure of the NWPO Program and whether it will be used as a controlled QA document.

2. Page 00-2 of the NWPO QA Program states that it is committed to relevant requirements of several master documents as they apply to NWPO's objectives and activities and then cites 10CFR50, App. B; 10CFR60 Subpart G; ANSI/ASME NQA-1-1986; NRC Review Plan; NUREG-0856; NUREG-1297 and NUREG-1298. Clarification is needed in the following areas:

a. There are several references throughout the QA Manual which state that the program meets/conforms to the intent of a referenced NUREG; for example:

   - Pg. 03-2 states: "...computer programs by NWPO conform to the intent of NUREG-0856;

   - Pg. 03-3 states: "...peer reviews are conducted in accordance with QAP-3.3 which conforms, as applicable, to the intent of... of NUREG-1297.

   The staff is unclear as to the degree of commitment to a requirement when the program states that it meets the "intent" of a document. Clarification is needed.

b. The NWPO QA Program does not clearly state which relevant requirements, of the documents referenced on Page 00-2, apply to the scope of the program and which do not.

   Clarification as to which specific requirements of the documents referenced on Page 00-2 apply to the scope of the NWPO QA Program needs to be provided.

3. Position 1.7 of the RP requests that organization charts clearly identify the "onsite" and "offsite" organizational elements which function under the cognizance of the QA Program and the lines of responsibility.

   The NWPO QA Program includes organization charts which describe the NWPO, contractor and subcontractor organizational reporting lines.

   Provide clarification by describing the responsibilities and activities that will be conducted by each of the organizational elements shown.

4. Position 2.8 of the RP requests that personnel qualification programs be established and that qualified personnel be certified in accordance with applicable codes and standards. In addition, Position 10.3 of the RP requests that a qualification program for inspectors be established and documented and the qualifications and certifications of inspectors be kept current.

   The NWPO QA Program, Section 02 Page 02-5 states, "Personnel are qualified in accordance with applicable standards and procedures." Provide clarification as to which standards are required as the basis of personnel qualifications and provide a description of the qualification program that will be implemented.

   The QA Program, Page 01-9, references NQA-1-1986 Supplement 2S-3 as the basis for certification of a Lead Auditor. The Program does not currently reference or contain an implementing procedure for qualification/certification of Lead Auditors. In addition, the program is not specific on the qualification standards to be used for inspection personnel and the implementing procedure that will be used to describe and implement the qualification activity.

5. The NWPO QA Program, Section 03, Page 03-1 states, "...Specifically, NWPO and its contractors and subcontractors perform activities such as, but not limited to: critical review and analysis of existing data, monitoring (surveillance) of DOE-sponsored core drilling, monitoring of DOE acquisition of hydrogeologic data, and detailed review of DOE proposed design."

   The NWPO QA Program does not provide for procedures to:

   - conduct critical review and analysis of existing data (also, specify the requirements which are the basis for this procedure, i.e.: NUREG-1298, Generic Technical Position on Qualification of Existing Data for High Level Nuclear Waste Repositories");

   - monitor (surveillance) of DOE-sponsored core drilling or DOE acquisition of hydrogeologic data;

   - conduct detailed reviews of DOE-proposed designs

6. The NWPO QA Program, Section 00-Introduction states in part: "...Through its QA Program, NWPO is committed to relevant requirements of the following master documents as they apply to NWPO's objectives and activities and as they do not contradict the State of Nevada Administrative Code or laws of the United States or of the State of Nevada."

   Clarify/identify the "relevant requirements" of the documents listed and justification for those not invoked. Clarify/identify any requirements which are known to contradict the State of Nevada Administrative Code or the laws of the U.S. or the State of Nevada that will not apply to the NWPO Program.

7. The NWPO QA Program states, Pg. 01-8, that the QA Manager has the responsibility and authority to "...recommend the stopping of unsatisfactory work." Provide clarification as to whom, within the NWPO organization, this recommendation is made and where ultimate stop work authority rests.

8. Position 1.8 of the Standard Review Plan (RP) requests a description of how the QA organization is involved in the aspects of the high-level waste repository program that affect safety and waste isolation and that the extent of QA controls be determined by the QA staff in combination with the line staff dependent on the specific activity.

   The NWPO Compliance Demonstration Report states, Page 01-9, "...NWPO considers all NWPO-sponsored activities equally significant for purposes of QA control. Contractors/subcontractors obligations are defined by the QA program... the QA Manager uses audits and other means to impose whatever degree of QA control is needed to assure the quality of any particular activity or item."

   Clarify how the NWPO program establishes/defines the degree of QA controls needed to assure the quality of an activity or item prior to the conduct of an audit.

9. Position 2.4 of the RP requests that the QA organization reviews and documents concurrence with the quality-related procedures relative to QA requirements. Although there are several areas in the NWPO QA Program which repeat this requirement, i.e.: QAP-2.1 and 2.2, the QA Program/procedures does not describe/define the specific review criteria to be used during the review. Clarification which specifies the review criteria is requested.

10. Position 2.6 of the RP requests that the existing or proposed QA procedures and detailed technical procedures which reflect each of the 10CFR50, App. B criterion, be identified. Although the QA Manual lists the QA procedures for Criteria 1-6 and 15-18, it does not list the procedures that will address Criteria 7-14. Also, a listing of the detailed technical procedures has not been provided. Clarification would assist the staff's review.

11. Position 3.6 of the RP requests that design drawings, specifications, criteria and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

    Page 03-6 of the Compliance Demonstration Report indicates the RP criterion is satisfied by the auditing process and review of procurement documents only. Audits generally are a random type activity which determine the adequacy and compliance of a particular procedure, code, standard, drawing etc. Audits also generally are not performed to determine process control or product acceptance. A review, however, is a detailed documented activity to assure the activity has been accomplished in accordance with a particular procedure, code, standard, drawing etc., and reviewed to assure it includes prescribed QA requirements.

    Clarification is needed to assure audits will accomplish the same purpose as a review.

12. Position 3.3 of the RP requests that organizational responsibilities be described for... approving... and validating design and design information documents. The NWPO QA Program, Section-03, Page 03-1, states, "NWPO... ensures documented preparation, independent review (or other forms of verification) and (as needed) approval and validation of NWPO-generated data acquisition or analyses documents...". Clarify how the determination will be made as to when "...approval and validation of NWPO-generated data acquisition or analyses documents" will be needed.

13. Position 3.7 of the SRP requests that, in exceptional cases, when the designer's immediate supervisor can perform the verification, the need is individually documented and approved in advance with concurrence of the QA Manager. This position does not appear to be addressed in the NWPO QA Program; clarification is requested.

14. Position 4.1 of the RP requests that procedures be established for the review of procurement documents by QA personnel to determine that applicable requirements/criteria are addressed to include "design bases". The NWPO Compliance Demonstration Report specifically states, Pg. 04-1, "...the QA Manager reviews procurement documents for QA requirements but not for technical requirements as implied by items such as "design bases" and "accept/reject criteria"... These are reviewed by others as indicated in QAP-4.1."

The staff's review of QAP-4.1 did not identify the inclusion of "design bases" as a review criteria for either QA or technical staff. Clarification as to whether this is included in the NWPO Program is requested.

15. Position 5.1 of the RP requests that instructions, procedures and drawings be verified and approved as described in Section 3.0. Provide clarification as to where this is addressed in the program.

16. Positions 9.1-9.5 of the RP provide for program requirements which address activities related to the control of special processes. The NWPO specifies in both its QA Program and the Compliance Demonstration Report that there are not NWPO-sponsored activities that fall within the scope of the term 'special process'. Provide justification that special process are not activities within the scope of the NWPO Program.

17. Position 10.2 of the RP requests that individuals performing inspections be part of the QA organization. However, the NWPO Compliance Demonstration Report, Page 10.2, states in its justification for not meeting this RP position that "...Inspectors are not part of the QA organization because such an arrangement would not be feasible or desirable considering the size and nature of NWPO's and contractor's organizations...".

    The staff requests clarification that describes the type of QA overview activity that would occur for inspections, such that when the individuals performing inspections are not part of the QA organization, the inspection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule are reviewed and found acceptable by the QA organization prior to the initiation of the activity.

18. Position 11.0 of the RP discusses the programmatic aspects of an acceptable test control program.

    The NWPO QA Program states that there are no NWPO, contractor or subcontractor activities that fit the definition of testing of NQA-1, 1986 or the NRC Review Plan. However, there are several examples throughout the QA Program which refer to "testing" activities, e.g.: QAP-2.2, Figure 4.18-1; QAP-4.1, Figure 4.3-1. [NOTE: Examples may not be inclusive of all references to "testing"]. Clarification is requested to establish whether testing activities are appropriate to the NWPO Program and, if they are, to have those aspects of the RP Position 11.0 described in the NWPO QA Program. If testing is not appropriate, then justification as to how this determination is made needs to be provided.

19. Position 11.4 of the RP establishes several criteria which are to be addressed in test plans and procedures. The NWPO QA Program, Section 11, establishes that these criteria will be used when technical procedures are developed/ implemented for "technical activities of an investigative nature including laboratory research activities."

    Several of these criteria are not addressed in the NWPO QA Program and clarification is requested as to how the following are included:

    11.4(a) requirements and acceptance limits are contained in applicable documents including precision and accuracy

11.4(c) Test prerequisites such as...adequate test equipment and instrumentation, completeness of item to be tested...

11.4(e) acceptance and rejection criteria, including required levels of precision and accuracy.

20. Position 12.1 of the RP requests that the scope of the measuring and test equipment control program be described.

    The NWPO QA Program, Section 12, states in part "...The equipment control procedures address all measuring and test equipment in which faulty accuracy or precision can significantly affect data generated by the equipment and analyses based thereon...".

    Provide clarification as to the criteria that are to be used to determine which instrumentation/equipment will included in the scope of the NWPO program based on the definition above.

21. Position 12.2 of the RP requests that QA and other organizations' responsibilities be described for establishing, implementing and assuring the effectiveness of the calibration program.

    The NWPO QA Program, Section 12, provides for QA involvement in the measuring and test equipment control program during the review of related nonconformances and corrective action.

    Provide clarification in Section 12 as to QA involvement in establishing, implementing and assuring the effectiveness of the calibration program.

22. 10CFR50, App. B-Criterion XIII Handling, Storage and Shipping states in part, "Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with... instructions to prevent damage or deterioration..."

    The NWPO QA Program does not address handling, storage and shipping requirements that apply to material and equipment per 10CFR50, App. B. Clarification as to how these requirements will be addressed in the program is requested.

23. Position 13.1 of the RP requests that for activities related to samples, requirements be established for sample, handling, preservation, storage, packaging, and shipping of same.

    The NWPO QA Program does not specify the requirements to be implemented for these activities. Applicable requirements need to be established in the QA Program.

24. Position 14.1 of the RP requests that procedures be established to indicate by the use of markings, the status of inspections and tests on individual items.

    Although the NWPO QA Program takes exception to Criterion 14 of 10CFR50, App. B and the Standard Review Plan, the QA Program, Section 10 provides for: "...mandatory hold points, methods for controlling status indicators (application and removal) and accept/reject criteria for inspections." (Pg. 10-2, (4)(7)(9))

As the NWPO QA Program provides for conducting inspections, e.g.: receiving inspections of purchased materials, equipment, apparatus or instruments, there are portions of the program that will implement Criteria 14 as NWPO activities are conducted. Clarification is required as to whether this exception is appropriate based on implementation of this criteria within the NWPO Program.

25. Position 15.1 of the RP requests that procedures be established for controlling nonconformances which address...identifying, segregating, dispositioning and notifying affected organizations of nonconforming items and activities.

    NWPO QAP-15.1 does not describe the nonconformance system controls for: identifying, i.e.: by marking, tagging or other means; segregating, i.e.: by placing the item in a clearly identified and designated hold area or other means; disposition, i.e.: final disposition, such as use-as-is, reject, repair, or rework of nonconforming items; notifying affected organizations, i.e.: the NWPO QAP-15.1 provides for notification of affected individuals only when a nonconforming activity has been identified. It is not clear whether affected organizations are notified of nonconforming items. Clarification of the types of dispositions which may be provided in the QA Program is requested. (i.e.: use-as-is; repair; rework; reject).

    In addition, the Compliance Demonstration Report states, Page 15-3, "...With reference to dispositioning,...the only disposition of a nonconformance is corrective action." Clarification as to the types of dispositions, that are included in the corrective action program, would assist the staff's review.

26. Position 15.4 of the RP requests that nonconformance reports are periodically analyzed by the QA organization to "...help identify root causes of nonconformances and the significant results are reported to upper management for review and assessment."

    The NWPO QA Program, QAP-16.1 Page 4.2.3 discusses the trend analysis process but needs to provide clarification as to whether identification of root causes and upper management review and assessment of the trend analysis results will be addressed in the program.

27. a. The NWPO QA Program, QAP-15.1 discusses the program for control of nonconformances. The discussion provides for "authorized nonconformances", "apparent nonconformances" and "nonconformances".

       "Authorized nonconformances" are discussed in QAP-4.1, Page 4.17, as part of the procurement process for handling "proposed deviations in services or items from procurement document requirements";

       "Apparent nonconformances" and "nonconformances" are discussed in QAP-15.1 which implies that there are differences between these conditions but does not define the differences. Provide clarification as to how "apparent nonconformances" are documented and whether they are dispositioned as discussed in RAI 24 above. Provide clarification as to the programmatic guidance which is to be used to distinguish/define an "apparent nonconformance" and a "nonconformance".

b. QAP-15.1 Page 4.3 states in part: "When a nonconformance is identified by means of a surveillance report, the QA Manager shall investigate the condition, inform the report author of the results of the investigation in writing, and initiate an NCR."

Provide clarification as to why nonconformances, which are identified during a surveillance, are not documented on an NCR and then controlled within the system. It would appear that the process described per Page 4.3 would allow for nonconformances, which are described in the text of a surveillance report and not documented on an NCR when detected, to provide the potential for inadvertent use or installation until such time that the QA Manager can investigate and make a determination of the condition.

28. Position 16.2 of the RP requests that the QA organization be involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied. The NWPO QA Program, QAP-16.1, Page 4.6, states "...The QA Manager approves all corrective action plans prior to their implementation...". Provide clarification as to the scope of the QA organization's review as described the Review Plan.

29. Position 17.1 of the RP requests that the scope of the QA records program includes geotechnical samples.

The NWPO Compliance Demonstration Report, Page 17-2, states: "...However, geotechnical or other samples, such as rock cores or water...are not classified as records..."

Justify this exemption to the Review Plan position.

30. Position 17.4 of the RP requests that suitable facilities for the storage of records be described and utilized.

The NWPO QA Program, QAP-17.1, Page 4.5.1 establishes that, "All NWPO, contractor, subcontractor and vendor/supplier records shall be stored in a single set of metal file cabinets located in the NWPO Records Center..."

Justify the exemption from the single or dual facility records storage criteria discussed in NQA-1-1986. It is noted by the staff that ANSI/ASME NQA-1-1986 is listed as a program requirements document in Section 00-Introduction of the QA Program; yet, specific exemption to certain requirements is not defined. Clarification would assist the staff's review.

31. Position 18.2 of the RP requests that audits be regularly scheduled based on the status and safety importance of the activities being performed and are initiated early enough to assure effective QA.

The NWPO QA Program, Page 18-2, states "...All significant aspects of the program and all participating organizations and their activities are audited...Scheduling and timing of audits depends on the nature and duration of the activity being audited."

In addition, the NWPO Compliance Demonstration Report, Page 18-3 states: "...The term "safety importance of the activities" is not directly relevant to NWPO's goals and objectives. NWPO considers all NWPO-sponsored activities equally significant for purposes of QA control. The frequency and scope of audits depend on the nature and duration of activities being audited."

Provide clarification as to the criteria that will be used to assure that audits are regularly scheduled based on their status and safety importance and to provide that they are initiated early enough to assure effective QA.

The staff's position on audit, scheduling is provided in Position C.3 of Regulatory Guide 1.28, Revision 3, August 1985. Clarification needs to be provided as to why this position does not apply to the NWPO QA Program.

32. Position 18.4 of the RP requests the QA organization to analyze audit data and report the results to responsible management for review, assessment, and appropriate corrective action.

Page 18-3 of the NWPO QA Manual indicates the QA manager performs a trend analyses of the audit findings and reports adverse trends to the Executive Director.

Clarification is needed as to whether all audit results i.e., not just adverse trends are reported and whether the Executive Director reviews, assesses, and takes appropriate corrective action when appropriate.