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102-7

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AUG 25 1986
(Return to WM, 623-SS)

William J. Purcell, Associate Director
Office of Geologic Repositories
U. S. Department of Energy MS/RW-20
1000 Independence Avenue, S.W.
Washington, D.C. 20585

Dear Mr. Purcell:

The purpose of this letter is to provide the Nuclear Regulatory Commission (NRC) staff's comments on the Quality Assurance (QA) Plan for the Nevada Nuclear Waste Storage Investigations dated January 14, 1986 and identified as NVO-196-17. The plan completed by the Nevada Waste Management Project Office (WMPO) sets forth detailed guidance as to project requirements to be used by WMPO contractors and participants. It is the staff's understanding that a second document identified as NVO-196-18 which details how WMPO implements the project requirements will be provided for NRC staff's comments at a later date. The NRC staff will also review and comment on selected implementing procedures approved and issued by WMPO, and on selected QA plans and procedures of WMPO contractors and participants after the documents are approved by WMPO.

The NRC staff's review of quality assurance planning documents is only a part of the overall NRC review to assure that Department of Energy (DOE) quality assurance programs in place at the start of any licensing-related work meet the requirements of 10 CFR 60. The NRC staff has issued guidance interpreting the QA requirements in Part 60 such as draft generic technical positions on specific issues and will develop and issue others as the need arises. The staff is also observing DOE audits and meeting with the DOE staff to discuss and resolve issues pertinent to the overall quality assurance program. The NRC's objective is to have no unresolved comments concerning the QA programs when site characterization starts.

The staff utilized 10 CFR 60, Appendix B of 10 CFR 50, and the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories - June 1984" to determine the adequacy of the WMPO QA plan.

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).

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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 requirements and will be useful to the DOE in its critique of NVO-196-18 now in preparation by the WMPO.

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 reflect this position.
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 reflect 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.
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

*See previous concurrence

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| OFC | :WMRP:rs | :WMRP | :I&E | :I&E | :WMRP | : | : |
| NAME | :DHedges* | :JKennedy* | :TAnkrum* | :BGrimes* | :JLinehan | : | : |
| DATE | :86/08/06 | :86/08/07 | :86/08/07 | :86/08/14 | :86/ / | : | : |

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..."

- 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.

The staff believes a working meeting between the WMPO personnel and NRC staff would be beneficial to develop a firm understanding of the functioning QA relationships and QA responsibilities of the WMPO and its contractors and to discuss the staff's comments. It is suggested this meeting take place within the next few weeks after the DOE receives this letter. Should you agree that a meeting would be useful, please call James Kennedy of my staff at (301) 427-4786.

Sincerely,

JSI

John J. Linehan, Acting Chief
Repository Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosures:

- 1) Staff comments on QA Plan for NNWSI 1/14/86 NVO-196-17

cc: Donald Vieth
Robert Loux

*See previous concurrence

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| OFC : WMRP:rs | : WMRP | : I&E | : I&E | : WMRP | : | : |
| NAME : DHedges | : JKennedy | : TAnkrum | : BGrimes | : JL Linehan | : | : |
| DATE : 86/08/06 | : 86/8/1 | : 86/8/1 | : 86/8/14 | : 86/8/14 | : | : |

REQUEST FOR ADDITIONAL INFORMATION
NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS
QAP NVO-196-17 REVISION 4
Effective January 31, 1986

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

* The number in parentheses after an RAI refers to the specific guidance in the NRC Review Plan.

- d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters. (1.10)
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)
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)
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)
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)
11. Describe how DOE/NV management (above or outside the QA organization) regularly assesses 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)
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 date of attendance.
 - d. Appropriate management monitors the performance of individuals involved in activities affecting 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)
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)
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)
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)
16. Describe interface controls among organizations or groups involved in design development and other design activities. (3.5)
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)

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)
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)
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)
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)
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)
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 requires of Participating Organizations and NTS Support Contractors in the area of document control. Clarify that WMPO requires the same of DOE/NV. (6.1)
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)
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)

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)
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 nonconformances from the procurement requirements dispositioned "accept as is" or "repair."

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

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

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)
35. Clarify that qualification programs for inspectors are established and documented, and the qualifications and certifications of inspectors are kept current. (10.3)
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)
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)
38. Describe measures which ensure that the acceptability of inspection results is determined and documented by a responsible individual. (10.6)
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)
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)
41. Describe measures which ensure the 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)

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)
43. Describe QA and other organizations' responsibilities for establishing, implementing, and assuring effectiveness of the calibration program. (12.2)
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 could affect measurement. (12.5)
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)
46. Describe QA responsibilities within WMPO, Participating Organizations, and NTS Support Contractors related to nonconformance control. (15.2)
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)
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)

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)
50. Describe the scope of the QA records program in more detail, i.e., identify the types of records to be maintained. (17.1)
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)
52. Describe requirements for the facilities used for the storage of records. (17.4)
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)
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)
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)
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.
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)
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)
59. QAP Appendix C provides modifications to ANSI/ASME NQA-1 for Level 1 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.
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.

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.

Editorial Comments:

1. A list of abbreviations should be included.
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.
3. Since DOE/NV stands for the Nevada Operations Office of DOE, "Operations Office" should follow "Nevada" in the heading of Section 1.4.
4. Section 1.10.2.3 states: "SNL is responsible for....thermal and mechanical properties of the host rock...." Clarify that this responsibility is for determining (or measuring or verifying or whatever) these properties.
5. It appears that the word "drawings" at the end of QAP Section 3.1.3 should be "drawings and specifications." Clarify.

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