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NOV 21 1986

Mr. James Knight, Director
Licensing and Regulatory Division
Office of Geologic Repositories
Office of Civilian Radioactive
Waste Management
U.S. Department of Energy RW-20
Washington, D.C. 20545

Dear Mr. Knight:

The purpose of this letter is to provide the Nuclear Regulatory Commission (NRC) staff's comments on the Nevada Nuclear Waste Storage Investigations (NNWSI) Project's "Quality Assurance Program Plan Requirements for NNWSI Project Participating Organizations and NTS Support Contractors and Their Vendors," identified as NNWSI-SOP-02-01 dated January 31, 1986. NNWSI-SOP-02-01 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.

The NRC staff's review of quality assurance planning documents is only a part of the overall NRC review to assure that the Department of Energy (DOE) quality assurance programs in place at the start of any licensing-related work meet the requirements of 10 CFR Part 60. The NRC staff has issued guidance interpreting the quality assurance (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.

It is critical that the limits of the review of QA program plans be recognized. The extent that the program is actually used throughout the high-level radioactive waste program as a management tool as opposed to being put in place merely to satisfy an NRC requirement cannot be measured through a QA program plan review. In the several cases where serious construction quality problems occurred at nuclear power plants, QA program plans had been reviewed and found acceptable by the NRC as meeting the requirements of Appendix B of 10CFR50. However, these programs were not properly implemented. The QA program plan review provides only a portion of what is necessary to develop confidence that work will be done adequately -- that is, to assure that adequate information on the quality of work implementation is being developed for management and being used by management and that regulatory requirements are being met in demonstrable fashion. A most important indicator of the successful implementation of these plans will be the detailed, results-oriented technical reviews that will be performed by the NRC staff as work progresses.





1234

The staff utilized 10CFR60, Appendix B of 10CFR50, and the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories" dated June 1984 to determine the adequacy of the WMPO QA plan.

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.

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.

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 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.

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

*See previous concurrence

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| NAME | :DHedges* | :JKennedy* | :TAnkrum* | :BGrimes* | :FHawkins* | :HMiller* | :JLinehan |
| DATE | :86/09/09 | :86/09/09 | :86/10/09 | :86/11/10 | :86/11/03 | :86/11/07 | :86/ / |

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,

Original Signed By: RCL

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

Enclosures:
1) Staff comments on NNWSI-SOP-02-01 Rev. 1

cc: Donald Vieth
Robert Loux

*See previous concurrence

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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. 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 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.

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,

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

11/3/86 Miller 11/7/86

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# NRC COMMENTS REGARDING THE NEVADA NUCLEAR WASTE STORAGE INVESTIGATIONS QA PROGRAM PLAN REQUIREMENTS FOR NNWSI PROJECT PARTICIPATING ORGANIZATIONS AND NTS SUPPORT CONTRACTORS AND THEIR VENDORS REV. 1 NNWSI-SOP-02-01

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)

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)

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)

D. Organization charts noted in A above should demonstrate that management controls and effective lines of communication exist both internally and externally to assure 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)

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.

* The numbers in parentheses refer to the specific guidance in the NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories dated June 1984.

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)

F. Section 1.2.2.2 of the SOP indicates that, for QA Level 1 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)

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)

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)

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.

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)

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 follow.

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)

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)

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

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)

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)

IV. Procurement Document Control - No comment

V. Instruction, Procedures, and Drawings - No comment

VI. Document Control

A. Section 6.1.1 of the SOP identifies the scope of the document control program to include documents such as instruction, 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)

B. Section 6.2.1.3 requires the review of documents concerning QA Level 1 activities for adequacy, completeness, and correctness before approval and issuance. This review should assure appropriate quality requirements and the quality-related aspects of documents should be reviewed and concurred in by the QA organization. (6.2)

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)

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)

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)

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)

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)

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)

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)

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.

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)

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)

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)

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)

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)

XIII. Handling, Shipping, and Storage - No comment.

XIV. Inspection, Test, and Operating Status - No comment.

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)

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

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)

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)

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)

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)

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)

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)

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)

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 suppliers' QA programs, procedures, and activities.

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.

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 10CFR60. 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.

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.

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.

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.

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.

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.

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 section s 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.

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.