RSTEIN LETTER

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APR 2 7 1989

Mr. Ralph Stein, Associate Director Office of Systems Integration and Regulations Office of Civilian Radioactive Waste Management U. S. Department of Energy, RW-24 Washington, D. C. 20545

Dear Mr. Stein:

On March 3, 1989, the U. S. Department of Energy (DOE) forwarded the Holmes & Narver (H&N) Quality Assurance Program Plan (QAPP), QAPP-Revision 1 for U. S. Nuclear Regulatory Commission (NRC) review and acceptance. The QAPP is a description of the QA requirements and controls for providing architectural and engineering services to support the Exploratory Shaft Facility (ESF) for the Yucca Mountain Project (YMP).

The NRC staff has reviewed the document to determine whether the QAPP contains adequate requirements and controls to address the applicable criteria of Appendix B to 10 CFR Part 50 which apply to H&N for the DOE YMP. The bases for our review were the criteria contained in the "NRC Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions" Revision 2 dated March 1989 and NRC staff guidance documents and consensus standards referenced therein. Selected procedures prepared by H&N to implement the QAPP were also reviewed by the NRC staff as a part of its evaluation of the upcoming DOE audit of H&N. As a result of our review, the NRC staff has generated the 19 enclosed comments which were discussed with DOE, the State of Nevada, and NRC during a April 13, 1989 telephone conversation. Upon receipt of an acceptable resolution of the 19 comments, the NRC staff will find that the H&N QAPP, Revision 1 meets the applicable criteria of Appendix B to 10 CFR Part 50 and is acceptable.

Should you have any questions on our review, please contact Bill Belke of my staff on (301) 492-0445.

Sincerely.

ORIGINAL SIGNED BY,

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

Enclosure: NRC Comments

cc: R. Loux, State of Nevada

M. Baughman, Lincoln County, NV

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ENCLOSURE

NRC COMMENTS

1. In the Introduction Section of the 88-9 QAP, paragraph 2.8 requires the YMP Project Quality Manager to approve the Project Participant QAPP's and changes thereto. The NRC staff does not see any information whereby this has been accomplished by the YMP Project Quality Manager for the H&N QAPP.

2. Criterion 1.5 of the Review Plan (RP) states, "DOE and prime contractors describe major delegation of work involved in establishing and executing the QA program, or any part thereof, to other organizations."

Section 1, page 1 paragraph III.B of the H&N Quality Assurance Program Plan (QAPP) indicates the TPO is the prime interface with the YMPO, participating organizations, and supporting contractors. Section 7, page 1, paragraph II.C of the H&N QAPP indicates that procurement of equipment and subcontracts is the responsibility of Reynolds Electrical and Engineering Co. Inc. with H&N supporting these activities. The H&N QAPP needs to provide in more detail, a description of the major delegation of work involved in establishing and executing the QA program, or any part thereof, to other organizations.

3 Criterion 1.15 of the RP states, "Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel."

Section 1, page 2, paragraph C.1 states that the Chief, Quality Assurance has direct access to responsible management including, if necessary, the YMPO Project Quality Manager, to resolve quality problems. It is not clear whether this responsibility includes provisions to resolve disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.

4. Criterion 1.17 of the RP states, "Provisions are established for resolving allegations of inadequate quality. These allegations may originate within the responsible organization(s) or from outside the responsible organizations(s)."

5. Criterion 2.2 of the RP states, in part, "The QA Program provides a commitment to comply with NQA-1," Quality Assurance Program Requirements for Nuclear Facilities," and the following position, relative to the NQA-1 standard: Appendix 2A-1, "Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel," provides guidance on the qualifications of inspection and test personnel.

In the Policy Statement and Section 2, Paragraph II.B of the H&N QAPP, it is stated that the H&N QAPP complies with the NNWSI/88-9 QAP. It is the NRC staff interpretation that H&N completely complies with the 88-9 QAP including a commitment to implement the requirements of ANSI/ASME NQA-1-1986. This should be clearly stated in the H&N QAPP to avoid future misinterpretations of this commitment.

6. Criterion 2.7 of the RP states, "Provisions are established which demonstrate through a matrix system or other means that each criterion of Appendix B is properly documented and covered by implementing procedures and/or instructions."

7. Criterion 3.1 of the RP states, in part, "The definitions of design, design information, and design activities used in the design control program are defined.... Design information and design activities refer to data collection and analyses activities and computer codes 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 analyses."

"Design information" and "design activities" are not addressed in the $\ensuremath{\mathsf{H\&N}}$ QAPP.

8. Criterion 3.5 of the RP states, "Design Control measures are established and applied to conceptual design, or parts thereof, which may at a later time become part of the final design."

The H&N QAPP, Section 3, Scope, states, in part, "This section applies to all design activities performed in support of the project."

Clarify what is meant by "all design activities" and whether they apply to conceptual through final design.

9. Criterion 3.6 of the RP states, "Organizational responsibilities are prescribed for preparing, reviewing, approving, verifying, and validating design and design information documents."

10. Criterion 3.12 of the RP states, in part, "Procedures for a design or technical review require, where applicable....the resolution methods for resolving comments."

- 11. Criterion 3.13 of the RP states, in part, "Design Verification procedures assure the following:
 - a. Criteria for determining the method of verification are established;....
 - b. The responsibilities of the persons performing the verification or validation are defined;...."

12. Criterion 4.3 of the RP states, in part, "Organizational responsibilities are described for: (1) procurement planning;....(3) supplier selection;...."

(See above NRC Comment #1). In Section 7, paragraph II.C of the H&N QAPP, it appears that Reynolds Electric & Engineering Co., Inc. has total responsibility for all procurement of equipment and contracts with H&N providing the oversight of these activities through surveillances and audits. If the NRC staff interpretation of the above is correct, it should be clearly described to avoid future misinterpretations.

13. Criterion 5.2 of the RP states, "Organizational responsibilities are described assuring that quality-related activities are: (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents."

14. Criterion 9.1 of the RP states, in part, "The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes is provided...."

Section IX, paragraph 2.2.1 of the 88-9 QAP requires the Participating Organization and Support Contractor to identify which portions of its activities involve the use of special processes. This criterion and the 88-9 QAP requirements do not appear to be addressed in the H&N QAPP.

15. Criterion 9.2 of the RP states, "Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel."

16. Criterion 10.2 of the RP states, in part, "Organizational responsibilities for inspection are described."

17. Criterion 12.2 of the RP states, "QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program."

18. Criterion 14.5 of the RP states, in part, "Procedures are established and described to control altering the sequence of required tests, inspections, and other operations important to safety."

19. Criterion 17.2 of the RP states, "QA and other organizations are identified and their responsibilities are described for defining and implementing record activities, particularly in the retention, duration, and safe storage of records."